

# Establishing a National Registry for Hand Surgery

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Hand surgery leadership in the United States must identify and define what quality care means for its patients. To achieve this, the surgical team needs a standardized framework to track and improve quality. This is necessary not only in our value-based health care system but also in light of considerable provider variation in the management of common hand conditions and the ongoing need for evidence-based guidelines to inform decision-making. Building a national registry for the field of hand surgery could be the solution and warrants serious consideration. A registry designed by hand surgery experts can collect data on process and outcome measures that are meaningful and specific to patients with hand conditions. These data inform the surgical team regarding where to focus their efforts for improvement. Existing methods of quality measurement are not compatible with hand surgery, a field with an ambulatory setting and rare incidence of mortality. Patient-reported outcomes, such as health-related quality of life, represent a more useful measure of quality for hand surgery and are just one example of the type of data that could be tracked using a national registry. An investment in a large-scale registry could seamlessly integrate patient preferences, values, and expectations into clinical practice so that desired outcomes can be delivered consistently across the nation. (*J Hand Surg Am. 2020;45(1):57–61. Copyright © 2020 by the American Society for Surgery of the Hand. All rights reserved.*)

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THE VALUE-BASED MODEL of the United States (US) health care system offers providers greater reimbursement if they deliver the best patient outcomes using a cost-effective approach. This evolving paradigm has major implications for hand surgeons who are now incentivized to follow evidence-based practices that are linked to high-quality surgical care.<sup>1</sup> Despite the shift to value-

based care, substantial provider variation is readily observed in the diagnosis and management of common hand conditions, such as nonsurgical approaches for carpal tunnel syndrome.<sup>2</sup> This ongoing variability may be a product of sparse comparative effectiveness data that exist for hand surgery. These data are necessary to inform clinical decision-making and encourage evidence-based practice.<sup>3</sup> However, even when consensus exists for best practice, it is difficult to assess how well providers are actually adhering to these processes in their day-to-day environment.<sup>2</sup> Unnecessary variation in practice can manifest as wasted resources, inefficient diagnostic workup, and care that is neither patient-centered nor aligned with value.<sup>2</sup> Hand surgery can benefit from a centralized system, such as a clinical registry, to identify and track quality of care measures that are specific and meaningful to its patients and their conditions.<sup>1</sup> Leaders of various medical specialties have already met these challenges in their own disciplines by leveraging the power of clinical data registries on a

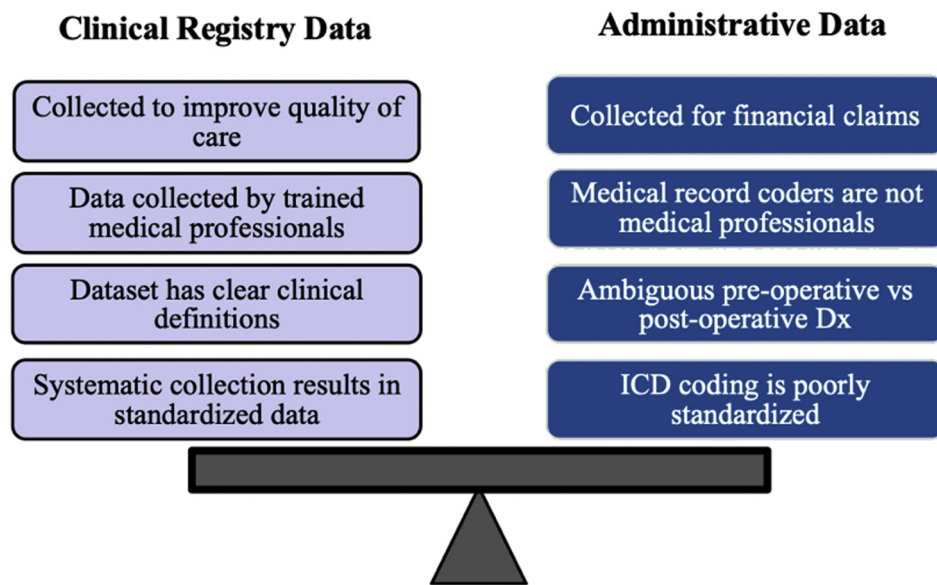
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**FIGURE 1:** Advantages of clinical registry data over administrative data. DX, diagnosis; ICD, International Classification of Diseases.

national scale.<sup>4–6</sup> This article investigates why a national registry can be the answer to integrating quality improvement efforts into the forefront of hand care and how it can shape the future of the field.

