February 15, 2018

Office of the National Coordinator for Health Information Technology  
U.S. Department of Health and Human Services  
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To Whom It May Concern:

The American Society of Hematology (ASH) is pleased to offer comments on the Draft Trusted Exchange Framework, released on January 5, 2018 by the Office of the National Coordinator for Health Information Technology (ONC), of the U.S. Department of Health and Human Services.

ASH represents over 17,000 clinicians and scientists worldwide who are committed to the study and treatment of blood and blood-related diseases. These disorders encompass malignant hematologic disorders, such as leukemia, lymphoma, and multiple myeloma, as well as non-malignant conditions, such as sickle cell anemia, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists were pioneers in demonstrating the potential of treating various hematologic diseases through bone marrow transplantation, and we continue to be innovators in the fields of regenerative medicine, transfusion medicine, and gene therapy. ASH membership is comprised of basic, translational, and clinical scientists, as well as physicians who are providing care to patients in diverse settings including teaching and community hospitals, as well as private practices.

The Society has reviewed the Draft Trusted Exchange Framework and is a proponent of how it will help harness the power of big data to conquer blood diseases worldwide. In particular, this Framework will allow for an easier flow of data which is critical, as organizations such as ASH develop and implement patient and research registries that play a vital role in facilitating the exchange of information on a full range of diseases, including hematologic diseases and disorders.

The Trusted Exchange Framework recognizes and builds upon the significant work done by health information technology (IT) vendors and organizations like HL7 over the last few years to broaden the exchange of data, build trusted frameworks, and develop participation agreements that enable providers to exchange data across organizational boundaries. ASH recognizes the impact the framework will have, as it relates to the following items:

- Providing a single portal to allow all types of healthcare stakeholders to join any health information network they choose and be able to participate in nationwide exchange regardless of what health IT developer they use;

- Aiming to scale interoperability nationwide both technologically and procedurally, by defining a floor, which will enable stakeholders to access, exchange, and use relevant electronic health information; and,

- Ease the flow of information across disparate networks and sharing arrangements which allow new and innovative technologies to enter the market and build competitive, invaluable services that make use of the data.
Patients especially benefit from interoperability nationwide. It ensures that providers across the care continuum, community and social services, and many more stakeholders can effectively and efficiently participate in interoperability leading to better patient care.

ASH believes that interoperability makes it possible to have the right information at the right time, for the right people to make the right decisions that will ultimately impact patient outcomes. Interoperability and collaboration are vital to positively transform health and healthcare for individuals and communities.

Specialties like ours, which focus on rare diseases and disorders, will particularly benefit from the opportunity to pull together information on small numbers of patients from many sources in order to amass enough data to learn how to improve care. The Trusted Exchange Framework will help pave the way for patients to get the care they need and researchers to continue developing innovative therapies for this population.

We applaud the ONC for recognizing the need for data provenance as supported by the Draft U.S. Core Data for Interoperability. By ensuring that metadata is an element within the Trusted Exchange Framework, clinicians and researchers can easily identify when and who created the data, made changes to the data, as well as determine if incorrect information is a system or human error. Specific hematologic examples in support of data provenance are as follows:

**Laboratory Results**

Appropriate diagnosis and management of hematologic conditions often depends on laboratory results. As described in guidelines\(^1\) by ASH and the College of American Pathologists on the workup of acute leukemia, the diagnosis of this hematologic disease involves numerous tests, some of which can take weeks to yield results. These tests require invasive procedures such as bone marrow biopsy and cerebrospinal fluid extraction. A battery of such tests is often ordered by a generalist physician when leukemia is first suspected, and the care of the patient may be transferred to a hematologist while some tests that can inform prognosis and treatment strategy are still pending. If details about these pending tests are not adequately conveyed when care is transferred, patients may be subjected to avoidable, repeat invasive testing. Data provenance pertaining to lab tests (i.e. when the test was ordered, where the test was ordered, and the status of the test as pending or final) could address this issue by making it clear to the receiving physician that test results are still pending.

Data provenance of laboratory tests can also contribute to more effective resource stewardship. It has been widely reported that many lab tests are unnecessary, and that excessive routine blood testing can contribute to anemia. To understand and prevent this phenomenon, details about when and where tests are ordered, and by whom, is necessary.

**Diagnosis**

ASH has included misdiagnosis and inappropriate treatment of Heparin-induced thrombocytopenia (HIT) as one of the items in its Choosing Wisely® campaign list\(^2\) which highlights potentially harmful tests and procedures in the field of hematology. HIT is a rare complication of heparin administration that is associated with substantial morbidity and mortality, and is treated urgently with anticoagulation. Misdiagnosis of HIT, however, can lead to avoidable complications such as bleeding. Data provenance pertaining to the diagnosis

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\(^2\)www.hematology.org/choosingwisely
of HIT (i.e. who entered the diagnosis and how it was established) could flag for the hematologist instances when this diagnosis has been inappropriately assigned and/or inappropriate treatment has been pursued.

ASH also supports the availability of comprehensive electronic health information that goes beyond what is stored in electronic health records. The ability to access information from several different resources provides physicians with a broader picture of the overall health of an individual which leads to better patient care. Additionally, it also allows organizations, like ASH, to tap into this data to populate registries, like the ASH Registry, which will ultimately help researchers develop new treatments and even cures for hematologic diseases. In order for this data to be interpretable and useful for research, the context of the data (i.e. data provenance) is required.

Thank you for the opportunity to comment on this important matter. If you have any questions or require additional clarification, please contact Melissa Francisco, Director, ASH Registries at mfrancisco@hematology.org, or Suzanne Leous, Chief Policy Officer at sleous@hematology.org.

Sincerely,

Alexis Thompson, MD, MPH
President