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Transparency of Artificial Intelligence/Machine Learning-enabled Medical Devices, Nov 14, 2021

Medical Device Context and State Information can support AI/ML Transparency

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FDA AI/ML White Paper

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

https://www.fda.gov/files/medical%20devices/published/US-FDA-Artificial-Intelligence-and-Machine-Learning-Discussion-Paper.pdf

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.

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Context-aware systems: A literature review and classification

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ABSTRACT

Nowadays, numerous journals and conferences have published articles related to context-aware systems, indicating many researchers' interest. Therefore, the goal of this paper is to review the works that were published in journals, suggest a new classification framework of context-aware systems, and explore each feature of classification framework. This paper is based on a literature review of context-aware systems from 2000 to 2007 using a keyword index and article title search. The classification framework is developed based on the architecture of context-aware systems, which consists of the following five layers: concept and research layer, network layer, middleware layer, application layer and user infrastructure layer. The articles are categorized based on the classification framework. This paper allows researchers to extract several lessons learned that are important for the implementation of context-aware systems.

1. Introduction

Emerging ubiquitous or pervasive computing technologies offer 'anytime, anywhere, anyone' computing by decoupling users from devices (Dey, 2001; Hill et al., 2004; Kwon, Choi, & Park, 2005; Kwon, Yoo, & Suh, 2005; Schilit, Adams, & Want, 1994). To provide adequate service for the users, applications and services should be aware of their contexts and automatically adapt to their changing contexts-known as context-awareness (Bolchini, Schreiber, & Tanca, 2007; Dey, 2001; Zhu, Mutka, & Ni, 2005). Context is very important, since it provides information about the present status of people, places, things and devices in the environment (Korpipää, Mäntyjärvi, Kela, Keränen, & Malm, 2003; Kwon, 2004). Context is any information that can be used to characterize the situation of an entity. An entity is a person, place, or object that is considered relevant to the interaction between a user and an application, including location, time, activities, and the preferences of each entity (Dey, 2001). Context-awareness means that one is able to use context information. A system is context-aware if it can extract, interpret and use context information and adapt its functionality to the current context of use (Byun & Cheverst, 2004). The term context-aware computing is commonly understood by those working in context-aware, where it is felt that context is a key in their efforts to disperse and transparently weave computer technology into our lives. One goal of context-aware systems is to acquire and utilize information on the context of a device in order to provide services that are appropriate to the particular people, place, time, event, etc. These systems aim to provide context-aware access to information, communication and computation.

In late 1980s, there was a period of beginning activity on context-aware computing. A few of context-aware computing has met the interest. However, the activity seems to be increasing dramatically. Nowadays, to overcome new challenges and requirements found in context-aware systems, many researchers have made efforts to design and implement network, user infrastructure and middleware which effectively provide users with context-aware services. Numerous articles of journals and conferences have published research related to context-aware systems. In other words, many people are interested in context-aware systems. Therefore, we feel that this is a good time for a review analysis, since it has been over a year since many papers were published. Currently, it is difficult to compare articles, because the available research is published in quite different journals. Accordingly, the main objectives of this review are:

- To classify and summarize research relevant for context-aware systems.
- To provide a conceptual framework for the integration and classification of articles.
- To derive suggestions for context-aware systems researchers based on the literature review.

Chen and Kotz (2000) surveyed the literature related with context-aware computing in mobile computing. They defined the terms context and context awareness, listed the context-aware applications that have been built, discussed approaches to sense and model the context, and looked into supporting infrastructures, security and privacy issues. However, in 2000, articles published in

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Context-aware systems: A literature review and classification, 2008

