Registries as a Knowledge-Development Tool: The Experience of Sweden and England

July 2013
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INTRODUCTION

A series of articles by Barry Meier in the New York Times since 2010 told the story of a medical disaster—a rapidly growing number of failures of artificial hips that had been implanted in a surgical procedure called arthroplasty. The initial article reported that a particular artificial hip—the Articular Surface Replacement or ASR—that had been introduced in the early 2000s as a breakthrough in design and that was supposed to last 15 years or more was being recalled by the DePuy Orthopaedics subsidiary of Johnson & Johnson, because of a high rate of failure. Failure was indicated by severe pain, soft tissue and bone destruction, the need for repeat surgery, and, in some cases, long-term disability. The ball and cup that comprised the device were both metal, unlike earlier ceramic devices.

In a subsequent article, Meier reported that an estimated 500,000 patients in the United States had received an all-metal replacement hip and that the Food and Drug Administration had received 5,000 complaints about metal-on-metal hips in the first six months of 2011. This was believed to be a substantial undercount of serious problems because only manufacturers, not doctors or hospitals, are required to file reports of device failures, and manufacturers may not know when one of their devices has been replaced.

The financial and legal consequences of these events are currently playing out, including investigations into when the maker of the ASR became aware of their high failure rates. What has gained less attention is the fact that research bodies in several other countries, including Sweden, England, and Australia, identified the danger of these devices before they were brought to light in the United States. They were enabled to do so by their use of registries—databases for tracking the long-term health trajectory of patients with a certain condition or who have received a particular treatment. In the case of the ASR, data from registries sounded early alarms in several countries, forestalling untold expense and patient suffering.

About 250,000 hip replacement operations are performed in the United States each year using devices made by multiple manufacturers, but there is no source of information about rates of complications and repeat surgery either with particular devices or in total.

REGISTERS AS TOOLS FOR IMPROVING CARE

The Agency for Healthcare Research and Quality’s user’s guide for patient registries defines a registry as “an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specific outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes.” By following patients over time and place, medium- and long-term outcomes can be observed. Registry-based information can be used for a variety of purposes, including tracking epidemics (as with HIV/AIDS or SARS), documenting the life course of and assessing treatment outcomes in patients with rare diseases, tracking the use of certain procedures, comparing the performance of service providers, and assessing outcomes of interventions as they occur in ordinary patient care settings. Their use has also improved outcomes in chronic disease patients.

Registries have a long history in many countries, including the United States, and there has been a recent surge of interest in the creation and use of registries as evidenced by such developments as the creation of a “register of registries” by the Agency for Healthcare Research and Quality, the proposal by an American Medical Association Committee of a National Quality Registry Network, the Food and Drug Administration’s sponsorship of The International Consortium of Orthopaedic Registries, and the Centers for Medicare and Medicaid Services’ “Summit to Advance the Use of Registries.”
Although interest has never been higher, registries in the U.S. are typically limited to the patients of particular organizations (such as Kaiser Permanente), of multiple organizations that voluntarily make data available to a coordinating organization (as with cancer registries), or people in a particular geographic locations, as with the New York City diabetes registry. An important limitation of such registers is that they can lose track of patients who move, change insurers, or obtain care from a new source.

This problem has been overcome in some countries, including Sweden and England—two countries with highly developed systems of registries that are used for planning, public health, quality improvement, technology assessment, and research. In addition to describing these countries’ overall systems of registers, we will focus in this paper on registers for hip replacement, cardiac surgery, and diabetes. Considering different kinds of registers is useful because a chronic disease such as diabetes that is largely treated on an outpatient basis presents different challenges for register operation than does a surgical procedure. Eligibility for the former is marked by a diagnosis and the latter by an intervention, but the logic of tracking how patients do over time and identifying factors that contribute to positive or negative outcomes applies to both.

THE SWEDISH SYSTEM OF REGISTRIES

Sweden’s national registers for cancer, hospitalizations, births and malformations, and prescription drugs were introduced for statistical purposes in 1958, and the first quality improvement registers (for knee and hip replacement) were started in the 1970s. Sweden now has 89 national quality improvement registers of three types: interventions or procedures (e.g., hip fracture repair and cardiac surgery); diagnoses and episodes of care (e.g., myocardial infarction and stroke); and chronic disease (e.g., diabetes and leukemia). These registers were established by medical professionals in clinical settings rather than by government or the county councils that are responsible for health care and public health. Today’s registers are certified and supported financially by the government and county councils, but their leaders emphasize that they are professionally led and are strongly supported by the relevant medical and nursing professional groups. The system also includes five “competence centers” in which several registers on related topics share the costs, staff, and systems and provide technical assistance in statistics, epidemiology, information technology, and clinical improvement to the register system.

In contrast to the national statistical registers (e.g., births and deaths), patient participation in the quality registers is voluntary. Although coverage and completeness is low in some new registries, it approaches 100 percent in well-established ones.

Data from the quality improvement registers can be linked to the national registers (e.g., pharmaceuticals, hospitalizations) after undergoing ethical review and a de-identification process for the resulting data sets. Biobanks are also being created, raising the possibility of linking biomarkers to birth and disease registers, creating new potential of understanding disease processes.

The overall vision is to “constitute an over-all knowledge system that is actively used on all levels for continuous learning, quality improvement, and management of all healthcare services.” Register data about patients’ problems, medical interventions, and outcomes after treatment can be linked across service providers and over time because since 1947 each resident of Sweden has been given a unique personal identification number. Linkage to the national death register permits patient deaths outside of hospitals to be incorporated in the register, thereby eliminating one source of loss-to-follow-up and increasing the currency of the data.

Analyzed data are commonly publicly reported at the hospital and/or county level. For example, county-level data on numerous (174 in 2011) measures of quality and efficiency in health care are published each year, and many of the measures are based on register data. Data available online enable counties or hospitals to compare their performance over time or against national averages. “It is critical,” said Bertil Lindahl, director of the cardiology register, for end users to say “it is not only a burden to put in data, but we also have use of it for our own purposes.” Trend data show many improvements in performance, particularly among poor performing units.