The overarching goal of a clinical registry is to track processes and outcomes from routine clinical practice.<sup>4</sup> The result is an observational database that increases our understanding of a particular therapy, clinical condition, or patient population.<sup>7</sup> As more providers participate in data submission, useful benchmarks can be identified. These benchmarks compare quality of care among providers and institutions on a local, national, or even international scale.<sup>4</sup> Registries also identify specific areas of poor performance within clinical practice. By providing this targeted feedback to members of the health care team, specific quality improvement efforts can be created, paving the way for better outcomes and lower complication rates.<sup>8</sup> Therefore, registry participation by itself is only half the battle. The full potential is realized when the health care team implements specific initiatives to address clinical areas identified by the registry as underperforming.<sup>9</sup>

The source of data for measuring quality of care usually comes from a clinical registry or an administrative database, although clinical registries offer several distinct advantages (Fig. 1). Data collection in registries is performed by trained medical professionals for the purpose of improving quality of care, whereas administrative data are often captured by medical coders for claims purposes.<sup>10</sup> In addition, registries ensure data are standardized across participating sites using systematic collection

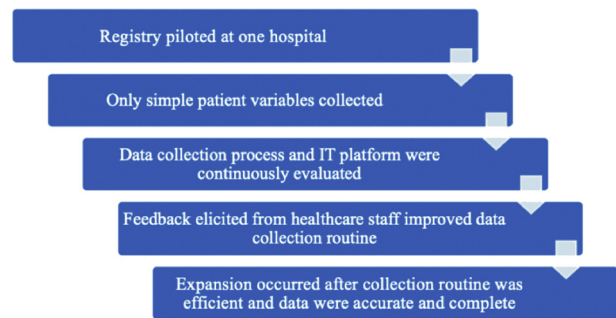
processes.<sup>7</sup> A registry contains data elements with clear clinical definitions to prevent ambiguity that is frequently observed among administrative databases regarding a preoperative versus postoperative diagnosis.<sup>10</sup> Finally, evidence shows that quality improvement efforts exclusively using administrative data are associated with poor discrimination of clinically meaningful postoperative outcomes.<sup>9,10</sup>

When investigating the utility of clinical registries, it is helpful to understand where registries came from and what factors drive their existence. The earliest clinical data registries geared toward quality improvement were developed in Sweden.<sup>11</sup> These efforts marked a departure from measuring patient outcomes under controlled laboratory conditions at highly specialized centers. Instead, the new goal was to track outcomes produced in real-world settings, under average conditions that were most representative of the general population.<sup>11</sup> The Swedish Knee Arthroplasty Register, developed in 1975, was the nation's first clinical registry that focused on improving quality. The database proved its worth because it could quickly pinpoint poor outcomes associated with specific patient characteristics, treatment methods, or implant models.<sup>12</sup> Of equal importance, the database efficiently disseminated this information on a national scale, stopping the use of faulty implant models before too many patients had a negative experience. Examples of discoveries generated by the Swedish Knee Arthroplasty Register include identifying rheumatoid arthritis as a contraindication to unicompartamental knee replacement, rapidly detecting widespread failure for implant

models from specific manufacturers, and revealing increased rates of myelodysplastic syndromes and melanoma after knee arthroplasty. Furthermore, it is no coincidence that the long-term revision rate for total knee replacement in Sweden is 4%, one of the lowest in the world.<sup>12</sup>

