Electronic Health Records in Oncology

Why Meaningful Use Matters

By Peter Paul Yu, MD

The problems that face our national health care delivery systems include fragmentation of the provider base, poor communication among providers and with patients, misaligned incentives among stakeholders, lack of a common governance structure, and insufficient financial and expert resources for instituting and managing change even where the will to do so exists. Although widespread adoption of electronic health records (EHRs) is frequently and correctly cited as necessary to meet the challenge of doing better with less, technology alone will not accomplish this. Societal change within both the medical system and the population that the medical establishment interacts with must accompany the adoption of health information technology (HIT). The reliance on financial incentives and disincentives to control medical behavior, improve value, and bend the rising burden of health care on the nation's economy will fail unless physicians and their professional societies are included as meaningful partners in health care reform. We will begin to advance health care only if we succeed in creating a new socio-technologic ecosystem that includes providers, patients, and payers.

The meaningful use (MU) criteria that unlock the American Recovery and Reinvestment Act (ARRA) stimulus dollars matter because these criteria are the tangible first efforts to redesign how health care is delivered while acknowledging the central role of HIT and EHRs. The underlying principles on which these criteria were constructed define the priorities and goals for national health and health care delivery redesign.

The Origins of MU

MU combines technology adoption by providers and hospitals, health information exchange, practice redesign, and consumer engagement in order to improve outcomes and efficiency of health care delivery. The Institute of Medicine (IOM) has been instrumental in laying out the underlying principles for the design of a more efficient health care delivery system capable of increasing value by simultaneously improving the quality of care delivered and reducing resources expended. Five overarching goals to achieve this have been identified by IOM and were subsequently adopted by the Office of the National Coordinator for Health Information Technology (ONC) as the underlying basis for MU¹:

1. Improve quality, safety, efficiency, and reduce health care disparities.
2. Engage patients and families.
3. Improve care coordination.
4. Improve population and public health.

5. Ensure adequate privacy and security protections for personal health information.

The importance of first two objectives of MU is understood by medical oncologists. HIT has a major role to play in enhancing the quality, safety, and efficiency of chemotherapy administration.^{2,3} Although engagement of patients and families in shared decision making happens daily in oncology practice, the use of HIT can greatly facilitate this by sharing information on diagnosis, staging, treatments, and expected outcomes. The process of shared decision making and the influence of families and social networks in that process will need to be better understood so that cancer-relevant HIT tools can be developed. These first two MU objectives illustrate that the EHRs is not the passive documentation tool of the paper medical record, but instead a more dynamic instrument that actively assists the physician in patient care.

The third MU objective is improved care coordination. Cancer care requires multidisciplinary coordination between primary care, medical specialties, and allied health professionals to achieve optimal outcomes and efficiencies. Fundamental to the third MU objective is that patient-centered care necessitates that health information follow the patient as he or she moves through the medical system.

The fourth MU objective, improving patient and population health, is a novel concept for most oncologists, accustomed as we are to focusing on health care one patient at a time. The office-based paper chart was meant for the personal use of the recording physician in providing care to an individual patient. It sufficed if the information contained within the paper chart complemented the knowledge stored in the physician's memory and provided documentation of services for reimbursement. This method of recording health data has become inadequate to support emerging health care systems that require actionable guidelines that support a complete episode of cancer care and define and measure health and economic outcomes. A new generation of clinical practice guidelines will be created with EHR implementation planned from the outset using clinical decision support tools. To write and validate these new guidelines will require data capture, aggregation, and reporting from the real-world patient experiences of practices as we begin to assemble new knowledge bases.

The fifth MU objective can be seen as a technical issue, but it is one that oncologists ignore with substantial medical legal risk. Maintaining the integrity of health data, restricting access to personal health data, and ensuring the secure exchange of data are often dependent on human actions and less so on the

underlying EHR's design. Policy and procedures need to be in place and followed.

