EDITORIAL

What Is Needed Now to Improve Cardiovascular Clinical Registries in the Future

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Every day, people enter health care systems looking for answers to their health problems. Clinicians search for the right answer for the patients in front of them, often in a complex, dynamic clinical situation. In these scenarios, patients and clinicians expect that the evidence is clear and decision making will be sharp and incorporate the individual's preferences and values for the best outcome. Unfortunately, this is often not the case because of uncertainty regarding choices, the evidence base, and the potential range of benefits or harms associated with both diagnostic and therapeutic decisions. To close this gap, the notion of learning through aggregated clinical experiences and clinical registries has been fundamental, dating back to the origins of the digital medical textbook.[1]

Viewpoint

Driven by the American Heart Association, the American College of Cardiology, and the Society of Thoracic Surgeons, cardiovascular medicine has led efforts to move registries beyond small-scale, local initiatives and expand across the entire United States.[2] Consequently, millions of people with a broad variety of cardiovascular conditions have benefited from the simple notion that people can be better cared for through continuous quality improvement and evidence generation.[3-5] Often, these registries were procedure-based and focused on early device use in populations less studied than those in the pivotal clinical trials in which clinicians faced the most vexing problems.[6] The success of these registries has led to vast improvements in appropriate use, safety, and expanded-use criteria for people with cardiovascular disease. Beyond procedures themselves, registries have served as a foundational element for understanding unmet cardiovascular health needs and how to fill in those gaps.[7]

Health Care Transformation and Registries

As Fleurence et al note in their Viewpoint,[8] the future of registries is changing. Similar to other areas of health care, registries are entering an era ready for disruption. The pace of data generation and device innovation is rapidly accelerating. Clinician burnout is increasing, in part because of the daily demands of electronic data entry.[9] Clinics, hospitals, and health systems are consolidating. Payers are demanding increasing accountability not just for a device or an isolated episode of care, but entire populations. Registry fatigue within health systems is growing, given the competing demands for resources more aligned with population health management. Patients are bringing forward their own data from a number of different streams in and outside traditional health care settings via the internet of medical things.[10] This intersection of patient-derived data and curated electronic health data from multiple streams is forming a multidimensional data stack that puts the potential for understanding the device-human interaction on an expanded scale, beyond previous experience.

Turning Real-world Data Into Real-world Evidence

In recognition of this tsunami of data, accelerations in technology development and the often-competing interests of stakeholders, the US Food and Drug Administration has developed a plan for leveraging real-world data into real-world evidence to transform the ecosystem of device-based health care.[11] While cardiovascular medicine has been viewed as the poster child for successful device-based registries, even there the challenge of a dedicated registry for each device that enters into care is recognized, because of the resource requirements, personnel time, and inefficiencies of manual data collection. Hence, there is interest in leveraging electronic health data generated as part of routine care to develop and follow the lifecycle of device-based evidence. While data may already be available, the FDA has wisely noted that it must be fit for purpose: high-quality data that can support regulatory decision making and improve public health. To reach the utopia of leveraging real-world data continuously for clinical care and research, it is worthwhile to consider why contemporary cardiovascular registries have been successful.

First, they were simple. Parsimonious data collection embedded with clinical care delivery at the time of a procedure has often fulfilled the needs of the clinical care team. Second, they have delivered results people cared about, including quality. To our knowledge, every health care system that has incorporated registries has used them to improve the care they delivered. Users' forums focused on quality of care have ben created, and people have come together to share their lessons from the data generated by registries. (The National Cardiovascular Data Registry annual users' meeting typically has more than 1000 attendees.) Third, the registries collected data that might not otherwise be collected as part of a billing system of health care, including (for example) important patient clinical characteristics, procedural information, and operator data vitally important to understanding the safety or effectiveness of procedures.[6] Ultimately, registries have generated value for all stakeholders, including patients and clinicians, albeit with diminishment over the lifecycle of devices.

Success Factors for the Future of Registries

Moving forward, cardiovascular registries will need to evolve to take advantage of changes in data flow and provide more real-time feedback to patients, clinicians, systems, regula-

Box. Key Issues for the Future of Cardiovascular Registries

1. Ensuring high-quality data
2. Delivering data liquidity or access
3. Generating high-quality evidence using best methods, from data science to randomized clinical trials
4. Matching patient and clinician interests on the most pressing unmet needs
5. Becoming financially self-sustaining
6. Protecting privacy and ensuring trustworthiness

tors, payers, and policy makers. Key issues (**Box**) include how the next era of registries will improve the value and quality data generated for device-based care. It will be crucial for cardiovascular registries to resist being reduced to the claims behind health care bills. Administrative claims and the incentives for reimbursement do not always capture the full clinical context that goes into decision making and differs from inpatient to outpatient settings. More importantly, incentives to make electronic health record systems easier and faster for clinicians by including cut-and-paste methods along with easy buttons for most common diagnoses will be optimal for billing but will risk losing the clinical phenotyping necessary to understand human health.

Instead, it will be important for new data systems that provide curated data from multiple sources including deep phenotyping with complete longitudinal outcomes to deliver the answers needed by patients, clinicians, health systems, regulators, and payers. Collaborative consortia as being formed by National Evaluation System for Health Technology (NEST) offer this promise.[12] Curating health data are 1 step. However, it will be crucial to fully understand when and how such data can be used by interested parties. There will be elements such as mental health or functional activity that are not routinely captured in electronic health data, so either care delivery would need to change to incorporate such data, or other methods will be needed to capture these crucial data. It will also be important to use the most appropriate analytical methods. In an era of big data, having more data does not necessarily equal having better information. One could generate precisely the wrong answer if appropriate methods are not used, including embedded randomized clinical trials that could be used with more frequency if data systems allow.[13]

All of this needs to be done in a manner that is financially self-sustaining. Adding infrastructure costs without returning value to stakeholders by delivering better, more efficient answers at lower costs while covering more devices will not solve the problems that registries are encountering now.

Finally, the trust between patients and their health care teams must be preserved. Violations of privacy or perceptions of financial gains without a return of meaningful results to patients will limit the future transformation of registries into multidimensional evidence delivery platforms that will drive care forward in a value-focused way.

ARTICLE INFORMATION

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