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Testimony of

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Clinical Operations Workgroup

Medical Device Hearing

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Hiatt Testimony
Clinical Operations Workgroup – Medical Device Hearing

Thank you for the invitation to be here today. I am Dr. Jo Carol Hiatt, Assistant Medical Director of the Southern California Permanente Medical Group. I also serve as Chair of Kaiser Permanente's National Product Council and Chair of our Interregional New Technologies Committee. I am testifying today on behalf of the national Kaiser Permanente Medical Care Program. We are the nation's largest integrated health care delivery system, providing comprehensive health care services to more than 8.7 million members in nine states (California, Colorado, Georgia, Hawaii, Maryland, Ohio, Oregon, Virginia and Washington) and the District of Columbia.

As part of our commitment to the highest quality care, Kaiser Permanente has made a significant investment in a program-wide Electronic Health Record ("EHR") system, KP HealthConnect® to securely connect our members to their health care teams, their personal health information, and the latest medical knowledge. KP HealthConnect represents a critical tool in Kaiser Permanente's integrated approach to health care.[1]

Kaiser Permanente strongly supports the adoption of health information technology through provider incentives for meaningful use. We have signaled our intent to participate in CMS' EHR Incentive Program through our Medicare Advantage organizations and are currently working to meet meaningful use objectives in the first year of Stage 1.

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?

Excluding medical imaging, approximately 250,000 biomedical devices are in use in across Kaiser Permanente (KP) today. Currently 85% of these devices are not attached to our enterprise network; however, we expect over 30,000 devices to be integrated into our networks over the next five years. Nearly all of will be from Anesthesia, Laboratory and Patient Monitoring.

Kaiser Permanente has undertaken a concerted effort to reduce variation in biomedical device use and management across KP regions. A critical element of the initiative encourages common standards across vendors through our procurement process.

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[1] KP HealthConnect has been implemented in every one of our 421 medical office buildings, ensuring that our approximately 14,000 physicians and other caregivers have appropriate access to members' clinical information. We also have implemented inpatient billing; admission, discharge, and transfer; scheduling and pharmacy applications; and bedside documentation and computerized physician order entry ("CPOE") in each of our 35 hospitals.

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

Mature standards exist at the network connectivity layer (e.g., TCP / IP), at the message syntactic layer (e.g., HL7) and for content (e.g., SNOMED) Document exchange based standards are fairly mature. IHE profiles are maturing, yet implementation has been slow.

Less mature but extremely important standards are those that promote highly integrated, patient-centric point of care integration and integrated clinical environments (ICE) – based frameworks that support intelligent or "smart" alarms, safety interlocks, real-time device to device synchronization.[2]

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

For the meaningful use of EHR technology, standards that support interoperability and related interoperability guidelines are needed to ensure reliable data exchange across systems.

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

Vendors' proprietary solutions create significant barriers to effective use of health care devices to advance health and wellness. Variation in data exchange and inconsistent data management increase the challenges and expense for providers seeking to integrate EHRs and devices. This lack of integration frameworks and standard interfaces among manufacturers forces some entities to create custom middleware. The lack of language standards for devices also impedes interoperability.

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?

Devices would be enabled, through semantic interoperability, to discover, learn, adapt and promote automation. Vendors and providers would promote intelligent devices that would operate across a spectrum of care delivery settings and health care services.

Biomedical Device Integration Council

To address the challenges of device integration, KP established the Biomedical Device Integration Council (BDIC) in 2009 as a cross-functional, inter-regional team working in collaboration with physicians, nurses, and technology groups (IT and biomedical engineering/clinical technology) to define, coordinate, and govern the biomedical device integration for KP

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[2] ASTM F2751-2009

Our goal has been to establish or facilitate consistent and reproducible integration of biomedical devices with network connectivity, to work toward including device-derived data in our EHR, and ultimately, to achieve interoperability across our systems. Our goal is to give clinicians and other caregivers access to technical tools as well as to information that will enhance their ability to deliver high quality patient care. Ultimately, we are aiming towards continuous feedback to lead to greater improvement in patient care, based on the clinical outcomes derived from the use of these tools.

