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on

# Why Do We Need a National Joint Replacement Registry in the United States?

## Abstract

**The continually increasing number of total hip arthroplasties (THAs) being performed, in conjunction with the rapid growth in new surgical techniques and implants related to THA, warrants ongoing and objective monitoring of results. National joint replacement registries have become powerful surveillance systems for monitoring contemporary THAs and improving outcomes. Despite the compelling evidence of their benefits, such a registry has yet to be established in the United States.**

**In this article, we provide a rationale for implementing a national joint replacement registry in the United States.**

Total hip arthroplasty (THA) is a commonly performed and highly successful surgical procedure for the treatment of end-stage osteoarthritis of the hip joint[1] and is considered one of the most cost-effective interventions of any surgical procedure in the 21st century.[2] In the United States, more than 200,000 primary THAs are performed annually,[3] and the THA rate is expected to increase dramatically during the next 2 decades.[4] It is estimated that by 2030 the annual demand for primary THA will have grown more than twofold, up to 572,000 procedures.[4] Annual demand for primary total knee arthroplasties is projected to grow by almost 700%, to more than 3 million procedures.[4] In addition, the demand for THA revision procedures is projected to double during the next 2 decades. The continually increasing number of THAs being performed, in conjunction with the rapid growth in new surgical techniques and implants related to THA, warrants ongoing and objective monitoring of results.[5]

**"In the United States, a national joint registry that provides a monitoring, warning, and feedback system for THA performance could help minimize THA complications and optimize outcomes."**

National joint registries—nationwide databases of joint arthroplasties—have become powerful surveillance systems for monitoring contemporary THAs and improving outcomes. The history of national joint registries commenced in the late 1970s, when the Swedish Knee Arthroplasty Register (1976) and the Swedish Hip Arthroplasty Register (1979) were founded.[6] Since then, several countries, including Australia, Canada, Denmark, England, Wales, Finland, New Zealand, Norway, Romania, and Slovakia, have followed suit and established their own national registries.[7] Several more countries have begun the start-up process. Although attempts are being made to build a national joint registry in the United States, such a registry has yet to be established.

In this article, we provide a rationale for implementing a national joint replacement registry in the United States.

## What Are the Aims of a National Joint Registry?

The overall mission for a national joint replacement registry is to improve the quality, outcomes, and cost-effectiveness of THAs. The principal goals of joint registries are to:

1. Provide orthopedic surgeons with timely feedback and thereby positively influence their clinical practices.
2. Minimize complications and optimize patient care related to THA.
3. Decrease the socioeconomic burden associated with failures and morbidity in THA.
4. Monitor the performance of THA types and surgical techniques on an as close to real-time basis as possible and on a national scale.
5. Provide a warning system for early implant failure.

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*Am J Orthop*. 2009;38(10):500-503. 

## How Do National Joint Registries Work?

Most joint registries are run by national orthopedic societies and are financed mainly by national governments.[7] For example, the Swedish National Hip Register is owned by the Swedish Orthopaedic Association and is funded by the Swedish national government, the National Board of Health and Welfare.

In most countries, participation is voluntary. In Sweden, all departments, including 81 public and private orthopedic units, participate voluntarily. Data are collected prospectively using paper- or Internet-based electronic systems. All collected data are protected, and confidentiality is guaranteed with respect to both patient and surgeon. In Sweden, data are reported mainly by Internet, with 90% of primary THAs and 75% of reoperations immediately reported online and the remaining surgical units submitting after a short delay.

Data are collected on all primary and revision procedures and include, at a minimum, the so-called registry level 1 data, which include patient identifier (eg, social security number), surgeon (de-identified), hospital, and basic surgical data (surgery date, diagnosis, surgical treatment, laterality, implant details, cement type, incision, surgical approach). The current endpoint for outcome analysis in most joint registries is failure, defined by need for revision surgery (exchange/extraction of all or some implant parts). Data are typically presented as survival data—that is, time to first revision, according to the Kaplan-Meier method, with separate consideration of the need for either cup or stem component revision. There is an ongoing effort (eg, in the Swedish hip register) to include patient-derived outcome data and basic radiographic data in order to improve outcome sensitivity and to allow cost-effectiveness and cost-utility analyses.[5]

A critically important feature of national joint registries is regular feedback given to participating surgeons and representatives of the implant manufacturers. In the case of the Swedish hip register, a substantial amount of the collected data (in the form of publications, annual reports, and scientific exhibitions) is communicated on a Web site (http://www.jru.orthop.gu.se). Successful national joint registries inherently rely on such rapid-response feedback systems to encourage compliance, stimulate reflection, and, ultimately, improve care for THA patients.

