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December 6, 2011

A RAPID LEARNING SYSTEM FOR ONCOLOGY CARE

On behalf of the American Society of Clinical Oncology (ASCO), I am pleased to submit this response to the Request for Information relative to a 21st Century Bioeconomy. ASCO and its more than 31,000 members is the world's largest medical professional society devoted to the treatment and cure of cancer. Our response centers around ASCO's efforts to harness the value of health information technology (HIT) to create an oncology care delivery system that interprets the fruits of genomic science, ensures that the proper treatment is delivered to every patient every time, and learns and improves through the daily practice of medicine. In short, we intend to learn from each cancer patient to make the treatment of subsequent patients better. We will foster economic activity through this project by:

- Engaging with numerous partners in the public and private sectors
- Eliminating unnecessary intervention, thus saving hundreds of millions of dollars in unneeded health expense that can be put to use elsewhere
- Increasing necessary intervention to improve the value of oncology care
- Promoting consistency and minimizing redundancy in HIT specifications and standards, and
- Increasing the survival of cancer patients, allowing them to return to productive activities in society. It has been estimated¹ that a 20% reduction in cancer deaths would be worth *ten trillion dollars* to this country. Our work has the potential to facilitate, empower and move us towards these types of gains.

GRAND CHALLENGES

One of the most important challenges facing the healthcare system is the daunting task of translating what we know about oncology care today - and the pending flood of genomic information that will be here tomorrow - into actionable decisions at the clinical practitioner level.

¹ Exceptional Returns, *The Economic Value of America's Investment in Medical Research* available at www.laskerfoundation.org/media/pdf/exceptional.pdf

We have reached a point, through the continued development of HIT and the increasing adoption of electronic medical records (EMRs), due, in part, to “meaningful use” standards promoted by the Centers for Medicare and Medicaid Services (CMS), where we can now envision harnessing the power of this technology to transform oncology care.

The need is clear. If one looks at major cancer treatment guidelines today, less than 10% of recommended cancer treatment decision can be made on the basis of rock-solid clinical research data, leaving over 90% to be made through our best thinking, case experience, and small clinical studies. Imagine a system that some have called a Rapid Learning System².

Here case data is collected seamlessly on each cancer case. The data is aggregated and analyzed by the type and stage of disease, the patient’s other medical conditions and treatments, the clinical outcomes as reported by the oncology team and the outcomes provided to the system directly by the patient. One will quickly be able to recognize what works best in various populations and sub-populations of cancer patients and feed that information back to oncology practices so that care decisions are improving in real-time. For the first time, oncology care will be placed on a cycle of rapid and continuous improvement and the 90% of decisions made by best consensus will be slowly and steadily replaced by empirical data.

Decision support built into the system will ensure that the key information about what is best reaches the healthcare team precisely at the point of care. Features will include knowledge resources and comprehensive support for increasingly complex and personalized clinical decisions, availability of patient-reported data in practice records, and data exchange among providers and sites of care. Automated and secure transfer of a specified data set to the RLS will allow for HIPAA-compliant quality improvement reporting, as well as other secondary data uses.

As new drugs are developed, their release into the clinic will be monitored and their use optimized for patients who, for a variety of reasons, would not have been eligible for the study that led to FDA approval. As new agents are studied, the system will alert patients and physicians as to the proper clinical trial for that particular setting. This will be increasingly critical as small sub-populations of patients with a specific molecular lesion are needed to assess a new targeted therapy. The impact on cancer genetics and genomics is discussed below.

A NATIONAL PRIORITY

Creating the Rapid Learning System for oncology care should be a major national priority. It will build on the substantial investment being made under the HITECH Act as well as the major commitment from CMS to measure “quality of care” through the Physician Quality Reporting System (PQRS). While the later may be an acceptable approach to monitoring the quality of care given in common chronic conditions such as hypertension or type II diabetes, PPQRS is woefully inadequate to monitor cancer care. The disease we term “cancer” is actually a family of diseases with 100 or more family members.

² Amy P. Abernethy, Lynn M. Elheredge, Patricia A. Ganz, Paul Wallace, Robert R. German, Chalapathy Neti, Peter B. Bach, and Sharon B. Murphy, *Rapid-Learning System for Cancer Care*, JCO Sep 20, 2010;4268-4274; published online on June 28, 2010; DOI:10.1200/JCO.2010.28.5478.

Within each cancer is a wide spectrum of cases, early versus late stage, aggressive versus slow progression, metastatic versus localized, and so on. There is simply no way for CMS to create enough classic performance measures to monitor the quality of cancer care in any meaningful way, yet such quality measurement is crucial. A fully electronic system that is designed to deal with massive amounts of data is what must be created. The RLS is such a system.

