

Orthopedic Registries: Second Thoughts

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Many assume that the American Joint Replacement Registry (AJRR) is moving forward as originally planned. No one has reported any obstacles that may cast doubt on its continued progress.

Despite the enthusiasm for AJRR, we must be realistic and admit that the project may not in the final analysis bring about its anticipated results. Therefore, periodic sober assessments of its course should be carried out, as they might result in identifying possible flaws and strengths. It is imperative to continue to express doubts regarding the true long-term value of this registry.

Much of the original support for an ongoing registry came from the example provided by the Swedish national registry. The Scandinavian registry had been said to dramatically reduce the number of complications and halve the revision rate for total hip arthroplasties. We need to question the claim that this reduction was solely the result of information produced by the registry. It is hard to believe that the literature had failed to report on those complications long before the registry publicized its findings.

As we take a fresh look at AJRR, it is perhaps wise to keep in mind the history of the AO Swiss Fracture Registry, founded by Maurice Müller and heavily subsidized by industry. Apparently, after gathering millions of pieces of information, primarily about equipment used for fracture fixation, the Swiss registry has failed to produce the greater benefits it had expected. Given the similarities between the Swiss Fracture Registry and AJRR, it is logical to assume that the latter may suffer the same fate.

I base my concerns on factors that, carefully analyzed, might be important in determining the future of AJRR. One major consideration is the difficulty in guaranteeing the veracity of data submitted—a factor shared by all registries.¹ To assume that all participating surgeons adhere to high ethical and professional standards is naïve. Some surgeons who stand to make large profits from their ownership of implants or equipment are submitting false and erroneous information. Other unscrupulous orthopedists are receiving large kickbacks for helping the industry market its implants. These people will be tempted to embellish and falsify information about successes

and failures and submit it to the registry.¹⁻³

Militating against the “guaranteed success” of AJRR is this tainted relationship between the implant manufacturing industry and some members of the orthopedics community. A 2002–2006 investigation by the US Justice Department found egregious unethical transgressions and corrupt relationships between 5 companies and hundreds of orthopedists—representing a widespread loss of professionalism in our ranks.⁴ More recently, the Centers for Medicare & Medicaid Services⁵ disclosed that, in the last 5 months of 2013, \$3.5 billion were paid by medical device companies to doctors and leading hospitals. As stated in a newspaper article, “‘Open Payments does not identify which financial relationships ... could cause conflicts of interest,’ said Shantanu Agrawal, the agency official overseeing the project. ‘It simply makes the data available to the public.’”⁶ Further, “an initial Associated Press analysis found that orthopedists, cardiologists and adult medicine specialists were among the likeliest to receive payments from drug and device companies. Most of the contributions came in the form of cash payments, followed by in-kind gifts and services, and stock options.”⁶

This official government revelation is disturbing. Although the number of people who are deliberately committing clear infractions may be small, some of these people are likely well-known, and their influence should not be underestimated, particularly with regard to AJRR publications. Some in the orthopedic community do not question the accuracy of these publications but accept their conclusions as fact, and such may be the case with orthopedic guidelines.⁷

Given these concerns and the facts of the situation, can AJRR solve real problems that traditional systems have so far failed to solve? We have enough journals and scientific meetings informing us of the failures and successes of implants. I suspect it is wrong to believe that the AJRR data on 1 million patients’ arthroplasties are necessarily superior to the data from a 20,000-patient registry. Such an erroneous conclusion ignores the fact that, with clinical issues such as the one currently being addressed by AJRR, having a larger registry and more patients does not necessarily imply more meaningful information. In addition, follow-ups longer than those used with traditional methods are not possible—death will continue to intervene. No matter how many patients are included in the system, the maximum follow-up will forever remain the same.

Financing of AJRR is expensive, time-consuming, and likely to be terminated if clear evidence of the true value of the registry is not provided within the next few years. In light of such an outcome, we should replace the current system with

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a more effective mechanism. For example, we could produce an annual publication that summarizes the peer-reviewed articles published on joint replacement, with an emphasis on controversial topics. Orthopedic fellows, rather than readily accepting AJRR findings and recommendations, will instead be able to decide for themselves what treatment to use for each particular patient and situation, based on information provided by a number of independent investigators.

Meaningful progress in managing clinical conditions, such as the ones we are discussing, is achieved not by expanding the size of a registry but by being committed as individuals to making improvements. A cursory glance at the history of hip arthroplasty easily proves the point. Registries, guidelines, and other popular systems sometimes inadvertently create an environment that inhibits independent thinking. When powerful nonmedical economic and political bodies become involved in medical issues in order to ensure their continued profit, our autonomy is lost or compromised in major ways. Such scenarios must be avoided as forcefully as possible.⁸

Questioning the future of AJRR does not derive from rigid thinking or from a lack of awareness or understanding of the registry's nature, procedures, benefits, goals, or highly altruistic and noble origins. However, pointing out a lack of evidence of success is not a crime. It is incumbent on us to look at this area and others with open minds while recognizing that honest

and sincere scrutiny often helps make a better future a reality. The United States is working to achieve major goals for health care—access for all, lower costs, and fewer abuses of the system. Our involvement is a mandate to be followed enthusiastically.

