Title: Registry-based learning systems: Co-producing health, improvement and science

Standfirst: Scores of registries have been developed but few have evolved to become patient-centered learning systems in which patients, clinicians, and scientists partner to co-produce better health outcomes, improved healthcare services and patient-centered research.


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Introduction

The idea that data should routinely be collected on patients’ experiences and outcomes has a long history. As far back as the 18th century, the London physician Sir Francis Clifton was recommending the regular, standardised recordings of clinical observations about diseases. 1 His insight that much can be learned by the systematic and disciplined collection of data was also at the heart of Ernest Codman’s 20th century mission in Boston, USA to track patients using what he called “End Result Cards”. 2 Codman’s Registry of Bone Sarcoma, established in 1921, rapidly established the value of this approach – yielding not only rich evidence about rare neoplasms, but also a model that could be emulated in other diseases. Building on this early work, 3 large-scale data collection and analyses have become staples of successful health systems worldwide. Reflecting different purposes, organizational structures, and histories, they go by various names, including registries, quality registries, clinical databases, clinical audits, quality improvement programmes, etc. 4 5 Common to all is the collection of standardised information on patients’ diagnoses, care processes, and outcomes, enabling systematic comparison and analysis across multiple sites. In this article, we identify what needs to happen to make the next generation of these entities genuinely patient-centered and valuable to patients and their families, to the clinicians who provide healthcare services for them, to those who seek to improve services, and to those who study health and illness.

Hundreds of what we will term, for simplicity, “registries”, now exist around the world. The UK is home to over 50 clinical audit programmes, 6 the US has over 110 federally qualified registries certified to report quality metrics, 7 and Sweden, perhaps the registry epicenter, has over 100, covering conditions from birth to frail old age. 8 The impact of these exercises is far-reaching. They facilitate, for example, systematic tracking of outcomes and processes of care, public reporting, retrospective and prospective research, professional development and service improvement. They are powerful in revealing variations in practices, processes, and outcomes, and in identifying targets for improvement. In the UK, they have been associated with many notable successes, including striking improvements in areas ranging from cardiovascular disease and stroke 9 10 to cancer 11 and joint replacement. 12
Despite the undoubted achievements of registries worldwide, few have realized their full potential. Feedback of data to participating clinical centres often lags well behind actual care, meaning the data are out-of-date and less meaningful and actionable. Many registries have been slow to catch up with the digital era of medicine, continuing to rely on manual data entry (and often double-entry—once to the EHR and once to the registry) of specific fields—a process that is tedious, expensive and prone to error. The uses to which these data are put may remain unduly restricted—for example research or performance management only—when the same data could potentially be used for many purposes. Perhaps most problematic of all is that many registries have limited patient involvement in their design, oversight or operations. Patients may not, for example, be asked to identify their priorities for data to be collected, so the information generated may only partly reflect what matters to them and their families. The data that are collected are typically inaccessible to patients themselves (even when it is about them), and few opportunities may be available for patients to input data outside clinically-orchestrated medical encounters. Patients therefore typically are denied the chance to learn from their own data to support self-management and shared decision-making. Overall, few registries would be characterized as highly patient-centered.

Signs of change are, however, beginning to appear. The UK’s Healthcare Quality Improvement Partnership (HQIP) has an explicit patient and public involvement policy, and now, for example, involves patient representatives in specification development for its registries. Though national clinical audits in the UK were until recently limited to clinicians’ reports of processes and outcomes, they are now, like those in Sweden, the Netherlands and elsewhere, beginning to incorporate patient-reported outcomes alongside clinical measures.

In the Netherlands, the Parkinson’s Disease registry not only tracks patient-reported outcomes and caregiver strain alongside clinical outcomes to support patient care, improvement and research, it also involves patients, families, physicians and clinical scientists in developing guidelines to promote a consistently high standard of care. In the USA, the ImproveCareNow network for inflammatory bowel disease (IBD) engages patients and families - alongside care teams and scientists - in its design, governance and operation, enabling improved sensitivity to what matters to patients. Thus, though the registry had initially focused on measuring simple
IBD remission rates, partnering with patients enabled recognition that patients and their families were much more interested in prolonged, steroid free-remissions, which have improved from 55% to 78% in participating practices, whereas simple remission is at 80% (Figure 1A). The network has now added two UK sites (in Cambridge and London), bringing the potential for benefit closer to NHS patients.