SPECIAL ARTICLE

Capturing Essential Information to Achieve Safe Interoperability

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In this article, we describe the role of "clinical scenario" information to assure the safety of interoperable systems, as well as the system's ability to deliver the requisite clinical functionality to improve clinical care. Described are methods and rationale for capturing the clinical needs, workflow, hazards, and device interactions in the clinical environment. Key user (clinician and clinical engineer) needs and system requirements can be derived from this information, therefore, improving the communication from clinicians to medical device and information technology system developers. This methodology is intended to assist the health care community, including researchers, standards developers, regulators, and manufacturers, by providing clinical definition to support requirements in the systems engineering process, particularly those focusing on development of Integrated Clinical Environments described in standard ASTM F2761. Our focus is on identifying and documenting relevant interactions and medical device capabilities within the system using a documentation tool called medical device interface data sheets[a] and mitigating hazardous situations related to workflow, product usability, data integration, and the lack of effective medical device-health information technology system integration to achieve safe interoperability. Portions of the analysis of a clinical scenario for a "patient-controlled analgesia safety interlock" are provided to illustrate the method. Collecting better clinical adverse event information and proposed solutions can help identify opportunities to improve current device capabilities and interoperability and support a learning health system to improve health care delivery. Developing and analyzing clinical scenarios are the first steps in creating solutions to address vexing patient safety problems and enable clinical innovation. A Web-based research tool for implementing a means of acquiring and managing this information, the Clinical Scenario Repository™ (MD PnP Program), is described. (Anesth Analg 2017;124:83–94)

Medical devices are generally designed to deliver adequate performance for a population, rather than performance tailored for the needs of an individual patient in a specific setting, thereby potentially exposing patients to unsafe conditions or less effective care. Determining how to optimize devices and algorithms for specific patients, disease states, or practice settings is prohibitively expensive for any single manufacturer because available data sets are often limited in size and scope, and the cost to research all potential subpopulations would be commercially prohibitive. Implementing proposed device or algorithm customizations or "personalizations" by the health care provider is complicated by current device designs and proprietary business practices often prevent algorithm customization. Proposed approaches, such as data fusion and other computational techniques that require real-time access to data from multiple devices, are especially difficult or impossible in the current environment because of the lack of interoperability between medical devices and between devices and health information technology systems. Where there is interoperability, the electronic health record is likely to store a small subset of patient and medical device data. Therefore, manufacturers, academic researchers, and clinicians have an overly complex, expensive, and inefficient path to researching and developing medical applications.

As noted in the information technology and health section of the 2015 review from the President's Council of Advisors on Science and Technology Networking and Information Technology R&D Working Group,[b] health care innovation is hampered by the nature of many of the innovations that "do not fit naturally into either clinical or basic science methodologies"[1] and the difficulty of translating innovations into the health care setting. This report included several findings that highlighted the need for new approaches, platforms, and tools to help address the current problems faced in health care innovation.

These barriers to innovation contribute to preventable medical errors, considered to be the third leading cause of

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The authors declare no conflicts of interest.

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Reprints will not be available from the authors.

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DOI: 10.1213/ANE.0000000000001351

[a]Available at: http://www.mdpnp.org/mdids.html. Accessed August 2, 2015.

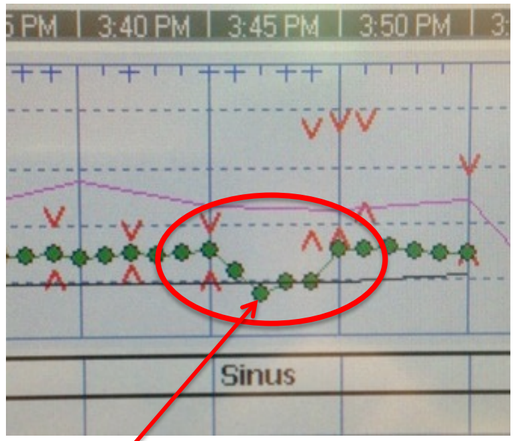
[b]The President's Council of Advisors on Science and Technology (PCAST) periodically convenes a working group to review the Federal Government's coordinated program of Networking and Information Technology Research and Development Program (NITRD).

Capturing Essential Information to Achieve Safe Interoperability. Weininger S, Jaffe MB, Rausch T, Goldman JM. Anesth Analg. 2017 Jan;124(1):83-94.