Two recent assessments of Swedish registers found that they are improving quality and efficiency in health care as well as providing a powerful resource for research. One was a comprehensive report by Professor Måns Rosén, Executive Director of the Swedish Council on Health Technology Assessment, and the other came from the Boston Consulting Group (BCC) that had been asked by a broad-based stakeholder group to assess quality in Swedish health care, including the register system. The BCC report, which focused on the potential of registers to increase value in health expenditures, estimated that an investment of $70 million in registers in the Swedish context would generate a cumulative return of more than $7 billion over ten years because of improvements in quality.
The Swedish Hip Arthroplasty Register

For example, you have heard about the ASR disaster in the States. We put in 394 [such devices] in Sweden, and we recognized by using that database after a short time that something was wrong. And if DePuy and Johnson & Johnson had used the [Swedish] database, which they [bought from us], they could have stopped that implant much earlier. And there was the so-called ‘oil cup’ manufactured by a firm called Sulzer. After we did 17 hips with oil cups in Sweden, we realized that there was something absolutely disastrous with that cup. In the States, they did about 17,000 and the loss I think cost $2.3 billion. The manufacturer does not exist anymore. The cost of the ASR disaster at the moment is something like $9 billion. [Göran Garellick, Director of the Swedish Hip Arthroplasty Register]

The Swedish Hip Arthroplasty Register traces its origins to the late 1970s. All 78 hospitals that do the surgery provide data to a center based at Sahlgrenska Hospital. The register is now governmentally funded; no device manufacturing industry funding is involved, though the register sells data (without identifiers) to industry. As of late 2011, the register included data about 400,000 operations.

Data about total hip replacement and hemiarthroplasty procedures are reported electronically to the registry by trained clerks at each hospital. The data are then cleaned and checked for completeness and internal consistency. For primary procedures, eleven pieces of information are reported (e.g., whether right or left side, indications for surgery, and details about the implant, surgical technique, and cementing). Patients also complete a 10-question form about satisfaction and health-related quality of life as a baseline for comparisons one, six, and ten years after surgery.

As per the Patient Data Act in 2008, patients are informed about the register, and they can decline to have their records included. However, virtually no one does. Patients can also review the information being reported. They have an option to withdraw their information from the register, though only three or four have chosen to do so over the past 20 years.

Data collection about reoperations is more extensive than for primary procedures. A copy of the medical record for each revision is sent to the register for a data-extraction process that picks up some 70 metrics, including technical matters such as the degree and kind of bone loss, the fixation method that was used, and reasons for surgery.

Although the register tracks 90 day mortality after surgery—it is .07 percent for hip replacement surgery—analyses of register data focus primarily on (a) re-operations, (b) short-term complications (as indicated by reoperations within 2 years), (c) revisions (i.e., surgery to replace a device), and (d) patient-reported outcomes. Information about patient characteristics also permits research on factors that may raise or lower the likelihood of the need for hip replacement.

Register data are linked six times a year to the national death register, so that patients who are no longer alive can be removed when calculating outcomes. There is little loss to follow-up due to immigration. A data match with an independent source (the National Board of Health and Welfare’s hospital register) shows the 2009 hip register captured 97.4 percent of total arthroplasties and 96.1 percent of hemi-arthroplasties. This has subsequently improved to near 100 percent.

An extensive report is published in Swedish and English each year. It provides national, county, and hospital level about procedures, reoperations, and patient-reported outcomes for total hip arthroplasties. The register’s 2009 report showed that reoperations accounted for about 12 percent of the 315,000 total arthroplasty operations going back to before 1979, and 81 percent of those (or 10 percent of the total) were revisions.

The revision rate has declined substantially over the years. One reason is that devices with a high failure rate are no longer used. More than 50 different devices were being used for hip replacement surgery in Sweden two decades ago. As a result of knowledge gained via the register, virtually all surgery now uses one of only six devices, all of which have a documented 95 percent ten-year survival rate. New devices move through a sequence of small initial trials, to multi-center studies, and then national observational studies.

Improvement in outcomes has also been stimulated by the public reporting of outcome information by county and by hospital so responsible parties can see how the local performance compares with outcomes achieved elsewhere and act accordingly. Figure 1 shows one of the ways that information is given to hospitals about their
performance. National performance on eight measures in the register is represented by the area in red; the performance of one hospital is overlaid in green. It can readily be seen where local performance exceeds national and where local performance falls behind.

Figure 2 compares the survival of hip replacement implants among Medicare patients in the United States (1997-2005) and patients age 65 and older in Sweden (and Norway). The failure rate is about three times higher in the U.S. than in the other two countries. "I don’t for a second think that we are better surgeons. Absolutely not," said Göran Garallick, the orthopedic surgeon who directs the Swedish Hip Arthroplasty Register. He believes the difference results largely from the application of register findings regarding devices and providing feedback to hospitals about their performance.

From its original focus on the devices themselves, the register has moved to analyze the whole process surrounding hip implant surgery to find predictors of good and poor outcomes. Because of the high survival rate of the most frequently used devices, the greatest future opportunities for improving outcomes will be in working to optimize indications for surgery, care processes involved in the surgery, and rehabilitation, as well as by improving the non-surgical early care of patients with hip osteoarthritis. The goal is “operating on the right patient at the right time with the right technique.”

Beyond the register’s quality improvement purpose, the data in the Swedish hip arthroplasty register have been used for research, including several doctoral dissertations and a stream of publications on outcomes associated with different prostheses and surgical techniques; age, ethnic, and socioeconomic predictors of outcomes of hip replacement surgery; the occurrence of rare adverse events; and patient-reported outcomes. The creation of the Nordic Arthroplasty Register Association that pools data from the Swedish, Norwegian, Danish, and Finnish registers is creating additional research opportunities both because of larger numbers and because the countries have different use profiles.

Notes: The red area represents national mean values; the green area is performance of a particular department (county or hospital). Satisfaction and pain after one year are patient-reported outcomes. The department has worse outcomes on some measures (e.g., 10-year implant survival) and better outcomes on the patient-reported measures.


Figure 1. Example of the Clinical Value Compass that Compares Local with National Performance on Eight Performance Measures in the Swedish Hip Arthroplasty Register.

Figure 2. Survivorship Curves (with 95% Confidence Intervals) for Total Hip Arthroplasty Implants in the United States, Sweden, and Norway.