An especially exciting development is that some registries are gaining the capacity to address the specific goals that patients prioritize and to support care in real-time. The Swedish Rheumatology Quality Registry is exemplary of what can be achieved through this kind of patient-centered approach. It enables patients to track symptoms at home to identify early signs of increased disease activity, supporting them to co-produce better care with their clinicians. The practices participating in the registry have documented a 50% decrease in inflammatory activity among rheumatoid arthritis patients across Sweden (Figure 1B).

Co-production of health, healthcare, improvement, and research: A proposed model

The growing emphasis on patient-centeredness in registries is consistent with the recognition that active partnerships between patients, clinicians, and health scientists to achieve shared goals are critical to the co-production of health, healthcare services, and research. We propose that patient-centered registries have a critical role in realising the vision for a learning health system articulated by the US Institute of Medicine as one where “knowledge generation is so embedded into the core of the practice of medicine that it is a natural outgrowth and product of the healthcare delivery process and leads to continual improvement in care”. In such a system, patient outcomes and experiences, as well as other valuable data, are continuously monitored and available in real-time to both clinicians and patients to facilitate their joint work, and can also be used to support service improvement and scientific inquiry. By building on the structure and function of the registries listed in Table 1, and the possibilities now offered by the rapid digitization of healthcare, it is possible to envision a generalisable model for a registry-based, patient-centered learning system for co-producing health, improvement and research (Box 1). An important feature of learning systems is that they are not simply a technical infrastructure: they are governed by strong values and a commitment to collective learning, not unlike Mintzberg et al’s vision of a learning culture.
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The model (Figure 2) brings together patients and families (left side) with clinicians and care teams (right side), so that when they come together (centre) they form a partnership. Key mechanisms supporting the system are shown in Table 2. One defining feature is that patients are able to share their own real-time perceptions of health, function, and well-being with their care team; they can select measures that matter to them and can enter their data outside clinical encounters, enabling them to monitor and continually assess their health status in their daily life beyond the confines of the healthcare system. They can contribute to pre-visit planning, assist in monitoring treatment responses, and help to ensure that resources are being used for services that truly matter to them.

Box 2 brings the model to life based on the Swedish registry, which features consultations in which the patient and clinician sit side-by-side in front of a dashboard displaying the patient’s treatments and patient-reported outcomes as well as population-based clinical, experiential, and functional data. By enabling conversations organised around real-time data that are relevant to patients’ priorities, patients and clinicians are supported to become competent, confident, and equal partners who can share decisions. The dashboard is fed by a shared clinical database (lower center) that is auto-populated by patient-reported and clinical data that flows into and out of electronic and personal health records.

The functions and possibilities of the registry-enabled learning system go well beyond the patient-clinical team dyad. The “small data” reported by patients and clinicians are recorded longitudinally in a secure registry platform (lower center). Configured appropriately, and with the right governance arrangements in place, this database of “big data” (lower centre) can be used for many purposes: it creates opportunities for continuous real-time access to peer and professional support using curated, facilitated networks for patients and families (lower left side), and collaborative improvement networks for clinicians (lower right side). It can be used to generate information to support service improvement activities, reducing the data burden for such activities and facilitating a more patient-centered approach to improvement. Clearly, the database will be invaluable for many forms of research, including observational studies, N of 1 experiments, augmentation of results from randomised controlled trials (RCTs), identification of
participants for RCTs, and as the basis of studies where randomisation is neither appropriate nor practical. Linking the database to other data sources and to biological samples, perhaps building on the Farr Institute model, opens up many new possibilities for patient-centered research.

**Discussion**

Registries have had a role in improving health and healthcare for decades. The increasing recognition that patients and their families should be involved in registry leadership and the growth in technical capacities and methods of measurement offer enormous opportunities to bring together interests and energies of patients and families, health care teams, and researchers. As the NHS embarks on its next phase of digitization, the critical role that patient-centered registries could play in creating the conditions for a learning healthcare system deserves careful consideration. Founded on principles of co-production, the model of a registry-based learning system that we propose calls for and facilitates equal partnerships in the patient-clinician relationship. The model intentionally aligns with the patient’s self-defined needs and priorities and refigures the opportunities for decision-making. Holding special promise for people living with chronic conditions for whom self-monitoring and self-management are needed to achieve optimal health results, it seeks to shift healthcare from a series of episodic encounters to a system in which all who care about a person’s health – patients, families, clinicians, scientists, policy makers and purchasers/commissioners – have the information they need for effective care, for the advancement of knowledge, and for service improvement. The model thus seeks to deliver on policy aspirations for quality and costs accountability and for care to become more patient-centered. If this model can be realised, many stand to benefit. (Box 3).

