The COVID-19 Pandemic Highlights Shortcomings in US Health Care Informatics Infrastructure: A Call to Action

Vikas N. O'Reilly-Shah, MD, PhD, FASA,* Katherine R. Gentry, MD, MA,*† Wil Van Cleve, MD, MPH,* Samir M. Kendale, MD,‡ Craig S. Jabaley, MD,§ and Dustin R. Long, MD*

GLOSSARY
COVID-19 = coronavirus disease 2019; **EHR** = electronic health records; **FHIR** = Fast Healthcare Interoperability Resources; **HIPAA** = Health Insurance Portability and Accountability Act; **HITECH** = Health Information Technology for Economic and Clinical Health Act of 2009; **HL7** = Health Level Seven International; **ICU** = intensive care unit; **NHSN** = National Healthcare Safety Network; **OHDSI** = Observational Health Data Sciences and Informatics; **OMOP** = Observational Medical Outcomes Partnership; **SARS-CoV-2** = severe acute respiratory syndrome coronavirus-2; **SMART** = Substitutable Medical Apps, Reusable Technologies

Severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), the causative agent of coronavirus disease 2019 (COVID-19), was designated a pandemic by the World Health Organization on March 11, 2020. By that date, hundreds of thousands of people around the globe had been infected, and millions more are expected to suffer physically and economically from the effects of COVID-19. Scientifically, the pace of progress toward understanding the virus has been dramatic and inspiring: the viral genome was rapidly determined,[1] and a 3.5-angstrom-resolution cryoelectron microscopy structure of the viral spike protein in prefusion conformation was published within weeks of its identification.[2] Initial small trials examining the impact of potential therapeutic agents have also been rapidly published; to date, more than 300 clinical trials have been registered, including several for candidate vaccines.[3]

In contrast, other aspects of the international COVID-19 response have not yet demonstrated similar progress. The need for rapid aggregation of data with respect to the epidemiology, clinical features, morbidity, and treatment of COVID-19 has cast in sharp relief the lack of data interoperability both globally and between different hospital systems within the United States. This global scale event demonstrates the critical public health and research value of data availability and analytic capacity. Specifically in the United States, although efforts have been made to secure the interoperability of health care data, countervailing forces have undermined these efforts for myriad reasons. In this study, we describe these forces and offer a call to policy action to ensure that health care informatics is positioned to better respond to future crises as they arise.

Data Silos
Efforts to develop a standard for health care data exchange have a long history, but the most promising arose from the passage of the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH). HITECH created an economic motivation for the implementation of electronic health records (EHR) across the United States and is, for this purpose at least, widely viewed as successful. By 2017, 93% of small rural hospitals and 80% of office-based physician practices possessed certified health information technology.[4] Notably, the staged approach to EHR adoption delayed interoperability requirements until the final stage of adoption.[5]

In the competitive US EHR vendor market, this delay led to differences in how vendors approached and implemented interoperability. Although it appears that there is general consensus on the use of the Substitutable Medical Apps, Reusable Technologies on Fast Healthcare Interoperability Resources (SMART on FHIR) standard developed by the nonprofit Health Level Seven International (HL7) for the interchange of data, the standard is not specific enough to ensure, and regulators have failed to require, that different vendors implement the specification in compatible ways. This failure has necessitated the development of health care integration engine software products to bridge the gap, yet another source of financial inefficiency in US health care.[6] Furthermore, aspects of the SMART on FHIR specification remain incomplete. For example, there is no implementation guide for intraoperative anesthesia data, although one may be developed by 2021.[7] It is notable that the HL7 development work in anesthesiology is done entirely by volunteers.