In 2010, the first national quality registry designed specifically for hand surgery, Handkirurgiskt (HAKIR; meaning “hand surgery”), was developed in Sweden. The registry began at a single hospital and was carefully expanded into nationwide coverage (Fig. 2). HAKIR shows great promise for driving quality improvement efforts in hand surgery by using patient-reported outcome measures as a key component of its registry dataset.<sup>11</sup> The *Quick*—Disabilities of the Arm, Shoulder, and Hand questionnaire is administered and uploaded to an online database before and after surgery in over 80% of all hand procedures performed annually in the nation. These data are able to demonstrate patients’ views on the effectiveness of one treatment approach versus another. Longitudinal data of this nature also permit a more realistic conversation of expectations between provider and patient regarding the impact of treatment on quality of life.<sup>11</sup> For instance, patients are encouraged to access data from HAKIR by going online to see aggregated reports of previous patients’ experiences regarding pain, functionality, and other quality of life variables. Patients can then see how these factors have changed from a preoperative to postoperative state. These online reports are available for patients with common hand conditions such as carpal tunnel syndrome, trigger finger, and carpometacarpal osteoarthritis. The initiative helps patients with hand conditions receive more comprehensive preoperative information and creates new opportunities for patients to participate in shared decision-making.<sup>11</sup>

Meanwhile, in the US, the adoption of clinical registries has been heavily influenced by legislation and health policy that rewards value of care and the use of electronic health records.<sup>13</sup> Signing of the Medicare Access and Children’s Health Insurance Program Reauthorization Act in 2015 showed that the US government had recognized the potential of registries for value-based care. For example, the Center for Medicare and Medicaid Services (CMS) now designates select registries as Qualified Clinical Data Registries (QCDRs) if they demonstrate the ability to improve quality and efficiency of care in participating institutions.<sup>13</sup> To increase participation in these CMS-endorsed registries, financial incentives are distributed for health care providers that submit



**FIGURE 2:** Process of registry expansion for HAKIR, a national quality registry for hand surgery in Sweden. IT, information technology.

outcome data to QCDRs. When an eligible provider submits data to a QCDR, it can satisfy the Merit-based Incentive Payment System track of the Quality Payment Program.<sup>13</sup> This will have major implications for Medicare Part B physicians, because performance during 2020 will affect reimbursement to a positive or negative degree of up to 9%.<sup>14</sup> Furthermore, payers and health care consumers increasingly want access to statistics on outcomes, quality of care, patient safety, and patient experience when selecting a provider or health plan. This trend in the U.S. health care climate should further motivate registry development. Comparing institutional outcome data in this transparent manner also creates new opportunities to guide and inform patients regarding where they can receive the best care.<sup>13</sup>

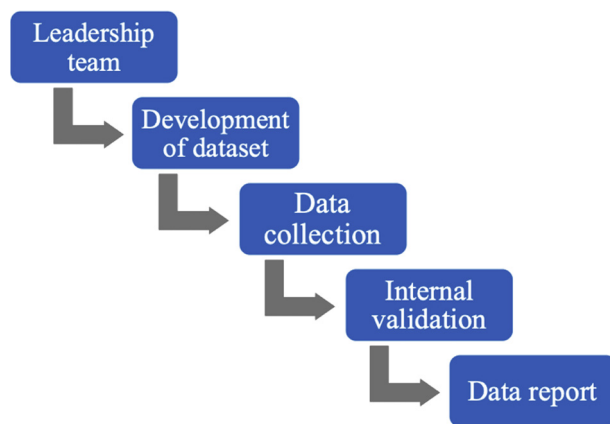
The founding and operation of a registry is frequently supported by a medical society.<sup>5</sup> An eminent example is the American Joint Replacement Registry (AJRR), established by the American Academy of Orthopedic Surgeons. As the largest orthopedic registry in the world, the AJRR captures over 30% of all hip and knee arthroplasties performed annually in the US.<sup>6</sup> The successful launch, rapid growth, and sustainable business model of the AJRR was made possible by a series of strategic partnerships with medical societies, government agencies, and international organizations.<sup>6</sup> The AJRR was able to expand its database immensely when CMS agreed to provide the registry with Medicare claims data for its registered patients for a more complete analysis of patient care.<sup>15</sup> Leveraging these relationships helps diversify the stakeholders of a registry, providing more comprehensive infrastructure, financial stability, and necessary resources.<sup>7</sup> The partnership between the AJRR and government agencies such as CMS also signifies an important and evolving implication of registries, in which governmental and

accrediting organizations require participation in registries for various purposes.<sup>5</sup> For example, health care facilities can receive Advanced Certification for Total Hip and Total Knee Replacement from the Joint Commission only if they submit data to AJRR.

