BUSINESS OF LIFESTYLE MEDICINE

Dana M. George, MA, Aaron E. George, DO, and Kelly L. George, PhD

Big Data Just Got Bigger: Implications of Real-World Evidence and Patient-Entered Data on Health Care and Health Care Policy

Abstract: *Advancing care delivery in lifestyle medicine and primary care has increasingly benefited from unique data sources and points. To remain competitive and relevant in modern practice, physicians and health systems must tackle and engage the implementation of big data and advanced applications for increasingly complex care. In many cases, information is being aggregated, though barriers exist in terms of accessing, interpreting, and making it actionable. New mobile device applications have eased some barriers, yet present challenges of their own. These new applications, designed to gather patient-entered data outside of traditional clinical settings, will require new policies, systems, and workflows. From a business perspective, collecting such data has potential value to patient care and patient engagement as well as financial incentives. If handled correctly, these additional data sources, including those not previously accessible, have the potential to vastly improve patient health.*

Keywords: health policy; registries; physician-patient relations; evidence-based practice; data science; predictive analytics; clinical trails

Advancing care delivery in lifestyle medicine and primary care has increasingly benefited from unique data sources and points. As opposed to traditional and outdated models of isolated and episodic face-to-face patient encounters, new delivery models expand both the touchpoints that patients make with their physician and the number of variables of health data aggregated from outside of the office. Whereas paper charts housed in large bookshelves have given way to various digital platforms, the fundamental constant for centuries has been the physician as the collector, cultivator, and keeper of patient medical records. Until recently, physicians have mostly served as the sole owners of patient data and have held the determination of what to do with it. However, new data streams, platforms, agencies, and private industries threaten this paradigm. If physicians and health systems do not remain alert, vigilant, and responsive,

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there exists the potential that such passivity could find them sitting on the sidelines.

New concepts from big data are now entering the medical lexicon, and this will require physicians to understand and implement within daily practice. Real-world data (RWD) refers to those data collected that relate specifically to patient health status and/or the delivery of health care. RWD can be derived from sources such as claims and billing data. In contrast, real-world evidence (RWE) is the clinical evidence derived from the proper analysis of RWD.[1]

The number of health variables assessed outside of the traditional office visit has grown substantially and extends well beyond simple vital signs such as blood pressure and body weight. Many innovative lifestyle medicine practices have sought to collect those variables that affect health on a day-to-day basis: food consumption, steps taken, hours slept, and a host of other social and environmental factors. That said, even the most innovative practices may struggle to keep pace with the competition. For example, the Target Corporation has successfully used data analytics and predictive modeling to identify pregnancy ahead of a physician's office and, with relative precision, can identify the window of the due date.[2] Meanwhile, the industry of wearable technologies continues to accelerate the number of health and data points collected, though not yet necessarily meaningfully shared or integrated with physician offices.[3]

From a business perspective, there is much to gain in collecting such data. First and foremost is the potential value to patient care. Moreover, integration of advanced platforms has the potential to enhance patient engagement, empowerment, and satisfaction. Finally, financial incentives are improving with the 3 new current procedural codes (99453, 99454, 99457) approved for remote patient monitoring in the 2019 Medicare Physician Fee Schedule.[4] Despite these incentives, gaps in data collection continue to persist within both physician offices and health systems.

New FDA Digital Platform

Looking to fill a large gap in health care data collection while utilizing the common consumers mobile device, in November 2018, the Food and Drug Administration (FDA) released a digital platform termed the *MyStudies App*.[5,6] The FDA's main goal for creating the app was to facilitate RWD collection directly from the mobile devices of patients. This open-source code provides the digital tools necessary for designing and distributing questionnaires directly to the mobile device of patients to gather data for clinical trials, research, or disease registries. Data collected can be linked to a patient's electronic health record (EHR) in a manner that is both safe and secure while also remaining compliant with the Health Insurance Portability and Accountability Act and Federal Information Security Management Act. As opposed to fragmented and state-by-state registries, the creation of a national framework that is supported at the federal level has promise for widespread adoption.

