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Perspective

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Ethics and informatics in the age of COVID-19: challenges and recommendations for public health organization and public policy

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ABSTRACT

The COVID-19 pandemic response in the United States has exposed significant gaps in information systems and processes that prevent timely clinical and public health decision-making. Specifically, the use of informatics to mitigate the spread of SARS-CoV-2, support COVID-19 care delivery, and accelerate knowledge discovery bring to the forefront issues of privacy, surveillance, limits of state powers, and interoperability between public health and clinical information systems. Using a consensus-building process, we critically analyze informatics-related ethical issues in light of the pandemic across 3 themes: (1) public health reporting and data sharing, (2) contact tracing and tracking, and (3) clinical scoring tools for critical care. We provide context and rationale for ethical considerations and recommendations that are actionable during the pandemic and conclude with recommendations calling for longer-term, broader change (beyond the pandemic) for public health organization and policy reform.

Key words: COVID-19, contact tracing, ethics, privacy, public health surveillance

INTRODUCTION

The United States was unprepared for the 2019 Novel Coronavirus Disease (COVID-19) pandemic, despite experiencing recent outbreaks from the same virus family such as the 2003 severe acute respiratory syndrome (SARS) epidemic.[1] General warnings about and predictions of future pandemics and calls for global preparation[2] as well as specific early warnings[3] concerning the COVID-19 outbreak in Wuhan, China went unheeded. The responses from US public health agencies were generally disparate, uncoordinated, and inadequate to the challenge, resulting in insufficient supplies of protective equipment, a dearth of testing facilities and kits, and delays in test processing and results. Taken together, this lack of coordination made evident a fragmented information infrastructure that could not promptly and reliably provide even the most basic information related to daily case trends, hospital capacity, and healthcare supply chain. Various "social distancing" strategies and economic shutdowns across states curbed the initial spread of the virus in many parts of the country, but the rapid "reopening" in several areas—due to concerns about exacerbating the economic crisis and the public's desire to return to work and social activities—resulted in infection surges across communities. Emerging from the pandemic and preventing additional cycles of the disease will require advances in scientific understanding of SARS-CoV-2 and extensive public health resources, in addition to a vaccine.

These events provide informaticians with an opportunity to reflect on how to effect much-needed changes in the US health system and the health information infrastructure and to inform public health policy with more reliable data and evidence. The biomedical informatics community, in collaboration with others, has a responsibility to assess the current information systems, regulations, and policies in responding to the pandemic and identify needed systemic changes. A substantial part of this assessment should address ethical, legal, and social issues that the SARS-CoV-2 outbreak brought to the fore. Consensus had been building prior to the pandemic that both privacy and research regulations were outdated and needed revisions to reflect technological changes, newer conceptions of privacy and bioethics, and the emerging view that expands health data to include many types of data collected by diverse entities, health related or otherwise.[4,5] The pandemic has brought further scrutiny to previously identified complex ethical, political, and social issues.[6,7] Building upon prior experiences and scholarship, we examine key informatics-related ethical issues in light of the COVID-19 pandemic and provide short- and longer-term recommendations for public health organization and policy.

BACKGROUND

The Ethical, Legal, and Social Issues (ELSI) Working Group of the American Medical Informatics Association (AMIA) has a long history of advocating for ethical and human-centered practices in applications of healthcare information technology. During April 2020, when the majority of US states had imposed stay-at-home orders or other activity restrictions, the ELSI working group launched a collaborative effort to identify and raise awareness about ethical issues that are crucial to the informatics community at large and to policy makers. The group identified 3 thematic areas of particular importance using a consensus-building process (see Supplementary Appendix A for details on methods): (1) public health reporting and data sharing, (2) contact tracing and tracking, and (3) clinical scoring tools. Although these themes intersect and have far-reaching implications at all levels of government and policy making, we consider issues related to public health reporting and data sharing to be centered at the *national level* (ie, the need for rigorous coordination at the national level, while the actual data collection occurs locally), issues related to contact tracing and tracking to be centered at the *community level*, and those related to clinical scoring and assessment tools to be more relevant at the *health system level*. In the following sections, we lay out context and rationale for ELSI considerations, followed by recommendations that are actionable during the pandemic and recommendations that call for long-term, broader change (beyond the pandemic) for public health organization and policy (see Appendix A for a summary of recommendations). Other topics identified by the group (eg, how the Health Insurance Portability and Accountability Act applies in light of COVID-19) were deemed outside the scope of this work, as they warrant separate and more extensive analyses or were addressed elsewhere.[8]