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"



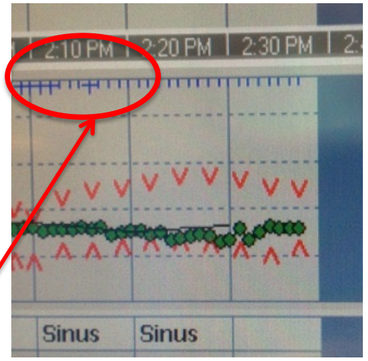
Minimum rate in EHR ~ 45

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

Missing low SpO_2 in EHR

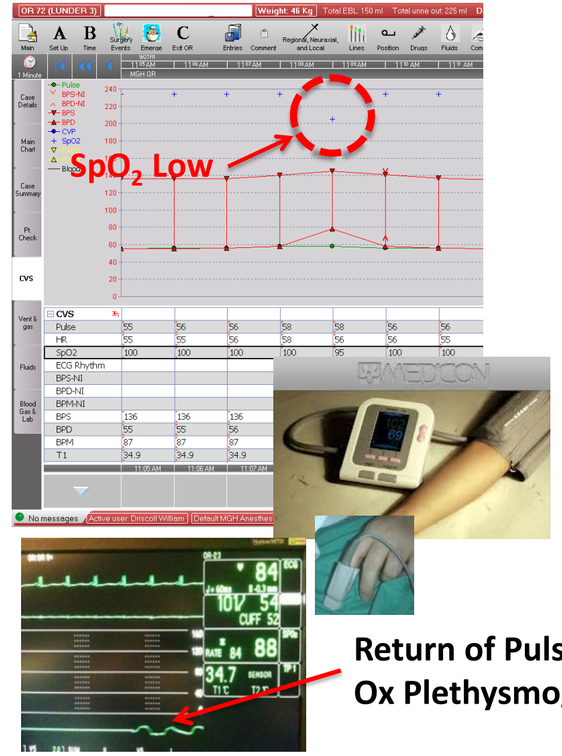
SpO_2 84% at 2:07

Monitor reveals low SpO_2 "84%" at 2:07



No evidence of SpO_2 = 84% in EHR
(Blue ticks representing SpO_2 values)

Falsely low SpO_2 data in EHR



Return of Pulse Ox Plethysmogram

Spuriously low SpO_2 in EHR caused by NIBP cuff inflation

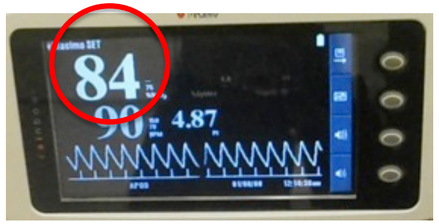
The Need to Apply Medical Device Informatics in Developing Standards for Safe Interoperable Medical Systems
Au: S Weininger, M Jaffe, J Goldman, Anesth Analg. 2017 Jan;124(1):127-135 DOI: 10.1213/ANE.0000000000001386

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

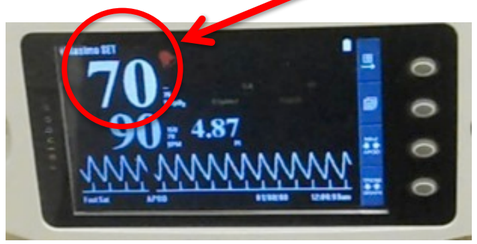
Pulse Ox is set to **16** sec averaging time

A

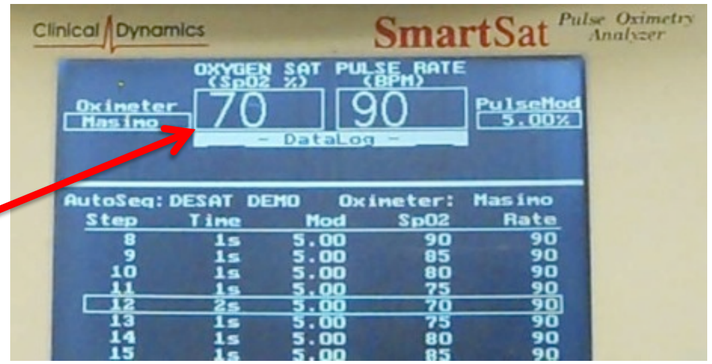


Pulse Ox is set to **2** sec averaging time

B



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



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

"The Importance of State and Context in Safe Interoperable Medical Systems", Translational Engineering in Health and Medicine IEEE Journal of, vol. 4, pp. 1-10, 2016, ISSN 2168-2372.

