Thoughts on the Orthopedic Guidelines and Joint Replacement Registry

Augusto Sarmiento, MD

It is not difficult to understand why so many have fallen in love with the Orthopedic Guidelines and the Joint Replacement Registry. The guidelines and registry make sense and appear to be altruistic. The question to ask, though, is whether they address real problems, or are simply windmills that are being fought, perhaps with unanticipated consequences. Furthermore, are the guidelines and registry really needed?

I have familiarized myself with the guidelines for distal radius fractures. The authors allegedly reviewed more than 1000 articles, but included only 96 in their final study. Therefore, almost 1000 articles were excluded for not meeting evidence-based criteria, which are not clearly identified. The authors wrote, "We suggest operative fixation as opposed to cast fixation for fractures with post reduction radial shortening greater than 3 mm, dorsal tilt greater than 10°, or intra-articular displacement or step-off greater than 2 mm. … We suggest adjuvant treatment with vitamin C for the prevention of disproportionate pain." Among the 96 articles included in the study, only 2 recommended use of vitamin C, and these were written by the same author.

Can we surmise that these conclusions were based on scientifically and clinically documented information worth carving in granite?

The guidelines do not say that radiographic deviations or failures to prescribe vitamin C are synonymous with malpractice, but some patients, with or without self-serving ulterior motives, will claim to be unhappy with their results and will obtain the services of attorneys, who will prosecute surgeons for departing from the "wisdom" of the guidelines. We all know there are circumstances—dictated by patient age, underlying diseases, and many other factors—that can lead to our accepting even larger radiographic deviations. Plenty of data indicate that some radiographic deviations from normal are usually clinically inconsequential.

In a given study, a large percentage of patients may be worker's compensation recipients, or may be claiming compensation for an injury sustained in an accident, and may be initiating litigation to obtain more financial benefits based on increased disability. These patients' judgments about their results are likely to be very different from those of patients who are not in these compensation categories.

It may be unwise to accept without questioning the judgment of a small group of experts, who after all are human beings like us, carrying the same innate weaknesses and prejudices. Although the guideline authors have claimed no conflict of interest, most of them have acknowledged industry associations, which might have, consciously or not, affected their views.

In the real world, litigation against surgeons who do not follow the American Academy of Orthopaedic Surgeons' (AAOS) recommendations will increase. Defending his or her actions vis-à-vis complications, a surgeon will have a difficult time proving the selected treatment was appropriate. The plaintiff's attorney will claim the surgeon should have followed the modality that the AAOS "highly recommended." Implant manufacturers will use the guidelines to support claims of "superiority" for their products and will overtly or covertly discredit other manufacturers' implants. Direct-to-customer marketing will be a ready-made vehicle for encouraging litigation.

The clavicle fracture guidelines will likely open a Pandora's box. According to a recent study, 26% of nonsurgically treated patients were unhappy with their final results, but 100% of surgically treated patients were happy. Do these completely subjective assessments pass for evidence-based orthopedics now? Some orthopedists will embrace the new dogmas out of fear of being accused of ignoring the gospel. Others, unscrupulous and greed-driven, will perform surgery, whether it is needed or not, to reap additional financial benefits. The actions of both will inevitably increase the already exponentially growing cost of orthopedic care.

Neither AAOS nor any other representative organization has the authority to recommend the treatments that are most appropriate. The role of these groups is to disseminate information, the knowledge traditionally acquired from personal experience, hundreds of journals and books, and thousands of scientific meetings. It has always been the case that orthopedists have used this information in judging the best treatment modality for each patient.

I have similar concerns about the Joint Replacement Registry. For example, registries allegedly have worked in

Dr. Sarmiento is Professor and Chairman Emeritus, University of Miami, Coral Gables, Florida, and University of Southern California, Los Angeles.

Author's Disclosure Statement: The author reports no actual or potential conflict of interest in relation to this article.

Address correspondence to: Augusto Sarmiento, MD, 10333 SW 72 Ave, Miami, FL 33156 (tel, 305-665-6790; e-mail, asarm@bellsouth.net).

Am J Orthop. 2013;42(6):257-258.

other countries, but their success there does not mean they will work in a similar way in the United States. Our cultural practices and systems differ in many crucial aspects from those of other countries, including those of the Scandinavian countries, and the latter are most frequently used to justify the currently proposed US Joint Replacement Registry.

Even the Maurice Müller AO Documentation Center, a Europe-based project that received millions of dollars' worth of personal and major industrial support over several decades, produced at the end nothing of value.

When I was president of The Hip Society in the late 1970s, I tried to establish a hip registry. My efforts failed. A few years later, Clement Sledge, MD, assumed the presidency and resurrected the project. He also failed.

