Testimony before the Clinical Operations Workgroup
HIT Standards Committee
-Medical Device Hearing-

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John Zaleski, PhD, CPHIMS

Thank you for the opportunity to provide testimony on this topic. I am the CTO & VP of Clinical Applications at Nuvon, Inc. The remarks I make today are not meant to be construed as an official policy position of my employer but, rather, are based on my accumulated experience over the course of nearly 20 years in this field.

GENERAL QUESTIONS

1. What is your experience with health care devices and device interoperability? Have you experienced specific problems where standards might contribute to solutions?

   My experience with patient care devices—biomedical devices that record observations or measurements on patient state at the point of care that assist in monitoring and managing patient physiological state—and their interoperability to electronic medical records extends back through nearly 20 years. I hold 4 patents related to biomedical device interoperability and have authored 2 books on the subject. During my doctoral work at the University of Pennsylvania School of Engineering and Applied Science and the University of Pennsylvania Medical Center, I conducted clinical trials involving patients who had undergone coronary bypass grafting for the purpose of weaning these patients more efficiently and safely from postoperative mechanical ventilation. It was during these trials that my attention was drawn to the need for rich, high quality, and accessible data collected from biomedical devices such as mechanical ventilators, physiological monitoring systems, and the like. Dense and complete measurements were the basis for the high fidelity modeling and highly accurate predictions associated with the clinical outcomes of these patients and it was revealed to me then how high fidelity clinical decision making was so dependent on accurate, timely, synchronized, and available bedside observations from all sources. The high fidelity data I collected during these trials enabled the formulation of clinical guidelines that facilitated the prediction of viability of weaning in these patients.

   I carried this experience and lessons learned forward in various roles, including my tenure as Director and Product Manager of critical care at Siemens Health Services and later in my role as Sr. Director of Bioinformatics at Philips. I managed and led the development of critical care departmental clinical information solutions and medical

surgical solutions. I have also been extensively involved in the use of real-time data for clinical decision making and informatics at the point of care.

2. Are there areas where standards are more mature or less mature?

   Health Level Seven (HL7) formatted messaging in the form of solicited and unsolicited observation reporting from physiological monitoring gateways and ancillary patient care devices into electronic medical records (EMRs) is relatively mature. Generalized data queries and interactive device communication to and from biomedical devices is not very mature or standardized. In general, biomedical devices communicate according to proprietary, vendor-defined protocols which require intermediaries and brokers in order to translate into more normalized formats such as HL7 solicited and unsolicited observation reporting.

3. What standards or standards-related capabilities are most relevant and important to the meaningful use of EHR technology?

   HL7 communication of observations reports—both in the form of solicited and unsolicited data and the more focused or tailored form of HL7 relating to the Patient Care Device (PCD) transactions are most relevant and important to the MU of EMR technology. It can also be argued that rules and workflow engines and related software which draw upon these data to establish and highlight comparisons between normal and abnormal trending—through computerized guideline syntactical frameworks such as the GuideLine Interchange Format (GLIF) or Arden Syntax, are also of key importance in terms of post-processing and assessing ALL data employed within the electronic medical record (EMR).

4. What do you see as key barriers to effective use of health care devices to advance health and wellness?

   Throughout my career the most obvious problems in terms of interoperability and interconnectedness which have impeded the seamless and complete integration of biomedical device data for use in clinical decision making has been in the lack of universal access to biomedical device data, requiring the construction of device drivers to enable access to the proprietary data contained within these devices. Proprietary interfaces lead to silos of data that require considerable post processing in order to provide for the necessary fusion of information, integrated with other bedside data, to support real-time clinical decision making.

   Stand-alone biomedical devices which do not employ device gateways or translators to HL7 formats generally do not communicate according to common methods either physically or semantically. Save for certain exceptions in the physiological monitoring space, most ancillary devices such as mechanical ventilators, ad hoc and spot vital signs monitors, anesthesia machines, and stand-alone devices such as some glucometers, spirometers, pulse oximeters, and blood pressure cuffs communicate through vendor-defined proprietary interface mechanisms that require stand-alone device

drivers that translate from the proprietary, vendor-specific into a more open standard such as HL7 solicited or unsolicited observation reporting.

