The American Academy of Ophthalmology's IRIS® Registry (Intelligent Research in Sight Clinical Data): A Look Back and a Look to the Future

David W. Parke II, MD - San Francisco, California
William L. Rich III, MD - Washington, DC
Alfred Sommer, MD, MHS - Baltimore, Maryland
Flora Lum, MD - San Francisco, California

The seeds for the Academy’s IRIS® Registry (Intelligent Research in Sight) were planted more than 3 decades ago with the initiation of the Academy’s Quality of Care Committee in 1985. This blossomed into one of the first medical society practice guidelines for improving care and promoting best practices based on expert consensus and scientific evidence from the peer-reviewed literature, known as the Preferred Practice Patterns. The committee then turned its focus on patient outcomes, with the launch of a National Eyecare Outcomes Network for measuring cataract surgery performance in 1995. At its peak, National Eyecare Outcomes Network collected data on 17,000 patients’ preoperative characteristics, operative parameters, and postoperative outcomes, but subsequently met its demise because the time required to enter data manually limited member participation. Continuing to highlight quality improvement, the Academy started creating performance measures for eye care drawn from the evidence-based Preferred Practice Patterns, enabling its members to participate in the federal government’s quality reporting programs, introduced in 2007.

The development of electronic health records (EHRs) and innovative data extraction software has enabled a new generation of digital clinical data registries to provide critical input on performance. A clinical data registry (CDR) may be described as an organized data system that collects uniform data (clinical and other) to enable the evaluation of specified outcomes for a population of patients that is defined by a particular disease or condition (as well as other parameters, like age, gender, and geography) and that serves 1 or more predetermined scientific, clinical, or policy purposes.1 Put another way, this new generation of CDRs allows direct uploading of information from an individual EHR into a database where it can be aggregated with information from other EHRs and analyzed to achieve multiple objectives, including, importantly, the identification of techniques and treatments that provide better (and worse) outcomes.

The American Academy of Ophthalmology initiated its quest for an information technology-based clinical data registry and learning healthcare system in the fall of 2012, when the Board of Trustees approved a task force to explore the purpose(s), structure, and principles of governance for such a system and the identification of an appropriate vendor. The task force identified the following primary purposes: (1) foremost, to facilitate the identification of processes and procedures that improved patient outcomes as the basis for individual member’s quality improvement; (2) to promote population health at the societal level by improving individual provision of eye care and to identify gaps in population coverage; and (3) to generate new scientific knowledge that advances discovery, essential to evidence-based evolution in clinical practice and application of new diagnostic and therapeutic interventions.

These decisions included essential safeguards: all patient identifiers would be protected according to the Health Insurance Portability and Accountability Act; every participating physician owned his or her data; no data would be linked to specific physicians or practices (unless the relevant physician[s] provided expressed, written permission to do so); and electronic entry would obviate the need for duplicative, time-consuming manual entry. A decision was made to make the registry all-inclusive—it would not be limited to a specific condition or procedure, thereby providing the greatest possible future usefulness as interest and opportunity permitted.

The Academy’s leadership decided that development of this living repository of clinical material was mission critical, that no industry or federal funding would be accepted (to eliminate any questions of conflict of interest or claims for unapproved data access), and no member fees would be imposed initially to facilitate acceptance by the Academy’s members and the rapid expansion essential to the registry’s success. It was understood that this critical endeavor would be very expensive and that needed financing would require that the Academy monetize the value of the aggregate data by offering data analyses to the life science industry, but only for purposes congruent with the Academy’s mission (i.e., contributing to the advancement of scientific knowledge or improvement in patient care). The registry was named the Intelligent Research in Sight Registry and was structured to qualify as a federally designated Qualified Clinical Data Registry.