The Swedish National Diabetes Register (NDR)

The NDR was initiated in 1996 by the Swedish Society for Diabetology (a professional association) to help reduce morbidity and mortality and improve cost effectiveness of diabetes care by providing a tool that enables local quality improvement efforts to benchmark performance against national, evidence-based treatment aims. The NDR, also based at Sahlgrenska University Hospital, collects information annually from primary care practices and hospitals about their diabetic patients and the services provided to them. Comparisons are then made with national care guidelines and quality indicators, with results reported back annually to participating care providers.

Early support by the pharmaceutical industry was a source of distrust and resistance among doctors so leaders sought different sources of support. The NDR is now primarily supported by the Department of Health, though the pharmaceutical industry supports the inclusion of questions pertaining to initiation of insulin treatment and the use of statin drugs. The NDR continues to be managed by the Swedish Society for Diabetology. The Swedish Diabetes Federation, a patient organization, also cooperates with the NDR and its goal of improving diabetes care.

The participation of primary care physicians and hospitals has steadily increased over the years, as has the number of patients in the register—more than 320,000 patients. All 90 hospitals and more than 80 percent of the 1,400 primary care clinics provide data to the register, and participation has come to be expected of any organization that purports to provide good care. Interviewed in late 2011, Soffia Gudbjörnsdottir, who directs the register, expected 100 percent of centers treating diabetes patients would be participating in the next year because this was to be a condition of reimbursement for treating diabetes patients. There is a high level of completeness in reported data; the major problem concerns information from visits that occur outside of the diabetes treatment context, particularly diagnostic information from eye clinics.

Patient participation in the NDR is not mandatory, but fewer than one percent decline to participate. There is 100 percent coverage of children diagnosed with diabetes and 75-80 percent of all patients. Data have been primarily used to make year-to-year comparisons but will also be used for longitudinal studies of the same patients in the future.

Several factors have contributed to the development and growth of the NDR, including annual visits by NDR director Gudbjörnsdottir to all hospitals, involving diabetes nurses as well as physicians, inviting doctors and nurses to an annual program at which developments in diabetes care and quality improvement are presented, acknowledging doctors and nurses who treat diabetic patients by name in the NDR’s annual report, and limiting the number of questions on the data-collection form.

The 20 question form includes disease (Type 1 or 2), clinical measures, risk factors, complications, services received, and demographic information. Completing the form takes 2-3 minutes per patient. Many physicians and nurses complete the form while the patient is present. The form has a component that can be printed out and shared with patients. The idea is to help the patient and doctor to work together in diabetes care.

Data reporting has become routinized. Data for about half the patients are reported electronically, and information for the other half is transferred directly from patients’ electronic medical records. The register aims to get a report on every diabetic patient at least once a year, but information is increasingly being reported after every visit.

Tracking Trends. The annual collection of data facilitates year-to-year comparisons that show how the management and care of diabetes is changing. Trends in clinical measures such as mean/median hemoglobin A1c and blood pressure levels can also be tracked. For example, the report on the first eight years of the register showed improvements in the proportion of patients achieving target HbA1c levels, blood lipid goals, and blood pressure goals. However, increases were shown in body mass index, overweight, obesity, and waist circumference for most groupings of patients. Trend data have also been published for the major complications of diabetes as well as for two process measures in diabetes care: examination of eye in the previous two years and examination of foot status in the previous year.

The cleaned and analyzed data are available online for all participating centers, showing how their results compare to national data as well as to national guidelines for diabetes care. Reporting units can also see how particular doctors and nurses are performing. More than 20 clinical measures (e.g., control of HbA1c, foot amputations) are publicly reported at the hospital and county levels, with county councils receiving data about identified primary care units. The result, said Soffia Gudbjörnsdottir, is that “there is competition [for improvement] between different counties.” The initially large county-level differences in the risk factors for complications have been decreasing.
**Studying Outcomes.** The power of the NDR has been increased by cross-linking it with the national hospital discharge, drug, and cancer registers. As the length of time that patients have been in the register has increased, the NDR is increasingly looking at patients’ outcomes, including factors that predict mortality. With the linkage since 2005 with the national drug register, researchers can do multi-year follow up studies on certain medications in diabetic patients, looking for uncommon side effects and doing comparative outcome studies. The link with the cancer register will uniquely permit studies of a possible link between insulin use and cancer risk. A growing list of scientific publications has come from NDR though its primary purpose has been to provide feedback to service providers to facilitate improvements in patient care.42

**Final Overview of Registers in Sweden**

At their best, Swedish registers are of high quality and completeness. The data are useful for multiple purposes. Success has been measured by both quality improvement and research output. A significant governmental commitment has been made to the expansion of the system of registers. Because the Swedish experience is so positive, it is important to bear in mind a number of special characteristics. Swedish registers cover a population of less than 10 million people, and it is possible for register staff to have face-to-face relationships with the health professionals who submit data. Also, the health care system has a long tradition of registers, universal patient identifiers, few private hospitals, and a structure of clear, county-level accountability. Even so, the quality of Swedish registers is acknowledged to be uneven,43 and “register fatigue” is a concern, particular in primary care practices whose patients are covered by multiple registers.

The physicians who manage major registries, including those on which this paper is focused, attribute registries’ success to (1) having a goal—improving the quality of care that patients receive—that is shared by the providers of data; (2) having the content and operation of the register in the hands of professionals; (3) acting to minimize the burdens of reporting, including taking advantage of advances in information technology and using few and valid metrics. The Boston Consulting Group, which studied registers in Sweden, summed the qualities needed for success into the six factors shown in Figure 3.