## What Is the Evidence in Support of National Joint Registries?

There is compelling evidence that the outcomes and cost-effectiveness of THAs significantly improve in countries with established national joint registries. For example, in Sweden, THA quality improved significantly for 2 decades starting in 1979, when the Swedish National Hip Register was implemented, owing to its influence on the clinical practice and attitudes of arthroplasty surgeons.[8] This result is supported by Swedish hip and knee registers data, which showed an almost 2.5-fold reduction, from 17% to 7%, in revision burden alone.

Similarly, in Australia, THA surgery has been strongly influenced by the country's National Joint Replacement Registry. In the late 1990s, hip resurfacing was reintroduced and underwent a renaissance there, as it did in many other developed countries.[9] The number of resurfacing hips as a percentage of all THAs performed in Australia subsequently progressively increased until 2006, from 5.6% in 2001 to 8.9% in 2005. This was particularly demonstrable in patients younger than 55, with 19.6% of all THAs in 2001 increasing to 29% in 2005. Subsequently, the performance of these hip-resurfacing procedures was assessed, and survivorship data were analyzed through the registry. Annual reports in subsequent years revealed that overall early revision rates were higher for hip-resurfacing arthroplasties than for conventional THA prostheses. This was most evident for females (smaller implant sizes), who had a twofold-higher revision rate for hip-resurfacing arthroplasties than for conventional THAs (4.2 vs 2.0%) in 2005. This example illustrates that the Australian registry acted as a monitoring and warning system, using real-time data collected on a national scale, to gauge performance of hip-resurfacing arthroplasties. Equally important, recognition of a sex-related risk for failure and an overall higher revision rate with respect to hip resurfacing prompted an immediate alert (through published annual reports of the Australian registry) to orthopedic surgeons. Starting in 2007, reaction to these reports engendered 2 consecutive yearly declines in the number of total hip-resurfacing arthroplasties, not only as a proportion of all hip procedures but also in terms of absolute numbers. A shift toward male patients was noted, and use of primary hip-resurfacing arthroplasty in females dropped from 28.8% of all hip-resurfacing arthroplasties to 23.6%.

The Australian registry reports further affected arthroplasty surgeons' choice of type of hip-resurfacing implant. The reports identified 3 hip-resurfacing implants with a revision rate higher than anticipated. These specific implants showed a more than twofold increased risk for revision compared with all other implants combined. The national registry again acted as a real-time monitoring and warning system. These reports led to complete abandonment of 1 of the 3 implants in Australia and to a decline in use of the other 2 implants since 2005. The hip-resurfacing analysis demonstrated that data from such registries are critical to monitoring and assessing THA outcomes. Australian registry findings suggested that hip resurfacing arthroplasty is appropriate for one subset of candidates but not for others. The case of hip resurfacing highlights the fact that a national joint registry can help identify appropriate patients for specific implants and procedures and allow fine-tuning of decisions regarding which devices and services should be provided to patients who undergo THA.

The feedback that surgeons receive from the registry data, collected almost in real-time, quickly improves the quality of THA outcomes—in essence creating a quality-control system.

## Why Do We Need a National Joint Registry in the United States?

In several developed countries, use of national joint registries has been shown to significantly improve THA outcomes and significantly lower overall costs.[8] In the United States, a national joint registry has yet to be established, even though this country has the highest absolute number of THAs being performed. Demand for primary and revision joint arthroplasty in the United States is expected to grow dramatically, according to recent statistical projections.[4] In view of these predictions and the proven worth demonstrated in other countries, it would seem that implementation of a national joint registry in the United States is vital and long overdue.

A national joint registry in the United States is warranted to allow nationwide monitoring of THA performance. In the United States, most THA procedures are done by "low-volume" surgeons, who perform fewer than 15 to 20 THAs per year. Half of all THA revisions are performed in centers where fewer than 10 THAs are done annually.[10] More than three quarters of these revision surgeries are performed by surgeons who do fewer than 10 a year.[10] On the other hand, most THA-related publications are submitted by high-volume surgeons working in high-volume centers.[10] In consideration of these demographics, it is highly likely that the reports of past and present outcome series are not truly representative of the THA cross-section in the United States. The problem seems somewhat endemic in this country, and steps are now being taken to resolve it. Attempts are being made to analyze THA outcomes on a larger scale, as in using Medicare claims data to analyze mortality and morbidity after THA.[11] The shortcomings of these approaches are that Medicare claims data cover only patients older than 65, whereas the number of younger patients who undergo THA is increasing, and the Medicare claims data do not differentiate between the right hip and the left hip. Overall, Medicare claims data analyses are estimated to cover approximately 60% of all THAs in the United States.

The United States needs a national joint registry to provide an early-warning system for detecting THA problems and failures in as close to real-time fashion as possible. History has taught us that lack of such a warning system can have serious consequences. In 2000, Sulzer Orthopedics recalled a hip-implant model because of unacceptably high failure rates with need for revision THAs. (This problem was probably caused by oil contamination during manufacturing.) In the United States, 17,500 of these THAs had been implanted, and, according to an estimate, more than 3,000 required revision.[12] Meanwhile, the Swedish National Hip Register alerted Sweden's orthopedic surgeons to the high failure rates of the Sulzer hip implants after not more than 30 patients had received them, and revision surgeries were necessary in only 5 cases (data from the Swedish Hip Registry, as communicated by one of the authors [HM] in January 2002).

