Connecting Sepsis Data: A National Sepsis Data Trust

Sepsis Data Roundtable Summary
May 18, 2023

Introduction

Progress on sepsis research and innovation is hindered by the lack of a national data network that provides affordable access to privacy-protected, sepsis-relevant, de-identified longitudinal patient and survivor data from multiple sources. With new research opportunities made available through advances in machine learning and related technologies, there is strong agreement across the sepsis community about the value of such a data source for accelerating progress on the early identification, rapid diagnosis, and effective treatment of sepsis and septic shock.

In January 2022, Sepsis Alliance held its inaugural Roundtable on Sepsis Data with over 50 participants, representing research institutions, industry, survivors, and healthcare nonprofit organizations. The roundtable discussions yielded 10 recommendations for moving a National Sepsis Data Trust (NSDT) forward.

1. Develop Specific Use Cases and Champions
2. Identify and Prioritize Sepsis Data Elements for Connection and Curation
3. Harmonize Data Vocabularies and Definitions Across Use Cases and Definitions
4. Leverage Data and Expertise Housed in Existing Data Repositories
5. Develop a Stakeholder-led Process to Address Operational Questions
6. Prioritize Pilots and Demonstrations
7. Engage Federal and State Agencies
8. Assure Data Security and patient Privacy Through Effective Governance
9. Provide Broad, Controlled Access to Connected and Curated Sepsis Data
10. Explore Ways to Recognize Patients' Contributory Role

The May 18 Roundtable advanced these recommendations by creating a sepsis data community with representation from the public and private-sectors, patients, and survivors; establishing a stakeholder-led process for addressing operational questions critical to a data trust; initiating processes to develop and prioritize use cases; and harmonizing data vocabularies and definitions by exploring a partnership with Health Level Seven International (HL7).

We are beginning this phase of work with a focus on data standards because they are the key enabler for the data fluidity needed for sepsis research collaborations both within and across institutions.

Welcome and Opening Remarks
Valerie Barton MA, Program Manager, Sepsis Data Community
Tom Heymann MBA, President and CEO, Sepsis Alliance
Daniel Yang MD, Program Director, Diagnostic Excellent Initiative, The Gordon and Betty Moore Foundation

Ms Barton welcomed participants and affirmed the need for a national data resource to accelerate research on sepsis. Ms. Barton noted the roundtable's action orientation and the need for people, processes, and technology to make such a data resource a reality. She then invited Tom Heymann to provide opening remarks.

Mr Heymann thanked participants, noting the size and complexity of this undertaking and the promise it holds for "moving the needle" for clinicians, patients, and survivors. He cited cancer registries' success in increasing understanding of the over 400 types of cancer, improving diagnosis and treatment, and lowering mortality rates. In like manner, our success in creating NSDT will lead to better understanding of and innovation in sepsis and help patients around the globe avoid the pain and suffering of sepsis. Mr Heymann concluded his remarks by thanking The Gordon and Betty Moore Foundation and Roche Diagnostics for sponsoring the roundtable.

Dr Yang, who leads the diagnostic excellence initiative at The Gordon and Betty Moore Foundation, welcomed participants and described the work of the foundation, which has a particular focus on sepsis. He shared that working with Sepsis Alliance has given him a greater understanding of sepsis and the impact the lack of data on sepsis has had on innovation, research, and quality improvement. He expressed the Moore Foundation's excitement in supporting this work.