The BDIC has developed "roadmaps" of clinical workflow, common and consistent nomenclature, common integration methodologies, network architecture, and security standards. We hope to leverage this expertise in our procurement program to drive common standards across vendors, therefore reducing variability, integration, and operational costs.

National Product Council

The National Product Council (NPC), the device procurement arm of KP, provides leadership to specialty-based sourcing teams to facilitate the appropriate acquisition and utilization of high quality products (goods, equipment, and services) to maximize total value. The NPC incorporates evidence-based analyses including technology assessments and clinical practice guidelines in its product selection process. The process is continually refined with clinical outcome-based decisions and rationales.

One key consideration in the purchase decision is the potential for products to be effectively integrated with our systems. Freestanding equipment with paper printouts is being replaced by equipment able to produce electronic data for entry into an EHR. This innovation impacts patient care but also makes interoperability and integration between devices and across systems achievable.

Meaningful Use

Incorporating device data into Stage 1 measures for the purposes of achieving meaningful use would require an overly aggressive (and probably not feasible) adoption and implementation for manufacturers and providers. However, in later Stages of the Meaningful Use Program, certain classes of device data could improve efficiency and quality by enabling automatically uploaded real to near- real time clinical data (e.g., test results, vital signs).

For example, patient vital signs are typically manually entered. Automating the acquisition of vital signs and laboratory analyzers through reliable devices will improve efficiency and reduce errors. Automated acquisition, integration, exchange of vital signs and lab data, and storage, accompanied by a summary record, will improve continuity of care and outcomes.

Device data has the potential to enhance patient-specific education and follow-up by linking certain device data with other meaningful use objectives, such as patient lists, patient reminders and clinical summaries.

Device data might enable certain population and public health objectives, like syndromic surveillance and it might ultimately expedite mandatory reporting.

However, as we noted in comments submitted to ONC on proposed objectives for Stage 3 meaningful use, the value of such data is dependent on its accuracy and also clinical decision support around data filtering. Device standards and interoperability will greatly enhance these important characteristics and capabilities.

Unique Device Identification

The benefits of standardizing Unique Device Identification (UDI) will reduce medical errors and facilitate recalls of implanted and other devices. More generally, device identification will improve supply chain management and inventory control, impede product counterfeiting, and aid in disaster recovery. Device identification will also promote consistency and uniformity of data

Currently, each KP region assigns all KP medical devices a unique Equipment Identification Number (EIN). EINs are unique within a KP region, but not consistent across the program. KP uses ECRI's Universal Medical Device Nomenclature System for equipment.

The Food and Drug Administration (FDA) is promoting a risk-based phased UDI implementation starting with the acute care market FDA Class III devices (e.g., implantable devices).

KP National Implant Registries and HealthConnect

The KP National Implant Registries track patient demographics, surgical techniques, implants, and outcomes for KP members nationwide. A national committee of representatives from all regions oversees KP's implant registries including physicians, quality experts, researchers, and members of the National Product Council.

KP has developed multiple orthopedic, cardiology, and cardiothoracic registries and is currently expanding to other specialties. The Total Joint Replacement Registry is KP's first and largest interregional registry and is now the third largest joint replacement registry in the world.

The KP national implant registries play a key role in advancing knowledge about health outcomes associated with implantable products and applying that knowledge for the benefit of patients. These registries report data on the utilization and associated health outcomes of implantable products to physicians, health care professionals and quality

personnel to support quality improvement and patient safety initiatives. They also provide product performance and utilization data to the National Product Council and the specific teams to support the selection of the highest quality implants and products. The national transplant registries utilize KP's Interregional New Technology Committee with data to assist in the review and selection of new medical technologies.

A Unique Device Identification System (UDIS) would provide uniform labeling and consistent data across KP interregional registry efforts, enabling comparative effectiveness research among KP's research collaborators and with other countries including Sweden, Finland, Norway, Australia and Denmark with similar registries.

Data Integration and Interoperability

Data integration and interoperability is a challenge for KP. Data for device identification and registration are priorities for all devices. Such data may include: unique device identification, device type, brand, serial number, manufacturer, and device intermediary information.

Information that can associate accurate patient identification and device data is important to integrating device information in the EHR. Ultimately, through innovation based on standards, devices should be able to communicate detailed measurement information to the EHR for effective patient monitoring and management. Data that provide measurement intervals and device setting information within the EHR, as well as data that communicate device and measurement information to the EHR when there is a lapse in EHR connectivity should be required.

