

Harnessing the Power of Data:

How AHRQ Is Catalyzing Transformation in Health Care

As an aging baby boomer with knee pain and trouble walking up steps, you want to know from your doctor the optimal time to get a knee replacement (if you need one) and which is the best type of prosthetic knee for you. As a surgeon, you want to know which prosthetic knee is likely to last the longest for the patient you are going to operate on tomorrow and how best to manage his diabetes while he is under anesthesia. If your child has moderate to severe inflammatory bowel disease, you want to know the best way to reduce her pain and enable her to join her classmates playing in the schoolyard. If you are a pediatric gastroenterologist, you want to know the best time to begin a powerful medication to improve the long-term control of a child's condition while minimizing the chance of side effects.

The Agency for Healthcare Research and Quality (AHRQ) is helping individual patients and their doctors find answers to these questions by pioneering innovative ways to gather and analyze multiple sources of health care data for evidence about what care works. This “mining of health data” has already led to practice changes that, for example, have reduced repeat knee replacement surgery and enabled children with inflammatory bowel disease to play with their friends three times as many days each month.

AHRQ is showing clinicians how to harness the power of big data in a way that is revolutionizing health care and fostering personalized medicine.

Specifically, AHRQ has supported collaborations of informatics experts, researchers, and clinicians to develop better ways to link electronic health records with administrative claims data, pharmacy data, and diagnostic data, and to collect patient-specific information (such as medication side effects, pain after surgery, disease symptoms, and experience of care) in

order to create a comprehensive picture of the patient experience, while protecting patient confidentiality. The Agency has also supported the development of new analytic tools to rapidly analyze the data to produce useful information that can improve decisions and clinical care. In this way, AHRQ is showing clinicians how to harness the power of big data, which has helped transform so many other industries, in a way that is revolutionizing health care and fostering personalized medicine.



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Message From the AHRQ Director

This AHRQ issue brief highlights how AHRQ is spurring the development and use of enhanced clinical registries to create learning health care systems. By using all of the data generated throughout the health care system, researchers, health care professionals, and patients are discovering how to improve care today by understanding how care was delivered yesterday. This powerful initiative is only just beginning to move from theory into practice. By funding innovations in methods, small pilot projects, and large demonstration projects, and by engaging researchers, clinicians, patients, and families, AHRQ is developing the foundations for a 21st-century health care system.

This work is part of AHRQ's strategic goal of improving health care quality through the generation of evidence, and is aligned with AHRQ's mission of not only creating new knowledge, but making sure it is understood and used. Our first issue brief highlighted examples of how AHRQ is advancing patient safety, another of our strategic goals. Future issue briefs will focus on understanding and improving access to health care and understanding and improving health care affordability.

Our work to advance the use of data to improve quality is one more way that AHRQ and the health systems researchers we support are working to build a health care system that delivers better care, through smarter spending, and results in healthier people.

Richard Kronick, Ph.D.
Director, AHRQ

Personalized Medicine

"Today, doctors and nurses are often guided by large studies on populations with a particular disease that conclude, for example, that a certain drug works 60 percent of the time," notes David Meyers, M.D., AHRQ's Chief Medical Officer. "However, this effort by AHRQ goes further, analyzing data on many people with the same disease being treated at multiple real-world sites. What this can do for me as a physician is identify that this medication actually works 90 percent of the time for one subgroup of patients, but only 10 percent of the time for another subgroup. Armed with this evidence, I am likely to recommend the medication for my patients who fall into the 90 percent subgroup. However, if the patient sitting in my office is in the group for whom it only works 10 percent of the time, then I am going to look for an alternative medication for him or her. In this way health care data from hundreds, thousands, or even millions of people help doctors personalize medicine and improve care for the one person they are caring for right now."