An Overview of Selected Existing Data Repositories
Jessica Aguilar BSN RN LSSGB, Sepsis Coordinator Nursing Clinical Services, JPS Health Network
Gregory Briddick MSHI BSN RN CCRN TCRN, Sepsis Program Coordinator, SUNY Upstate University Hospital
Jon Glaudemans MPA, Project Director, Sepsis Innovation Collaborative, Sepsis Alliance
Vincent Liu MD MS Regional Director, Hospital Advanced Analytics, Kaiser Permanente Northern California
Chris Seymour MD MSC, Associate Professor of Critical Care Medicine and Emergency Medicine, University of Pittsburgh School of Medicine; Clinical Research, Investigation and Systems Modeling of Acute Illness (CRISMA) Center, University of Pittsburgh

This session opened with Mr Glaudemans providing an overview of Sepsis Alliance and the Sepsis Innovation Collaborative (SIC), of which the Sepsis Data Community (SDC) is a part. He described how the work of existing SIC workgroups is interrelated, and how the SDC will benefit from the expertise and knowledge of the members of the broader SIC community.

Mr Glaudemans then introduced Ms Aguilar and Mr Briddick to discuss their work as sepsis coordinators on the front lines of improving sepsis care within their hospital systems. Each described the data

repositories they created and key use cases, including quality measurement, as well as challenges they encountered. Ms Aguilar explained that JPS' sepsis data warehouse, MIDAS, was created by their sepsis team to enable real time abstraction and to meet the requirements of SEP-1 by the Centers for Medicare and Medicaid Services (CMS). Both Ms Aguilar and Mr Briddick presented key technical challenges encountered, including the variation and granularity of the data within their hospitals, as well as difficulties abstracting data within EMRs. Mr Briddick remarked that this is largely due to limited staff knowledge of coding, and that it is often the case that "add-on" data models are primarily created for billing purposes and not designed for clinical/quality measurement. He noted that "When we look at how each facility in our system adopted standardized, structured languages, there is a lot of variability in the adoption of those languages, even within individual EMRs." Ms Aguilar observed that coded and abstracted data is "too late to impact patient outcomes, as the patient is already discharged."

Dr Liu and Dr Seymour presented their work on *Sepsis on FHIR*[1], the goal of which was to design a framework for interoperable sepsis data across two health systems, Kaiser Permanente of Northern California (KPNC) and University of Pittsburgh Medical Center (UPMC). The team worked with professionals at both delivery systems as well as staff at both Epic and Cerner. The combined team sought to form the backbone of FHIR-based sepsis data across several sites. They created a HAPI[2] FHIR structure to allow data analysis and reformatting of the data coming out of FHIR so that it can be integrated. Their proof of concept was to identify the sepsis phenotypes from previous work so that they could identify, in real time, patients who were in the alpha and beta phenotypes. Dr Liu commented that, for those in the sepsis research and therapeutics field, the limitations are less about the identification of early patients with worrisome features indicative of sepsis based on point-based or AI-models, but "where we are stymied is targeting treatments which are relevant to a patient's condition which arise from immunology, host-pathogen interactions, organ dysfunction, physiologic states, and pre-existing cormorbidities."

Their goal was to focus on identifying sepsis phenotypes using FHIR queries that are usable in real-time, as well as in HAPI FHIR enabled data from retrospective sources. The team also spent considerable time producing FHIR mappings, value sets, etc. based on Epic and Cerner EHR implementations. Dr Liu observed that "it became clear about half-way though that the future of this kind of interoperability effort would require this being seen as a priority for informatics and interoperability, healthcare data infrastructure, etc., including future development of a sepsis Implementation Guide (IG)."

Dr Liu described technical challenges they encountered. First, the lack of an IG created difficulties and "this work would have to build towards that EHR FHIR implementation maturity." He mentioned that the lack of other intraorganizational policies, access, and implementation as well as interorganizational practices explains "why UPMC is using retrospective data while, at KP, we're using real time data."

Dr Seymour concluded by laying out next steps for their work on *Sepsis on FHIR*.

[1] Fast Healthcare Interoperability Resources
[2] High-Level Application Programming Interface

- Formalize sepsis FHIR mappings and value sets in available online repositories
- Complete forthcoming publications describing the challenges faced across KPNC and UPMC in instantiating Sepsis on FHIR infrastructure.
- Support advocacy for the development of sepsis FHIR IGs and the idea of sharing across institutions.

