August 24, 2020

Don Rucker, MD  
National Coordinator for Health Information Technology  
Office of the National Coordinator for Health Information Technology (ONC)  
330 C Street, SW  
Floor 7  
Washington, DC 20201

Submitted electronically to identity.onc@hhs.gov

Dear Dr. Rucker,

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (ASCO) in response to the Office of the National Coordinator for Health Information Technology’s (ONC) invitation to stakeholders to submit comments\(^1\) on strategies to improve patient identification and matching in the context of the nation’s health information technology infrastructure.

ASCO is a national organization representing nearly 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are also dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

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Background

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191, was enacted on August 21, 1996. HIPAA mandates the creation of a unique patient identifier (UPI) by the Department of Health and Human Services (HHS); however, before the regulation went into effect in 2009, Congress passed a funding ban that effectively barred the department from using funds to develop or promulgate the use of the identifier. Since that time, the language banning a UPI has been inserted into subsequent Congressional appropriations bills up through the present time.

\(^1\) Available at https://www.healthit.gov/topic/patient-identity-and-patient-record-matching
ONC’s Current Request for Comments

In 2019, in a departure from previous years, the House of Representatives added an amendment to its Departments of Labor, Health, Human Services, Education, and Related Agencies Act of 2020, which removed the ban on the use of federal funds for development of a UPI. However, a Senate Appropriations Subcommittee’s 2020 fiscal budget bill draft continued to ban HHS from developing a UPI. Subsequently, in December 2019, a Congressional Appropriations Agreement for 2020 directed ONC, along with other pertinent Federal agencies, to provide a report to Congress studying and evaluating current technological and operational methods that improve identity and matching of patients. It also requests analysis of the risks and benefits of UPI standards.

Current Considerations Related to a Unique Patient Identifier

According to ONC’s definition, patient matching is defined as the identification and linking of one patient’s data within and across health systems in order to obtain a comprehensive view of that patient’s health care record. At a minimum, this is accomplished by linking multiple demographic data fields such as name, birth date, phone number, and address. Patient matching is critical to enable access to a patient’s health history at the point of treatment, avoid duplicative services (including imaging scans and other services that can pose a risk for patients), and deliver efficient health care services.

There are longstanding and valid concerns on both sides of the debate regarding the development and use of UPIs. Those opposed to UPIs point to the potential for breaches of sensitive protected health information (PHI) while those in favor argue that advantages of a UPI include increased patient safety, decreased medical errors, financial savings, and decreased administrative burden. Ultimately, the decision regarding whether or not to adopt a UPI rests upon a risk-benefit analysis of the potential for breaches and subsequent patient harm versus the many advantages and avoidance of harm inherent in the ability to connect patient data accurately across multiple providers, settings, and health systems. In addition to the real-time advantages for clinical care, the ability to connect patients’ health records would significantly increase the ability to learn from patients’ treatments, outcomes, and interactions with the health care system through research.

Actual and potential patient harm from patient/data misidentification has led to the emergence of patient identification as a significant safety concern. Over time, multiple large provider and hospital groups, insurers, health information technology developers, and major health informatics groups have come out strongly in favor of a UPI, but it should be noted that not all groups agree with this position and that their concerns, unless meaningfully addressed during development and implementation of a UPI, remain valid.

Adoption of a Unique Patient Identifier

ASCO urges ONC to work across federal agencies and with the private sector to enable development of a UPI. Priority should be given to technology that provides the highest level of data security and the input of patient groups and patient safety groups should be actively solicited and incorporated.

A UPI is necessary because our nation’s health information technology infrastructure was not built a priori with the goals of patient-centric care delivery and interoperability across health care providers. ONC and the Centers for Medicare and Medicaid Services (CMS) have released final rules\(^6,7\) intended to enhance interoperability and portability of patient records between and among health systems and to greatly enhance patient access via third party “apps”; however, a meaningful increase in interoperability and portability can only occur if patient records from disparate systems can be correctly identified and matched. Currently, different health systems use different algorithms and procedures for matching patient data and some of the work remains manual and resource intensive. Some of the demographic data underlying many matching algorithms is subject to change and hence open to potential matching errors leading to incorrect information or omissions in the patient’s record. A UPI would provide more certainty that a specific record does indeed belong to a specific patient and enable much more accurate record sharing and integration.