The model does not, of course, promise a utopia. Some adverse consequences and risks can be anticipated, including those linked to the so-called “quantified self”, where some patients might become the subject of surveillance and control (rather than empowered citizens). Innovators must keep in mind the risk that registry participants will focus too much on the numbers tracked by their fitness devices, and not on the goal of overall health, which is complex and adds up to more than the sum of all the numbers associated with any given patient. Also important will be ensuring that the model does not inadvertently create or exacerbate inequalities; some older
people, for example, may continue to prefer paper-based rather than digital methods of data-collection, and “big data” may create new forms of disadvantage. Issues of governance and regulation, including but not limited to the use of clinical data for research and other purposes, will need to be carefully worked through. Data security for registries will be critical, as will models of consent that are sufficiently agile to respect patients’ preferences and to cope with evolution of systems, mutations in the purposes for which data may be used, and changes in who may access and use which data over time.\textsuperscript{39} Although many problems will need to be overcome,\textsuperscript{40} exemplars of successful registries provide important direction on how they may be tackled (Box 4).

\textbf{Conclusion}

Registry-based learning systems could unite patients, clinicians, and researchers to strive for, and ultimately co-produce, optimal health, high value services, and new knowledge that can be rapidly deployed to benefit individual patients and the public. The challenges are real, but many are likely to be tractable. Today’s registries have brought us a long way since Francis Clifton. Tomorrow’s registries, as patient-centered learning systems, could bring us even further.
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Key Messages

- Registries can evolve to become patient-centered learning systems in which patients, clinicians, and scientists partner to co-produce better health outcomes, improved healthcare services and patient-centered research.

- Registries can be used to make “dashboards” for use by patients and clinicians that integrate patient-reported and clinical data for real-time feedback and decision support, care management, and tracking outcomes over time in relation to treatments.

- Transformed into patient-centered learning systems, registry data can be used also to support (a) practice-based quality improvement and comparative benchmarking reports; (b) public reporting on relevant outcomes; (c) clinical improvement networks; (d) facilitated patient networks; and (e) retrospective and prospective research on the effectiveness of biomedical and care delivery innovations.

Contributors and Sources

This article is based on a literature review and environmental scan that was conducted with support from the Robert Wood Johnson Foundation and the desire to draw attention to a novel registry approach that can be the basis for establishing a learning health system for clinical populations. ECN, PBB, EE, SL have expertise in patient registries, clinical collaboratives and quality improvement; KH and CL have expertise in patient-centered care; MDW and JO have expertise in improvement and implementation science; ADVC and WH have expertise in formal literature reviews and program evaluation; TSM and ESF have expertise in public policy, communications and health care delivery science. ECN is the guarantor of the article.

Competing interests

We have read and understood BMJ policy on declaration of interests and declare ECN owns stock in Quality Data Management; all other authors have no competing interests to declare. This work is supported by funding from the Robert Wood Johnson Foundation (Grants: #71211 and
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Table 1. Two registries that are evolving to become highly patient-centered

<table>
<thead>
<tr>
<th>Feature of Registry</th>
<th>ImproveCareNow (ICN) Chronic Care Network</th>
<th>Swedish Rheumatology Quality Registry (SRQ)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical population</td>
<td>Pediatric inflammatory bowel disease (IBD)</td>
<td>Rheumatoid arthritis (RA) &amp; 98 other rheumatologic diagnoses</td>
</tr>
<tr>
<td>Sponsor</td>
<td>Participating care centers</td>
<td>Karolinska University Hospital</td>
</tr>
<tr>
<td>Number of clinical sites</td>
<td>76</td>
<td>60</td>
</tr>
<tr>
<td>Improvement evidence</td>
<td>Improvement in IBD remission rates from 55% to 78% in 5 years (see Figure 1A)</td>
<td>50% decrease in RA inflammation activity in Sweden in past 10 years (see Figure 1B)</td>
</tr>
<tr>
<td>Patient-reported data included in registry</td>
<td>Symptom reports</td>
<td>Symptoms, life style, functional status, HRQoL [2]</td>
</tr>
<tr>
<td>Feed forward patient reported data used at point of care</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Transparent public reports</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Collaborative improvement network for providers</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Facilitated network for patients &amp; families</td>
<td>Yes</td>
<td>No</td>
</tr>
</tbody>
</table>

