Registries

OVERVIEW

Registries capture valuable, real-time patient data on an ongoing basis in a real-world setting and expand our knowledge of clinical patterns, processes, disease trajectories, patient outcomes, and delivery of care. A patient registry is defined by the Agency for Healthcare Research and Quality (AHRQ) as an "organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more stated scientific, clinical, or policy purposes."[1] A quality-improvement registry is similar in that it uses systematic data collection and other tools to improve quality of care, but its focus is on healthcare professionals.[2] Clinicians submit data on their patients which they, along with hospitals and healthcare organizations such as the American Heart Association (AHA), use to evaluate healthcare effectiveness, patterns of care, and safety in order to improve care. Quality-improvement registries usually incorporate evidence-based clinical practice guidelines which promote better care.

The data captured in a registry, through a case record form, are clinically important events relevant to a particular condition or treatment (including medications and procedures) and sometimes to a subpopulation such as women or children. Registries (which can be integrated with patient electronic health records) may collect hundreds of variables, including vital signs, medical diagnoses, and treatments. Registries also amass demographic information, such as age, sex, race, ethnicity, and zip code. The law requires all registries to safeguard the privacy of the information in a registry.

Registries may be run by researchers, patient organizations (including the AHA), professional societies, government agencies, and healthcare providers. Pharmaceutical companies and device manufacturers may also support registries to gather more information following approval of their therapies.

USES OF REGISTRIES

Registries serve many purposes. For example, researchers use registry data to analyze various outcomes. (Requests for registry data, along with a proposal describing what data are needed and how the data will be used, are submitted to an oversight committee. If the application is approved, researchers sign a data-use agreement before receiving the requested information.) Registries can also connect patients to clinical trials. When patients in a registry participate in a trial, any registry data (including any findings of biomarker tests, imaging, and genomic information) save researchers the time and expense of collecting data already acquired. In addition, registry data can generate research hypotheses and answer questions which are not practical or ethical to address through a clinical trial.

The Food and Drug Administration (FDA) also uses registry data (and other real-world evidence) in its regulatory decisions; in fact, the FDA used data from the Transcatheter Valve Therapy Registry in approving a heart valve.[3] The FDA recently provided industry with relevant guidance: *Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices* (finalized in August 2017) and *Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products* (released in draft form in December 2021).

Surveillance of Healthcare Systems. Registries can be a way to monitor trends in the use of certain treatments and the prevalence of certain conditions.[4] Registries are used for a number of other reasons:

- Assess the progression of a disease, evaluate treatments utilized at various stages of disease, and observe treatment outcomes and adverse events;[5,6]
- Evaluate trends in healthcare usage and the provision of medically necessary care (including underuse, overuse, and misuse);[7]
- Monitor the impact of prevention efforts and public health awareness campaigns;[8]
- Analyze referral and diagnosis patterns;[9]
- Describe patient population demographics and provider characteristics;[1,10] and
- Track incidence of health events and recurrent events.[11]

Surveillance of Underrepresented Populations. Registries play an essential role in providing meaningful, actionable data about the healthcare needs and the services used by populations of patients that traditionally have been underrepresented in epidemiological

studies and clinical trials, including racial and ethnic minorities[12, 13], women[14], the elderly[15], individuals with multiple comorbidities,[16,17] and individuals with rare diseases.[18] With data from a registry, researchers can:

- Identify and evaluate healthcare disparities within a patient population;
- Examine underrepresented populations and their access to healthcare services;
- Investigate disease progression and healthcare utilization in particular populations;
- Study the costs of treating particular groups; and
- Collect data on sex, gender, race, ethnicity, language, and other demographic information that impact health.

By collecting and tracking information over time, data can be used to expose disparities in care for minority populations as well as to address them. For example, the AHA's Get With The Guidelines® (GWTG)-Stroke Registry has documented poor quality in stroke care for Black patients as compared to White and Hispanic patients[12] while GWTG-Coronary Artery Disease (CAD) was associated with both a reduction of and an elimination of disparities in the quality of care for acute myocardial infarction (AMI) regardless of race or ethnicity.[13]

Measuring Quality and Safety. Registries are frequently used to evaluate and to improve healthcare quality. Because a registry can continuously capture data, registries have the potential to identify unnecessary or inappropriate variation in care and to drive quality improvement by creating a continuous feedback loop to pinpoint areas of poor quality. Other ways that quality-improvement registries support efforts around quality and safety include the following:
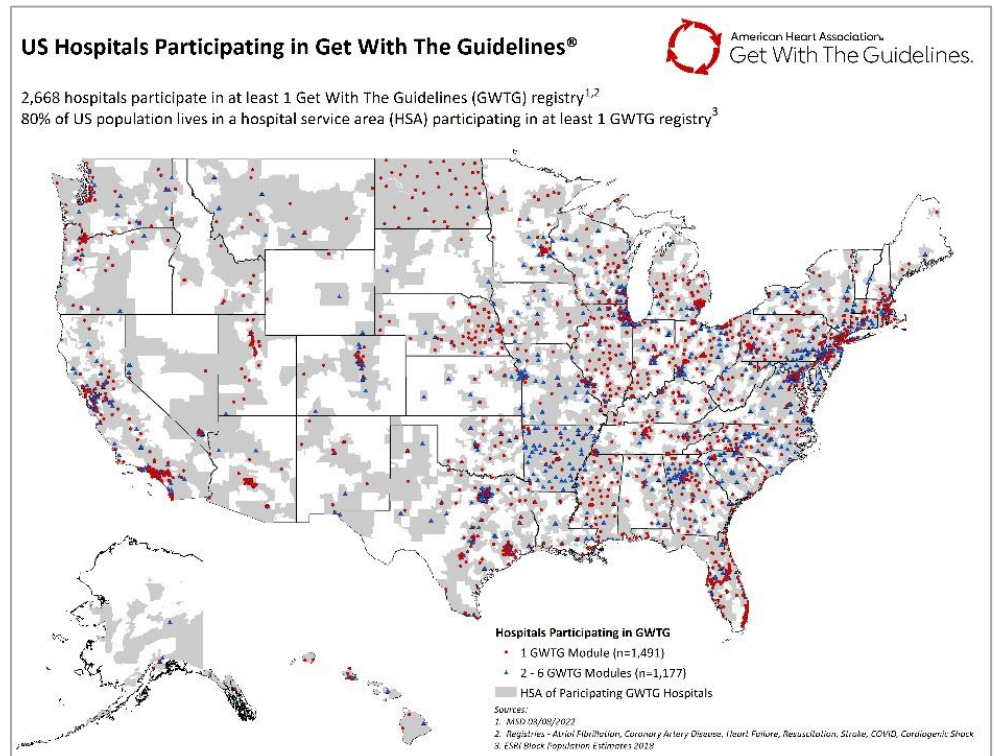
- Monitoring adverse events related to particular therapies, drugs, or devices;[19,20,21]
- Examining provider adherence to safety protocols and clinical practice guidelines;[22] and
- Surveilling the quality of care patients receive (e.g., tracking rates of re-admissions, coordination of care post-discharge, orders for preventive care at discharge, etc.).[7,11,23]