The interoperability framework offered by SMART on FHIR is, by itself, not sufficient for public health and research purposes. SMART on FHIR is specifically designed for patient-level data sharing. In the absence of regulations that mandate a specific solution, academicians have developed approaches to the organization and dissemination of standards that allow for multicenter data analyses. The Observational Health Data Sciences and Informatics (OHDSI), a collaborative group of investigators mostly funded by public granting agencies, is presently in the sixth version of its Observational Medical Outcomes Partnership (OMOP) common data model. Once an organization transforms its data into the OMOP model, as many have, it can participate in data analysis with any number of arbitrary partners through a federated mechanism.[8] As with HL7, there is no standard in OMOP for anesthesiology data, and standards for data from critical care environments remain underdeveloped. Within anesthesiology, the Multicenter Perioperative Outcomes Group offers arguably the most comprehensive candidate common data model, although costs of participation are high, and most participating sites are academic centers.[9]

While the lack of standard specification by regulatory agencies has contributed to these challenges, EMR vendors themselves have also played a role. Exposing standardized data reduces barriers to adoption of competing EHR platforms, which clearly explains the reticence of vendors to do so. This year, the Chief Executive Officer of a dominant US EHR vendor wrote a letter in which it urged its customers to oppose proposed regulations that would simplify the sharing of patient data; perhaps unsurprisingly, vendors with less market share and other companies attempting to enter the space voiced support for those same regulations.[10–12] Amidst the COVID-19 crisis, further delays in regulatory implementation are under consideration at the very time that data sharing is urgently needed.[13]

It is worthwhile to note that the widespread penetration of EHRs into hospital systems facilitated by the HITECH Act did allow individual systems to react and adapt to the COVID-19 pandemic in intelligent, data-driven ways. As an example, UW Medicine—one of the first health care systems in the United States to encounter the disease—developed a comprehensive set of information technology solutions in response to the pandemic, including order sets, documentation templates, and dashboards.[14] The value of the ability to rapidly collate and present information at the institutional level should not be underestimated, even as the potential benefits of interinstitutional data sharing during a pandemic remain as yet unrealized.

Privacy and Ethics of Data Sharing

The framework of proportionality is helpful for considering the ethical ramifications of broad data sharing, especially as seen through the lens of a pandemic. It is critical to balance the probable public health benefits of an intervention with the potential infringements on patient privacy or autonomy.[15]

The many benefits of real-time data sharing in the context of a global health care emergency have already been outlined. To briefly recap, if hospitals across the country were able to observe and interpret data being gathered at other institutions in real time and to contribute their own data to the shared repository, the health care system could be learning about and improving its care of COVID-19 patients continuously and collaboratively, based on the sum total of available information rather than incrementally in silos. Even as biomedical publishing gradually evolves to become more agile and rapid, traditional approaches to medical knowledge creation and dissemination remain unacceptably slow and continue to permit the dissemination of inaccurate information in the midst of a pandemic. Indeed, calls have been made to address the ongoing "infodemic" (as it has been dubbed by the World Health Organization).[16] Additionally, the sharing of data across health systems would hold hospitals accountable for providing care that is consistent with agreed-upon ethical principles during public health crises, such as allocating treatments in ways that maximize the number of lives saved and treating patients equitably with regard to race, ethnicity, and insurance status.

Who would monitor and report back on such issues? The US Centers for Disease Control National Healthcare Safety Network (NHSN), established to gather data on (primarily bacterial) health care–associated infections, provides a model for centralized

aggregation and reporting but would require heavy revision for our purposes. Because the system relies on manual case review and entry, data captured are delayed and results are aggregated on a quarterly basis, too slow and too error prone in the context of a rapidly evolving pandemic.[17] The centralized approach also introduces concerns related to oversight and performance penalties, as well as barriers to use by academic researchers. Unlike the NSHN, such a system would need to automate aggregation to real-time or near real-time status, provide mechanisms to allow research use of data, provide systems for deidentification of data and protections against reidentification of patients, and potentially be firewalled from traditional quality and pay-for-performance reporting purposes to maximize public health surveillance and research capabilities.

Potential harms that must be considered include breaches of patient privacy, premature decision-making based on preliminary or inaccurate information, and the potential misuse or misinterpretation of shared data. Privacy concerns have been raised by EHR companies and health care providers as a major reason not to enter into data-sharing agreements. While it is true that the risk of data breaches might increase with increased interoperability, they need not necessarily become more probable. Effectively implementing safeguards around encryption, authentication, and data use can mitigate these risks (the risk of EHR data exposure is not, eg, uniquely greater than financial data compromise), which must be balanced against the potential benefits to patients and public health.