As a novel tool in the hands of patients, the MyStudies App will soon serve to broaden the diversity of information collected beyond EHR and claims data. Patients are empowered to directly add a host of relevant health factors, reported outcomes, and social and environmental contributors, all from the comfort of their home. The goal is to expand the range of data types available while enhancing the amount of data derived from the patient perspective such as patient-reported outcomes, scales of specific symptoms in real time, and reports of drug and supplement use. Meanwhile, project administrators can additionally push resources such as pdfs, websites, or videos directly to the mobile phone of participants, allowing patient engagement beyond face-to-face encounters.

The MyStudies App is just one of many recent exciting movements toward the integration of RWE into health care decisions.[7] These efforts will continue to transform the dynamic of the patient-physician data exchange as well as patients' views of the medical practice. Like the early stages of clinical trial designs in the 1960s and 1970s, these efforts will take time to properly form and develop in a meaningful way. The future questions many will need to answer are the following: how to integrate, validate, and trust new data sources? This will be particularly relevant when large registry data conflict with traditionally accepted evidence-based medicine and research. An algorithm, a referee, or a validating mechanism will be needed to merge findings from these sources and inform clinical decision making. Ultimately, there is tremendous potential once natural biases are lifted and protocols are established.

Potential Impacts on Traditional Relationships: Knowledge and Decisions Going Forward

Technologies such as the MyStudies App will alter the paradigm of the patient-physician data interchange as well as affect autonomy and agency in data ownership. The open source nature of the MyStudies App suggests that other interested parties could customize or capitalize on the design. Patients are no longer passive observers of their medical records, and physicians and health systems may soon be scrambling for full access to all patient health data. This new paradigm of patient ownership of data may lead to patients engaging with entities outside of health care. Increased global patient engagement may come at the expense of physician disconnection.

The Data

Mobile device applications, such as the MyStudies app, are building an entirely new type of data set that data scientists have desired for decades. The substantial amount of additional data will help physicians understand the broader picture of their patients only if the patient is using the data collection tool truthfully and if they are willing to share it. However, these new data streams will require new management systems that

are different from those that have traditionally stored EHR data. Similar to survey data, concerns regarding data integrity and standardization will exist for patient-entered data. Additionally, advanced algorithms to interpret and meaningfully aggregate free text data will need to be used that move beyond methods used for binary and defined data types.

Researchers must also be aware of patient demographics because it has been observed that patients of higher socioeconomic classes or those incentivized by a health care provider are more likely to seek out mobile devices to track their health.[8] This raises concerns about external validity and broader extrapolation of findings to disparate populations. Overall, the MyStudies App was designed to diversify the data collected in clinical trials and ultimately improve our understanding of health outcomes. If companies leverage the open source code for the FDA app and continue to build new apps to better track the patient experience, data integrity will be strengthened and health outcomes may be positively affected.

Strong consideration must be given to how data are meaningfully integrated, including costs. For larger systems, administrative barriers may slow or restrain systemic adoption. Conversely, the lack of resources and infrastructure in small practices may preclude their participation. It remains to be seen if large systems and private practices will be motivated to overcome these barriers to realize the potential benefits of incorporating RWD and RWE into patient care.

The expansion of the FDA into the digital space for more global patient tracking is a pivotal moment in health care. These new data tools hold the potential to transform patient delivery and improve health outcomes. Yet physicians are often so consumed by the need to update their own patient electronic medical records that there is the possibility that they may overlook or outright miss changes on the horizon. Applications and registries, such as the MyStudies app, appear as developments that are progressing relatively silently outside of traditional health care. There exists the very real possibility that these will be disruptive innovations, and if physicians and health care systems are not listening, watching, and advocating, they may just be carved out of the picture.

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Informed Consent

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Trial Registration

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