By linking data from patients, clinicians, and researchers at multiple clinical sites, these big-data systems form what are called enhanced clinical registries.¹ These registries lay the foundation of what the Institute of Medicine calls a learning health care system,² because they provide the necessary "real-time access to

Information About AHRQ Issue Briefs

AHRQ Issue Briefs examine important national health care issues consistent with the Agency's mission to produce evidence to make health care safer, higher quality, more accessible, equitable, and affordable, and to work within the U.S. Department of Health and Human Services and with other partners to make sure that the evidence is understood and used. Each brief describes the scope of a particular problem, ways AHRQ and its partners approached solutions to the problem, and emerging trends and policy implications. These briefs are intended for health care providers and administrators, policymakers, and researchers.

knowledge and digital capture of the care experience.” This is a system in which clinicians are consistently learning better ways to care for patients with a particular disease based on treatment and other data from their site and others.

“The goal is not just learning, but using the data to change practices and behavior in order to improve patients’ lives.”

Gurvaneet Randhawa, M.D., M.P.H.

Because enhanced registries include data on outcomes important to patients and their families, they provide clinicians with information they can use to partner with patients to make personalized decisions on their care based on the best available evidence on patients just like them. And quality of data matters. AHRQ is

pioneering best practices in this area with its registry user’s guide,³ which provides practical information on the design, operation, and analysis of registry data to produce quality data on any condition.

“We are at the cusp of a transformation of clinical and research practice driven by the rapid collection and analysis of data that can yield actionable information in real time,” says Gurvaneet Randhawa, M.D., M.P.H., AHRQ Senior Advisor on Clinical Genomics and Personalized Medicine. “The goal is not just learning, but using the data to change practices and behavior in order to improve patients’ lives. To accomplish this, we need to design data infrastructure that meets the needs of researchers, clinicians, and patients, and create a collaborative and trusted environment to share and effectively use the data across organizations.”

Success Stories

Showing clinicians how to use evidence to improve practice and behavior is part of AHRQ’s mission to make sure clinicians understand and know how to use evidence, such as that gleaned from big data, to improve care and patient outcomes. The following three AHRQ-supported projects demonstrate how big data has dramatically improved patient care and outcomes.

Pediatric Inflammatory Bowel Disease Project

Pediatric inflammatory bowel disease (IBD) includes Crohn’s disease and ulcerative colitis. Ulcerative colitis causes inflammation and sores (ulcers) in the lining of the large intestine (colon), usually affecting the lower colon and the rectum. Crohn’s disease usually affects the lower part of the small intestine, but can



Two parents (in orange and yellow) of children with IBD interact with clinicians and clinic staff at the ImproveCareNow community conference in Chicago.



occur in any part of the intestine, stomach, or esophagus. The main symptoms of both inflammatory diseases include abdominal tenderness or pain, chronic diarrhea, rectal bleeding, fever, and weight loss. Complications can range from joint pain and eye problems to liver disease.

Children and adolescents with IBD face unique challenges, since IBD can stunt growth, weaken bones, and delay puberty, as well as negatively affect overall quality of life. Youngsters with moderate to severe IBD must typically take steroids, immune system modulators (called biologics), or other medications for symptom relief, remission, and reduced risk of complications. Patients, their families, and their doctors want to know which medications will work best and when is the best time to start them.

They are finding answers through big data mined as part of the AHRQ-supported ImproveCareNow Enhanced Registries Project, which is led by Peter Margolis, M.D., Ph.D., of Cincinnati Children's Hospital Medical Center, and Chris Forrest, M.D., Ph.D., of Children's Hospital of Philadelphia. "These data include thousands of little stories about children with IBD," notes Richard B. Colletti, M.D., pediatric gastroenterologist and president and executive network director of the ImproveCareNow Enhanced Registry. "Since 2007, the remission rate of these children has increased from 55 to 78 percent, with thousands more kids able to attend school regularly, play sports, do overnights with friends, and be much happier." What's more, 94 percent have achieved satisfactory growth, 91 percent show satisfactory nutrition, and 95 percent are not taking steroids.

"Funding from AHRQ enabled ImproveCareNow to harness the power of big data in ways that have been transformational," asserts Dr. Margolis. "The ability to capture data directly in the electronic health record has dramatically accelerated the work of improving patient outcomes. It also provides clinicians with the information they need to make care far more reliable, directly impacting care on a day-to-day basis."