The Food and Drug Administration (FDA) is also increasingly involved in mandating specific registry participation, usually for long-term surveillance of medical devices and implants.<sup>5</sup> After the discovery of breast implant–associated anaplastic large cell lymphoma, the FDA partnered with the Plastic Surgery Foundation and the American Society for Plastic Surgeons to create the Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma Etiology and Epidemiology (PROFILE). The FDA has required certain breast implant manufacturers to submit data to PROFILE for postmarket approval.<sup>5</sup> As participation becomes required by more reporting agencies, hand surgeons should be wary that a registry for their field may be launched without their input unless hand surgery leaders rise to the occasion and commence a dedicated effort to become part of the registry movement.<sup>5</sup>

Several innate characteristics of hand surgery create challenges for traditional measurements of surgical quality. Compared with inpatient surgery, efforts to measure and improve quality in the ambulatory setting remain underexplored.<sup>16</sup> The Center for Medicare and Medicaid Services has a set of quality measures that determine reimbursement for ambulatory procedures, but none are particularly relevant to hand surgery.<sup>16</sup> Typical benchmarks used in surgical quality improvement, such as mortality rates, are applicable to inpatient settings yet rarely useful in hand surgery.<sup>17</sup> An example of a useful benchmark in hand surgery outcomes is quality of life, which can be influenced by factors such as aesthetics, functionality, and pain.<sup>16</sup> Measurement of health-related quality of life is a more holistic concept that captures outcome in terms of patients' abilities to perform daily functions.<sup>16</sup> Because routine practice rarely tracks health-related quality of life in the electronic health registry, a national registry could be the ideal solution for capturing and aggregating these data.

Although the primary objective of clinical registries is quality improvement, their capacity to launch research projects is increasingly recognized. This holds particular importance for hand surgery, a field in which the randomized controlled trial (RCT) comprises 2.2% of its literature.<sup>18</sup> This is unsurprising considering RCTs are expensive, require immense resources, and are particularly challenging



**FIGURE 3:** Conceptual model depicting basic operational structure of a registry.

for surgical outcome research. Meanwhile, low-quality evidence represents over 82% of published hand surgery research.<sup>18</sup> One solution may be a registry-based RCT, an emerging trend in scientific literature.<sup>19</sup> The infrastructure of a registry is the key to understanding why this study design is advantageous (Fig. 3). Because a registry is engineered to collect standardized process and outcome data from routine clinical practice for a specific patient population, it is primed to cut down on the labor-intensive and costly nature of an RCT.<sup>19</sup> An example of this design is the Thrombus Aspiration During ST-Segment Elevation Myocardial Infarction trial, conducted in Scandinavia. The investigators attributed their use of a national registry to highly efficient patient enrollment, excellent follow-up rates across clinical sites, and the low operating cost observed in the trial.<sup>20</sup>

A registry gives the health care team a direct window into its performance, pointing it in the right direction for how it can improve. Some registries choose to focus on one specific type of intervention such as arthroplasty, whereas others aim to collect data on an entire surgical subspecialty such as HAKIR. Hand surgery societies and experts in the field should discuss specific aspects of quality improvement in hand surgery that are most important and feasible for investigation using a registry. The success of other national registries, particularly evident in Sweden, demonstrates major potential for advancing value-based care and capturing patient-reported outcomes as part of routine practice. As new treatments and surgical methods are devised for the field of hand surgery, a registry can track outcomes in real time and identify poor performance associated with a specific approach, patient demographic, and comorbidity. Creating a central



database to serve as a repository for future hand surgery research will aid in launching initiatives such as a registry-based RCT and expand the presence of high-level evidence in the hand surgery literature.

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