The presentations were followed by an active discussion among participants. Dr Steven Simpson inquired whether Dr Liu and Dr Seymour's work yielded solutions that could be widely applied or whether the addition of new sites would require solving some of the same issues. Dr Liu responded that the only way to get to that level of interoperability is by working through "groups like this [Sepsis Data Collaborative], bringing together stakeholders across the full spectrum, those that need to produce data, those that want to use the data for innovation or new discovery, regulators for what they need from this standardization process. This process is not going to be driven just by the innovation of research but it's going to require that collaboration and that sustained voice that we're all moving in the same direction, and we see the same need."

The discussion turned to the US Core Data for Interoperability Standards (USCDI). Dr Raymund Dantes predicted that the core requirements will not keep pace with the relatively granular data that is needed to subtype sepsis patients in real-time. He noted that, of the 150+ mappings to what the literature has identified as clinically relevant variables, many fall into the observation bucket. These don't include social determinants of health (SDOH), blood pressure, etc. Dr Dantes called for building a consensus process to identify what is unique to sepsis and what is similar to other high acuity conditions in patients.

Mr Briddick raised challenges with FHIR. He warned that there is a multiplicity of EMRs and EHRs that aren't easily accessible through FHIR because they are not FHIR-compatible and the connections don't exist, the standards don't capture what is needed, and there are not sufficient resources to get them into most hospitals. He estimated that 60-70% of hospitals in New York State use MediTech's EMR and don't have the capability for FHIR. He compared FHIR to other HL7 interfaces – the FHIR standard provides easier access but narrows the ability to pull data versus using a direct stream HL7, which is the old standard.

HL7, Vulcan Accelerator, and More
Bret Heale PhD, Founder and Principal, Humanized Health Consulting LLC

Dr Heale's presentation described HL7 and the Vulcan Accelerator Project, serving as an introduction for participants unfamiliar with HL7 and a refresher for those with some familiarity with the body's purpose, goals and processes. He began by answering the question "What is a data standard?" and presenting examples. Dr Heale described the HL7 governance processes, procedures, and timelines and the active participation of the development and implementation community for HL7 projects. He highlighted HL7's open meetings and rigor in balloting standards and its intention that the implementation community is a critical part of that process.

Dr Heale introduced the concept of FHIR IGs, the development of which will be an important foundational workstream for NSDT. He pointed out that Core[3] FHIR already provides strong syntactic specification and some semantic interoperability, but FHIR IGs are needed to support and clarify interfacing communication for specific use cases. These IGs are computable and they can contain value set guidance, which are definitions for the codable concepts that will be used.

Dr Heale made the case for engaging with an accelerator for the sepsis project. The HL7 accelerator model is attractive because it provides ready tools for community collaboration and places the effort directly into HL7, which is populated by a community of potential early adopters with technical skills. He stated that adoption of innovations requires a strong community implementing the innovation and strong communication to broaden adoption more widely. He laid out some benefits of accelerators.

- Innovation – improved with an engaged, active community of support
- Time – an accelerator can help speed up the process of dissemination of the innovation in HL7
- Social system – it's easier to diffuse an innovation in a well-developed social system, especially one that has bought into the innovation
- Development – an accelerator program can be a tool for helping the community focus on extending the capabilities of FHIR in a specific domain. Participation creates buy-in and helps ensure that an organization's work lines up standards in the domain
- Adoption – An accelerator program can be the nucleus for a community of implementors to support each other, which can positively impact adoption

Dr Heale then described the Vulcan Accelerator which is the target HL7 project for the NSDT. He gave examples of other projects within Vulcan that are focused on adverse events; phenopackets; real world data, electronic product information (ePI); and a mapping of FHIR to the Observational Medical Outcomes Partnership (OMOP) Common Data Model. If Vulcan agrees to partner on Sepsis on the NSDT, it would provide guidance on the HL7 process as well as infrastructure and tools to aid in team collaboration under the HL7 name. Dr Heale described how HL7 would provide a framework for engaging community to support adoption and implementation of FHIR standards for sepsis. He mentioned a further benefit - our initiative would gain visibility, credibility, and cache by working with the HL7 FHIR accelerator program. Finally, partnership would enable our project to attract additional contributors.

