



Date: June 1, 2013

MacKenzie Robertson
FACA Program Lead
Office of National Coordinator
mackenzie.robertson@hhs.org

Dear MacKenzie,

These are my comments in preparation for the June 7th Clinical Quality Hearing, for Panel 1: High Performing Healthcare Improvement Organizations and the Analytics Systems to Support Them. My testimony and comments are grounded in long experience as a quality improvement / safety leader and innovator in several different topic areas, including prevention of venous thromboembolism (leg clots and pulmonary emboli), inpatient diabetes care and prevention of hypoglycemia, and transitions of care. I have experience locally at UC San Diego, as well as via a multitude of national quality improvement efforts. I am Senior VP for the Society of Hospital Medicine (SHM) Center for Healthcare Innovation and Improvement, and have been involved in a variety of national improvement efforts involving over 300 hospitals, via SHM's Eisenberg award winning "Mentored Implementation" programs. SHM is the home organization for hospitalists, the fastest growing medical specialty group in the US, representing an estimated 34,000 practitioners. Dedicated to promoting the highest quality of care for hospitalized patients, hospitalists are nationally recognized leaders in patient safety and quality, both in practice and research. We are also the frontline clinicians using information technology, closely aligned with the goals of the institutions where we work. An increasing number of hospitalists are involved heavily in Health IT implementations and research.

In addition, I have worked with a multitude of other national improvement efforts, partnering with great organizations like AHRQ and the American Society of Healthsystems Pharmacists, and assist other

CENTER FOR INNOVATION AND IMPROVEMENT SCIENCE

Director, Greg Maynard MD, MSc, SFHM

200 West Arbor Drive, MC 8485 San Diego, California 92103-8485 TEL: (619) 471-3900 FAX: (619) 543-8255

medical centers in the region in QI via my role as Director of the UC San Diego Center for Innovation and Improvement Science.

These experiences have allowed me to view a wide variety of EHRs, CDS tools, and IT / improvement environments, and I feel well positioned to tackle the questions you are asking me to testify on.

1. What factors limit Health IT's ability to support quality measurement/improvement?

This is a question with a long answer, because there are currently many factors limiting Health IT's ability to support quality measurement and improvement. Some limiting factors:

- Health IT was traditionally built for fiscal and administrative purposes, not for quality improvement and safety. The administrative / fiscal roots of today's IT systems led to poor availability of clinical, quality, and safety data. In many medical centers and practices, the great majority of information available is months old administrative data that does not lend itself to rapid cycle improvement. While progress is being made, today's systems still have a long way to go. Many current "quality measures" are driven by the availability of information from administrative data bases. The alternative strategy of building high integrity quality measures and making sure they are embedded in a retrievable fashion into the Healthcare IT system, is in its infancy.
- Documentation of patient problems and data repositories are still often built in silos. It takes conscious effort and a lot of customization to build a communication platform in the EHR that puts the patient at the center, and fosters collaboration and teamwork, instead of isolation and lack of coordination.
- Poor interface design and counter-intuitive work flows are commonly found in EHRs, at times with features that can lead to safety problems.
- Improvement teams often report that EHRs and their supporting systems are incapable of basic functions, such as providing hierarchical decision support, effective displays of data, and formatting limitations.
- It remains difficult to pull data from several different data repositories. Everyone is working on this, but this remains an incredibly tedious and difficult job at most institutions. Lack of interoperability and a relative paucity of skilled workers and tools to address the "connectedness" and access to clinical information are large barriers to improvement.
- Implementation of EHR and other IT tools is a large and all-consuming process that stops QI and safety issues in their tracks in the months leading up to deployment, and for several months afterwards. Even in mature systems, EHRs often do not facilitate rapid cycle PDSA style improvements on a small pilot scale. Most improvement teams get one shot to get the CDS and data capture tools correct after months of waiting in queue and development time. Any request for revisions and refinements are treated as a failure of the improvement team, and it is often difficult or impossible to pilot new tools in a limited setting.

- IT departments (including vendor IT) often do not have a thorough grounding in quality and safety science or in human factors engineering. Subsequently, unqualified and inexperienced staff often place dysfunctional tools into the patient care environment. "Starter materials" provided by vendors in CDS and order sets are often offering guidance far from standard practice and that are not up to date.
- There is no central clearing house for vetting the quality and safety of Healthcare IT quality and safety.
- There is no accountability on the part of the vendors for products that may contribute to patient harm.
- There are limited venues in which to transparently share best practices, identify and eliminate unsafe or dysfunctional features, or allow spread of outstanding features that work. The Society of Hospital Medicine, as a Patient Safety Organization, tried to create a venue to share and disseminate information about IT tools, we met great resistance asking for sign off from hospital administrators, due to fear over contractual issues with vendors.
- Market forces discourage rapid dissemination of best practices, and in truth, once an institution has invested in an expensive IT system, the competitive nature of the EHR / IT market is lost, and the vendor enjoys a relative monopoly over all related products.

2. How can Health IT better support quality measurement/improvement?

and

3. How can the quality lifecycle be accelerated?

will be addressed together.

