Guest Editorial

The next critical role of orthopedic registries

There is an urgent need for the introduction of new implant technology in orthopedic surgery to be conducted in a more controlled manner than in the past. Inadequate regulation and lack of effective post-market surveillance have meant that patients have not been protected from potentially harmful implants and procedures. Compounding the problem is a lack of questioning, a lack of critical appraisal, and lack of a requirement for clinical evidence by both surgeons and manufacturers before large-scale introduction of new technology to the market.

There is a long and growing history of failed innovation, demonstrated by the failure or recall of individual products such as Boneloc (bone cement), The Capital Hip (total hip arthroplasty), and the ASR hip system (total hip arthroplasty) among others, as well as whole classes of devices such as large-head metal-on-metal bearings. This demonstrates simple, yet severe flaws in the mechanisms that should protect patients from increased risk associated with introduction of new technology. Insufficient or inadequate preclinical data, a lack of clinical data from timely RSA (radiostereometric analysis) studies, and limited larger, multicenter cohort studies prior to general release all increase the risk to patients. The 510k process, where the majority of so-called innovative new designs have been cleared or approved by FDA- or CE-notified bodies for clinical use, is based on similarities to previously used implants. In the 510k process, there is no requirement for specific clinical evidence, so manufactures have not obtained clinical data. Registry post-market surveillance has proven to be a powerful method for detection of increased risk of implant failure, but this is not available in all countries. When registries do identify poor-performing devices, regulators and manufacturers are often slow to respond. The main problem with the current approach to the introduction of new technology is the inability to identify unanticipated failures before wider release (Bauer 1992).

It is 20 years since the stepwise introduction of new implants was first described (Malchau 1995). The basic concept of this approach is that the smallest possible numbers of patients (after sufficient preclinical testing) are exposed to the implant prior to general release. Stepwise introduction uses a combination of (1) outcome measurements with high-precision metrics in small cohorts, such as RSA, and (2) limited clinical introduction in a larger cohort, prospectively monitoring outcomes and revisions. Adoption of this concept would certainly have reduced the large number of poor-performing new implants introduced in recent years. The concept has, however, never been implemented due to lack of support from surgeons, manufacturers, and regulatory authorities.

Now trends have changed, with increasing focus on implementing an effective approach to pre-release clinical assessment. The ongoing work and discussions in the International Society of Arthroplasty Registries (ISAR), the reports from the Australian Orthopaedic Association total joint registry, and the actions taken in the UK to put a "beyond compliance" program into action will facilitate a more cautious market introduction. In addition, the Arthroplastywatch project (www.arthroplastywatch.com) is in action: data are collected on the web through a specially developed search routine. Based on examination in several steps using medical and statistical expertise, a caution could be warranted or a warning declared. These combined initiatives say one thing: that close monitoring of new implants by well-established registries during a phase of controlled introduction must be a universal requirement.

We propose a structured model for clinical trials involving 4 levels: (1) a pure observational study using reoperation data from multiple registries, as shown in several papers by the Nordic Arthroplasty Register Association (NARA); (2) patient-reported outcome measures, either from national implant registries or from other registries for specific studies; (3) radiographic data plus other parameters such as blood levels of metal ions, based on specific needs for a new technology; and (4) options for randomized studies with use of, for example, RSA in the evaluation. The cornerstone in this structural model should be the expanded use of existing and future registries with a high degree of coverage and completeness.

While registries have a strong tradition in arthroplasty surgery, this is not as well developed in other areas of orthopedic surgery. It is the responsibility of orthopedic surgeons and their professional bodies to support and implement registries where they can be of benefit. The arthroplasty registry experience has shown that it is possible to use registries to effectively monitor the introduction of new technology. Without this registry-based surveillance, identification of many of the failed innovations would have been delayed or might even have gone unrecognized. It is encouraging that registries in fracture surgery are now emerging, where implants are inserted in large and increasing numbers.

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Finally, implant performance is potentially confounded by the technical difficulty of inserting the implant, the knowledge and abilities of the surgeon inserting them, and the complexity of the cases. Many registries monitor performance at the surgeon level. This together with continuous education and training in how to use new implants should be an integral part of the process of a more cautious market introduction. If training is linked in with the stepwise introduction, it will be possible to identify the need for and the extent of training.

Our proposed regulatory change to require registry-based monitoring of new implants during the phase of limited introduction must be accompanied by a change in the way we think and act as orthopedic surgeons. In the training of future orthopedic surgeons, emphasis must be placed on developing a healthy skepticism to innovation, on recognizing the need for evidence-based introduction, and on building a culture holding the view that reporting to a registry is imperative. The registries will then be able to offer back data to enable surgeons to choose the best clinical practice.

To increase innovation and to ensure that innovation is effective and beneficial, the role of registries should be expanded. The registries should not undertake the role of a regulatory authority, but in compliance with the industry and the orthopedic community they should ensure that a more cautious approach is used when new technology is introduced. This could lead to a better balance between the inborn conservatism that a registry represents and the continuous need for innovation.

The independence, infrastructure, and expertise of the registries can be used more fully to optimize how new implants are introduced. All stakeholders need to join to ensure that first and foremost, we do no harm.

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