Dr Heale closed by providing detailed information on the balloting process, the FHIR maturation model for projects, and expected timelines for each stage of project maturity.

Use Case Review, Discussion, and Prioritization
James Shalaby PharmD, Principal and CEO, Elimu Informatics, Inc

Dr Shalaby opened this session by providing context for the work to define, classify, and prioritize use cases. These initial use cases will be the foundation for evolving the standards and informing

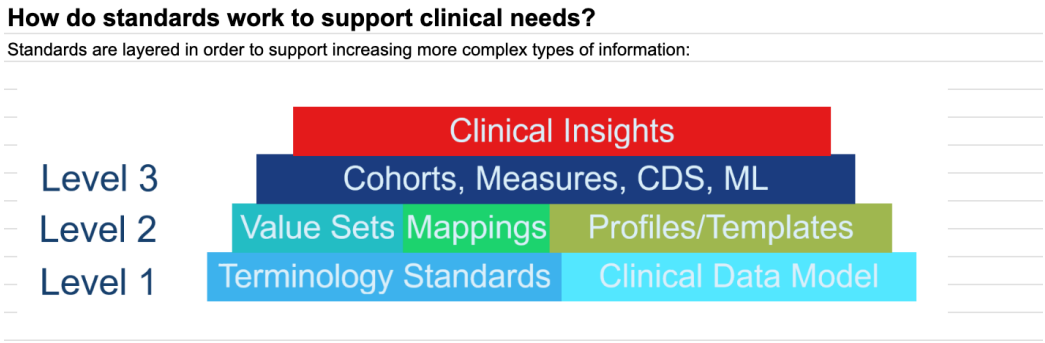
[3] Refers to USCDI

implementation focus areas and activities. Use cases will drive a Technical Workgroup's scope of requirements. Dr Shalaby discussed broader challenges such as governance policies and driving adoption of the standards. He emphasized the critical role of a workgroup comprised of subject matter experts (i.e., clinicians) upon whose output the Technical Workgroup will rely.

Dr Shalaby acknowledged frustrations with the maturity of the FHIR standard – is FHIR rich enough? He introduced the three aspects of maturity. First, he pointed out that, for the current use cases to be discussed, the FHIR standard is "highly mature," but he reiterated previous speakers' emphasis on the need for IGs. He then turned to the maturity for EMR implementation of FHIR standards. He remarked that, while the standards are moderately mature, he acknowledged that some work is needed on the EMR vendor side, which will depend on the development of a focused IG. Third, he cited the maturity of provider institution implementation of EMR to support for FHIR standards. Institutions will need to "turn on" certain capabilities that exist in their EMRs but are not enabled, which may require moving to new versions of the EMR that support FHIR standards implementation.

Dr Shalaby then discussed governance and policy challenges. He referred to Dr Liu and Dr Seymour's experience with KPNC and UPMC – "Is there a process in governance and policy that allows efficient access to clinical data for research?" Further, he raised the need for institutional resources to support providing access to FHIR and native EMR data. He emphasized that, while these issues are not addressed in the standards, they must be addressed through inter-institutional policies. Dr Shalaby stressed that it's important to put these in place before attempting intra-institutional policies. What kind of data is available? Who can access it? These governance policies get in the way of implementation the most.

Pivoting to the task of defining and prioritizing the submitted use cases, Dr Shalaby introduced layers of standards, into which the Sepsis Data Collaborative will categorize use cases.



Level 1 represents the founding pillars to support any use cases. They call out the need for terminology standards and models. They provide consistency in the structural way, for example, temperature or a lab value is communicated between systems, standardizing not just the language but the structure, as well.
Level 2 represents artifacts that are built on top of Level 1 value sets, mappings, profiles, and templates.