"Big data led to a bigger and happier boy."

Richard Colletti, M.D.

Dr. Colletti explains how analyzing big data is significantly improving children's lives. He says, "At my center [University of Vermont Children's Hospital], we used our automated population management report from the ImproveCareNow Enhanced Registry to find a child who hadn't been evaluated in over 6 months. We called the family, and when the child was examined, we found anemia, poor growth, and fatigue that were corrected

within a few months by appropriate treatment and followup. Big data led to a bigger and happier boy."

The ImproveCareNow Registry is the world's largest pediatric IBD registry and includes 77 care centers and 710 physicians caring for 22,000 children and youth with IBD, which is 45 percent of children and youth with IBD cared for by pediatric gastroenterologists in the United States. The registry participants collect patient- and family-reported data on symptoms, medication side effects, outcomes, and the care experience via mobile apps and during clinical visits. These data are entered into the registry database along with clinical data on medications and other interventions used for these patients and data on patient outcomes.

Clinicians, parents, and patients regularly interact to share information about how to improve a child's care. Registry participants also benefit from biannual community conferences in which clinicians, researchers, parents, and patients exchange information. Notes Tania Moon, a parent volunteer, "The data have helped complete the circle between patients, families, and care teams that were once missing pieces before ImproveCareNow. ImproveCareNow is creating the answer key to the puzzle of how to make sick kids feel better."

Impact of ImproveCareNow Enhanced Registry since 2007:

- 77 care centers and 710 physicians care for 22,000 children with inflammatory bowel disease
- Children's remission rate increased from 55 to 78 percent
- 49 percent of children sustained remission for at least 1 year
- 94 percent have achieved satisfactory growth
- 91 percent have achieved satisfactory nutrition
- 95 percent do not take steroids
- Thousands more children are able to attend school regularly, play sports, and enjoy overnights with friends

For example, clinicians used the registry data to compare alternative treatment strategies for pediatric Crohn's disease patients, with a special focus on the timing of biologic agents to see if children did better depending on when biologic agents were introduced. Another study examined whether over a period of 6 months, children and teens with moderate to severe Crohn's disease who received biologic therapy did better than those who received standard care (thiopurines and steroids). The results of these and other studies done with registry data led to practice changes that resulted in the dramatic improvement in children with IBD cited above.



Dr. David Flum (left) and fellow surgeons operating with use of the surgical checklist shown on the two monitors.

Surgical Care and Outcomes Assessment Program

Checklists have been used for decades in the aviation industry to reduce variation, standardize procedures, and boost safety. The AHRQ-supported Surgical Care and Outcomes Assessment Program (SCOAP) has helped translate that concept into surgical practice in the majority of hospitals in Washington State. SCOAP was founded by David Flum, M.D., M.P.H., of the University of Washington School of Medicine. "All around clinicians are seeking data that can help them take better care of patients in the

next week based on the care they delivered in the last week," says Dr. Flum. "What we're trying to do is harness all these data and turn the data into information—find the patterns and trends in yesterday's care so we do a better job caring for our patients today."



Hospitals participating in SCOAP collect and share details about what surgeons are doing in operating rooms and how patients fare afterwards. Data from 38 of 62 Washington State hospitals that provide surgical care are included in SCOAP's Surgical Outcomes Registry. The registry data enable clinicians to examine patient outcomes and to learn how they and their hospital compare to others and to national standards. The data also help identify areas that need improvement.

Early on, when analyzing these hospital data, Dr. Flum and his team began seeing patterns around presurgical patient characteristics as well as operating room behaviors and procedures that strongly influenced surgical outcomes. This information led to the development of checklist-based programs that improved surgical care and reduced costs. For example, in 1 year alone, participation in SCOAP saved Washington State hospitals an estimated \$67.3 million by helping avoid costly complications.