Device data are also context specific to work flows. Not all data require integration. It depends on intended use. Clinical Decision Support systems are needed for aggregation and filtering, converting data into useful information.

As an integrated health care delivery system, our goal is to adopt interoperability standards for medical device interconnectivity across our organization. We also recognize that the necessary standards are not yet fully developed or widely implemented by medical equipment vendors.

Adoption of standards-compliant interoperable devices and systems will enable the development of innovative approaches to improve patient safety, healthcare quality, and provider efficiency. Standards will also enable coordinated analysis of more complete and accurate patient and device data which will support individual, institutional, and national goals for improved healthcare quality and outcomes. Our goal is to strongly encourage the development and adoption of medical device interoperability standards and related technologies.

For example, the ability to synchronize taking an x-ray with a ventilated patient's breathing cycle improves image quality. Unfortunately, the ability to interconnect and

synchronize these devices is not available today. Similarly, a safety interlock to stop the flow of opioid pain medication from an infusion pump and alert the nurse if a patient showed signs of respiratory distress could save lives, but does not exist today. There are numerous other examples whereby medical device interoperability and medical system integration would improve patient safety and result in better clinical outcomes.

Standards-based medical device interoperability provides real-time comprehensive information updates to the electronic medical record which is essential for the creation of integrated error-resistant medical systems. Advanced capabilities would be enabled such as automated system readiness assessment; physiologic closed-loop control of medication/fluids delivery and ventilation; decision support; safety interlocks; device performance; plug-and-play modularity to support "hot swapping" of replacement devices and selection of "best of breed" components from competitive sources. These and other innovations will improve patient safety, treatment efficacy, and workflow efficiency.

The Impact of MDDS Rule on Kaiser Permanente

There will probably be little direct impact. While the Final Rule specifically excluded EHRs (and CPOE) from the devices defined as MDDS, the regulation will apply to those devices that act only as "communication conduits" through which medical data from devices can be transferred, stored, converted and/or displayed; some of those data may end up in the EHR. Because the Final Rule reclassified MDDS into the less stringent Class I (general controls), more off–the–shelf or custom hardware or software products used alone or in combination that display unaltered medical device data, or transfer, store or convert medical device data for future use, in accordance with a preset specification may be available.

Integrating Home and Remote Monitoring with EHR's

KP is actively engaged in identifying challenges and barriers to home and remote monitoring with an eye towards useful integration with our EHR. We recommend appropriate certification of devices to ensure accurate patient association and identification, patient safety, system effectiveness and data and system security for home/remote device interoperability with EHRs.

It will be important to design the interfaces for these systems to mitigate any risks to maintaining the security, accuracy and integrity of data within the system. A real challenge will be how to associate a patient with a particular device; this is a priority for patient safety and effectiveness of treatment.

There need to be processes for validating the accuracy of protocols for sending and receiving data, and for data aggregation, data filtering, patient confidentiality and clinical decision support associated with devices.

Communication links are important: Wireless networks are typically less reliable and have less bandwidth than wired networks. A risk analysis should be performed as part of implementation.

Summary

KP supports the continuous improvement of health care quality and patient safety promoted through meaningful use and through healthcare reform. We have already invested in technology, through our system-wide EHR, KP HealthConnect, and have taken steps to integrate medical devices into our systems. However, we believe that our own efforts to integrate devices, as well as the efforts of those across the industry to design, develop and implement such interoperable devices, will be enhanced by the adoption of standards. Late Stages of the Meaningful Use program may be able to support some initial, basic requirements for interoperability with EHRs, but it may not be realistic to expect Meaningful Use to drive the adoption by both (non-EHR) vendors and providers.

We have not been as successful as we would have hoped in encouraging our "supplier-partners" to develop integration framework with our EHR as we have with our image storage and PACS.

Driving toward consistent and interoperable standards for devices will encourage innovation that focuses on integration to improve clinical outcomes and patient safety through accurate data available to providers and patients through EHRs.

Thank you to the Committee for the opportunity to provide this testimony. I would be happy to answer any questions.