**Figure 3. Success Factors for Quality Improvement Registers, as Identified in the Boston Consulting Group Study of the Swedish Register System**

1. **Strong core team**
   - One team
     - Clear process leadership
     - Personal dedication
     - Sense of ownership
   - Strong support from specialists
     - Data collection is team effort
     - Entrepreneurial "can-do" spirit
     - Creating winners
2. **Committed specialists**
   - Atmosphere of cooperation
     - Evidence-based discussion
     - Mutual respect and team spirit
     - Peer pressure in joint efforts
     - Evidence-based approach
     - Strong foundation in research
     - Willingness to measure
3. **Valid & reliable metrics**
   - Strong foundation in research
     - Internationally tested metrics
     - Proven causality
     - Possible to benchmark
   - In touch with clinical practice
     - Practicality filter
     - Risk adjustment possibilities
     - Collect relevant patient data
4. **Systematic feedback**
   - Fast feedback of results
     - To allow comparisons over time for own results
   - Learnings linked to feedback
     - Learning from others
     - Workshpsof and seminars
     - Organized best-practice sharing
5. **Easy-to-use IT interface**
   - Easy to enter data
     - Only collect what is needed
     - Easy-to-use IT interface
     - Move towards integration with EMR systems
   - Easy to receive feedback
     - Fast feedback of own results
     - Decision-support tools
6. **Stable financing**
   - Access to stable financing
     - Backing from institutions
     - Clearly delineated budget for registry admin, maintenance
   - Arms-length relationships with private financiers
     - Access to funding without compromising data integrity

Source: Boston Consulting Group
REGISTERS AND AUDITS IN ENGLAND

England has an extensive array of clinical data bases (called registers or audits) whose central purpose is quality improvement. Their content is similar to that of the Swedish registers. As in Sweden, the original English ones were set up as ad hoc “clinical enthusiasms” of individual clinicians or groups of committed specialists, and they often involved specialist societies, royal colleges, and disease-oriented charities. They have trended toward more formal governmental support and oversight and have evolved from a focus on comparing performance against quality standards toward a greater emphasis on outcomes. The number of audits and registers is growing.

Audits and registers collect similar kinds of information about patients, services received, and outcomes, but audits, as part of the National Clinical Audit and Patient Outcomes Programme (NCAPOP), have a more regulatory flavor. As part of the management structure of the National Health Service (NHS), they are used to compare the care that patients receive against national quality standards, including those published by the National Institute of Health and Clinical Excellence (NICE). The information they produce may also be used in setting standards.

Supplying data for the national audits has been made mandatory for NHS hospitals (and their specialist physicians) and is nearly so for general practitioners (GPs). This promotes completeness, but there is some worry that making providers’ participation compulsory will adversely affect the quality of information that gets submitted. Registers that are not part of the NCAPOP also track patients and the care they receive, but they are less compliance oriented, and the participation of doctors, hospitals, and patients is voluntary. Some activities that began as small registries of relatively uncommon conditions have evolved into audits. The distinction between audits and registries is blurry, and all would likely be called registers in the Swedish context.

England has some 200 regional or national audits and registries. Many are for diseases; some are for procedures; some are for kinds of services (e.g., intensive care units). Many have become a routine part of practice. According to Robin Burgess, the CEO of the Healthcare Quality Improvement Partnership (HQIP), the quasi-governmental body that has broad oversight and standard-setting responsibility for registers and audits, about 70 of these are national clinical audits in the British terminology—30 of which are supported (“commissioned”) by HQIP. The NHS through HQIP is the major funder, with a 2012 budget of £16 million (about $25 million). Even with the current austere NHS budget, funding has been increased for some registers (e.g., registers for congenital anomalies and some cancers). Some registers, however, are funded from other sources (e.g., research grants; provider subscriptions).

Decisions about what information to collect was historically in the hands of the professional bodies and interested clinicians who developed the registers, but HQIP is very much involved in determining the content of any new audits and registers that they fund, in part because of concerns about overburdening clinicians. Participation in the HQIP-funded registers/audits is generally around 85 percent; coverage of other registers varies. Data are generally entered (commonly by nurses) manually and submitted electronically, but extraction from electronic health records is becoming more common, particularly for registers/audits that collect data from GPs, most of whom use electronic health records. (Electronic records are not yet widely available in hospitals.)

With cancer, registration occurs electronically when pathologists enter a cancer diagnosis in a pathology report. As in Sweden, patient-reported outcome data are also collected as part of the audit process. HQIP requires contractors conducting audits to clean and triangulate its data with other sources. Each audit has responsibility to publish its own data. There is considerable support from HQIP to ensure this happens, and audits are increasingly reporting in a similar format and style and to a standardised level of detail.

Data from different providers can be linked via a patient’s NHS identification number. This works for most patients. However, a small (but declining) number of providers do not use NHS identifiers in their own patient records, and not all patients consent for inclusion of their identified data in audits and registers. There are two paths around the consent requirement. NHS numbers can be scrambled with a code retained, but this complicates data linkages and does not permit follow-up. There is also an administrative procedure for allowing identifiable patient information to be used without consent; conditions include that the purpose is improving patient care, that it cannot be achieved with de-identified data, and that seeking patient consent is not practicable. This consent exception has commonly been used for audits, but such use is being made more limited, and the potential effect on data quality is a concern for register leaders.
According to Burgess, compliance with audit requirements has increased in recent years, and the quality of audit data at its best is quite high. But some commentators argue that data quality varies. Burgess suggests that the best audits blend methodological competence with good patient engagement, clinical ownership and leadership, and the use of the audit in measurement/improvement cycles.

Audit/register data are primarily used for quality improvement purposes. The data are also potentially useful for comparisons of the cost-effectiveness of alternative devices or procedures. They have not, however, been used to limit the device-selection choices of surgeons, though this may be done for joint replacement devices with high failure rates. Their use for the assessment of new procedures is still limited.

**National Joint Registry (NJR) of England and Wales**

The NJR was established in 2002 after a government investigation that was stimulated by a paper presented at an orthopedics conference showed a high revision rate for a widely used hip-replacement device. The NJR aims “to provide information regarding surgical and implant performance and clinical best practice to all those involved in the management and delivery of joint replacement surgery.” With over one million hip, knee, and ankle replacement procedures recorded since 2003, the NJR purports to be the largest database of its kind in the world. Slightly more knee replacement operations than hip operations are recorded annually (81,979 vs. 76,759 in fiscal 2010-11 along with a relative handful (382) of ankle procedures). (Ankle replacement was added to the registry in 2010.) Though larger than the Swedish Hip Arthroplasty Register, the NJR is much newer and thus trails the Swedish experience in some ways, particularly in uses of the data and the study of long-term outcomes.