Table Notes


2. HRQoL denotes health related quality of life based on self-reports
Table 2. Key mechanisms that are used to build a registry-based learning system

<table>
<thead>
<tr>
<th>Key Mechanisms</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data feed-forward systems</td>
<td>Feed-forward patient-reported and clinical data are continuously available both for patients and at the point of care for health tracking and care planning.</td>
</tr>
<tr>
<td>Decision support “dashboards”</td>
<td>Graphical charting of patient-level data allows for visualization of patient-reported and clinical data over time, resulting in the ability for patients and clinicians to detect relationships between symptoms and interventions.</td>
</tr>
<tr>
<td>Reports for patients and providers</td>
<td>Registry data is returned to both the patient and provider in meaningful summary reports that show trends over time. As a byproduct, registry databases can provide comparative data for practice improvement, research, and public reporting.</td>
</tr>
<tr>
<td>Patient and provider facilitated networks</td>
<td>Patient facilitated networks can foster social support and learning among patients with similar health conditions. Likewise, provider facilitated networks can support the work of interdisciplinary care teams. Both types of networks ideally are co-curate by patients and professionals, and provide information to support optimal health and high value care.</td>
</tr>
<tr>
<td>Multi-stakeholder engagement</td>
<td>Collaborative networks -- including patients, providers, and researchers -- working together to: share expertise, measurably improve outcomes and healthcare value, and conduct needed research.</td>
</tr>
</tbody>
</table>
Box 1. Key Features of Registry-Based Learning Systems

a) A social network of patients and families encouraged to engage in the patient’s healthcare and supported by measures and tools that enable them to track their own health outcomes and to support self-care;

b) A collaborative network of clinical teams that can provide care to their patients and who engage in a system of longitudinal and comparative data;

c) Sharing of power and responsibility among patients, clinicians and scientists for designing, governing and evaluating services, improvement and research;

d) Digital collection and use of both clinical and patient-reported outcomes to guide the interaction between patients and the healthcare team and to be used as a basis for improvement, research, and public health policy;

e) Demonstration of measureable improvement in individual and public health outcomes based on improving adherence to current evidence and disciplined experiments that have contributed to better outcomes important to patients, clinicians, and scientists; and,

f) Dissemination and translation of ideas/findings through publication of research results in peer-reviewed journals, presentations at meetings, and outreach to other patients, clinicians, researchers, and health policy analysts.
Box 2. How the Swedish Rheumatology Quality Registry (SRQ) Works: Bringing the Model to Life (See http://www.youtube.com/watch?v=wjhkP8t1EmM)

Vignette 1. Karin Arvidsson is a middle-aged professional woman whose passion is gardening and who developed rheumatoid arthritis (RA) several years ago. She has taken four different biologic drugs that make her life much better and she states that she manages her RA by “working with my doctor and my computer.” She also states that using her computer to track her outcomes “helps me get through bad periods by myself.” Her trusted physician, Dr. Anita Domargard, points out that her patient, Ms Arvidsson, is one of 25,000 Swedish patients who are in the national registry that tracks RA care using “nationally agreed upon outcomes” and that she can “compare her results to the rest of Sweden.” Dr. Domargard and Ms Arvidsson sit together when they meet for a visit and view a dashboard that shows Ms Arvidsson’s longitudinal outcomes (e.g., functional status, quality of life, joint counts, C-Reactive Protein) and her medications and then they decide on which types of drugs are most likely to work best for Ms Arvidsson. Because they are dealing with expensive biologics, Dr. Domargard says that she “feels confident that these (expensive) drugs are used in the best way.” (http://www.youtube.com/watch?v=wjhkP8t1EmM.)