PUBLIC HEALTH REPORTING AND DATA SHARING

Public health responses should be premised on an evidence base which relies heavily on the collection, assessment, and dissemination of results from standardized public health reporting. Critical data elements required for reporting include several domains such as 1) hospital capacity (eg, number of intensive care unit beds and mechanical ventilators), 2) healthcare supply chains (eg, inventory of personal protective equipment (PPE) and testing and ventilator supplies), 3) healthcare staffing needs (eg, required number of respiratory therapists), and 4) demographic and outcome data on both presumptive and confirmed infections. Since the first confirmed case in the United States in late January 2020, the COVID-19 outbreak has exposed systemic vulnerabilities in the national public health reporting system that impeded timely evidence-based decision-making. These vulnerabilities stem in part from nonstandardized, ad hoc reporting,[9,10] as opposed to standardized, systematic, electronic reporting of data from state to federal agencies, such as the Center for Disease Control and Prevention (CDC) and the Federal Emergency Management Agency (FEMA). Furthermore, the CDC's decision not to use the World Health Organization (WHO) COVID test, but to develop its own, and the subsequent failure to deliver reliable results, initially resulted in delays of distributing approved testing kits. This approach motivated local institutions to develop their own testing and reporting protocols, albeit with varying clinical validity and persistent delays in test results. To further exacerbate reporting issues, the Department of Health and Human Services (HHS) abruptly changed the process used by hospitals to submit daily COVID-19 reports about testing, hospitalizations, and hospital capacity in July 2020. Hospitals were instructed to submit data through a system developed by a commercial contractor—TeleTracking Technologies Inc. Data would then be aggregated and analyzed using a new platform, called HHS Protect, built by another commercial entity—Palantir Technologies Inc., effectively bypassing the CDC.[11–14] The stated purpose of this change was to streamline data collection and analysis, however it is as yet unclear whether and how aggregate trend data will be made publicly available. These events, together, highlight issues of not only efficiency and timeliness in obtaining and analyzing data but also trust and transparency in how this data will inform policy responses as the pandemic evolves.

Short-term recommendations

Disease surveillance efforts that report critical data elements (eg, viral and antibody testing results, hospital capacity, PPEs, and healthcare staffing and supply needs)[15] should be consolidated, coordinated, and well-supported at local, state, and national levels. Current reporting standards are not robust enough,[16] and may lead local and state public health departments to take precaution- or fear-driven, rather than evidence-driven, action. In the aftermath of the 2014–2016 Ebola pandemic, for example, the CDC provided funding to develop PPE guidance and surveillance measures[17] that can be reliably integrated, interpreted, and used for modeling and decision-making. However, this ongoing effort was too late for deployment of nationwide standards. Researchers and journalists have also sought to compile their own COVID datasets in the absence of centralized efforts to track infections and supply shortages at local and regional levels.[18,19]

The principle of justice instills a responsibility to understand how COVID-19 may disproportionately impact some communities, workers, and demographic groups. Outbreaks among nursing home residents, prisoners, and low-wage workers in meat-processing plants[20] and higher rates of severe illness among racial and ethnic minority groups,[21] underscore the need to report data elements that make subgroup analysis possible. To better capture the social inequalities observed in COVID-19 patient outcomes,[22] public health reporting should include sociodemographic factors such as age, race, income (zip code or census tract level), gender, gender identity, ethnicity, disability status, and comorbidities in health outcome analyses. As of this writing (late July 2020), the CDC had released early reports on geographic and demographic differences and clinical outcomes among COVID-19 patients.[23–25] Although these results are useful, more nuanced and more rapid reporting is needed at local and state levels to direct public health resources to communities at greatest disease risk, and expose broader health disparities that have long plagued the US health services infrastructure.

Longer-term recommendations

Informed by this pandemic and prior AMIA work,[6,7] we concluded that a more robust, standardized national reporting system is needed to effectively respond to future infectious disease outbreaks. A federal agency, such as the CDC, should be further empowered with coordinating data collection with local and state public health departments, and funded at a level that reflects the complexity and importance of this work. Major investments in building an informatics-based infrastructure are needed, as demonstrated by the continuing use of fax machines for case reporting to local health departments. Our call to modernize the infrastructure and process of disease surveillance is not new. The CDC's National Notifiable Diseases Surveillance System was launched in 2014, but results have fallen far short of the comprehensive change needed to efficiently and effectively conduct public health surveillance.[26] Modernizing the public health reporting system will require 1) effective use of data standards and interoperable systems that use those standards (eg, LOINC codes established during the pandemic to identify laboratory tests for viral RNA or antibodies to the virus[27]) 2) unique identifiers and metadata for testing facilities and tests, 3) robust management of the entire data pipeline from local to state to national public health agencies, and 4) abolishment of paper-based systems and authentic collaboration with and support from electronic health record (EHR) vendors and the standards community to build and maintain the necessary technical infrastructure to automatically collect and report critical data elements.