The IRIS Registry software extracts electronic data from the EHRs of participating members using a systems integrator, software installed on the member’s server containing that practice’s EHR database. This software uploads relevant data from the practice data base nightly to the central
IRIS Registry data repository, which resides in a massive cloud-based data warehouse. The IRIS Registry’s system integration software is designed to work with essentially any EHR system. To date, it has integrated successfully with 43 different EHR systems, including ophthalmology-only and specialty-agnostic (not specifically ophthalmic) medical record systems. The IRIS Registry systems integrator software runs in the background of a practice EHR; no practice physician or staff involvement is needed. The Academy pushes a summary of individual practice performance, as measured against established clinical measures, to each participating ophthalmologist once per month, which allows the practice to monitor and benchmark its own performance.

Although the ophthalmologist owns his or her own data, the Academy (and by virtue of membership, all its members) owns the de-identified, aggregated data. The aggregated database has the same protections and safeguards from legal discoverability as hospital-based peer-review processes.

The IRIS Registry went into effect in March 2014 to take advantage of the growing popularity of EHR systems and uses these systems to help members report on the increased number of quality measures required for optimal Medicare reimbursement. By July 1, 2017, the IRIS Registry already had amassed 148 million patient visits of 37.3 million unique patients, with a total of 13199 registered ophthalmologists and eligible providers in their practice on EHR systems. The IRIS Registry may well be the largest single-specialty clinical data registry in the world, allowing ophthalmology to pioneer registry-based discovery and quality clinical improvement.

The rapid success of the IRIS Registry stems from several factors: (1) no initial cost to the physician to participate, (2) strong economic benefit from Medicare reimbursement (currently approximately $18 600/year per physician), (3) very low hassle factor (generally limited to initial data mapping, needed to integrate the IRIS Registry with the practice’s EHR), (4) no manual entry of patient data, (5) satisfaction of a key portion of American Board of Ophthalmology Maintenance of Certification program, (6) entirely confidential benchmarking by individual practices of their (a) process of care and (b) outcomes of care, (7) use of IRIS Registry data for scientific discovery, and (8) potential to use IRIS Registry for patient-reported outcomes.

Currently, American physicians providing clinical care to patients covered by federal health insurance (Medicare and Medicaid) must demonstrate that they comply with a critical number of Clinical Quality Measures. The IRIS Registry data are currently extracted for the calculation of 15 pertinent electronic Clinical Quality Measures. In addition, the IRIS Registry collects data on 22 outcome measures for subspecialists, empowering them to evaluate care most relevant to their patient populations. As data and experience grow, the IRIS Registry can refine these measures, including adjusting risk for severity of illness and comorbidities, thereby increasing their specificity, value, and usefulness.

New clinical measures, of greater value and usefulness, can be designed and incorporated based on real-world clinical practice. Real-world outcomes dramatically expand the information garnered from rigidly controlled randomized trials, adding important new dimensions to outcome expectations, particularly among populations not included in the randomized controlled trials.

We are only beginning to appreciate the value of the IRIS Registry for each of its participating practices. At this time, every ophthalmic practice that participates in IRIS Registry has access to a web-based dashboard. Each participant can track individual performance and their patient outcomes in real time by logging in to the IRIS Registry website from their home or office computers. Participants also can run queries on their own patient populations, identify which patients did not meet quality measure criteria, and target their outreach and follow-up efforts on specific patients or patient populations. Within a practice, physicians can compare their use and outcomes across locations and in different risk-adjusted patient populations. Physicians also can evaluate their results against a national benchmark of their peers.

Actionable performance information, in a readily accessible format, is delivered in a timely manner, not months or years later. Real-time data and analytics are essential for driving improvement. The Academy already has seen that participating practices are accessing their patient data, making appropriate comparisons with their peers, and changing their practice patterns, particularly by using the IRIS Registry dashboard to improve performance as a self-initiated practice improvement activity for maintenance of certification. Even in this initial, tentative use, the IRIS Registry already has proved itself a valuable learning system. With more experience and use, its value can only grow.