The NJR is supported by a levy (£20 per joint) on the sale of the devices themselves. This levy, which is built into the price paid by the NHS, generated revenues of £2.5 million in 2009-10. The NJR is one of the NCAPOP audits funded by HQIP, which contracts with a private organization, Northgate Information Solutions (UK), Ltd., for data collection and cleaning and with the University of Bristol for statistical analysis. A volunteer nongovernmental steering committee guides the strategic direction and work of the NJR. It is chaired by a lay person who is herself a joint replacement patient, and its members include orthopedic surgeons, patient representatives, implant manufacturers/suppliers, public health/epidemiologist, NHS management, and a GP with a special interest in orthopedic care.

The NJR publishes three measures of its own completeness and quality. Compliance is measured the number of procedure records received by the NJR as a percentage of the number of implants on which a levy was assessed. The latter figure is believed to be virtually complete. Consent refers to the percentage of submitted records on which the patient has consented to having his or her personal data stored in the NJR data base. Linkability is the percentage of records that contains the patients’ consent and NHS identification number, which facilitates linking primary and revision procedures on the same patient. Measuring outcomes requires linking different data sources (since different providers may be involved) and is facilitated by a common identification number, although it is possible for analyses that are internal to the NJR to match records using other characteristics (e.g., age, gender, postal code). Even so, between 2003 and 2009, some 3,582 revisions found in the NHS’s hospital discharge data (called episode statistics) for England and Wales could not be linked to any records in the NJR. Since revisions are a major outcome of interest, this was a concern, and a quality audit has been undertaken to assess the problem and to attempt to make the needed data linkages.

The NJR’s completeness has increased over the years. Patients consented in almost 89 percent of the reported procedures in 2010, and most data submissions (83 percent of the total) included the patient’s NHS number. An additional problem is that some revision surgery may not get entered, which undermines the validity of data about revision rates. Continued improvement is anticipated. In mid-2011, data collection for the NJR was made mandatory for NHS hospitals, with penalties for non-compliance. Even so, patient consent is a continuing source of concern.

**What the National Joint Registry Shows.** The NJR’s annual reports include trend information and data analyses about patient characteristics (age, sex, fitness, and body mass index) and indications for surgery, surgical techniques, methods of prophylaxis, brands and sizes of the devices, and methods of fixing devices in place. Analyses include simple counts (e.g., use rates for different devices or methods) and the relationship between demographic factors and the types of devices and methods that were used.

The trend data show that numbers of procedures have been increasing annually, patient demographics such as age and sex are stable, and patients have been getting less healthy and more obese. Two-thirds of procedures were done in NHS hospitals, and one-fourth in independent hospitals, with the former getting disproportionate...
numbers of the less healthy patients. (The remaining 9 percent of procedures were split between NHS and private treatment centers.)

Of particular importance are analyses focused on revision surgery to replace an implant. In 2010, revisions constituted 11.4 percent of the hip replacement procedures. Revision rates increase over post-surgical time, from 1.1 percent within the first year after the initial hip replacement to 4.7 percent by year seven. The seven-year revision rate for hips ranged from 3 percent for “cemented prostheses” up to 11.8 percent for resurfacing procedures and 13.6 percent for stemmed metal-on-metal devices. The higher rates for the latter two procedures remained after controlling for age and sex, but the problems were more common for women than men. Analyses of the performance of different devices began in 2010.

Using a data link from the Office of National Statistics, the NJR annual report also includes mortality information for patients 30 and 90 days after surgery (.3 percent and .6 percent respectively) as well as overall death rates among people who had undergone joint replacement. Interestingly, the percentage of hip replacement surgery patients who died within seven years of their operation was lower than death rates among people of comparable age and sex in the general population, suggesting that patients having hip arthroplasties tended to be otherwise healthier than patients who did not.

**Uses of NJR Data.** In additional to documenting trends in joint replacement surgery, NJR data have been used to detect poor performing prostheses and helped to detect identify some problematic surgeons. Surgeons can also go online and get comparative information about their own performance. Unlike the Swedish hip arthroplasty register, the NJR did not initially publish outcome measures for identified hospitals or regions. Publication of identified hospital trusts began in 2012, with the names of surgeons being given to the trusts for their use.

Also, unlike Sweden where most surgery now uses one of six devices, NJR data have not been used to limit which devices are used in the NHS, although results regarding revisions may have influenced surgeons’ device choices. Even so, Paul Gregg, an orthopedist who was involved in the creation of the NJR and is a member of its steering committee, said in late 2011 that 150 different hip prostheses were in use in the country. However, the NJR’s 2011 annual report noted that the documentation of a high rate of revisions for a particular device had led to its recall by the manufacturer in 2010 and to continuing regulatory investigations of revisions in patients receiving metal-on-metal implants.

The NJR data are being supplemented by data from 35,000 patients who consented to be surveyed 12 months after their operation regarding pain and functionality in their replaced joints. The intent is to compare pain and functionality before and after the surgery, to assess the effects on outcomes of a variety of risk factors, and to learn more about the effects of arthroplasty on healthcare utilization and satisfaction.

The NRJ’s increased research orientation is reflected in establishing a research committee, appointing a dedicated researcher and two research fellows, and adding a “research” page to its website.

**The National Diabetes Audit (NDA)**

The NDA was established in 2002 to collect information for comparing the care that diabetes patients were receiving with standards of care. Unlike the NJR, which is designed to follow patients from the time of their surgery until they die, the NDA collects cross-sectional data annually. It is primarily about ambulatory care by GPs, but information about hospital care is increasingly being collected. The NDA focuses on the extent to which people with diabetes are receiving evidence-based recommended services. Year over year, comparisons of quality measures shows whether performance is improving or declining.

The NDA is supported by the NHS and run by the NHS’s Information Center, which oversees data collection, cleaning, and matching, as well as publication of the annual report. Diabetes Health Intelligence contributes to the data analysis, and Diabetes UK, a charity, works with professionals and patients to encourage participation. The NDA is budgeted at about £700,000 per year, about fifty cents a patient.