Features that would better support Health IT quality measurement improvement and accelerate the quality lifecycle would include:

- User friendly interface for clinicians, and for data analysts / reporters.
- Common data formats to allow for sharing of clinical information across disparate systems.
- Expansion of high quality data systems such as the CDC system.
- Research, registries, and other more open and transparent venues to identify the best CDS and reporting strategies, and encouragement / incentive for their dissemination and adaptation into a variety of environments. These same systems and front line feedback would also more rapidly identify problematic interfaces and ineffectual or unsafe CDS and reporting methods as well.
- A change in architecture of EHRs and other Health IT tools that allows for not just interoperability, but substitutable options. In the more "App" like environment, innovation and flexibility would be the rule. An underlying architecture could have different plug and play modules for different functions. Some companies are overcoming the current barriers to provide wonderful, easy to generate and useful reports, but most are stymied by proprietary systems. A very nice description of this improved construct for Health IT is was recently published in the New England Journal of Medicine (Mandl, K. Kohane, IS. No Small Change for Health Information Economy NEJM March 26, 2009; 360: 1278-1281.)
- "Real time" data capture and reporting, with flexible reporting and programming tools. When supported with other QI basics of standardization and good CDS, this kind of real time data capture

can lead to both timely **measurement** related immediate **intervention**, which we have termed "**measure-vention**". For example, vital signs that indicate clinical instability in the inpatient setting may be ignored, but when pushed to a color coded "dynamic dashboard" displaying all patients on a given ward, a quick summary of all patients with potentially problematic is readily available at a glance, and the situational awareness of the need for patient evaluation and a rapid response team activation triggers more timely interventions. In another example, the DVT prophylaxis methods in place on every patient on a given unit can be made available on demand, and the percentage of patients on anticoagulant prophylaxis vs mechanical prophylaxis vs no prophylaxis is made readily apparent to the end user at a glance. Focused attention can be directed at patients without any DVT prophylactic measures in place, spurring real time intervention. This kind of system has been used in many centers. An illustrative screen shot is displayed in figure 1.

BED_LABEL	Service	VTE Risk Category	Medication	Dose	SCD	Lab Contra	Orders state contra	Orders state LOW VTE Risk
2250A	Medicine Thornton	LOW	warfarin (COUMADIN) tablet 3 mg	3 mg EVERY EVENING Oral	Y	N	N	Y
2250B	Medicine Thornton	MODERATE	enoxaparin (LOVENOX) injection 30 mg	30 mg DAILY Subcutaneous	Y	N	N	N
2251	Medicine Thornton	MODERATE	heparin injection 5,000 Units	5000 Units EVERY 12 HOURS Su	Y	N	N	N
2252	Cardiothoracic Surgery	MODERATE/HIGH	No Anticoag Med	No Anticoag Dose	Y	Y	N	Y
2253	Medicine Thornton	MODERATE	enoxaparin (LOVENOX) injection 40 mg	40 mg DAILY Subcutaneous	Y	Y	N	N
2254	Medicine Thornton	MODERATE	heparin injection 5,000 Units	5000 Units EVERY 8 HOURS Sub	Y	N	N	N
2255	Medicine Thornton	MODERATE	heparin injection 5,000 Units	5000 Units EVERY 12 HOURS Su	Y	N	N	N
2256A	Medicine Thornton	MODERATE	enoxaparin (LOVENOX) injection 40 mg	40 mg DAILY Subcutaneous	Y	N	N	N
2256B	Pulmonary Vascular Medicine	MODERATE/HIGH	enoxaparin (LOVENOX) injection 50 mg	50 mg EVERY 12 HOURS Subcut	Y	Y	N	N
2257A	Medicine Thornton	MODERATE	enoxaparin (LOVENOX) injection 40 mg	40 mg DAILY Subcutaneous	Y	N	N	N
2257B	Gynecology	MODERATE/HIGH	No Anticoag Med	No Anticoag Dose	Y	Y	N	N
2258	Medicine Thornton	MODERATE	enoxaparin (LOVENOX) injection 30 mg	30 mg DAILY Subcutaneous	Y	N	N	Y
2259	Medicine Thornton	MODERATE	No Anticoag Med	No Anticoag Dose	Y	N	N	N
2260	Pulmonary/Critical Care	LOW	No Anticoag Med	No Anticoag Dose	N	N	N	Y
2261	Medicine Thornton	MODERATE/HIGH	No Anticoag Med	No Anticoag Dose	Y	Y	N	N
2262A	Medicine Thornton	LOW	enoxaparin (LOVENOX) injection 40 mg	40 mg DAILY Subcutaneous	Y	N	N	Y
2262B	Medicine Thornton	MODERATE	enoxaparin (LOVENOX) injection 40 mg	40 mg DAILY Subcutaneous	Y	N	N	N
2263	Medicine Thornton	MODERATE/HIGH	No Anticoag Med	No Anticoag Dose	Y	Y	N	N
2264	Pulmonary Vascular Medicine	MODERATE	warfarin (COUMADIN) tablet 5 mg	5 mg EVERY EVENING Oral	Y	Y	N	Y
2265	Pulmonary Vascular Medicine	LOW	heparin injection 5,000 Units	5000 Units EVERY 8 HOURS Sub	Y	N	N	Y
2265	Pulmonary Vascular Medicine	LOW	warfarin (COUMADIN) tablet 10 mg	10 mg EVERY EVENING Oral	Y	N	N	Y
2266	Medicine Thornton	MODERATE	heparin injection 5,000 Units	5000 Units EVERY 8 HOURS Sub	Y	N	N	N
2267	Pulmonary Vascular Medicine	HIGH	enoxaparin (LOVENOX) injection 100 mg	100 mg EVERY 12 HOURS Subcu	Y	Y	N	Y
2268	Cardiothoracic Surgery	LOW	enoxaparin (LOVENOX) injection 40 mg	40 mg DAILY Subcutaneous	Y	N	N	Y
2269	Cardiothoracic Surgery	No Risk Category	No Anticoag Med	No Anticoag Dose	N	N	N	N
2270	Cardiothoracic Surgery	No Risk Category	No Anticoag Med	No Anticoag Dose	N	N	N	N
2271	Medicine Thornton	MODERATE	heparin injection 5,000 Units	5000 Units EVERY 12 HOURS Su	Y	N	N	N
2272	Pulmonary Vascular Medicine	HIGH	fondaparinux (ARIXTRA) injection 7.5 mg	7.5 mg DAILY Subcutaneous	Y	Y	N	Y