HL7 is the beginning but not the end of standardization in terms of biomedical device communication. As a messaging standard, it is good for communicating basic device data and observations from source to EMR. Yet, in terms of the more sophisticated two-way communication required between end user and device, it is inadequate to support interactive communication, command, and control of biomedical devices. For instance, no standardized approach yet exists for controlling biomedical devices subject to calculations or conditions determined based on the measured observations from the patient. This area is extremely embryonic in its development and sophistication and will require significant research and testing to ensure safety and to minimize hazards to the patient. This is even more of a challenge in remote environments with ambulatory patients since communicating data from outside the health enterprise, in a relatively well-defined and uniform communication infrastructure, is lacking.

Indeed, HL7 communications from physiological monitoring and infusion pump gateways is maturing. However, the two-way communication and interaction with stand-alone physiological devices and physiological monitoring systems is almost nonexistent but necessary to support more sophisticated computerized guidelines and protocols to care for the most acutely ill of patients or for managing patients in more autonomous settings, such as ambulatory patients at home. Furthermore, device communication from stand-alone physiological devices used for managing and monitoring of chronic ailments are all typically supported only through proprietary interfaces that limit their use outside of vendor-supplied or developed systems. In summary, the seamless access to data from anywhere, to anywhere from within or outside of the healthcare enterprise is a key barrier to evolving progress.

5. If you could wave a magic wand to effect one change to enable more effective and widespread use of health care devices, what would that be?

Obtaining data from biomedical devices should be as easy and ubiquitous as plugging in a USB cable to your laptop: automatic detection, association, identification and communication, securely accessed, reliable, scalable, and available without the need for specialized device drivers or dealing with the vagaries and quirkiness of proprietary communication hardware and software.

DATA ACCURACY & INTEGRITY PANEL

14. What are the data accuracy and data integrity requirements for device data in EHRs?
    a. Product metadata (data about devices)
        - *Latest firmware or software version;*
        - *device communication protocol (both physical and syntax);*
        - *time of last service;*

- *time of last synchronization with NTP servers, if available.*

b. Interoperability data (health data from devices);
   - *All observations/measurements or spontaneous values;*
   - *all settings or mandatory values;*
   - *high frequency waveform data, if available;*
   - *network time stamp on last observations, if available;*
   - *device time stamp, if available.*

c. What are the differences and similarities for patient-collected data vs. provider-collected data, and what are the requirements for both?
   - *Similarities are typically found in the specific observations or measurements obtained from the biomedical (e.g., home blood glucose measurement is similar to in-hospital measurement in terms of accuracy).*
   - *However, provider-collected data also needs to carry with it context associated with the validity of the observation and other clinical context that may make the measurement or reading more clinically relevant for downstream decision making.*
   - *Patient observations or context surrounding measurements are useful in terms of context but can lack the clinically relevant information that are necessary for bedside clinical decision making.*

d. Are there different accuracy and integrity requirements for patients or providers in different care settings, e.g. SNIF vs. Hospital vs. Home?
   - *Challenges in remote or unsupervised environments include ensuring that the data are collected accurately; ensuring the data are actually collected from the correct individual; ensuring the data are collected within the correct context.*
   - *Supervision by trained staff in the hospital environment at the point of care tends to remove these as variables from questioning the integrity of the data.*

15. What risks relate to device data accuracy and integrity?
    - *Data timing and synchronization—time stamp differentials can register as different columns within charting Flowsheet;*
    - *time stamp differentials can result in late / no posting of findings within chart with potential impact on orders and assessments;*
    - *Ensuring data are collected accurately and in proper context (e.g.: patient standing on scale properly, taking blood pressure properly, etc.)*
16. How does patient identification relate to device data in different care settings?

    In high acuity settings where patients are associated with biomedical devices for an extended period of time, a fixed patient to bed association can be used rather reliably and accurately. However, in situations where devices are mobile or patients are ambulatory

and some ambiguity between the data collected and the patient can exist, a risk results from this ambiguity in associating the correct data with the correct patient. Methods such as barcode or radiofrequency identification can serve to mitigate or reduce the risk or uncertainty. However, this is never 100%. In mobile or home dwelling settings wherein a many-to-one association takes place between the device and the patient, the need for positive association of the device and the data to the patient is essential in terms of minimizing the risk due to incorrectly associating a patient with a device.