

JOINT REPLACEMENT REGISTRIES: THE HURDLES AHEAD

Augusto Sarmiento, MD
Department of Orthopaedics and Rehabilitation
University of Miami School of Medicine 13-27
PO Box 016960 Miami, FL 33101
USA
Email: asarm@bellsouth.net

Fuelled by the alleged success of the Scandinavian Joint Replacement Registries, interest in the subject in several countries has increased in the recent past. It appears that in the opinion of some, Joint Replacement Registries will settle the many controversies besetting the field by establishing reliable criteria that will chart and guide the future of joint surgery. This radical view might, on the other hand, unintentionally create a system likely to compromise progress.

Despite the attractiveness of Joint Replacement Registries and my sincere desire to see them become a reality, I am of the opinion that there are a number of concerns about their likely success, which, appear to me, have not been addressed as carefully as they need to be. Among them are: 1) The credibility of the information submitted to the main repository and, therefore, the subsequent final conclusions; 2) The role the implant manufacturing industry will play in their unfolding.

I will not allow unrewarding personal experiences with orthopaedic registries to cloud my views, as I realise those experiences took place at a time when the sophistication of computer communications were still in their relative infancy. Nonetheless, I will briefly share them because they might shed some light on the subject at hand.

During my chairmanship of the AAOS Committee on Injuries in 1976 I proposed the establishment of a National Fracture Registry. The Board of Directors approved the project and provided financial support for a pilot study limited to femoral fractures. A handful of major teaching hospitals scattered across the land were to participate in the study. After a short time it became apparent that the information submitted to the central computer was frequently flawed. I requested the termination of the project.

Shortly afterwards, while serving as president of the Hip Society for two consecutive years, I made the creation of a Hip Registry the centerpiece of my administration. Despite the fact the fellowship at that time was probably no larger than 30 orthopaedists, I failed to persuade the group of the benefits of a registry. A computer expert met with the Society's fellowship and tried to convince them of the feasibility of the project. He failed in his objective. For a while I felt the reluctance of some members to go along with the idea was the fear they had of losing their already established systems of documentation. This was despite the fact that they were assured it was indeed not a possibility. Now I realise that their vision was probably better than mine. They anticipated problems which I had dismissed rather cavalierly.

Just a few years later, Clement Sledge, as newly elected president of the Hip Society, revived the idea and tried to make the registry a reality. He also failed after his efforts to have NIH (National Institutes of Health) fund the project proved futile.

More recently, the AAOS has embarked on a similar endeavor, which has been welcomed with great enthusiasm in some quarters. It is about this venture, and similar ones, that I have reservations, which if not properly addressed at an early state might result in bitter disappointment at the end.

In order to illustrate my concerns, I create several potential scenarios and raise some questions.

1) The Scandinavian Joint Registries, which have engendered support to the creation of similar registries, have reported data on a relatively small number of implants; definitely smaller than the American registry would require, since the number of different hip joint implants used in the United States is estimated to be over 300.

It has been stated that the Scandinavian Registry has dramatically reduced the number of complications with certain implants, and has cut in half the revision rate of total hip replacements. I doubt the claim that such reduction was solely due to information produced by the registry. It is hard to believe that the literature had failed to report on those complications long before the Registry displayed its findings.

The Scandinavian countries are smaller and disciplined. Medicine operates under a socialist-like system conducive to the success of registries, since universal or near universal participation is not difficult to achieve. The United States more capitalist laissez-faire system of healthcare delivery does not permit enforced participation, therefore creating obstacles the Scandinavians have not experienced. How does the American Registry, and similar registries, propose to overcome this major hurdle?

What plans do registries, facing this potential problem, have to obtain broad participation by the thousands of orthopaedic surgeons and hospitals throughout the nation? If efforts to gain greater involvement fail, will the project be terminated or be limited to a relatively small number of participants? In this case-scenario, it is likely that a relatively small number of major hospitals and clinics with available funding and already established documentation facilities will constitute the ones feeding data into the Registry. Will this lopsided composition appropriately reflect the status of joint replacement surgery in the general orthopaedic community? Since the cost of operating a registry is expensive and time consuming, wide participation is not likely to occur in many nations.