The 2009-10 report was based on records of more than 1.9 million people with diabetes and included more than 80 percent of people with diabetes in England. (Data are reported separately for Wales.) Data were submitted by 6,507 general practices (about 80 percent of the total), 61 acute care hospitals (of about 165), and 141 (of 177) registered pediatric units. Participation subsequently became mandatory for hospitals, but GPs could opt out. Patient consent is required for the use of identifiable data (e.g., with NHS ID number), and diabetes activist organizations support the audit as a way to improve quality. The audit has also begun to collect data on patients’ experiences.
Data collection takes place in a month-long window each year, mostly via automated extraction from GPs’ electronic health records. The audit collects information about each patient’s diagnosis, glucose levels, blood pressure and cholesterol, demographics (age, sex, ethnicity and a geographic measure of social deprivation), body mass index, receipt of nine basic care process recommended by the National Institute for Clinical Excellence (NICE), and complications. The nine care processes pertain to clinical measures (e.g., hemoglobin A1c), foot risk assessments and retinopathy screening, and smoking cessation advice. Data from the NHS’s Hospital Episodes Statistics (HES) database is used to identify hospital admissions for relevant complications of NDA patients.

Summary reports based on the data are published about diabetes and pediatric diabetes, and reporting units have web access for comparing their results to those of similar NHS organizations (e.g., general practices or hospitals). Current and trend information about adult diabetics, broken down by demographic factors, is published at the national and regional level.

The data are used for two primary purposes. The first is public health surveillance—tracking trends in the number of cases and their distribution in the population. The second is monitoring of health system performance—the extent to which recommended services are being provided and the frequency with which adverse complications of diabetes are developing. Thus, for example, the extent to which patients received the nine care process was published in the 2009-10 report for each primary care trust and ranged from fewer than 10 percent to almost 70 percent. Although performance had improved from the previous year, there is clearly still a long way to go. The variations help identify where improvements are most needed and what level of performance is achievable under current circumstances. Data are not reported about individual providers.

Trend data from the NDA show improvements in some measures (blood pressure and cholesterol), but less so for HbA1c control. Improvements have also been seen for some complications (myocardial infarction and stroke, amputations have leveled off from previous increases), but increases are seen in ketoacidosis and end-stage renal disease.

**DRAWING LESSONS FROM THE SWEDISH AND ENGLISH EXPERIENCE**

Even considering only two types of registers—one for a chronic disease and one for a surgical procedure—it can be seen that registers can serve multiple purposes. They provide data about quality for feedback to service providers or for the use of purchasers or patients, facilitate planning by providing information about incidence of health conditions or utilization of services, foster the evaluation of the safety of interventions and the soundness of practice guidelines, and provide the basis for research on interventions and outcomes. Registers that begin with a narrow purpose can evolve into something that is much more substantial.

**How Registers Evolve**

The experience of Sweden and England shows that registers can change in various ways as data accumulate and potential uses expand. The quality improvement activities undertaken by idealistic clinicians can grow into broader regional or national efforts that involve a significant degree of governmental oversight and support. Voluntary registers can become mandatory, and piecemeal funding can become more secure.

As registers become more complete, pressure increases on hesitant doctors and hospitals to participate, even if participation is voluntary. As registers become better established, providers’ failure to participate can lead to criticism from patient groups, professional leadership, and governmental officials.

Registers in the two countries have been evolving toward greater comprehensiveness in both data collection and outcomes examined. Registers that once consisted only of clinical information arising from encounters with the health care system are being supplemented in both countries by patient-reported outcome measures. In the hip replacement registers, for example, outcome measures, such as whether additional surgery has occurred, are being supplemented by more sensitive patient-reported measures of pain and functionality.

Another change is toward the consolidation of registers that have overlapping patient populations. In Sweden, for example, four registers that covered different coronary diseases and procedures were brought together several years ago into SWEDEHEART (The Swedish Web-system for Enhancement and Development of Evidence-based care in Heart disease Evaluated According to Recommended Therapies). Discussions were underway in Sweden in late 2011 between leaders of the cardiac-related and diabetes registers about the possible consolidation of these registers because of the extent to which their populations overlap.
Changes in Focus

The utility of information that registers collect can change and expand over time. One shift is temporal—from cross-sectional to longitudinal. A register is initially useful primarily for documenting the incidence or prevalence of measures of interest (e.g., the number of new or existing cases or the frequency with which different procedures are being used) and for comparing clinical performance in a given year against standards and benchmarks, as with the registers/audits for diabetes in Sweden and England. However, collection of data year after year creates opportunities for addressing questions that require longitudinal data, such as predictors of outcomes. Obviously, one cannot study the 10-year survival of a hip replacement device until the register has 10 years of data.

Another shift concerns focus of attention, which can change if variation largely disappears in the measures being studied. Almost all hip replacement procedures in Sweden now use one of only six devices that have a greater than 95 percent ten-year survival rate. Concerns about the performance of different devices—the register’s original primary focus—have become less central, though device performance continues to be monitored. Elimination of a different kind of variation happened in Sweden’s cardiac registry where county-level deviations from care standards on several process measures largely disappeared between 2006 and 2010. Register leaders recognize the need to change focus to other areas or to patient populations where care improvement is still needed.

The elimination of undesired variations in services or outcomes does not exhaust the utility of a register. The sentinel effect may have continuing value, and the register can also be used to assess outcomes of new care innovations. The focus may also broaden, as with the Swedish Hip Arthroplasty Register, where attention is moving beyond the devices themselves to other predictors of outcomes, including differences in patient care before and after the surgery, as well as differences in surgical technique. A similar trend is occurring in Britain’s NJR. By including osteoarthritis patients as soon as they are diagnosed instead of when they have hip replacement surgery, the registry will be able to collect more data on factors other than the surgery itself that may help improve patient outcomes. In this case, a procedure registry (hip replacement surgery) transforms into a disease registry (osteoarthritis).

Routinization and the Use of Electronic Health Records

The growth and success of registers has led to interest in finding ways to reduce the reporting burden on providers, lessen the costs of the register system, and automate the creation of register information. Data entry accounts for about a third of the cost of registers and duplicate entry of information into patients’ medical records and registers has been a source of complaint among providers. Primary care practices in Sweden now report to eight registers—for diabetes, heart failure, dementia, palliative care, chronic obstructive lung disease, asthma, chronic wounds, and nutrition/fall prevention/pressure sores.

As the use of electronic medical records (EMRs) has grown, so has interest in extracting register information electronically from the EMR, as is happening extensively in the National Diabetes Audit in England and is beginning to happen in Sweden, where a national effort is underway in large registers to integrate register and patient record information. One vision is to have a national electronic primary care record (perhaps regionalized) that would meet the information requirements of all registers that draw on primary care.