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The in-hospital surgical checklist is a key part of SCOAP's surgical improvement efforts. It guarantees that vital steps to a successful procedure are carried out and reinforces a culture of patient safety. Prior to surgery the team confirms the surgical site, exact procedure, and any anticipated difficulties or blood loss. The team also confirms that antibiotics were given at the right time, and whether the patient is diabetic, on certain medications, or has important allergies. For example, if the team notes that a patient is allergic to metal, the team will use sutures instead of staples to close the incision. After the surgery, the checklist ensures that no sponges or other objects are left inside the patient and that they are continued on important medications they were taking prior to surgery, such as blood pressure and cholesterol medicines.

Following the success of the in-hospital surgical checklist, Dr. Flum began shifting the focus even earlier, addressing risk factors in the presurgical clinic setting. Examining the surgical outcomes data identified important factors that were both easy to modify and strongly tied to patient outcomes. This led to the launch of a public health campaign called "Strong for Surgery," which promotes the use of presurgical checklists. These checklists help clinicians screen patients for certain risk factors and recommend appropriate interventions to optimize patient health before surgery to improve their outcomes after surgery.



The development of surgical checklists and continued analysis of clinical data about procedures and outcomes among Washington State hospitals have resulted in reduced complication rates, shorter hospital stays, and fewer 30-day rehospitalizations. For example, SCOAP data revealed that people who smoked had worse surgical outcomes. Therefore, surgeons started asking patients about their smoking status when they discussed the probability of surgery and gave them interventions to reduce smoking. They saw a decrease in smoking rates and improved surgical outcomes. In this case, data mining allowed the surgeons to provide the right intervention at the right time to improve the outcomes of a patient's surgery.

To leverage SCOAP's quality improvement activities, AHRQ awarded a grant to develop the Comparative Effectiveness Research Translation Network (CERTAIN), which addresses questions across a wide range of clinical areas. Together, SCOAP and CERTAIN are developing a learning health care system that is driving process improvement and reducing variations in care, adverse outcomes, and health care costs. Learning health care systems apply the experiences of prior patients to inform care and help guide decisionmaking for current patients.

Many Washington State hospitals have limited resources for quality improvement activities, and their surgeons are looking for practical, actionable, low-cost tools that can help them deliver optimal care. The SCOAP-CERTAIN partnership was designed to do that. It reinforces behavior change by tracking surgical

Impact of SCOAP Surgical Improvement Project:

- Reduced surgical complication rates
- Saved an estimated \$67.3 million by avoiding complications
- Shortened hospital stays
- Reduced 30-day rehospitalizations
- Decreased adverse outcomes
- Reduced variations in care
- Lessened health care costs
- Identified surgical risk factors to target prior to surgery

performance and patient outcomes so that surgeons can address lapses in care delivery. It also serves as a forum for research to examine the link between process of care and outcome. CERTAIN links hospital outcomes data with patient-reported information about function and quality of life to create a patient-centered, disease-based research network. This network is evaluating the effectiveness of surgical interventions and translating evidence into improved practice.

Total Joint Replacement Project

Millions of Americans experience pain from knee and hip arthritis, which can be very debilitating when the disease has advanced. Each year, more than 700,000 U.S. adults with advanced arthritis choose to have knee or hip replacement surgery to relieve pain and improve function and mobility. To examine procedures, types of implants used, and patient outcomes from total joint replacement, AHRQ awarded \$12 million to the University of Massachusetts Department of Orthopedics and Physical Rehabilitation to develop the Function and Outcomes Research for Comparative Effectiveness in Total Joint Replacement (FORCE-TJR) project.



This project is co-led by Patricia Franklin, M.D., M.B.A., M.P.H., who directs the registry data coordination center, and David Ayers, M.D., lead surgeon. The project established the TJR Registry with a national sample of U.S. patients and surgeons to conduct studies comparing the effectiveness of TJR procedures and

various implants and to examine patient outcomes. It is the most comprehensive U.S. database on total hip and knee joint replacement patients and their surgical outcomes. “This project is only a few years old, and it is already starting to have an impact on practice and patients,” notes Elise Berliner, Ph.D., Director of AHRQ’s Technology Assessment Program.