Over the next 5 years, if the MU goals are achieved, we will have an established digital infrastructure for our nation's health care system. Looking to the future, the IOM has advanced concepts to build on the foundation of MU. The use of patient data to feed into a rapid cycle of knowledge creation and quality and outcomes improvement could speed the process of translating clinical research into routine care. A Rapid Learning Health Care System (RLHS) is based on the use of every patient's medical experience to contribute data, which when aggregated and analyzed can generate new insights into disease mechanisms and treatment approaches. This is an iterative process; as new knowledge is generated, it will feed back to inform and revise best practices of patient care. An IOM workshop in 2009 examined how a RLHS for oncology might take shape.⁴ RLHSs will be heavily dependent on electronic capture and transmission of patient data and presuppose the implementation of a national system for exchanging health data between patients, providers, and entities engaged in public health. Thus viewed, MU is not merely a government incentive program to induce physicians to exchange paper for a digital version of the medical record. Misunderstanding this is to risk expending a minimum effort to meet the regulatory requirements to qualify for the MU incentive dollars without instituting the lasting changes needed to prepare for the models of health care delivery that will follow.

Setting up MU

ARRA became law on February 19, 2009. Title IV of Division B of ARRA established incentive payments to eligible professionals, hospitals, critical access hospitals, and Medicare Advantage Organizations to promote the adoption and meaningful use of interoperable HIT and qualified EHRs. Title IV of Division B and Title XIII of Division A of ARRA together are also referred to as the Health Information Technology for Economic and Clinical Health Act or HITECH Act. ONC was charged with establishing a Health Information Technology Policy Committee and a Health Information Technology Standards Committee to respectively recommend criteria for the meaningful use of EHRs by providers and establish technical standards for EHRs. Although ONC through its Policy Committee makes recommendations on MU criteria, the final decision on MU criteria is determined by the Centers for Medicare & Medicaid (CMS). ONC does determine the certification standards and testing process for EHRs to be designated as "certified EHR technology." Physicians and hospitals can choose one certified EHR that meets all technical requirements or can cobble together individual components or modules that are each certified to perform a portion of the certification requirement. As of the end of 2010, one of the certifying bodies, the Commission for the Certification of Health Information Technology, had certified 92 EHR technical products for eligible providers, of which 73 were complete systems and 19 were EHR modules.⁵ Providers qualify for the MU incentive only if they are using certified EHR technology and can demonstrate

that their use of it fulfills the MU performance criteria. If both are achieved, the physician qualifies for up to \$44,000 under Medicare rules or \$63,750 under Medicaid rules over a 5-year period. Providers participating under the Medicaid program have one extra year of incentive payments, and in the first year do not need to demonstrate meeting MU performance criteria. To qualify under the Medicaid program, providers need to have at least 30% of their patient volume under Medicaid. Providers may begin participation in MU in 2011, but there is no loss of incentive dollars for starting in 2012. Starting after that reduces the total incentive package. However, the first year's participation requires only a 90-day period; thereafter, full year participation is required (Table 1).

The MU requirements will be rolled out in three stages, the first in 2011, second in 2013, and third anticipated in 2015, with the introduction of new criteria and higher performance standards with each successive stage. In 2015, providers who do not meet MU requirements will be penalized, starting at 1% of CMS reimbursement, increasing to 2% in 2016, 3% in 2017, and thereafter as the Secretary of Health and Human Services deems necessary to ensure widespread adoption of an electronic infrastructure for health care. The focus of stage 1 requirements is capturing health information in a structured format, tracking key clinical conditions, coordinating care, supporting clinical decision making, engaging patients and families, and reporting quality measures and public health information. Stage 2 will "encourage the use of health IT for continuous quality improvement at the point of care and the exchange of information in the most structured format possible . . . and the expectation that providers will electronically transmit patient care summaries to support transitions of care across unaffiliated providers, settings and EHR systems."^{6(p35)} Stage 3 will focus on "promoting improvements in quality, safety, and efficiency leading to improved health outcomes, focusing on decision support for national high-priority conditions, patient access to self-management tools, access to comprehensive patient data through robust, patient-centered health information exchange and improving population health."^{6(p36)}

The Final Rule defining stage 1 of MU was published on July 28, 2010, after extensive public hearings and comment period in which ASCO actively participated. The Final Rule establishes MU criteria and the threshold levels of performance that must be met to qualify for incentive dollars. A core set of 15 objectives must be met, and from a menu set of an additional 10 items, five must be selected, including at least one of the two population and public health measures.⁷ The core set of MU objectives requires eligible providers to submit three clinical quality measures from a list of six core or alternate core quality measures (Table 2) and any three additional ones from a menu of 38 quality measures.⁶ Of these, the ones most likely to be useful to medical oncologists are listed in Table 3. There are no threshold quality performance levels that are required; this is a reporting activity only. Note that for 2011, providers will attest to meeting the MU measures, and in 2012, CMS plans to be capable of receiving electronic transmission reporting of the clinical quality measures.