Though eliminating duplication is compelling from an efficiency point of view, some register leaders fear that the quality of register information will decline if EMRS become the source of data because of well-known problems in and limitations of information in patient records. Register data are far more rigorous, using carefully defined data fields into which personnel, often with special training, enter information. Nonetheless, the proliferation of registers and the growing availability of electronic health records create an impulse to find ways to use the latter as the data source for the former. Registers thus become a source of pressure for improving the quality of patient records.

The Research Use of Register Data

The primary purpose of most data collection by registers and audits has been quality improvement, but the data can often be valuable for research on diseases and treatments. The line between quality improvement and research is often not bright. The analyses of register data that led to the removal of a certain hip replacement device from the market can be seen both as quality improvement and research. This may be generally true of analyses of factors that affect the outcomes of care.
There is a growing interest in both Sweden and England in using registers for research. There are many examples, with lists of publications available from the registers themselves. Registers can also be used for randomized clinical trials. In Sweden’s SWEDEHEART, patients at centers that participate in trials (and all do) can receive a randomized treatment after giving consent, and all the patient characteristics and outcome measures will be captured in the normal functioning of the register. With this mature register in place, virtually all patients being treated for a condition for which a trial is being done can participate, and data accumulate quickly and inexpensively.

The growing number of international collaborations among registers provides additional evidence of the usefulness of register information for research. For relatively small countries, combining data across countries speeds the accrual of cases and facilitates detection and understanding of important clinical events, even those that are rare. Also, when there are cross-country differences in patient populations or clinical practices, comparative studies may produce valuable information.

**Accountability and Professional Control**

The relative role of government and professional organizations is a topic that frequently arises in discussions about registers in Sweden and England. This is more of a worry than a serious concern in Sweden, where registers remain in the hands of professional organizations, but a transition is taking place as recent increases in government funding for registers has been accompanied by greater public accountability, governmental oversight and direction setting, pressures to improve coverage, and expectations for productivity. Concerns about the government’s use of audit data are stronger in England, where the system of audits and registers has a more regulatory flavor, even though the government contracts out much of the management and oversight for audits to quasi-governmental organizations.

The success and growth of registers that were created by professionals dedicated to quality improvement created the need for the sort of funding that government can provide, but such funding comes with strings attached—with regard to how the data are collected (voluntary vs. mandatory; degree of standardization), access to and use of the data beyond the register itself, and the potential use of register data as a management tool (e.g., tying performance to economic incentives).

The quality of the information being reported to a register may be affected by the attitude of professionals toward the register. This may be affected by whether they think the data they report will come back to them in ways that they find useful or be used to exercise greater control over their professional lives. An important question, then, is how to sustain the desirable level of professional input and support while having necessary public accountability. The balance will vary across different countries and change over time, even in countries with universal health care coverage and national patient identification numbers.

**IMPLICATIONS FOR THE UNITED STATES**

I noted at the beginning of this paper that registers are not a new idea in the United States, that many successful ones exist, and that the Agency for Healthcare Quality and Research has been offering guidance for the creation of registers. Health policy changes may increase the ways that registers could be used—for example, generating data for the Patient Centered Outcomes Research Institute, the monitoring of quality under health reform, and reducing some of the quality shortfalls that result from the fragmentation that permeates the U.S. healthcare system.

To date, the completeness and accomplishments of the register/audit systems of Sweden and England go well beyond the American experience for several reasons.

The first is relative scale, both in the number of patients and the number of hospitals and physicians. Sweden has fewer than ten million people living in an area about the size of California. The Swedish registers involve fewer than 100 hospitals and 1,500 primary care centers, making it possible for register leaders to get to know the suppliers of register data via personal visits or conferences. Register leaders in England say that the personal touch round in some Swedish registers is not feasible in a country with 50 million people. The idea of a national register in a country with 300,000,000 people is daunting. For the time being, the greatest completeness is possible for relatively rare diseases or procedures that are performed in a relatively small number of major medical centers. The growing use of electronic medical records will also increase the feasibility of developing more good registers in the United States.
Second, patient consent has not constituted a major barrier in either country, though for different reasons. Cultural factors help explain why Swedish registers can achieve high levels of patient consent. In England there has been an administrative path around consent requirements for quality improvement audits, though this path has been narrowed. Patient consent could be a substantial barrier in the United States with its legal environment and high sensitivity to privacy concerns, but patients are important beneficiaries of the knowledge that can be generated in registers and they may be receptive to information about the benefits of the quality improvement and patient outcome activities of registers. Increasing patients' understanding of ways that information about the care they receive can be used to improve quality will be an important challenge as interest increases in developing new registers or expanding existing ones.

A third advantage for register creation in Sweden and England is the existence of unique identification numbers that are used with patients no matter where in the country they are treated. This makes it possible to follow patients over time and connect their experiences even if different sources of care are being used. Certain uses of register data depend heavily on capturing outcome data. If some patients have second hip replacement operations in institutions that do not participate in the register, it lessens the validity of the register's information about the frequency with which different devices fail.

Although the United States is disadvantaged in this regard, the problem is not insurmountable. First, there are already organizations that cover large numbers of patients who have an identification number. Most people aged 65 and above have Medicare numbers, and that age is appropriate for many purposes for which registers are created. The potential exists for greater use of registers in the Medicare population, although such uses would be politically sensitive. The CMS “Summit to Advance the Use of Registries” in 2011 is a positive step. The Veterans Health Administration is another possibility, though most registry activity to date has been regional and for clinical care rather than quality improvement or outcomes research. The Kaiser-Permanente health plan has both the size (enrollment is about the size of the Swedish population) and conception of mission to support the creation of registers that have meaningful numbers, and the organization already has a large number of device and disease registers in place. Important registry work has also been done at Group Health Cooperative of Puget Sound. The inevitable year-to-year turnover is a limitation of a register based in any health plan, however.

But there are also alternatives to using existing patient identification number when linking data from different organizations that provide care. The new American Joint Replacement Registry hopes eventually to collect register data from most or all U.S. hospitals and will use an algorithm that will transform existing identifiable patient information (e.g., social security number, birthdate, zip code) into a unique but not-identifiable number. The resulting data base can be kept completely separate from the location at which the link between the patient-specific information and the research ID is kept.