There are few remaining legal barriers to the sharing of health information.[18] However, legal, ethical, and logistical challenges arise when a health care system houses data that are not necessarily from that system's patients. Large institutions may serve as reference laboratories for broad geographic areas and therefore house assay data from external clients that may or may not have agreed to this type of data sharing. Indeed, without careful handling, inclusion of outside clients' results, when combined with data from other regional systems, may lead to unrecognized data duplication. Institutions must also consider how they will manage and protect the data generated from testing their own employees in the context of a pandemic. Apart from legal restrictions on handling of employee health information that stand apart from Health Insurance Portability and Accountability Act (HIPAA) restrictions, there are ethical challenges in understanding how these data might best be used to study the risks to health care workers while also respecting health care worker privacy.

On balance, the ethical obligation, then, is for the companies facilitating data sharing and/or storage to ensure their systems meet the highest standards for security. By contrast, risks to privacy may actually be increased as long as EHR systems are not interoperable, given that patient data may be scattered across multiple systems.

Other risks that may accompany the sharing of real-time clinical data should be acknowledged. For example, the information itself may be inaccurate due to charting errors or coding inconsistencies. Decision-makers may jump to premature or biased conclusions based on apparent associations between an infectious disease and groups that have been the object of adverse implicit or explicit association bias (eg, racial and ethnic groups, homeless, prisoners, sex workers), leading to further stigmatization and limited access to care. Such risks might be increased in the setting of a global crisis characterized by a rapidly spreading virus, widespread fear, and unreliable media sources.

On balance, however, our view is that there are no public health benefits to the status quo. Proprietary control over EHR data benefits only EHR vendors themselves—who profit from institutional contracts and inhibitors to marketplace competition—and their customers—who may retain patients by virtue of limited or absent interoperability. The harms of the status quo include increased health care costs, such as duplicate testing when records are not transferable. The failure to implement interoperable health care records may also harm patients by trapping their data in balkanized systems, keeping physicians from accessing needed information in an efficient manner. Access to prior documentation of critical conditions (eg, a difficult airway or history of malignant hyperthermia or critical aortic stenosis) would allow anesthesiologists to make safer, more efficient diagnostic and care decisions.

What Is Needed: Yesterday

Frontline providers shouldering the burdens of health care under pandemic conditions are rapidly realizing that competent physicians and other health care workers can only go so far to solve problems that arise from systemic dysfunction. Lack of data infrastructure inhibits communication and study of rapidly evolving clinical practice. Hospitals within blocks of each other are relying on ad-hoc interpersonal communications rather than working from a coherent multiorganizational playbook. The seamless capability to share ideas, care plans, and experiences based on reliable data would dramatically alter the US health care landscape. On a smaller scale, interoperability challenges also exist within hospital systems or single hospitals themselves. Lack of data interoperability at the device level has ensured that hospital systems have to navigate and manage streams of data from diverse legacy devices, creating challenging data acquisition issues in the context of a surging number of COVID-19 cases.

When confronted with a novel disease process, small and often poorly conducted studies rapidly proliferate. These studies are disseminated in mass and social media and may drive therapeutic decisions that could be ineffective at best and cause substantial harm at worst. In the context of COVID-19, a context where millions have contracted the disease and hundreds of thousands will likely die, timely but robust science is needed. The ability to share and combine data across systems serves as the foundation of such efforts. With data standardization and sharing, variability in care approaches could be harnessed to identify best practices and therapeutic avenues in a much more cohesive, data-driven manner.