Table 1. Schedule of Incentive Payments By Starting Year Payments

Start Year	2011	2012	2013	2014	2015	2016	Total
2011	18,000	12,000	8,000	4,000	2,000	—	44,000
2012	—	18,000	12,000	8,000	4,000	2,000	44,000
2013	—	—	15,000	12,000	8,000	4,000	39,000
2014	—	—	—	12,000	8,000	4,000	24,000
2015	—	—	—	—	—	—	Penalty 1%

Table 2. Core and Alternate Core Clinical Quality Measures

Measure	Type
Adult weight screening and follow-up	Core
Hypertension: blood pressure measurement	Core
Preventive care and screening measure pair: (a) tobacco use assessment, (b) tobacco cessation intervention	Core
Preventive care and screening: influenza immunization for patients ≥ 50 years old	Alternate core
Weight assessment and counseling for children and adolescents	Alternate core
Childhood immunization status	Alternate core

Table 3. Menu Set Clinical Quality Measures of Interest to Medical Oncologist

Oncology breast cancer: hormonal therapy for stage IC-IIIc estrogen receptor/progesterone receptor-positive breast cancer
Oncology colon cancer: chemotherapy for patients with stage III colon cancer
Smoking and tobacco use cessation, medical assistance: (a) advising smokers and tobacco users to quit, (b) discussing smoking and tobacco use cessation medications, (c) discussing smoking and tobacco use cessation strategies
Breast cancer screening
Colorectal cancer screening
Pneumonia vaccination status for older adults

The Future

Under the leadership of David Blumenthal, MD, MPP, ONC adhered to an ambitious schedule for launching stage 1, while demonstrating responsiveness to what providers, hospitals, and vendors believed were realistic objectives. The ONC HIT Policy Committee presented their timeline for stages 2 and 3 on December 13, 2010. Through 2011, the HIT Policy Committee will release draft stage 2 MU criteria, collect public comment, and finalize its recommendations to CMS in the third quarter. It is anticipated that CMS will set the final stage 2 MU criteria in the fourth quarter. Whereas stage 1 has been about primary care, stage 2 is expected to begin to address specialty-based criteria. The HIT Policy Committee has released proposed stage 2 criteria that raise stage 1 benchmark thresholds and create new criteria. Possible new criteria include the use of clinical decision support tools to improve performance in high-priority health conditions such as cancer, required use of electronic notes by providers, threshold levels for patient use of a

personal health record, and secure patient messaging online. Health information exchange criteria may require electronic data exchange with external providers, which would facilitate coordination of care. Longitudinal care plans for patients with high-priority health conditions are under consideration and may provide an opportunity to promote cancer treatment plan and summary documents. Additions to the list of clinical quality measures are expected, possibly including more specialty specific measures.

One of the underlying assumptions of MU is that HIT will result in vast savings in health care costs that will sustain the building of a national digital infrastructure. The incentive dollars by themselves will cover a small part of the overall costs of providers' HIT investments. The greatest challenge to the success of MU is whether expected financial gains materialize and whether some of those gains are used to support HIT development. Other challenges exist. At a time where health care providers are realigning into larger merged entities, providers may find themselves saddled with EHRs that no longer serve their needs. At the present time, MU is designed for primary care and is poorly suited for surgical and medical specialties, and CMS itself will require vast investments to update its information systems.

The ASCO HIT Work Group has been closely following the development of MU as it breathes life into its five overarching objectives and will continue to provide public comment to ONC and CMS as stages 2 and 3 crystallize. ASCO itself has begun a comprehensive review of its guidelines development process and quality measurement programs such as the Quality Oncology Practice Initiative to ensure that ASCO remains optimally positioned to speak to the future of cancer care and build a Rapid Learning Oncology Care System.

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Author's Disclosures of Potential Conflicts of Interest

The author indicated no potential conflicts of interest.

