SHEA

Letter to the Editor

Leveraging real-time patient data during the COVID-19 pandemic

John C. O'Horo MD, MPH[1,2] ⓘ, Douglas W. Challener MD, MS[1] ⓘ, Cory Kudrna MBA[3], Jason R. Buckmeier BS[3],
Steve G. Peters MD[2] ⓘ, Daryl J. Kor MD[4,5] ⓘ, Mark W. Matson MBA[5], Andrew D. Badley MD[1,6],
Charles D. Burger MD[7] ⓘ and Rajeev Chaudhry MBBS, MPH[8,9] ⓘ

[1]Division of Public Health, Infectious Diseases and Occupational Medicine, Mayo Clinic, Rochester, MN, USA, [2]Division of Pulmonary and Critical Care Medicine, Mayo Clinic, Rochester, MN, USA, [3]Department of Information Technology, Mayo Clinic, Rochester, MN, USA, [4]Department of Anesthesiology and Perioperative Medicine, Mayo Clinic, Rochester, MN, USA, [5]Center for Digital Health, Mayo Clinic, Rochester, MN, USA, [6]Department of Molecular Medicine, Mayo Clinic, Rochester, MN, USA, [7]Division of Pulmonary, Allergy and Sleep Medicine, Mayo Clinic, Jacksonville, FL, USA, [8]Division of Community Internal Medicine, Geriatrics, and Palliative Care, Mayo Clinic, Rochester, MN, USA and [9]Department of Quantitative Health Sciences, Mayo Clinic, Rochester, MN, USA

The Society for Healthcare Epidemiology of America (SHEA) policy position highlights some critical lessons learned on how data management must be modernized to meet the data challenges of the COVID-19 pandemic.[1] We highlight some of our lessons learned from the pandemic with regard to effective use of data as a pandemic response tool.

Mayo Clinic is a large, multistate academic healthcare center, and 3 core work groups at our institution leveraged clinical data to inform our COVID-19 response. First, researchers needed various COVID-19 data to inform prospective clinical trial eligibility and enrollment, retrospective cohort studies, and the clinical outcomes of both study types. Second, decision-makers required real-time numbers of SARS-CoV-2 infections and resources used (eg, ventilators and hospital beds) for maintaining operational excellence and reporting to government agencies. Finally, clinicians needed guidance to ensure that patients with COVID-19 were receiving care congruent with the emerging set of best practices.

Data definitions between these groups were not consistently harmonized. Research registry definitions tended to be study-specific, policy definitions evolved, and practical guidance developed independently from either registry or policy definitions. The SHEA position statement calls for modern data collection and harmonization. Electronic health registries use rules-based logic for reporting purposes or driving changes in clinician behaviors.[2] Despite nuanced differences between electronic health registries and research registries, the similarities for registry functionality present an opportunity to use standard definitions.

The COVID-19 pandemic led to a strain on information technology resources; therefore, we sought to create a translational research and clinical practice application to support a diverse array of both research and clinical needs. We termed our tool Cohort Knowledge Intelligence Solutions (CKIS). Use of standardized data definitions allowed for more scaled and reusable solutions that addressed the research, operations, and clinical care needs related to the COVID-19 pandemic. We viewed CKIS as an opportunity to embrace the learning health system model.[3]

Previously at Mayo Clinic, registry efforts were primarily dedicated to helping clinical practices manage care for specific patient cohorts of interest, typically those with chronic health conditions. When the COVID-19 pandemic began, we realized that the schema used to build registries to support clinical practice could also be leveraged to support research of SARS-CoV-2. The registry launched in March 2020. We initially manually validated registry data on a case-by-case basis, but in less than 2 months, the performance of the registry system was sufficient that manual review became redundant.

We harmonized the metrics and end points needed for various research and clinical operational uses. These end points included common outcomes (ie, National Institute of Allergy and Infectious Diseases Ordinal Scale of COVID-19 Severity score),[4] relevant comorbid conditions for risk scoring,[5] and key clinical metrics, such as intensive care unit admissions or need for mechanical ventilation. This information was shared with the COVID-19 treatment review panel created by the Mayo Clinic COVID-19 Research Task Force to assist identification of patients at high risk for severe disease and potential trial candidates.[6] Examples of the metrics collected by one of our heavily used registries are shown in Table 1.

The CKIS tool was used to identify patients and provide data for a comprehensive COVID-19 data mart, thereby supporting clinical operational use, predictive analytics, and research throughout the Mayo Clinic healthcare system.[7] Rules that were used for clinical trials of investigational treatments that later became standard of care (eg, remdesivir) were adapted to identify patients who had potential care gaps. Clinical decision support (CDS) rules were built from CKIS data to alert frontline clinicians about potential actions that could improve care for patients with COVID-19. This, in turn, provided another opportunity for ongoing CKIS validation, with real-time feedback on the utility and accuracy of CDS alerts.