ASCO acknowledges that there are real concerns regarding the safety and security of PHI and would not support the development of a UPI that fails to utilize technology that provides the highest level of safeguards for patient data. However, given the use of such technology, the benefits of a UPI will be numerous in terms of patient safety, decreased cost, and likely increased patient satisfaction with coordination of care and greater efficiency in health systems’ operations. In addition to the use of technology providing the highest degree of data security, robust processes for investigation and remediation in the case of data breaches need to be maintained, strengthened, and rigorously adhered to.

Data Privacy and Security and UPI Design

From a data privacy and security perspective, we believe that additional privacy risks associated with implementing a UPI can be mitigated through the continued implementation of the administrative, technical, and physical safeguards already required by the HIPAA rule. These safeguards include clearly defined policies and procedures, audit logs, access controls, encryption, and strong authentication and authorization measures to prevent unauthorized access to PHI both physically and technologically. Furthermore, continuous risk assessments of vendors and other third parties will also assist in reducing the security risk posed by using UPIS.

In considering the design of a UPI, there are certain inherent attributes that a UPI should and should not possess. For example, there is almost universal consensus that the use of Social Security Numbers (SSNs) or similar should not be considered; SSNs in particular are tied to an individual’s financial and tax


information and pose a more inviting target for fraud, identify theft, and other malicious activities capable of causing great harm to individuals. Ideally, a UPI should be associated only with an individual’s health information and not with other data sets or financial information. This UPI should be considered an integral part of a patient’s PHI and patients should safeguard a UPI the way they would their SSN or medical records.

Furthermore, it should be noted that, within HHS, the Centers for Medicare and Medicaid Services (CMS) has already developed and adopted a de facto UPI for its Medicare beneficiaries which embodies many of the attributes discussed above. The Medicare Beneficiary Identifier, which recently went into effect, is a randomly generated number assigned to a beneficiary through the Medicare program which can then be used to connect the beneficiary’s health records across providers and systems.

Considerations Related to Clinical Data Registries

Population-based cancer registries play a critical role in cancer surveillance and are foundational for cancer research, as well as in planning and evaluation of cancer prevention, control and survivorship activities. In addition to the commonly recognized advantages of a UPI, including improvements to patient safety, decreases in unnecessary repeat testing, and decreased overall costs, additional advantages include the movement of accurately identified patient data through and across clinical data registries for quality improvement and research purposes. Due to the fractured nature of health care delivery, insurance coverage, variable payer networks, and desire for second opinions and consultations, many people do not stay within a single health care system for their health care services. In particular, cancer patients typically see multiple health care professionals over the course of their illness consequent to the clinical impact of cancer and its treatment on many aspects of their health. Linking a patient’s health information across multiple care settings and clinical data registries provides a much greater ability to accurately assess all factors contributing to a person’s health.

ASCO maintains several clinical registries, including our long-established CancerLinQ registry\(^8\) and our recently developed ASCO Survey on COVID-19 in Oncology (ASCO) Registry\(^9\). CancerLinQ embodies the concept of “big data” and contains data on millions of patients with cancer; our COVID-19 registry is collecting data on the impact of COVID-19 on patients with cancer. As with all registries, issues regarding “de-duping” arise when patients move from one cancer care setting to another but remain in the registry; these issues have become even more prominent with the overlap of individual patient data contained in multiple registries. A UPI would greatly reduce the burden of patient matching and requirements for de-duplication and lead to more reliable data in individual patient records as well as registries.

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\(^8\) https://www.cancerlinq.org/
\(^9\) https://www.asco.org/asco-coronavirus-information/coronavirus-registry
ASCO thanks ONC for the opportunity to submit comments on patient matching, specifically on the utility of a unique patient identifier. If you have any questions or would like to discuss further, please contact Karen Hagerty (karen.hagerty@asco.org).

Sincerely,

Monica Bertagnolli, MD, FACS, FASCO
Chair of the Board
Association for Clinical Oncology