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References

1. Health Literacy and Meaningful Use of Health IT. http://www.iom.edu/~media/Files/Activity%20Files/PublicHealth/HealthLiteracy/2010-MAY-27/4_Seidman.ashx
2. Shulman LN, Miller RS, Ambinder EP, et al: Principles of safe practice using an oncology EHR System for chemotherapy ordering, preparation, and administration, Part 1 of 2. *J Oncol Pract* 4:203-206, 2008
3. Shulman LN, Miller RS, Ambinder EP, et al: Principles of safe practice using an oncology EHR System for chemotherapy ordering, preparation, and administration, Part 2 of 2. *J Oncol Pract* 4:254-257, 2008
4. Institute of Medicine: A Foundation for Evidence-Driven Practice: A Rapid Learning System for Cancer Care-Workshop Summary. <http://www.iom.edu/Reports/2010/A-Foundation-for-Evidence-Driven-Practice-A-Rapid-Learning-System-for-Cancer-Care.aspx>
5. Ray A: Real World Experiences Working with Meaningful Use. <https://www.cchit.org/sites/all/files/cchitTestimonyRayHITStandards20110110.pdf>
6. Department of Health and Human Services, Centers for Medicare & Medicaid Services, 42 CFR Parts 412, 413, 422 et al. Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule. <http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf>
7. American Society of Clinical Oncology: A Guide to the Meaningful Use Measures for Eligible Professionals. Government Incentives for EHR Adoption Stage 1 Meaningful Use. <http://www.asco.org/ASCOv2/Department%20Content/Cancer%20Policy%20and%20Clinical%20Affairs/Downloads/EHR/EHR%20Policy%20Documents/SummaryMeaningfulUseMeasures10.25.10.pdf>

Electronic Health Record Certification in Oncology: Role of the Certification Commission for Health Information Technology

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Introduction

Physicians have consistently cited upfront costs and uncertainties about potential system obsolescence as major barriers to the adoption of electronic health records (EHRs) in ambulatory settings.¹ Likewise, concerns about capital costs and return on investment were identified as impediments to EHR adoption by 74% and 32%, respectively, of acute care hospitals.² A fundamental deficiency that underlies many of these barriers, characteristic of a large number of EHRs currently marketed, is a lack of standards-based interoperability. This inability to exchange health information has historically deterred physicians from making the enormous investment often required to purchase and implement a clinical information system, particularly when they might feel such systems could limit future integration and expansion. Furthermore, small and medium-sized physician practices often lack the resources to engage consultants or to navigate a vendor-centric landscape of products on their own. Consequently, they perceive the risks of health information technology (HIT) purchase and implementation to be high, and until recent government incentive programs were introduced, they have shown considerable reluctance to make the leap from paper to digital records.

Origin and Structure of the Certification Commission for Health Information Technology

The HIT landscape in the United States began to change dramatically in 2004 with the creation of the Office of the National Coordinator for Health Information Technology (ONCHIT, often shortened to ONC), part of the US Department of Health and Human Services (HHS), and the appointment by President Bush of David Brailer, MD, PhD, as its head. On July 21, 2004, Brailer's office issued a *Framework for Strategic Action*,³

which listed four goals, each with a set of corresponding strategies, to enable the transformation of health care through the use of IT: (1) inform clinical practice, (2) interconnect clinicians, (3) personalize care, and (4) improve population health.³

One of the strategies under the "inform clinical practice" goal was "Reduce the risk of EHR investment."³⁽⁹⁾ One specific action envisioned was the creation of a private-sector certification process to "develop minimal product standards for EHR functionality, interoperability, and security."³⁽⁹⁾ From this *Framework for Strategic Action*, the Certification Commission for Health Information Technology (CCHIT) arose. CCHIT was founded as an independent, limited liability company (LLC) in 2004 through the sponsorship of three professional associations involved in HIT and health information management: the American Health Information Management Association, the Healthcare Information and Management Systems Society, and the National Alliance for Health Information Technology (an organization no longer in existence). The goal was to represent the interests of three key stakeholder groups: providers, HIT vendors and developers, and payers. Supplementary funding was provided in 2005 by additional sponsors, including the American Academy of Family Physicians, the American College of Physicians, and several corporate entities. In 2005, HHS contracted with CCHIT to develop the first EHR certification programs, and HHS officially recognized CCHIT as a certifying body in 2006. Under the terms of this government contract, CCHIT developed independent certification criteria for EHRs and began evaluating vendor products. The original LLC was dissolved in 2007, and the organization evolved to its present status as an independent nonprofit 501(c)3 corporation, registered in the state of Illinois and sustained by certification fees paid by vendors.⁴ Currently, its work is guided by two volunteer boards: a nine-person Board of