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Elise Berliner, Ph.D.

As of June 2015, more than 25,000 patients were enrolled from 152 orthopedic surgeons in 22 States. FORCE-TJR data are collected directly from patients, including patient-reported outcomes of pain and function, early postoperative adverse events, and implant failures. These data are supplemented with clinical data from surgeons and hospitals.

Clinicians are using the registry data to examine the best timing for joint replacement, the impact of certain implants versus others, and tracking of patient outcomes. Beyond research, the registry data also provide surgeons with feedback on their practice compared to other TJR surgeons to support quality improvement efforts and to meet quality monitoring requirements of the Centers for Medicare & Medicaid Services (CMS).



Patients also benefit from the registry. Before scheduling surgery, their pain and disability scores can be compared to national TJR norms to see outcomes for patients with similar symptom severity. After TJR surgery, improvement can be quantified and care tailored to support recovery. The registry also provides valuable feedback to surgeons by answering questions they previously could not answer, for example: How do my patients' risk factors such as body mass index and coexisting conditions compare to other surgeons? How does the timing of patient surgery as described by pain and functional limitations compare to national practice? Is the degree of pain relief and improved function in my patients comparable to the national norm?

What's more, surgeons can find out how patients fare with certain types of implants. Details about implant use were not available before, because implant information was typically stored in the operating room supply software, not electronic health records. The TJR registry now includes that data.

“Orthopedic surgeons discuss with patients the right time to replace the knee or hip,” says Dr. Berliner. “Orthopedic surgeons have to decide how much weight to give the physical exam, the x ray, and the medications the patient is on to make the decision. With FORCE-TJR, they can now let the patient see their pain and function scores compared to similar patients before and after surgery to help them make their decision. The registry data allow surgeons to consider all these factors along with the patient to make the right decision for that patient.”

With AHRQ funds, the project is also developing a mobile app that individuals can use to input how much pain they are in and their functioning. Based on data on similar patients in the registry, the app tells them whether now is a good time to get joint replacement surgery, and what is likely to happen to them if they don't do it. “In this way, big data is helping individuals make decisions about this really common, life-changing condition,” notes Dr. Berliner.

The FORCE-TJR clinical and patient data were recently merged with the library of implant design and materials developed by the International Consortium of Orthopedic Registries to evaluate outcomes associated with varied implant characteristics. With this enhanced data, clinicians observed that joint pain was the first sign that metal-on-metal implants were failing, resulting in a high rate of revisions. Researchers are now looking at the pain level and effectiveness of different types of implant materials and designs.



The TJR Registry enables patient-centered research. Patients are partners in the research, since each patient consents to provide their feedback directly each year going forward. The registry also collects data surgeons never saw before. For example, now a surgeon knows if their patient went to another hospital after the surgery and what happened to them, because the registry includes data from many institutions and follows patients for many years. Dr. Ayers notes that, “Events requiring hospital care in the first 30 to 90 days after TJR are important to hospitals and surgeons, since they contract using bundled payments and are at risk for these costs.”

“The patient is the best source of information on how the implant is working, whether they can remain active, and if they need revision.”

Patricia Franklin, M.D., M.B.A., M.P.H.

Surgeons also want to know how many years the implant serves the patient well. Because patients move or seek revision surgery at another hospital, U.S. surgeons did not have this information and relied on implant survival data from other countries. “The patient is the best source of information on how the implant is working,

whether they can remain active, and if they need revision,” says Dr. Franklin. “Thus, FORCE-TJR contacts all patient members directly each year to reassess their status.”

These and other AHRQ-supported projects are laying the foundation for regulatory, cultural, and technical shifts in use of health care data by clinicians and health care systems, CMS, and the Food and Drug Administration (FDA) to improve care delivery.