Later, as chairman of the AAOS Committee on injuries, I proposed that a fracture registry be created. The Board of Directors accepted the proposal and funded a pilot project. A few institutions across the country were selected to participate. Despite this apparently successful start, I soon discovered some participants were fabricating or embellishing data. Immediately I recommended that the AAOS cancel the project.

Subsequent advances in computer technology may have increased registries' chances of success, but human nature has not changed.

The veracity of the data submitted to the Joint Replacement Registry is the seminal and most important issue in the entire project. To assume that every participating surgeon will adhere to high ethical and professional standards is naïve. Will unscrupulous surgeons receiving industry kickbacks to use or market certain implants be tempted to embellish information? There are some unscrupulous surgeons and of course they will be tempted. Will registry officials' plans for dealing with this potential scenario be effective?

The ongoing US Department of Justice investigation into the "corrupt relationship between industry and orthopedists" has already documented a widespread loss of professionalism in our ranks as well as "serious unethical transgressions." Although these infractions are being committed by a small number of people, many of these individuals hold high positions and have an influence that should not be underestimated. For example, academic medicine has a captive audience of medical students, residents, and fellows trained to accept their mentors' right and wrong practices and judgments.

Conclusions reached by registry officials are likely to be accepted by the general population, as many people will assume that participating orthopedists are exempt from unethical flaws. These conclusions, rather than being questioned for accuracy, can become dictates. Once they acquire the odor of sanctity that accompanies all dogmas, these dictates can become difficult to challenge.

Another major concern is that implant manufacturers will come to play a pivotal role in charting the course of the registry. Given the high cost of registry membership, manufacturers will be ready and willing to subsidize participants. Industry representatives, now with a permanent seat at the head table, could eventually dominate the entire effort. If this happens, it will be the end of the game for unbiased evidence-based medicine.

The flood of "new and improved" products, many ridiculous, will not cease. The effective marketing efforts of the industry will not be derailed. Implants that have been fully discredited will continue to be advertised.

I have concluded that the Orthopedic Guidelines and the Joint Replacement Registry, as now structured, will not accomplish what the AAOS and the fellowship want. Quite the contrary, they could become a problem for the profession as a whole.

Instead of devoting time, money, and effort to relatively inconsequential projects, we should temper our infatuations and concentrate on important issues, such as the loss of professionalism in our ranks; the need to shift orthopedics from strictly a business governed by codes of commerce back to its status as a profession; and the need to regain control of education, which we so foolishly relinquished to industry. Correcting this serious situation will silence the embarrassing investigation being conducted by the US Department of Justice. ■

Commentary

Peter D. McCann, MD

In "Thoughts on Orthopedic Guidelines and the Joint Replacement Registry," Dr. Sarmiento challenges us with his keen insights based on his enormous experience in the field of orthopedic surgery as a clinical leader, administrator, and thoughtful educator. He addresses many good points regarding Orthopedic Guidelines and the formation of a Joint Replacement Registry in his characteristically provocative style. As is usually the case, I agree with him on some points and very much disagree with him on others.

Dr. Sarmiento is correct to state that the quality of the data used to establish Orthopedic Guidelines and a Joint Replacement Registry is absolutely essential. Where we differ is in our confidence in our ability to verify that the clinical data is accurate and truthful. The editors and staff of our professional journals deal with this challenge every day, and we have policies and procedures to ensure the accuracy of data included in papers submitted for publication. Are we successful 100% of the time? Certainly not. But we are close.

Dr. Sarmiento is concerned that the recommendations in Orthopedic Guidelines may be used against orthopedic surgeons in malpractice litigation if an orthopedic surgeon does not follow those recommendations. While this is a legitimate worry, I believe there is a simple and logical response: guidelines suggest treatment and are not meant to be rigid rules that must be followed. Guidelines are intended to help orthopedic surgeons make the best choice for their patients and not at all to be accepted as dogma "without questioning."

Finally, I do agree with Dr. Sarmiento on the absolute importance of full disclosures and transparency regarding contributors to Orthopedic Guidelines and a Joint Replacement Registry. We should certainly assume that contributors are professional and have high integrity, but this would not preclude the necessity to verify their submitted data by independent sources.

We are always grateful to Dr. Sarmiento for his stimulating contributions that invariably compel us to review and debate important issues of the day such as Orthopedic Guidelines and a Joint Replacement Registry.

Dr. McCann is Editor-in-Chief of this journal; Chair, Department of Orthopaedic Surgery, Beth Israel Medical Center; and Professor of Clinical Surgery, Albert Einstein College of Medicine of Yeshiva University, New York, New York.