To date, the CKIS COVID-19 registry at Mayo Clinic has directly supported more than 3 dozen published studies, in which the registry was leveraged to identify eligible patients, determine study feasibility, facilitate outcome assessments, and report results. Additionally, more than 70 CDS rules are driven directly by the CKIS COVID-19 registry, which yielded more than 65,000 best practice advisories during the COVID-19 pandemic. The CKIS COVID-19 registry was also used to support various other reporting tools for operational COVID-19 work and modeling. As

Table 1. Representative metrics used in the Cohort Knowledge Intelligence Solutions COVID-19 registry at Mayo Clinic[a]

Metric	Description
Inclusion criteria	Identifies patients with positive SARS-CoV-2 polymerase chain reaction test results (and most recent date)
Symptom onset date	Returns date of first symptoms consolidated from several flow sheets and documentation data elements
Various index scores: Charlson Comorbidity Index, MASS, CAST score, and NIAID Ordinal Scale of COVID-19 Severity score	Stores scores and references other metrics to identify component information of the score
Treatment dates	Reports treatment with candidate medications (eg, remdesivir, tocilizumab, or corticosteroids), including start and stop dates
Reinfection dates	Stores potential reinfection information and intervals between positive test results
Last COVID-19 vaccine	Returns most recent date for COVID-19 vaccination[b]
Demographics and social determinants of health	References financial class, principal language, sex, and geographic region
Eligibility information	Returns eligibility for specific treatment studies or informs clinical decision support about whether a current treatment should be adjusted

Note. CAST, COVID-19 Antibody Screening Tool; MASS, Monoclonal Antibody Screening Score; NIAID, National Institute of Allergy and Infectious Diseases.
[a]At the time of publication, more than 500 metrics are included in the COVID-19 registry, which also has the ability to cross-reference other Mayo Clinic registries (eg, transplant and vaccination registries) for relevant information.
[b]Other metrics capture number of vaccinations administered, what type, and date of each vaccination.

of May 1, 2023, the registry consists of 19 subregistries (including registries used for vaccination outreach and confirmed COVID-19 cases), which contain information from more than 1.2 million patients and 887 distinct metrics.

The success of this approach to registry architecture led to several other CKIS tools. At the beginning of the 2022 monkeypox virus outbreak, we designed a similar CKIS registry and readied it to withstand similar challenges encountered during the COVID-19 pandemic. A similar CKIS solution is being deployed for *Staphylococcus aureus* and endocarditis.

Our experience with the CKIS COVID-19 registry is a practical example of the benefit of expending effort for harmonizing data collection methods, as recommended by the SHEA position statement, as well as the critical role of the multidisciplinary data management team. Early engagement of researchers, clinicians, informaticists, and information technology professionals made rapid deployment of a sustainable tool feasible. We support the framework and the call for strong data governance with defined stewardship and data definitions to yield substantial gains for patient care. In our viewpoint, this effort by SHEA is needed to not only prepare for the next pandemic but also ensure optimal care for patients who are affected by infectious diseases.

References

1. Branch-Elliman W, Banach DB, Jones Batshon L, *et al.* SHEA position statement on pandemic preparedness for policymakers: pandemic data collection, maintenance, and release. *Infect Control Hosp Epidemiol* 2024;45 (forthcoming).
2. Gliklich RE, Dreyer NA, Leavy MB. AHRQ methods for effective health care. In: Gliklich RE, Dreyer NA, Leavy MB, eds. *Registries for Evaluating Patient Outcomes: A User's Guide*. USA: Agency for Healthcare Research and Quality; 2014.
3. Agency for Healthcare Research and Quality. About learning health systems. https://www.ahrq.gov/learning-health-systems/about.html. Updated May 2019, Published March 2019. Accessed January 30, 2024.
4. Beigel JH, Tomashek KM, Dodd LE. Remdesivir for the treatment of COVID-19 - preliminary report. Reply. *N Engl J Med*. 2020;383:994. doi: 10.1056/NEJMc2022236
5. Nyman MA, Jose T, Croghan IT, *et al.* Utilization of an electronic health record integrated risk score to predict hospitalization among COVID-19 patients. *J Prim Care Community Health* 2022;13:21501319211069748. doi: 10.1177/21501319211069748
6. O'Horo JC, Cerhan JR, Cahn EJ, *et al.* Outcomes of COVID-19 with the Mayo Clinic model of care and research. *Mayo Clin Proc* 2021;96:601–618. doi: 10.1016/j.mayocp.2020.12.006
7. Mayo Clinic COVID-19 Predictive Analytics Task Force, Pollock BD, Carter RE, *et al.* Deployment of an interdisciplinary predictive analytics task force to inform hospital operational decision-making during the COVID-19 pandemic. *Mayo Clin Proc* 2021;96:690–698. doi: 10.1016/j.mayocp.2020.12.019