A national joint registry is needed to provide the US orthopedic community with a regular feedback system. It is clear that, in countries in which joint registries are established, orthopedic surgeons learn in a timely fashion of the risks and results of large-scale experimentation with new implants and technologies. It is likely that implementation of a national joint registry in the United States would create a similarly conservative and more evidence-based attitude toward new technology. Joint registries in the United States would help provide more evidence-based medicine. Governments in various developed countries, including the Netherlands, the United Kingdom, Canada, Japan, Germany, and Switzerland, have already begun implementing physician reimbursement based on following current scientifically based guidelines regarding the best operative procedure to pursue in any given case. It is likely that US orthopedic surgeons will face similar stipulations in the near future.

In the United States, a national joint registry that provides a monitoring, warning, and feedback system for THA performance could help minimize THA complications and optimize outcomes. From a socioeconomic standpoint, this system could also control the burgeoning costs associated with THA. The relative burden caused by failed THAs for both patients and the US economy is significantly higher than that in registry-driven countries, such as Sweden. In the light of the current economic crisis, cost-effectiveness becomes even more essential. The data speak for themselves. For example, in Sweden, 6.4% of patients older than 65 required THA revision between 1992 and 2000, compared with 16.9% of patients older than 65 in the United States during a similar period (1990–2002).[13] The potential savings just from a reduction in the high revision rates in the United States are significant. For each percentage drop in THA revision from 16.9%, the direct annual cost savings are estimated to range from US $42.5 to $112.6 million.[13] A 10% reduction in the THA revision rate in the United States (down to the Swedish level) could therefore save upward of $1 billion annually.[13]

## Limitations and Legal Issues

A clear limitation of registry studies is lack of causative explanation in the registry results. An implant can be identified as suboptimal, but the etiology for an increased failure rate cannot be identified. Therefore, even in the future, we will need prospective and, ideally, randomized trials when

new technology is introduced to the market. High compliance (>85%-90%) is needed, and biased results could be a consequence of unreported revisions. Continuous review from an unbiased authority and quality control of the reported data are therefore essential. The level 1 registry data proposed for a US joint registry will naturally capture only revised implants and pain, and radiographically loose implants; patient dissatisfaction (expectations not fulfilled) will still not be considered in the determination of successful outcomes. However, there will be options to collect detailed outcome data and thus compensate for this potential bias. A vital issue is legal protection of collected data; all involved parties (ie, patients, physicians, hospitals, manufacturers) must be protected. The mission of a registry is not to punish and publicly identify "below-average performers" but to improve THA performance through systematic feedback. A US joint registry will not be initiated unless confidentiality can be ensured.

## The Proposed Structure for a US Joint Registry

Should compliance be ensured through incentivized or mandated reports? The registry level 1 data set (except for laterality and implant identification) is already included in the mandatory Medicare reports. By including the 2 missing items (laterality, implant identification), we would have the data needed. The data could thus be reported by the hospitals as part of a general quality assurance system and would cover all patients instead of only the Medicare cohort. This would ensure the 90% compliance level and minimize the burden on the individual physician.

Registry data should be placed under the ownership of a professional, physician-administrated organization (eg, American Academy of Orthopaedic Surgeons, American Orthopaedic Association, American Association of Hip and Knee Surgeons) to ensure that all data analyses and annual reports are made under the direction of arthroplasty experts. The funding model will be developed in cooperation with but not mandated by the device manufacturers, though health care providers will realize large savings over the long term. A model for multi-stakeholder governance is being developed, and, preliminarily, the national agencies, device industry, patients, and most of the orthopedic surgeons will be represented.

## Summary

National joint registries have been successfully established in several developed countries to improve care and outcomes of patients who undergo THA for end-stage hip arthritis. Despite the compelling evidence of their benefits, such a registry has yet to be established in the United States. Establishing a national joint replacement registry in the United States would amount to setting up a timely monitoring, warning, and feedback system for THA outcomes in this country. A US joint replacement registry could provide hospitals, surgeons, and the public with annual reports of critical demographic information regarding THA patients; could help identify clinical THA-related problems, including implant-specific survivorship data with volume effects; and would be useful in making cost-utility and -effectiveness estimates. In addition, early-warning surveillance of new technology would be possible. In short, there is compelling evidence that a US national joint registry would be useful in fundamentally improving the outcomes and cost-effectiveness of THA.

## Authors' Disclosure Statement

Dr. von Knoch reports no actual or potential conflict of interest in relation to this article. Dr. Malchau wishes to note that he is a paid consultant to Smith & Nephew and Biomet.

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