Figure 1. Report on Venous Thromboembolism (VTE) Prophylaxis in place for an inpatient unit, displaying the potential for "measure-vention". Of the 28 patients on this unit, 20 are on anticoagulation (green), 4 are on mechanical prophylaxis only, but have a documented lab contraindication to anticoagulant (orange), 1 is on mechanical prophylaxis only, without any documented lab contraindication to anticoagulant (yellow), and 3 are no VTE prophylactic measures at all (red). Nursing staff can focus their evaluations and possible real time interventions to boost on those color coded in red or yellow. (Maynard G, Stein J. Designing and Implementing Effective VTE Prevention Protocols: Lessons from Collaboratives. J Thromb Thrombolysis 2010 Feb;29(2):159-166.)

4. What is the role of Clinical Decision Support (CDS) in the quality lifecycle? How does CDS relate to quality measurement?

Clinical decision support has a potential role at every phase of the quality lifecycle. Properly done, CDS can be efficient, timely, effective and unobtrusive. CDS can help health care providers "get it right the first time" as they assess and order tests and treatments for their patients. At other phases, CDS can raise awareness when a patient falls between the safety / quality cracks, as described above. CDS should be deployed in areas in which there are opportunities to improve quality or safety, and should positively impact relevant measures of quality process and outcomes when deployed. CDS deployment should be questioned when there is no method in place to assess its effectiveness, or the potential unintended consequences.

5. What is the Health IT vendor role in quality improvement programs?

Current vendor roles are highly variable and have uneven effectiveness. Some are making good strides in building tools that help promote and monitor quality and safety. However, even with the best vendors, this performance is spotty, and often covers mostly the mandatory bases. The lack of transparency, portability, and accountability significantly retard the vendor roles in QI programs, in my opinion, and the EHR implementation can retard QI efforts in many areas, while end users suffer through a steep learning curve. Again, the lack of a process to identify and spread best practices, or to pull the best features from different vendors, retards innovation and acceleration of QI efforts.

6. Are there viable business models in which vendors can/should share risk/reward with providers?

I do not consider myself an expert in business models, but I am confident better business models than the current one exist. Vendors currently lack accountability for safety problems or ineffectiveness of their product, and market forces, once an institution commits to a vendor, are currently insufficient to drive rapid correction of issues. This is not to say the vendors are not make valid efforts now, and is not intended to disparage their talent or dedication, but a better business model would definitely help, I think.

In closing, I would also like to endorse the findings of the recent Institute of Medicine Report:

Health IT and Patient Safety: Building Safer Systems for Better Care. Virtually all of these findings can be expanded to the larger arena of Quality Improvement, and I encourage all attendees to read this report.

I look forward to discussing these issues with the variety of stakeholders and experts you have convened for this hearing. I appreciate the opportunity to express my views, and to learn from the views I will actively pursue while I am there.

Respectfully submitted,

A handwritten signature in black ink that reads "Gregory A. Maynard". The signature is written in a cursive style with a large, prominent initial "G".

Gregory A. Maynard M.D., MSc., SFHM
Clinical Professor of Medicine
Director, UC San Diego Center for Innovation and Improvement Science
Sr. VP, SHM Center for Hospital Innovation and Improvement

CENTER FOR INNOVATION AND IMPROVEMENT SCIENCE

Director, Greg Maynard MD, MSc, SFHM

200 West Arbor Drive, MC 8485 San Diego, California 92103-8485 TEL: (619) 471-3900 FAX: (619) 543-8255