Vignette 2. In 2008 Dr. Sven Tegmark became the director for rheumatology care for Gavle County in Sweden which provides services in four different geographic locations. His rheumatology program had been participating in the SRQ for many years by providing data on treatments and outcomes on all RA patients. Unfortunately, the comparative results showed that Gavle County’s patients had a decade’s worth of highly variable outcomes that were worse than the rest of Sweden. Dr. Tegmark decided to use the SRQ, not just for public reporting and research, but also for direct use in improving patient care. He led two key changes in the way care is delivered to rheumatology patients in the County. First, he encouraged all of the physicians to actually use the outcomes “dashboards” with each and every patient as a clinical decision support and patient engagement tool. Second, he developed a new delivery model that they call an “open-tight” system. In effect, by encouraging patients to use the dashboards at home for outcomes tracking, patients would know if they were in remission or not. If they were doing well, they were “open” to visit their physicians but making a visit was up to them. But if their outcomes suggested that they were out of remission, they were encouraged to make an
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appointment immediately and that they would be “tightly” cared for until they once again achieved remission. This helped to make it possible for patients to be seen when they really needed to be seen and to use enlightened self-management when they were doing well. The outcomes for Gavle County’s RA patients improved dramatically after these changes were (see Figure 1A) such that Gavle’s RA patients had better outcomes than the rest of Sweden.
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Box 3. Benefits of patient-centered registry-based learning systems to Patients, Clinicians, Scientists and Other Key Groups

**Patients** can benefit by incorporating person-centered outcomes (e.g., clinical, functional, quality of life, personal goal attainment) into the flow of care and feeding that information forward to enable them to actively participate in decision-making, developing personalized care plans, and self-managing their health in between visits with their care team.\(^1\)

**Clinicians** can benefit by partnering with their patients in a more effective care model, advancing their learning by participating in collaborative improvement networks that draw information from officially qualified registries that show their outcomes compared to others, and meeting both maintenance of certification and quality reporting requirements.\(^2\)

**Scientists** can benefit by conducting research in “collaboratories” that use data that flows, at low marginal cost, from registries that collect key standardized information (e.g., patient characteristics, treatments, test results, and longitudinal outcomes), they can recruit patients for clinical studies, biobank sampling, \(^3\) and registry-based randomized controlled trials \(^4\) and many other types of study.

**Purchasers/commissioners and the public** can benefit by gaining access to information that can be used to show comparative, case-mix adjusted data on the outcomes and costs of care for similar patients treated by different providers and by establishing benchmarks for value-based payments (i.e., outcomes in relationship to costs).

**Pharmaceutical companies and medical device manufacturers** can benefit from systematic data collection on patients, interventions (e.g., including the specific pharmaceuticals and devices that they sell), and outcomes to evaluate their products in real world practice and their effective use for patients.

**Health agencies** can have required data (e.g. mandatory reporting of infectious diseases or drug adverse events) collected at the point of care.
Box 4. Challenges and Current Solutions

**Motivation:** How to motivate participation? All exemplars motivate participants by focusing on key, measurable, improvable health outcomes (e.g., BMI, remission rates).

**Organization:** How to organize, govern and share power and influence? The ICN uses community organizing and peer-production principles and methods to start and manage the operation.

**Adoption of Innovation:** How to fit new ways to collect, display and use “dashboards” into clinical workflows without adding extra work? The SRQ registry employs trained quality coaches to fill the dashboard with previous data and then work with frontline clinicians and staff to adopt new work routines utilizing the dashboard to prospectively improve health.

**Empowerment:** How can patients be more empowered to make decisions and increase their capacity for self-management? The SRQ uses the decision support dashboard as a catalyst for shared decision making and for enabling the patient to create self-management treatment plans. The ICN uses a shared governance model (patients, clinicians, scientists) for planning, designing and governing all of their work.

**IT Integration:** How to efficiently collect valid patient reported and clinical data in busy practices that use many different electronic medical record (EMR) systems? The SRQ uses a third party, internet-based IT solution offered for free to extract selected clinical data elements from the electronic health record and the clinician, to collect self-reported measures from patients using validated tools, and to instantly analyze and display all data in a “dashboard” for use during office visits and for home use. All of this is done using secure, privacy-protected processes that feed into the SRQ’s longitudinal patient database.

**Improvement:** How to use data for learning, transparent reporting, and quality improvement? All exemplars provide transparent, comparative, case-mix adjusted reports on variations in outcomes across practices, and encourage practice-based improvements and adoption of best practices. They hold annual meetings to review performance, to discuss lessons learned, and to promote specific improvements and adoption of best practices.
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**Research:** *How to conduct useful research?* The SRQ has a long history of epidemiologic and comparative effectiveness research as well as post-marketing surveillance of medications including new biologics.

**Scaleable and Sustainable:** *How to spread and sustain the system?* The SRQ covers all of Sweden and the ICN has grown to include 80 pediatric specialty practices in just five years. Funding comes from several sources including government sources (SRQ), foundations (SRQ), life science companies (SRQ), and membership fees (ICN).