Level 3 represents cohorts, measures, clinical decision support, and machine learning. Dr Shalaby clarified that these use cases are very specific things we want to compute or identify or do, but to do them, the foundation is Level 2, which enables Level 3 layers.

Dr Shalaby raised a philosophical point: it may be that machine learning can leapfrog all the standards to generate insights and this can be debated. However, he asserted that machine learning can always benefit from structure by accelerating how quickly clinical insights can be reached. He described how Levels 1, 2, and 3 yield clinical insights.

The session then pivoted to a discussion of use cases submitted in advance of the roundtable and offering additional use cases for consideration.

In reviewing the use cases prior to the roundtable, Dr Shalaby observed that many of the submitted use cases relate to each other and noted that the total number of use cases over time will be much larger and more expansive. He began the open discussion with use cases that would be foundational for all other use cases (Level 1). He explained that beginning with identifying Level 1 use cases will enable further work on how standards evolve once these foundational elements are in place.

Dr Shalaby then facilitated an open dialogue of the use cases. Participants had time to discuss nine of the 15 use cases submitted and, throughout the session, several additional use cases were identified but time did not allow for discussion of those use cases. The nine use cases considered at the roundtable are below, with proposed levels, priority designations, and key comments.

Use Case 1: Contribute standardized patient clinical data with a defined community of researchers

- Proposed Level 1
- Proposed High Priority
- Participants recommended that this be broadened beyond researchers to include data users and data consumers.

Use Case 2: Access patient specific clinical data that is highly standardized (structured and codified in a consistent manner)

- Proposed Level 1
- Proposed High Priority
- Participants pointed out that this use case is similar to Use Case 1 and could be merged.

Use Case 3: Ability to share research queries or cohort definitions within the research community

- Proposed Level 2
- Proposed High Priority
- Participants recommending rewording this use case to capture the intention for a standard structure and value sets (e.g., terminology components) to support cohort definitions

Use Case 4: Ability to create or enable researcher creation of longitudinal patient records linking patient-specific data collected at multiple sites by multiple providers of care

- Proposed Level 2
- Proposed High Priority

Use Case 5: Align infection documentation across systems

- Proposed Level 3
- Proposed High Priority
- Participants observed that use cases 4 and 5 are related – Use Case 4 concerns longitudinality and Use Case 5 concerns a specific clinical topic. The discussion then turned to clinical challenges with documenting, for example, antibiotic administration. Participants agreed that there is great variability in the accuracy of the documentation and that this challenge applies to prophylaxis; an initial suspicion of infection may become confirmed but it may not get changed in the antibiotic indication. One participant noted that better documentation could be useful from a retrospective perspective, but that it's not useful in real-time for practitioners. Dr Shalaby cited this is a perfect example of a Level 3 use case.

Use Case 6: Access patient data with all relevant clinical information to retrospectively label the patients with sepsis onset time stamps based on standard sepsis definitions

- Proposed Level 3
- Proposed High Priority
- Dr Shalaby indicated that this use case is high priority and it's also supported by Levels 1 and 2 use case categories.

Use Case 7: A clinically vetted diverse sepsis patient cohort as a standard and complete validation set for comparing algorithms for early prediction of sepsis

- Proposed Level 3
- Proposed High Priority
- Dr Shalaby commented that this use case can be applied on models that represent Use Case 6 and, "perhaps even reach a higher level of reliability, so it could be that sequencing that comes first."

Use Case 8: Access to patients' clinical information from pre-hospital admission and post-hospital discharge

- Proposed Level 3
- Proposed Medium Priority
- Participants recommended that this use case be merged with Use Case 4.

Use Case 9: Access to patient information- sepsis stage, response to antibiotic/s, treatment efficacy and microbiology and/or pathogen genomic sequences.

- Proposed Level 3
- Proposed Medium Priority
- Dr Shalaby observed that this use case overlaps significantly with other use cases of standardization and observational data (e.g., labs, microbiology, other inpatient contexts. The variables are quite specific and "we can list for that."