CONTACT TRACING AND TRACKING

One of the major pandemic mitigation strategies promoted by WHO has been summarized as *Trace, Test, and Treat,*[28] which stands for identifying new cases, tracing their social contacts, and then testing and treating them. Given the inadequate response to measures intended to limit the spread of the virus and avert a worsening economic crisis, the US is contemplating a "tracking" strategy rather than contact tracing. *Trace* and *Track* seems similar at first glance, but there is a difference between contacting an infected person and asking them (voluntarily) for their contacts who then can be alerted versus an automated, and potentially covert, system that tracks the general public and may lack transparency.

Automated tracking raises ethical concerns related to privacy and control of personal devices. Countries such as Taiwan have shown that geo-tracking using mobile phones can be used not only to enable contact tracing, but also to ensure that citizens are complying with self-quarantine orders.[29] Such constant data collection and analysis through mobile applications is highly intrusive and is prone to abuse when the data are sold or reused for commercial purposes, such as in advertising, targeted marketing, or employment and credit decisions. Tracking puts privacy and autonomy at risk and may endanger safety, including financial security, especially when data are used by banking or billing apps.

In the context of tracking during this crisis, we assert that all collected data have implications to health, insofar as a trip to the grocery store or gas station, a jog in the park, or a take-away food order all contribute to an individual's potential exposure to SARS-CoV-2. With certain coordinates, the collected geodata can identify an individual. The majority of mobile apps do not specify how long their data collections will persist nor whether the collected data will be purged. The extent of (ab)use of such collected data, sometimes deprecated as "digital or data exhaust," has been exposed by both scholars and journalists[30] but is still not widely known to the public.

Short-term recommendations

Few privacy-preserving methods and tools exist to support benign contact tracing. Such tracing does not identify persons to others but, rather, notifies exposed persons directly about when and where they may have been exposed.[31,32] These methods are more reliable because information is retained on the user's phone while only general geolocation details, such as a visit to a specific location, are known to the developer or vendors. It is important to leverage such techniques and use the least intrusive technology and collect the minimally required data for tracking. If tracking must be based on a particular technology, the choice should be justified by providing integral privacy protections to safeguard the data from unintended or undisclosed use and to ease concern about surveillance. With resurgence of infections throughout the country and mounting determination to "flatten the curve," it may be ethically defensible to heighten tracking as a way to enhance safeguards during public health emergencies. However, the long-term risks to privacy and the potential repurposing of collected information remain problematic. Balancing the use of data and technology for public good versus protection of privacy is key. Laws and/or regulations might be enacted and/or amended as necessary to prevent COVID-19 data from being exploited, whether by governments or commercial entities. Such

amendments may include mandating complete transparency about what data are being used and how, in both short- and long-term.

Longer-term recommendations

Location and contact tracing illustrate how all data can function as health data, which then implies that all personal data should receive the same protection as health data. Both concurrent and retrospective analyses are needed that examine how effectively and efficiently different technological solutions have addressed problems during the pandemic in terms of public health outcomes (eg, infection and case fatality rates and other clinical outcomes), at what cost to the economy, and at what cost to personal, family, work, and civic life. The highly mobile nature of American culture necessitates a national effort to be maximally effective.

Given some relaxation in HIPAA enforcement (eg, for telehealth providers and in using/disclosing protected health information related to substance abuse to authorized personnel) due to the public health emergency, discussion of HIPAA, and other privacy reform should continue at the national level. This is an excellent opportunity for the US to consider harmonizing the patchwork of sector-based privacy regulations to enable a more uniform and responsive set of protections nationwide, along with significant attention to improved cybersecurity.