Several concrete examples are illustrative. Infection control procedures and equipment or medication shortages related to COVID-19 are significantly impacting the timing of surgery, default approach to airway management, maintenance of anesthesia, and the setting in which postoperative monitoring occurs. Such rapidly developed policies are intended to protect anesthesia providers and other health care workers and to conserve critical resources, but is there a signal for patient harm associated with such sudden and profound changes in practice? Additionally, anesthesia departments are increasingly relying on the results of preoperative SARS-CoV-2 testing to guide such policies. The efficacy of these screening systems (particularly when applied to asymptomatic patients or those in whom such a determination is not possible) is unknown but is of critical importance for airway management, for determining personal protective equipment requirements during anesthetic care, and for determining safe postoperative disposition. Collectively, surgical patients undergoing preoperative evaluation are poised to become the largest cohort of asymptomatic patients tested for SARS-CoV-2, and yet the power of this potential resource to broadly inform health care policy will likely go unutilized. Unexpected but fundamentally important aspects of this emerging disease, such as the large number of patients presenting for endovascular therapy for acute ischemic stroke, may be uncovered through coordinated approaches to discovery.[19] Finally, there has been a rapid shift toward the use of anesthesia machines to meet surge demands for mechanical ventilation. Reasonable evidence exists to suggest that modern anesthesia machines are virtually indistinguishable from intensive care unit (ICU) ventilators; however, ICU ventilators are more fault tolerant, handle circuit leaks more optimally, and handle fresh gas in very different ways. Anesthesia machines set improperly and operated by health care providers unfamiliar with their use may unnecessarily waste medical gases or (in the worst case) deliver hypoxic gas mixtures in the context of inadequate oxygen flow into the circle system. Again, the impact of such a rapid retasking of medical equipment will, under the current infrastructure, remain unknown for much longer than should be necessary.

CONCLUSIONS

The public has a pressing interest in ensuring that data standards (eg, OMOP, FHIR) are rapidly developed, adopted by appropriate international standards organizations (eg, HL7), and implemented by EHR vendors in a manner that facilitates interoperability for individual patient care, public health, and research purposes.[20] We agree with others that this will require changes to the regulatory environment created by the HIPAA.[21] Anesthesiologists, along with nurses, respiratory therapists, advanced practice providers, emergency room physicians, intensivists, and other critical care professionals, stand at the front line of the COVID-19 public health crisis. Better data are required to delineate every aspect of this pandemic: supporting local operations and quality work; informing research queries, such as investigations into provider risk following airway management and quantifying the efficacy of therapeutic options; and bolstering public health efforts by providing real-time prevalence, tracking disease spread, and facilitating risk stratification. Integration of health care data with nonhealthcare source data is currently an impossibility in the United States due to lack of a universal health care identifier.[22] Public funding agencies and their grantees have shouldered the burden of creating stopgap solutions that policymakers have failed to require and major EHR vendors have avoided due to risk of competitive disadvantage. Policymakers and funders are called upon to prioritize the modernization of health informatics. Anesthesiologists and our specialty societies are called upon to advocate policymakers for these changes and to involve themselves in these organizations in the coming months and years and contribute to development or otherwise risk failing again in optimizing a data-driven response to the next pandemic. ▣

DISCLOSURES
Name: Vikas N. O'Reilly-Shah, MD, PhD, FASA.
Contribution: This author helped draft and revise the article.
Name: Katherine R. Gentry, MD, MA.
Contribution: This author helped draft and revise the article.
Name: Wil Van Cleve, MD, MPH.
Contribution: This author helped draft and revise the article.
Name: Samir M. Kendale, MD.
Contribution: This author helped draft and revise the article.
Name: Craig S. Jabaley, MD.
Contribution: This author helped draft and revise the article.
Name: Dustin R. Long, MD.
Contribution: This author helped draft and revise the article.
This manuscript was handled by: Thomas R. Vetter, MD, MPH.