The RLS will be a robust and ready-made solution for quality measure reporting requirements related to federal programs (such as the EHR Incentive Program and the Physician Quality Reporting System). Federal agencies overseeing such programs will not need to build or maintain independent systems related to cancer care. Furthermore, the RLS will facilitate surveillance initiatives, such as risk evaluation and mitigation (REMS). The RLS objectives are aligned with those of other important public and private sector health care initiatives.

MOVING LIFE SCIENCES BREATHROUGHS FROM LAB TO MARKET

The \$1,000 genome is fast approaching. Soon, large numbers of patients will have their cancer and normal tissue genomes sequenced and compared. How will this information be interpreted? Once a therapy is given, how will we track what happens so we can use this genetic data more effectively to learn what works and what doesn't in actual clinical practice?

The RLS in oncology will be a key component of making sure the genomic data is used appropriately and that we learn from every patient experience. The RLS will provide an extensive and nearly real-time data set for researchers, including both clinical and patient reported data. These data will far surpass existing oncology data sets.

This becomes especially important as we further elucidate the disruptions to cellular pathways that are actually causative in cancer. Before long, even a common disease like lung cancer with over 200,000 cases per year will devolve into 20 or 30 (or more) distinct molecular subtypes. Within those subtypes are early-stage and late-stage patients. Within the stages are young and old, male and female, with and without diabetes, and so on. Without having the ability to learn from EVERY patient we will not be able to have enough data to understand in the optimal therapeutic option for EACH patient.

FOSTERING BIOINNOVATION

It takes many years and hundreds of millions of dollars to develop a new cancer drug. We must find ways to make the process of drug development and testing more efficient. The RLS is an indispensable part of that process.

Consider the following scenario. A defect in a molecular pathway in colon cancer is identified and a company has produced a drug that targets the defect. But colon cancer patients must be screened with genetic testing and the small subset of patients whose cancers contain that abnormality must be identified. Once they are, the patients and their physicians must be made aware that a drug exists that might help them. The option to enroll in a clinical trial for that drug must be brought to their attention. Once the patient and the drug trial are linked up, the outcomes from the therapy, both clinically and from the patient's point of view, will need to be collected and analyzed.

Different populations of patients with the defect may respond more or less favorably based on factors outside the cancer itself (age, gender, other medical conditions, other drugs being taken, etc.). In every step of this process the RLS can be of immeasurable assistance in facilitating the testing of the new agent and doing so far more quickly and accurately than the process that exists today.

PUBLIC-PRIVATE PARTNERSHIPS

Our work will require us to build many partnerships. While we are still at the beginning of the work, talks have been held with:

Database platform/analytics companies:

- Microsoft
- Oracle
- Google
- IBM (Watson program)

Electronic health record companies:

- Varian Medical Systems
- Altos Systems
- IKnowMed (part of US Oncology)

Pharma/biotech:

- Numerous companies

Government agencies:

- Office of Science and Technology Policy
- Veterans Administration
- National Cancer Institute
- Patient Centered Outcomes Research Institute

Non-profits:

- National Comprehensive Cancer Network
- eHealth Initiative
- Komen for the Cure
- Lance Armstrong Foundation

Patient reported outcome companies:

- Patients Like me
- Healthy Circles
- WellDoc

SUMMARY

The American Society of Clinical Oncology is committed to creating a cancer care system in which information learned from every patient encounter is used to accelerate progress against cancer.

The Rapid Learning System (RLS) for Oncology is the model to achieve this vision.

As outlined above, ASCO is building a technology-enabled infrastructure that: 1) allows data routinely collected during clinical care to be integrated, analyzed, and applied to inform and improve clinical care decisions, 2) promotes patient education, empowerment, and self-management, and 3) supports timely surveillance, research and knowledge generation.

The RLS for Oncology will connect cancer patients, survivors, families, their cancer care teams, and other health care providers. ASCO-developed, evidence-based content will form the core knowledge base, which will be continually updated by real-time data aggregation and analysis. ASCO is uniquely positioned to lead such an effort:

- ASCO is a multidisciplinary professional society that includes the full spectrum of professionals who provide cancer care.
- Initiatives from ASCO are viewed by oncologists as the work of trusted peers.
- ASCO has a longstanding commitment to and engagement in quality measurement, management and improvement, and to defining functionality and data standards for oncology information technology systems.
- ASCO has a demonstrated ability to facilitate culture change in oncology practice.

Most importantly, ASCO recognizes the crucial importance of partnerships and collaborations to achieve the RLS for oncology. We are actively seeking a host of partners from the public and private sector to provide critical support for this effort. Without such support, from commercial companies, non-profits, and government agencies such as CMS, the NCI, and providers like the Veterans Administration, it will be extremely difficult for the endeavor to succeed. However, working together, we will transform oncology care for the 21st century.