Measuring quality has become essential to the Centers for Medicare and Medicaid Services (CMS) as it moves in recent years towards value-based payment models which track quality measures, just as quality-improvement registries do. In 2020 CMS named several of the AHA quality-improvement registries as an alternative quality-reporting option for providers participating in the Bundled Payments for Care Improvement Advanced (BPCI Advanced) Model.

THE ASSOCIATION'S REGISTRIES

As part of its commitment to improving patient care for cardiovascular disease (CVD) and stroke, the AHA has developed and maintains a number of quality-improvement registries. Because hundreds and even thousands of sites around the country may contribute data to a registry, millions of patient records may be included in a registry. (The more data included in a registry, the more reliable the findings will be.) The GWTG registries aggregate patient care data and generate real-time reports for providers that assess their performance compared to national benchmark data.

The AHA registries are more than registries; they are a comprehensive suite of programs that provide many additional resources and tools to clinicians, e.g., clinical guidelines; videos, newsletters, and webinars for professionals; and patient educational material.

US Hospitals Participating in Get With The Guidelines®

American Heart Association. Get With The Guidelines.

2,668 hospitals participate in at least 1 Get With The Guidelines (GWTG) registry[1,2]
80% of US population lives in a hospital service area (HSA) participating in at least 1 GWTG registry[3]

Hospitals Participating in GWTG
- 1 GWTG Module (n=1,491)
- 2 - 6 GWTG Modules (n=1,177)
- HSA of Participating GWTG Hospitals

Sources:
1. MSD 03/08/2022
2. Registries - Atrial Fibrillation, Coronary Artery Disease, Heart Failure, Resuscitation, Stroke, COVID, Cardiogenic Shock
3. ESRI Block Population Estimates 2018

Get With The Guidelines-Stroke. Developed in 2001, GWTG-Stroke gathers data on patients hospitalized with stroke and transient ischemic attack (TIA).[17] As of March 2022, the registry contains almost 11 million stroke/TIA patient encounters presenting to more than 2,500 hospitals nationwide.

Get With the Guidelines-Coronary Artery Disease. GWTG-CAD is an Acute Myocardial Infarction (AMI) registry and performance improvement program for hospitals to improve the quality of care and outcomes for patients hospitalized with heart attacks. It is also the essential source of data for the AHA's Mission: Lifeline initiative that focuses on improving systems of AMI care, including emergency medical services, referring hospitals, and treatment centers.

Get With the Guidelines-Heart Failure. Numerous published studies demonstrate the program's success in achieving significant patient outcome improvements, including reductions in 30-day readmissions (a measure now used by CMS in determining CMS reimbursement rates).[24]

Get With the Guidelines-Atrial Fibrillation. The newest AHA registry, GWTG-AFib has a catheter ablation feature which tracks and benchmarks this treatment which is growing in use. It also provides a 180-day follow-up form to measure post-ablation patient outcomes. These data will lead to a greater understanding of catheter ablation as a care option for AFib patients.

Get With the Guidelines-Resuscitation. GWTG-R's roots are in the AHA's National Registry of Cardiopulmonary Resuscitation (NRCPR) started in 1999 to collect resuscitation data from hospitals nationwide and to create evidence-based guidelines for in-patient CPR.[25]

AHA registries outside of GWTG include the **COVID-19 CVD Registry** and the **Vascular Medicine Consult Registry**.

Given the size, scope, and duration of the AHA suite of registries, researchers have a rich source of patient-level data on presenting characteristics, diagnostic testing, treatments, quality-initiative adherence, and in-hospital outcomes to support ongoing national surveillance, innovative research, and quality-improvement efforts that promote evidence-based care.

THE ASSOCIATION ADVOCATES
We support the use of registries to improve quality of care and to help identify risk factors to reduce chronic diseases. Specifically, we:
- Urge policy makers to create federal, state, and local CVD and stroke registries in order to monitor incidence and to support the development of relevant quality-improvement initiatives,
- Encourage policy makers to use patient-centered, evidence-based, broadly adopted registries like GWTG to meet many of the quality-improvement and reporting requirements of federal programs and those enacted in health reform, and
- Encourage use of registries as an efficient data-collection tool as part of payment and delivery-reform initiatives.

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