Addressing Privacy Concerns to Advance Research

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In addiction science, there is increasing urgency around the question of how to protect the privacy of people with substance use disorders (SUDs) while also ensuring that data on individuals with SUDs are not left out of large-scale research initiatives. Science depends on access to data, and advances in information technology and informatics have revolutionized what can be achieved with healthcare data — from basic research to enabling a learning health system that evolves in real time in response to data analytics and provides clinical decision support at the point of care. These efforts have tremendous potential to advance our understanding of health and disease and to drive the evolution of the healthcare system. Unfortunately, the important protections around patient data can also create impediments to research that slow progress in learning how best to identify and treat patients with substance use disorders.

SUDs affect an estimated 21.6 million Americans, or 8.2 percent of the population over age 11[1]; apart from their incalculable toll on individuals and their families and loved ones, SUDs cost society many hundreds of billions of dollars each year in healthcare and criminal justice costs[2]. They also have direct impacts on physical health status through the deleterious effects of drugs and alcohol on multiple organ systems, as well as the potential interactions between medications and recreational drugs[3]. Indirect effects on physical health are also often seen since compliance with treatment can be compromised in persons suffering with behavioral health disorders[4].

How can we balance the need to protect patient privacy with the need to ensure that SUD data are meaningfully included in large-scale analyses of health data?

While ensuring adequate insurance coverage and enforcing parity protections are critical for improving access to and quality of SUD treatment, research indicates that insurance coverage is not the only barrier to engaging people with SUDs in treatment, and this highlights the importance of privacy protections[5]. Maintaining strict confidentiality in the provider-patient relationship has always been a cornerstone of clinical practice, and privacy and confidentiality are even more important for individuals with SUDs than with other conditions. Seeking treatment for illicit drug use or the medical consequences of substance misuse could potentially expose a patient to legal consequences such as arrest or losing custody of a child. In addition, people with SUDs are still stigmatized due to the lack of understanding of the medical nature of their condition, including changes in the brain that make it difficult for an individual with an SUD to weigh the consequences of their actions. Thus, seeking treatment can also have social and employment consequences as well as legal ones.

In order to avoid systematically excluding one of the most vulnerable populations served by the healthcare system, it is critical that research efforts include both physical and behavioral health data on patients with SUDs. However, privacy and confidentiality laws pose challenges to including mental health and substance use disorder (SUD) treatment data in large-scale research projects. This has the potential to have profound negative consequences for the field and for patients suffering with behavioral health disorders.

Privacy protections for data on SUD care were written into federal statute and codified as regulations in 42 CFR Part 2 (Part 2) in 1975 to combat the effect that the negative consequences mentioned above were having on the willingness of people with SUDs to seek treatment. Part 2 was recently updated "to ensure that patients with substance use disorders have the ability to participate in, and benefit from health system delivery improvements, including from new integrated health care models while providing appropriate privacy safeguards." However, implementation is currently on hold, along with other recent regulations[6]. Implementation of the Final Rule, published on January 18, 2017, will not occur before March 21, pending review by the new Administration.

Regardless of whether the update to Part 2 is implemented, it is important to ensure that individuals with SUDs are able to benefit from the scientific advances that come from large-scale research projects. Both the current and the proposed final rule have specific requirements for patient consent, but notably, sharing data with qualified researchers for research purposes without patient consent

is allowed. It is important to note that many states also have privacy laws to protect data on SUD treatment, but these rules do not prohibit the sharing of data for research; rather, they set the standards for how information can be shared.

These privacy rules also permit data sharing for the purpose of treatment coordination if consent requirements are met. However, people with SUDs can be left out of delivery system transformation efforts that could improve care for individuals with SUDs if healthcare systems allow these privacy protections to hinder information sharing. Many developments in the past several years are improving the integration of addiction screening and treatment into the wider healthcare system, including ambulatory primary care and emergency medicine. This includes wider utilization of effective medications for opioid use disorders such as buprenorphine, which can be administered by licensed clinicians and even effectively initiated in emergency room settings[7].

Preparing for the hurdles associated with the federal and state privacy laws is critical to ensure inclusion of behavioral health data. For example, in 2009, the American Recovery and Reinvestment Act (ARRA) provided funding to develop health information exchanges (HIEs) across the country, intended to foster sharing of patient clinical records between different healthcare providers to support improvements in healthcare integration. Because of the short timeline for expending the appropriated funds, the complexities associated with incorporating behavioral health data while complying with existing privacy protections were not addressed in the initial implementations. As a result, the vast majority of HIEs were set up without the ability to share data from specialty behavioral health treatment organizations, including SUD treatment facilities. While initially there may have been an intention to retrofit the technology infrastructure to support inclusion of behavioral health data, it has generally been found that compliance with the privacy laws could not be achieved without enormous expense. As a result, only a very small minority of HIEs currently include behavioral health treatment data, presenting a major impediment to effective integration of behavioral health and general healthcare services[8].

The exclusion of individuals with SUDs from delivery system transformation efforts continues to be problematic, and the potential exclusion of individuals with SUDs from large-scale research projects is also deeply troubling. If the research that will become the basis for future development and implementation of evidence-based practices excludes individuals with SUDs, the dataset and the resulting research will be biased. If their data are excluded, patients suffering with SUDs — a particularly vulnerable population that already experiences significant health disparities[9] — may be excluded from the potential advances that are to be reaped from data-driven initiatives[10]. Further, studies of other health conditions will not adequately account for how best to treat people with comorbid SUDs.

For example, in order to comply with the federal SUD treatment confidentiality regulations, research datasets from the Centers for Medicare & Medicaid Services (CMS) do not include SUD treatment data, which equates to approximately 4.5% of inpatient Medicare claims and approximately 8% of inpatient Medicaid claims. As described recently in the *New England Journal of Medicine,* this omission affects crucial research to evaluate policies and practices related to care for patients with addiction. Also, most of the suppressed data concerns claims for which a SUD was a secondary diagnosis, thus its impact extends to other disorders[11].

Since behavioral health problems disproportionately affect populations who are already vulnerable and underserved due to economic disadvantage, age, and other factors, it is crucial to incorporate behavioral health information into the data-driven efforts of coming years. If research activities and investments exclude individuals with SUDs, this can bias results and worsen existing disparities, since any research results that are translated into practice will not account for the needs of individuals with SUDs. The question remains: How can we balance the need to protect patient privacy with the need to ensure that SUD data are meaningfully included in large-scale analyses of health data? Answering this will become increasingly important in coming years.

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