For some regulatory and policymaking purposes, the U.S. could make more use of register data from other countries. Tens of thousands of patients in the U.S. received the DePuy A.S.R. hip replacement device in the years after use of the device had been halted in Sweden based on the experience of 329 patients who were followed in the Swedish Hip Arthroplasty Register. The amount of unnecessary pain and suffering is incalculable. No one has added up the cost in dollars to Medicare and private payers, but Johnson and Johnson set aside $3 billion in the last quarter of 2011 for anticipated product liability litigation. It has been projected that annual costs of revision surgery for hip replacement in the U.S. will increase from about $1 billion in 2005 to about $4 billion in 2015. (Similar costs are projected for revision total knee arthroplasty.) The best available data show that the revision rate in Sweden is half what it is in the U.S. (3.2 percent vs. 7.0 percent after 7 years). The annual costs of the excess do-overs of hip replacement surgery in the U.S. will thus grow from about a half a billion in 2005 to about $2 billion in 2015.

The experience of Sweden and England (as well as other countries not discussed in this paper) shows that while assessing the long-term safety of drugs and devices is a valuable function of registers, the contributions that they can make in the improvement of patient care and the reduction of waste goes far beyond product safety. Reports in Sweden also point to the economic development potential of registers as a resource for epidemiological and outcomes-related research. The relatively low cost of registers and the value that they create justify finding ways to overcome the barriers to their creation and to make more extensive use of this valuable tool.
ENDNOTES


6. Terminology related to registers is not standardized and can cause confusion. A distinction is sometimes made between registers (data bases) and registries (where data bases are housed). Modifiers are sometimes attached, as, for example, with “quality registers” or “disease registers.” However, because the data in registers can be used for multiple purposes and include only diagnosed cases, the use of a more generic term such as “clinical data base” has been proposed (Nick Black, personal interview, December 7, 2011). Finally, the British distinguish between registers and clinical audits, which, as will be described later, operate for somewhat different purposes under different rules.


18. Lindahl interview.


20. The Rosén report was done at the request of the government and the Swedish Association of Local Authorities and Regions and is not published in English. A presentation of his main findings can be found at http://www.ltleinge.se/download/18.6a1838391326b98aa5a98000124+M%C3%A5ns+Rosén+28092011.pdf (Accessed January 3, 2011)


22. Göran Garellick, Director, Swedish Hip Arthroplasty Register, personal interview, December 5, 2011.

24. Garellick interview.


26. Garellick interview.


28. Only four years of data were available for hemi-arthroplastices and the reoperation rate was 5%.

29. Garellick interview.


33. Ibid.


36. Gudbjörnsdottir interview.

37. Ibid.

38. Ibid.

39. To be more precise, data points collected include type of diabetes (1 or 2), duration of diabetes, HbA1c and type of hypoglycemic treatment, blood pressure and use of antihypertensive drugs, blood lipids and use of lipid reducing drugs, risk factors (e.g., smoking, body mass index, physical activity), micro- or macroalbuminuria/creatinine value, coronary heart disease, cerebrovascular disease, use of acetylsalicylic acid (ASA), retinopathy, visual disability, whether eye status assessed in last 2 years, amputation above foot level, whether foot status assessed in last year, demographic data (age and sex), and where treated (center, county).

40. Gudbjörnsdottir interview. For this, records must be based on the SNOMED clinical terminology and information must be recorded in a certain way. Downloading information from EMRs both reduces the register’s cost and makes it more feasible to capture register data whenever a patient visit takes place, not just annually.

41. Gudbjörnsdottir interview.

42. Sofﬁa Gudbjörnsdottir, director of the NDR, is co-author of more than 60 papers on diabetes shown in Google Scholar.

43. Måns Rosén, Interview, December 6, 2011.

44. The term is from Robin Burgess, CEO of the Healthcare Quality Improvement Partnership, interview December 19, 2011.

45. Mechanisms differ. It is part of the terms and conditions set by the NHS for hospital trusts, and is one of the “good medical practice” conditions set forth for GPs by the General Medical Council, which registers doctors to practice in the U.K. Email from Helen Laing, National Clinical Audit Lead, Healthcare Quality Improvement Partnership, January 27, 2012.


47. Robin Burgess, telephone interview, December 19, 2011.

48. Ibid.

49. John Newton, personal interview, December 8, 2011.

50. Burgess interview.

51. Black interview.

52. A breast implant register failed because patients having the procedure were not asked to consent to follow-up, which precluded the register from doing so to obtain outcome information. John Newton, personal interview, December 8, 2011.
53. The provisions for waiving confidentiality are in Section 251 of the NHS Act of 2006.
54. Burgess interview.
55. Black interview; John Newton, personal interview, December 8, 2011.
57. Burgess interview.
58. Paul Gregg, National Joint Register board member, personal interview, December 8, 2011. The device in question, Gregg recalled, was made by an American company and the study showed that it had a 9-10 percent five-year revision rate.
60. Unless otherwise indicated, all of the data in this section come from National Joint Registry for England and Wales. 8th Annual Report, 2011.
62. Gregg interview.
64. Gregg interview.
65. Ibid.
66. Ibid.
70. A regulatory provision that permitted use of the data for audit purposes without consent is being closed off as a result of a change in policy. The effects on access to identified data is not yet known.
71. Young interview.
73. Gudbjörnsdóttir interview.
74. Lindahl interview.
75. This estimate comes from Måns Rosén, director of the Swedish Council on Health Technology Assessment, based on his study of Swedish registers. Personal interview, December 6, 2011.
76. Måns Rosén, personal interview, December 6, 2011.
77. Ibid.
78. Lindahl interview.
79. Bodil Klintberg, project manager, the Swedish Association of Local Authorities and Regions (SALAR), personal interview, December 6, 2011.
81. Susan M. Kirsh, chronic disease consultant for the Patient Aligned Care Team (VA’s PCMH) Office of Patient Care Services, Washington DC, telephone interview, January 31, 2012.
82. David Lewallen, chair, American Joint Replacement Register, telephone interview January 30, 2011.
84. Kurtz et al. 2007.
85. Kurtz et al., p. 150.
Support for this research was provided by The Commonwealth Fund. The views presented here are those of the authors and should not be attributed to The Commonwealth Fund or its directors, officers, or staff.

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