CLINICAL SCORING TOOLS

Several clinical scoring systems that assess the severity of the disease and estimate the risk of mortality and other intensive care unit (ICU) outcomes are available for critical care medicine. Examples include Acute Physiology and Chronic Health Evaluation (APACHE), Sequential Organ Failure Assessment (SOFA), quick SOFA (qSOFA), modified SOFA (mSOFA), Pediatric Risk of Mortality (PRISM) and others. Clinicians need reliable appraisals of the varying efficacy and safety of these different critical care-scoring tools and how they apply to COVID-19 and other patients. We highlight this as an important need because several crisis standard-of-care protocols incorporate such scores as an integral part of decision-making related to ICU admission triage, ventilator allocation/reallocation, and initiation of cardiopulmonary resuscitation.[33,34]

Short-term recommendations

EHR vendors are rapidly building and deploying features to collect underlying clinical data needed for the score, compute the severity score, and repeat measurements as appropriate, though not all institutions have enabled such features. It is important to ensure that computerized versions of clinical scores are well-calibrated and used as intended in crisis standard-of-care guidelines. Scoring tools should not be used for purposes for which they were not designed. For example, the original SOFA score should be repeatedly assessed to evaluate the severity of the disease and the duration of ICU resource needs[35] but has not been validated for predicting the risk of mortality. Should there be shortages of ICU beds and ventilators due to the crisis, clinicians and triage panels need to be able to reliably use the scores to allocate resources. Second, EHR implementations of clinical scores should be adaptive to local circumstances and to emerging observations and evidence from pandemic investigations. For instance, early studies suggest that not many COVID-19 patients go into respiratory failure earlier than organ dysfunction,[36] which makes the use of SOFA as a part of standard of care less appropriate.

Longer-term recommendations

The pandemic postdrome is an unparalleled opportunity to study, critique, and improve crisis standard-of-care guidelines and tools. First, there needs to be a robust, retrospective evaluation of the specific scoring tools used for triage and resource allocation, which often include assessment of COVID-19 severity, possible need for critical care, and likelihood of interventions such as intubation. Second, local conditions, patient preferences, and continuous monitoring and availability of critical resources must be considered. Some patients may not want measures such as ventilator care. If resources or treatment options that were previously unavailable (eg, extracorporeal membrane oxygenation) now become available, reassessment of decisions are needed. Algorithms and clinical scores rarely include these data. If scoring tools are used for ICU admission triage and allocation of resources, they may well need reengineering to incorporate patient preferences, resource availability, and other aspects that are not now considered. Third, healthcare organizations and public health agencies should develop future crisis standards in consultation with key stakeholders and community groups. For instance, a number of disability rights organizations have faulted COVID-19 treatment guides as embedding discrimination against people with disabilities, in part because of the use of comorbidities as a way to fine-tune SOFA scores. Although these concerns were adequately addressed in some jurisdictions, more work is needed to build and sustain the trust of vulnerable populations.

CONCLUSION

By early April 2020, the United States reported the world's highest incidence of, prevalence of, and mortality from COVID-19. Gross shortages in medical supplies at the point of care, rapid community transmission, insufficient testing capacity, and ultimately, increasing incidence and mortality have come to define the national emergency in the United States thus far. Underlying issues include the lack of a standardized, nationally-coordinated reporting system for critical data elements, lack of trustworthy and accountable ways to deploy technological solutions for contact tracing, and lack of well-calibrated algorithms that can be used in standards-of-care applicable during a crisis. This work introduces each of these issues, along with short- and longer-term recommendations to guide future public health and institutional policies and practices. Having a sound ethics-based rationale and transparent approach for responses to severe public health threats can lead to better public acceptance, harmonized and strengthened standards across different domains related to data and information technologies, and increased public trust in governmental and commercial entities for routine as well as crisis practice. In addition to the longer-term recommendations described in this perspective, future work at the intersection of ELSI and informatics will include a stronger focus on (a) regulatory waivers and potential policy reform as it relates to telemedicine and other digital health solutions, (b) impact of informatics infrastructure in enabling health equity in the context of clinical trials and distribution of vaccines for COVID-19, (c) public-private partnerships in pandemic data management, governance, and/or analytics, and (d) role of digital health technologies (eg, mobile apps for symptom tracking and contact tracing; digital immunity passports) in reopening of workplaces, including research and educational institutions.

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AUTHOR CONTRIBUTIONS

VS, AS, and MC initiated the project and organized the author group into 4 initial thematic areas: (1) public health reporting, (2) policy and legal issues, (3) clinical issues, and (4) contact tracing. VR, MC, and CUL contributed to area 1. CP, EP, PD, and YS contributed to area 2. RS, CUL, VS, and KG contributed to area 3. AS, BK, RK, and PD contributed to area 4. VS drafted the manuscript based on contributions from each area. All authors reviewed the manuscript and provided critical feedback. CP, CUL, and RS assisted with final copyediting.

SUPPLEMENTARY MATERIAL

Supplementary material is available at *Journal of the American Medical Informatics Association* Online

CONFLICT OF INTEREST STATEMENT

None declared.

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