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The Value of National and Hospital Registries

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Following Dr. Sarmiento's commentary, "Orthopedic Registries: Second Thoughts," we agree that it is important and appropriate to question the value of any new additions to the orthopedic field, and registries are no exception. We thank Dr. Sarmiento for his comments on the viability of registries and the need for continued critical evaluation. Before joint registries, however, we had to rely on small-cohort analyses to assess outcomes and complications. Now, national and hospital registries, specifically joint registries, may be an invaluable source of information for orthopedic

surgeons, patients, health care administrators, regulators, and implant suppliers.^{1,2}

Contrary to Dr. Sarmiento's belief that registry data results are likely to have been reported in the literature, it is difficult to refute the value of recent years' registry data in helping surgeons shape their practice. For example, according to Lewallen and Etkin,³ the National Joint Registry of England and Wales information has provided orthopedic surgeons with crucial findings regarding the outcomes of metal-on-metal hip arthroplasties. Using the England and Wales registry data from more than 400,000 primary total hip arthroplasties, Smith and colleagues⁴ noted that metal-on-metal stemmed articulations led to poor implant survival, particularly in young women with large-diameter heads, and indicated these articulations should not be used. Australian registry data on metal-on-metal devices and reports of failure rates up to 11%⁵ led one manufacturer to recall its implants.⁶ In addition, the Norwegian Arthroplasty Register evaluated survival rates and reasons for revision for 7 types of cemented primary total knee arthroplasty

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(TKA) between 1994 and 2009.⁷ Data on more than 17,000 primary TKAs allowed Plate and colleagues⁸ to confidently determine that aseptic loosening was related to certain TKA designs. Using registry information, they identified patients at risk for dislocation in total hip arthroplasty and concluded that large-diameter femoral head articulations could reduce dislocation rates.

Obtaining such large cohorts of patients in individual studies is not only difficult but highly unlikely. Unlike registry data, these studies are often impractical in evaluating factors of low incidence, such as revision rates, as it is often difficult to find significant differences in small populations.⁹ Furthermore, these controlled trials homogenize patients—using exclusion and inclusion criteria to eliminate potential confounders—and thus poorly represent the heterogeneity of a typical hospital's patient population.¹⁰ Although the literature may indeed have alluded to such complications, only a database as extensive as a registry can allow us to fully comprehend the outcomes of particular implants and devices.

Dr. Sarmiento points to the AO Swiss Fracture Registry as being of little benefit and raises the concern that the American Joint Replacement Registry (AJRR) may follow with the same results. However, realizing a registry's benefits may take time and the gradual accumulation of data. Supporting this, Hübschle and colleagues¹¹ recently used AO Swiss Fracture Registry data to validate use of balloon kyphoplasty for vertebral compression fractures and concluded that the technique is safe and effective in reducing pain—thus possibly providing the federal office with the evidence needed for reimbursement for this intervention. Therefore, this registry is now providing useful information.

We can never truly know the veracity of participating surgeons, but it is naïve to assume that this issue arises only vis-à-vis registries. If we were to debate the ethical and professional standards of colleagues in our field, such questions could extend to all studies performed, even peer-reviewed studies. Therefore, we do not think this is reason to exclude the patient data and outcomes found in registries. We must emphasize that ultimately registry data are often most useful in highlighting trends and determining triggers for further study rather than in arriving at conclusions.¹ In particular, registry data may be used in cohort studies that evaluate the risk factors for and incidence of certain outcomes. Focused higher-level interventional studies can then follow the trends observed.¹ However, registry data are also valuable on their own, when higher-level, randomized controlled trials may be impractical or unethical.¹²

Dr. Sarmiento refers to corrupt relationships between companies and orthopedists as “representing a widespread loss of professionalism in our ranks.” Despite a US Justice Department investigation into these relationships, only a few doctors were found to have had inappropriate relationships.¹³ In addition, the investigation and prosecution of companies led to an agreement requiring federal monitoring and new corporate compliance procedures, which should ensure stricter adherence to regulations.¹⁴ We do not believe this should undermine the

value of registries and the work that has been contributed by thousands of surgeons hoping to improve the field of orthopedics. In addition, concerns about the influence of well-known individuals may be better directed at individual institution-based research, particularly as these specific authors also often have conflicts of interest that may skew the presentation of results. The strength of registry data is in providing collective data and large samples from a multitude of surgeons rather than from just high-volume surgeons, and therefore registry data provide a better overall picture of patients and their procedures.¹⁵ Furthermore, trends observed in national registries in countries such as New Zealand¹⁶ may aid in effectively reducing the revision rate, possibly up to 10%.¹⁷ If a US national joint registry is marginally as effective, then we may see considerable savings for our health care services.^{17,18}

We wholeheartedly agree that a yearly review of registries may be constructive. Dr. Sarmiento suggests an annual publication summarizing peer-reviewed articles and the opportunity for orthopedists to decide for themselves what treatments to choose based on reports from independent investigators. Although this sounds feasible, it would be difficult to decide which articles should be selected as pertinent for this type of publication. Any selection would be biased, and not all studies with high-level evidence are necessarily important or relevant. Therefore, selecting what is most appropriate to cite is not without its difficulties. We appreciate that there are problems in standardizing data reporting among registries. However, to improve interregistry collaboration, the US Food and Drug Administration is sponsoring the International Consortium of Orthopaedic Registries (ICOR) to facilitate data presentation.¹⁹ ICOR aims to increase cooperation, standardize analyses, and improve reporting, which will only strengthen the data available to us. Such efforts will ultimately enhance coordination and international collaboration among registries.¹⁵ In addition, incorporating patient-reported outcomes into our national registry will aid in quantifying arthroplasty outcomes from the patient's perspective and will continue to improve total joint arthroplasties.²⁰

Overall, this debate is useful and highly relevant in highlighting potential issues with registries. Although registries are not without their flaws, like all aspects of orthopedics they are ever evolving, and they must be continually modified and improved. However, disregard for the potential value of AJRR, which has benefits for orthopedists and patients alike, is premature. Once again, we thank Dr. Sarmiento for starting this discussion, which will allow us to continue to evaluate and improve our registries.

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