MD PnP™ Getting connected for patient safety™ Lab data

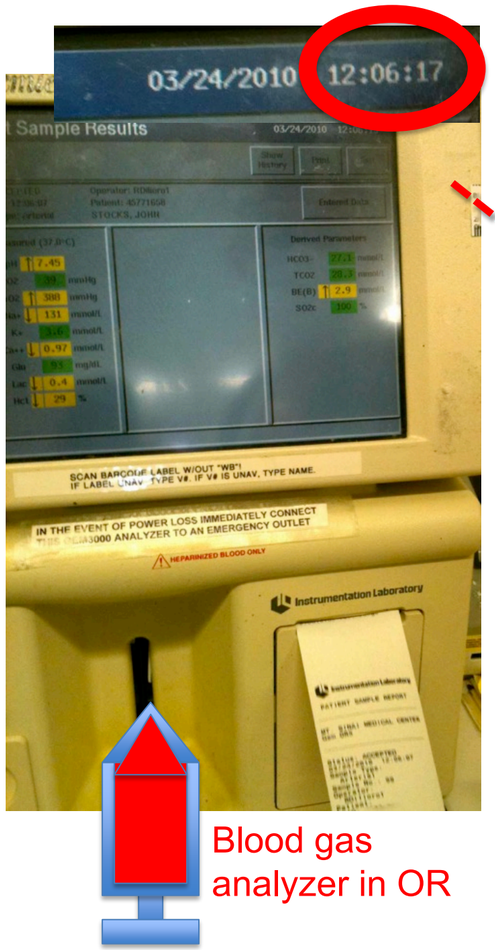
Data time-stamp errors:

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

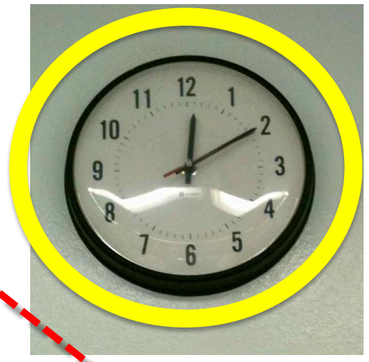
Blood-gas machine clock is <u>incorrect at 12:06</u>

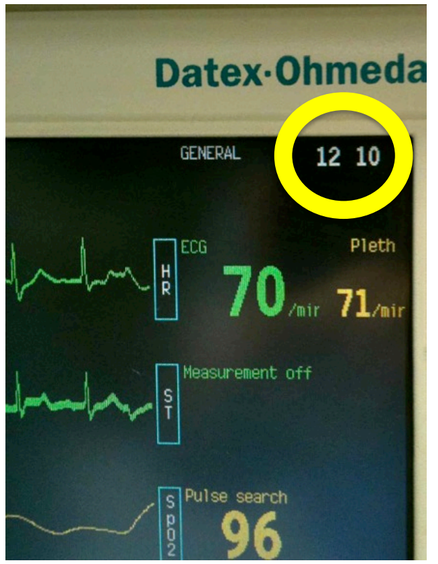
The incorrect lab measurement time is stored in lab system.

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



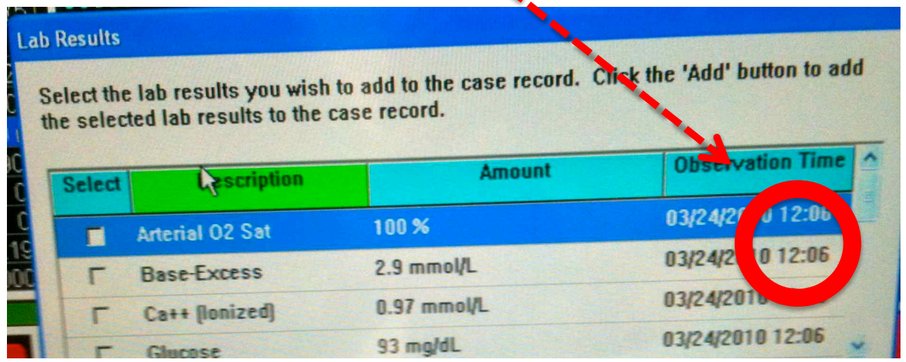
Blood gas analyzer in OR





Correct time was 12:10

EMR time stamp error



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