Participants then raised and discussed adding genomic data to the FHIR accelerator process. Dr Shalaby and Dr Heale mentioned an existing, mature genomic accelerator program with an expressed interest in adding antimicrobial genomics to it. Participants remarked that some of this data can be captured under LOINC but due to the lack of standardization from laboratory's information systems, the data is inconsistent.

Further, participants were concerned about the lack of standardization of the microbiology data and debated whether this thorny challenge could be addressed in the near term. Several participants expressed that, though this data may be sloppy and difficult to use, it is impactful for the whole project and advocated for, at least, capturing it in the short term, even if it is only in free text.

The discussion surfaced a need that, throughout the work on the NSDT, both those participants with high-level viewpoints and experiences and those who are "in the trenches and see that certain things are not practical" are integral to the creation and broad adoption of the data standards to be developed.

Other key comments from participants included the following.

- Consider other datasets that could be incorporated
- Consider antibiotic stewardship and what data those researchers need
- Business relationships are important because setting the standards is important but getting them widely adopted is also important
- Partnering with other HL7 projects (e.g., SDOH) could be valuable
- Standing up workgroups is essential because individuals and research partnerships have taken sepsis data as far as it can
- In the very near term, start a shared document to structure outcomes we'd like to measure and the data needed

Dr Shalaby then described the goal to reach consensus on the high-level use cases.

Next Steps/Workgroup Creation
James Shalaby PharmD, Principal and CEO, Elimu Informatics, Inc
Jon Glaudemans MPA, Project Director, Sepsis Innovation Collaborative, Sepsis Alliance

Dr Shalaby identified the next steps needed to approach HL7. First, a subject matter expert (SME) workgroup comprised of clinicians who have contributed Level 3 use cases should be formed. These individuals may or may not have relevant technical expertise, but more importantly for this workgroup, they must have the clinical experience to identify the high-level issue or problem. He described the task of this workgroup as defining the initial set of approximately 5 use cases that will be used in the first approach to HL7. This phase of this work group typically runs 2 to 3 weeks.

Second, a Technical Workgroup will work from the SME Workgroup's priority list to assess the reality and "implementability" of the prioritized use cases, identifying potential areas that must be developed

to make it feasible. The Technical Workgroup will be engaged over a longer period to iterate on the use cases to fully understand them and to assess feasibility.

Once participants have agreed on a set of use cases that will be prioritized, including agreeing upon the clinical variables of interest, these workgroups will have shaped the preliminary work needed to engage with HL7. Dr Shalaby emphasized that, at this point, it's not necessary to define the HL7 data elements of interest, but he observed that the feasibility assessment should consider what those data elements are to address in the use cases.

The results of this work will be a presentation based on the preliminary output of the workgroups and a readiness to engage with HL7 to vet our approach and discuss the priority use cases that we'd like to take to the Vulcan Accelerator.

Dr Shalaby also emphasized that this project will gain tremendously from the identification of sponsors, including the Centers for Medicare and Medicaid Services, the Office of the National Coordinator for Health IT, other regulatory organizations, and/or professional organizations that stand to benefit from a national sepsis data source. He encouraged the group to develop a business/sponsorship group to really "give the National Sepsis Data Trust teeth."

Mr Glaudemans closed the roundtable by asking for volunteers to participate in workgroups. Volunteers include the following.

- Jessica Aguilar
- Gregory Briddick
- Al Cardillo
- Jason Crites
- Raymund Dantes
- Sheena Gill
- Ankit Gupta
- Andrew Heiler
- Troy Keyser
- Anne Kim
- Kellen Krick
- Bill Lawrence
- David Nerenz
- Benjamin Ranard
- Chanu Rhee
- James Shalaby
- Steven Simpson
- Manoj Teltumbade
- Gabriel Wardi

Participants (those in italics were invited but unable to attend)

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