Use of the IRIS Registry has grown rapidly and dramatically. In 2014, the year the IRIS Registry was launched, it provided relevant data for quality reporting for nearly 3000 eligible providers. One year later, in 2015, the number had more than doubled, to 7000 eligible providers. By 2016 it had grown to more than 11 000 providers. For 2016 alone, the participating ophthalmologists avoided as much as $95 million in penalties, providing these participants with a very tangible return. The American Board of Ophthalmology recognizes participants’ use of the IRIS Registry dashboard to improve performance as a self-initiated practice improvement activity for maintenance of certification. Even in this initial, tentative use, the IRIS Registry already has proved itself a valuable learning system. With more experience and use, its value can only grow.

The de-identified, aggregated data on patient treatment and outcome of thousands of Academy members will provide an extraordinarily rich and unique database for increasing our understanding of the value of alternative treatments and procedures and will serve as a powerful engine for advancing our profession. This same data set can provide real-world evidence for health policy decisions, advancement of population health, understanding of the natural history of disease, identifying varying practice patterns and their relative values, diffusion of technology, and filling present and future gaps in knowledge about the applicability of results of rigorous clinical trials in...
populations not studied, and under less-rigid real-world conditions of care. A few scientific articles already have been published using this unique registry.\textsuperscript{3,5} But these investigations, tentative and exploratory, only begin to scratch the surface that this rich, unique database will provide. The registry will become richer still, with the potential addition of digital images, unique device identifier data, and more robust ways of interfacing with other databases (including data registries from other societies such as diabetes, cardiology, etc., and government databases), along with data emanating from the laboratory, operating room, and molecular and genetic information. Ultimately, it likely will provide rapid feedback: predictive analytics and clinical decision support at the point of care. Randomized clinical trials themselves are beginning to use registries to reduce significantly the time and costs of recruitment of patients and collection of data.\textsuperscript{6,7}

The data analyzed in CDRs can provide information on comparative effectiveness of various diagnostic and treatment options, information on rare diseases (given the uniquely large patient database), impact of comorbidities on patient outcomes, detection of hidden clinical associations, early detection of clinical patterns (such as complications or infection hot spots), the adequacy of care and the degree to which various populations receive the care they need, and why. The IRIS Registry meets 3 critical criteria as a potentially extraordinary research tool: (1) it contains a very large number of patients and the variations in practice of large numbers of providers (e.g., a very big data set); (2) given the size of the data set and its unique attributes, it is amenable to, and attracts the interest of, those skilled in complex analytics; and (3) it is compiled from near real-time inputs, not an accumulation of practices that potentially have morphed over a long period. Large pharmaceutical companies have begun organizing real-world data divisions focusing on what actually happens in clinical practice, not just in rigorously controlled, multicenter randomized trials. Randomized controlled trials are the gold standard for what will work under strictly controlled conditions in populations represented by those involved in their study, not what happens with less than compulsive follow-up and participation in populations unrepresented or underrepresented in formal trials.

The holy grail of health care is to improve value by enhancing patient outcomes, improving the process and experience of health care, and reducing unnecessary or ineffective care. Disease registries have shown themselves to be a valuable tool for the patient, the profession, and the health care system as a whole in helping physicians and their practices better evaluate their performance, more rapidly adopt best practices, and complete the cycle of continuous care improvement by learning from one another and reaping the benefits of big data.

The IRIS Registry has shown it can empower practitioners effectively to improve their practice. The next goal is to develop appropriate processes for engaging clinical researchers to interrogate this unique, growing resource to reveal patterns of disease, their determinants, and approaches to prevention and treatment that advance the ophthalmic profession to the benefit of our present patients and those in the future.

Footnotes and Financial Disclosures

Financial Disclosure(s): The author(s) have no proprietary or commercial interest in any materials discussed in this article.

References


Correspondence:
Flora Lum, MD, American Academy of Ophthalmology, 655 Beach Street, San Francisco, CA 94109. E-mail: flum@aoa.org.