2) The veracity of the data submitted to registries is the seminal and most important issue in the entire subject. To assume every participating surgeon and institution will adhere to high ethical and professional standards is extremely naïve. Will unscrupulous surgeons, and there are some, with their own prostheses generating them millions of dollars, and others within the same category receiving large kickbacks from industry for using or marketing certain implants, be tempted to provide embellished and false information on successes and failures? How do the registries propose to prevent or deal with this potential scenario? The ongoing investigation of the relationship between orthopaedists and industry by the United States Justice Department, has already documented the growing degree of wide-spread loss of professionalism in our ranks. Though the number of individuals committing the infractions may be relatively small, many of them are well-known individuals whose influence should not be underestimated.¹⁻³ Greater credibility will be given to pronouncements made by registries, since many readers will assume that these organised institutions are exempt from such flaws. Rather than questioning the accuracy of registries publications, their conclusions will become fiats difficult to challenge once they acquire the odor of sanctity that frequently accompany correct and incorrect dogmas.^{3,4}

3) It is reported that the registries provide early warnings regarding trends suggestive of increased risk of failure with various techniques and implants. Will their mechanism of reporting be more effective and expeditious than the existing publications in medical journals, or through presentations at various meetings? Even if it is true, which I doubt, that registries announce complications at an

earlier date, I suspect that there will be times when premature disclosure of trends may do more harm than good.

During the past 30 years, we have witnessed the birth of a number of hip and knee prostheses that because of failures in the hands of some surgeons were soon discredited and many of them removed from the marketplace. That was the fate of unicondylar knee implants, metal-on-metal total hip prostheses, surface replacement arthroplasties, total ankle prostheses and ceramic implants. The orthopaedic community learned about the failure rate of those implants through published reports in peer-reviewed journals and from formal presentations at scientific meetings.

Now, many years later, many of these originally discredited concepts are in use and some of them quite successfully. What would have happened if registries had been in existence at that time? I assume that if registries had made public the initial alleged bad results, it would have been tantamount to permanent commendation that would have made it very difficult for the original investigators, or their successors, to embark in the development of better implants. In other words, can we extrapolate that registries could unwillingly stymie progress and research?

4) Whether we wish to admit it or not, it is likely that the implant manufacturing industry will do its very best to influence the development and conduct of registries. Because the high cost of running them, financial support from Industry will be considered essential by some. If and when Industry begins to play a role, how do the registries propose to establish boundaries of involvement to prevent the eventual take-over of the project, in the same manner that industry succeeded in gaining major control of the education of the orthopaedist through its almost universal subsidy of continuing education? Some might argue that this scenario can be prevented by marketing surveillance and adherence to Codes of Ethics. However, Codes of Ethics, frequently updated, are ignored by many. The number of ethical violations committed in our profession today is many times greater than three or four decades ago when such codes were documents deeply stapled in the original foundations of the discipline.^{3,5,6}

Based on the above concerns and the reality of the current situation, what are the real problems the Joint Replacement Registries attempt to solve? Don't we have enough journals and scientific meetings to make us aware of early failures and successes of implants as it is? Could new methods of publication be established to bring forth on a regular basis summaries of recent data regarding complications and trends of perceived importance?

The leaders of some Joint Replacement Registries are upbeat about the project. However, a precipitous approach to their implementation may not bring about the anticipated results. A sober assessment of a grand narrative would allow them to move forward in a manner more likely to bring success.

I suggest that existing not-for-profit groups, currently studying the results from various documentation centers in a serious and practical manner, be encouraged to continue their work with additional support from the orthopaedic community. We should expect them to eventually render a verdict either favorable or unfavorable to formal Joint Replacement Registries.

References

1. **Christie C.** Five companies in hip and knee replacement industry avoid prosecution by agreeing to compliance rules and monitoring. *Public Affairs* Sept 27, 2008
2. **Sarmiento A.** Medicine and industry: the payer, the piper and the tune. *Annals-royal college of physicians and surgeons of canada.* 2000;33:144-9.
3. **Sarmiento A.** *Medicine challenged. Publish America, 2008*
4. **Carr AJ.** Which research is to be believed?: the ethics of industrial funding. *J Bone Joint Surg [Br]* 2006;87-B: 1452-3.
5. **Callahan D, Wasunna A.** *Medicine and the market: equity vs choice.* John Hopkins, 2006
6. **Cruess R, Cruess SR.** Teaching medicine as a profession in the service of healing. *Acad Med* 1997;72:941-53.