REFERENCES

1. Wu F, Zhao S, Yu B, et al. A new coronavirus associated with human respiratory disease in China. *Nature*. 2020;579:265–269.
2. Wrapp D, Wang N, Corbett KS, et al. Cryo-EM structure of the 2019-nCoV spike in the prefusion conformation. *Science*. 2020;367:1260–1263.
3. US National Library of Medicine. Search of: COVID-19 - List Results - ClinicalTrials.gov. Available at: https://clinicaltrials.gov/ct2/results?cond=COVID-19. Accessed April 4, 2020.
4. The Office of the National Coordinator for Health Information Technology. Health IT Quick Stats. Available at: https://dashboard.healthit.gov/quickstats/quickstats.php. Accessed March 25, 2020.
5. Electronic Medical Record Adoption Model. HIMSS Analytics - North America 2017. Available at: https://www.himssanalytics.org/emram. Accessed March 25, 2020.
6. G2. Best Healthcare Integration Engines Software in 2020. Available at: https://www.g2.com/categories/healthcare-integration-engines. Accessed March 25, 2020.
7. HL7 International. Anesthesia - Documents. Available at: https://www.hl7.org/Special/committees/gas/docs.cfm. Accessed March 25, 2020.
8. Observational Health Data Sciences and Informatics. Collaborators – OHDSI. Available at: https://www.ohdsi.org/who-we-are/collaborators/. Accessed March 30, 2020.
9. Who We Are. MPOG. Available at: https://mpog.org/whoweare/. Accessed March 30, 2020.
10. Farr C. Epic's CEO is urging hospital customers to oppose rules that would make it easier to share medical info. CNBC. 2020. Available at: https://www.cnbc.com/2020/01/22/epic-ceo-sends-letter-urging-hospitals-to-oppose-hhs-data-sharing-rule.html. Accessed March 25, 2020.
11. Landi H. Epic, Cerner growing EHR market share with increased hospital consolidation: KLAS. FierceHealthcare. 2019. Available at: https://www.fiercehealthcare.com/tech/epic-cerner-growing-ehr-market-share-increased-hospital-consolidation-klas. Accessed March 25, 2020.
12. Landi H. Apple, Cerner call for interoperability rule release "without further delay," highlighting industry rift. FierceHealthcare. 2020. Available at: https://www.fiercehealthcare.com/tech/apple-microsoft-cerner-and-major-health-plans-call-for-omb-to-release-interoperability-rules. Accessed March 25, 2020.
13. Pifer R. HHS considers rolling back interoperability timeline amid COVID-19. Healthcare Dive. 2020. Available at: https://www.healthcaredive.com/news/hhs-considers-rolling-back-interoperability-timeline-amid-covid-19/574399/. Accessed March 25, 2020.
14. Grange ES, Neil EJ, Stoffel M, et al. Responding to COVID-19: the UW Medicine Information Technology Services experience. *Appl Clin Inform*. 2020;11:265–275.
15. Schröder-Bäck P, Duncan P, Sherlaw W, Brall C, Czabanowska K. Teaching seven principles for public health ethics: towards a curriculum for a short course on ethics in public health programmes. *BMC Med Ethics*. 2014;15:73.
16. Caulfield T. Pseudoscience and COVID-19 — we've had enough already. Nature. 2020. Available at: https://www.nature.com/articles/d41586-020-01266-z. Accessed April 28, 2020.
17. Bordeianou L, Cauley CE, Antonelli D, et al. Truth in reporting: how data capture methods obfuscate actual surgical site infection rates within a health care network system. *Dis Colon Rectum*. 2017;60:96–106.
18. Mello MM, Adler-Milstein J, Ding KL, Savage L. Legal barriers to the growth of health information exchange-boulders or pebbles? *Milbank Q*. 2018;96:110–143.
19. Sharma D, Rasmussen M, Han R, et al. Anesthetic Management of Endovascular Treatment of Acute Ischemic Stroke During COVID-19 Pandemic: Consensus Statement from Society for Neuroscience in Anesthesiology & Critical Care (SNACC)_Endorsed by Society of Vascular & Interventional Neurology (SVIN), Society of NeuroInterventional Surgery (SNIS), Neurocritical Care Society (NCS), and European Society of Minimally Invasive Neurological Therapy (ESMINT). *J Neurosurg Anesthesiol*. 2020. Available at: https://www.snacc.org/snacc-home/click-here-for-covid-19-resources/snacc-consensus-statement-on-anesthetic-management-of-endovascular-treatment-of-acute-ischemic-stroke-during-covid-19-pandemic/. Accessed April 6, 2020.
20. Padakandla UB, O'Reilly-Shah VN, Poterack KA, Rothman BS. Perioperative documentation and data standards--anesthesiology owned and operated. *ASA Newsl*. 2018;82:8–10.
21. Lenert L, McSwain BY. Balancing health privacy, health information exchange and research in the context of the COVID-19 pandemic. *J Am Med Inform Assoc*. 2020. Available at: https://academic.oup.com/jamia/advance-article/doi/10.1093/jamia/ocaa039/5814212. Accessed April 1, 2020.
22. Yaraghi N. The US lacks health information technologies to stop COVID-19 epidemic. Brookings. 2020. Available at: https://www.brookings.edu/blog/techtank/2020/03/13/the-u-s-lacks-health-information-technologies-to-stop-covid-19-epidemic/. Accessed March 25, 2020.