Force-TJR data has helped:

- Determine the best timing of joint replacement
- Compare the impact of certain implants versus others
- Track presurgery pain and function and postsurgical outcomes
- Provide feedback to orthopedic surgeons about their patients and outcomes compared with other orthopedic surgeons



AHRQ Helps CMS and FDA Improve Care Delivery

“Unless you are very confident about how good the data are and how well they represent the patient care experience, you won’t be able to draw the right conclusions about how to improve care delivery,” asserts Dr. Randhawa. AHRQ’s registry user’s guide has become the gold standard for best practices in designing and analyzing registry data. The resulting increase in the quality of registry data has enabled new initiatives, such as a CMS rule allowing participation in a qualified clinical data registry as a proxy for care quality reporting.

The guide is part of a larger project to develop a Registry of Patient Registries (RoPR).⁴ The RoPR is a database of more than 107 clinical registries, and is intended to reduce duplication of registries on the same disease, promote collaboration, and improve transparency. It includes disease registries that are focused on treatment effectiveness, quality improvement, public health, postmarketing surveillance of drugs or devices already on the market, and other issues. The design of the RoPR involved many stakeholders and resulted in a searchable, national database of disease data that allows data sharing and patient recruiting for specific disease registries, while preserving patient confidentiality.

Both CMS and the FDA are using registry data for policy decisions.

Both CMS and the FDA are using registry data for policy decisions. For example, CMS uses registry data to decide which procedures or medical devices to cover for a specific condition and to find out which procedure/device works for patients older than 65. CMS announced a new measure to encourage hospitals to participate in a general surgery registry⁵ as part of the Hospital

Inpatient Quality Reporting Program⁶ beginning with the FY 2014 payment determination. The goal is to improve the safety and quality of surgical care using the high-quality data in the registry. Registry data can also be used to meet regulatory requirements such as the CMS Patient Quality Reporting System, and value-based proposals for accountable care.

The FDA uses registry data for evidence evaluation throughout the product life cycle, including premarket evaluation, postmarket surveillance, labeling extension, and device tracking. For example, the TJR registry provides the FDA with early postmarketing surveillance data on different types of artificial knee joints. In contrast to registries that define implant failure as revision surgery, FORCE-TJR surveillance includes post-TJR implant complications and patient-reported pain, both events that precede revisions. FORCE-TJR is also testing novel methods for monitoring implant performance using direct-to-patient strategies, including a pilot study of an FDA-developed app that patients use to report adverse events. Thus, AHRQ is helping the FDA monitor the safety and effectiveness of devices once they are being used in the marketplace.



“Big data has revolutionized industries from banking to marketing. We are using it to help clinicians revolutionize health care.”

David Meyers, M.D.

Challenges and Future Directions

Despite the rapid growth of big-data systems in health care, there remain challenges. For example, inputting data from different electronic systems requires interoperability that is

often not present. In addition, there is a need to harmonize clinical definitions, which vary in different systems, for example, defining the prostate-specific antigen threshold in the same way. Finally, practice workflows need to be analyzed and adjusted to support registry data collection requirements. Future overall development of big-data systems may require establishing standards related to patient identity management, record localizations, and automation of data loading.

Despite these challenges, AHRQ-supported projects are leading the way by showing clinicians and health care systems how to improve care and patient outcomes, while protecting patient confidentiality. “These are still the early days of using health care data to inform decisions at the point of care, with only the most advanced health care systems able to do this,” cautions Dr. Meyers. Nevertheless, AHRQ understands delivery system research, and the Agency is using the expertise of researchers to find answers to questions that make a difference for doctors and patients. In this way, AHRQ is merging the research and the clinical enterprise to transform health care delivery.

“Data and registries can only change care if clinicians understand the evidence and know how to use it,” asserts Dr. Meyers. “And that is AHRQ’s mission—creating evidence about how to improve health care delivery, ensuring that this evidence is understood, and helping health systems, health care professionals, and patients and families use it. Big data has revolutionized industries from banking to marketing. We are using it to help clinicians revolutionize health care.”



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Photo on page 3 is courtesy of Dr. Peter Margolis and colleagues of the ImproveCareNow Registry.

Photo on page 5 is courtesy of Dr. David Flum and colleagues at the University of Washington School of Medicine.



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