Guest Editorial

New Medical Device Regulations ahead – What does that mean for Arthroplasty Registers?

Background

Against the background of several major adverse incidents involving orthopedic implants, such as the Articular Surface Replacement (ASR) hip arthroplasty, the European Union (EU) Commission and the US Food and Drug Administration have addressed the issue of component safety and post-market surveillance. The aim is to improve the quality of care and patient safety (Sedrakyan 2012a, b). The regular procedures of CE approval and market monitoring and also the basic data used for these processes—for the most part derived from clinical and experimental studies—were unable to ensure sufficient patient safety and prevent adverse events (Godlee 2011).

The EU therefore intends to recast the Medical Device Directive, which forms the basis for national medical device legislation (Medical Device Directive, last amended in September 2007).

One of the main reasons for the deficiencies in identifying inferior products is the difference in methodological requirements between pharmaceutical and medical devices regarding clinical studies, which serve as a basis for decisions. At present, the regulatory processes do not adequately consider fundamental differences between orthopedic implants and drugs, such as limitations in randomization and blinding during surgical interventions, or the often long time until implant failure (Curfman and Redberg 2011). The validity of clinical cohort studies concerning medical devices is limited and includes a high risk of misinterpretation (Labek et al. 2011a, b).

We argue that comprehensive data collection by means of high-quality registries can make a substantial contribution to solving this serious issue that physicians and other decision-makers in the public health system are facing.

Regulator's request

The new regulations will involve 3 major measures:

1. Recognition of all outcome data available, including clinical studies and registry data. At least once a year, manufacturers will have to submit safety reports to be assessed by notified bodies (such as BSI (British Standards Institution) or TÜV (Technischer Überwachungsverein)). Every 5 years, CE-recertification processes will have to be conducted based on a methodology that takes account of the typical circumstances of medical devices, which will be defined in the next few years. If the CE certificate is not issued, the implant will be excluded from the market.
2. Regulators at the national and EU levels will perform expert reviews. The proposal by the EU Commission includes "device-specific expert panels" supporting a Medical Device Coordination Group at the EU Commission, a group including physicians from the individual medical fields. Since registry data will be a core dataset for assessment, experts on that topic will be welcome.
3. Article 83 of the proposed Medical Device Directive update and also the "Dalli Action Plan" published in 2012 as an immediate reaction to incidents that have occurred, compel all EU member states to establish registries for all high-risk medical devices—not only those used during arthroplasty, but also frequently used products in other medical fields, such as pacemakers, stents, ocular lenses, and cardiac valves.

Existing registries will be standardized in order to support multinational assessment of aggregated datasets. Countries that have not yet implemented registries are requested to set up such monitoring systems. First attempts at standardization of processes and methodology are in progress at the EU Joint Action PARENT, and expansion of these activities is to be expected.

The final goal is to spread the positive effects evident from existing registries, e.g. those in Scandinavia, to the entire European Union.

Effects of novel device regulation on registries and physicians

At present, there is no accepted standard (by regulators) regarding the features that characterize a good registry. The Scandinavian concept that has been implemented in all successful arthroplasty registries in Europe today, i.e. registration of all interventions performed in a given geographic area in a central database and life-long monitoring of the patients who received the implants in question, has proven to be efficient (deSteiger et al. 2011, Smith et al. 2012, Seppänen et al. 2012). But there are other, much more general definitions—e.g. by AHRQ (Agency for Healthcare Research and Quality)—which would include a large proportion of sample-based clinical studies (Polygenis 2013, Gliklich and Dreyer 2014). As a consequence, the final goal of improvement in patient safety might be compromised. The need for development of a specific methodology for registry data appears logical and well-founded. Orthopedic surgeons, statisticians, and public

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health experts should take an active role in this process, as registry data will also be used for decisions in public health in the future. Registries must be an integral component of the respective national health system and take account of the general framework in order to be effective. The Scandinavian registries have provided impressive evidence of this over the past couple of decades; complication rates have been reduced significantly. Sweden has the lowest documented revision rate worldwide (Swedish Hip Arthroplasty Register, Annual Report 2013). Inferior implants have been detected early and surgeons have stopped using them without any legislation being involved (Furnes et al. 1997). One should, however, consider that the basic conditions in these countries have been particularly favorable for the development of registries. This has enabled physicians and registry experts in these countries to take a key part in data use in a variety of fields.

In other countries such as Germany, the UK, and the Netherlands, the circumstances require entirely different organizational structures for registries. Public health authorities, healthcare financiers, and other stakeholders, such as patients and implant manufacturers, also need to be involved in data collection and storage. Linking of all data to a unique patient identifier must comply with strict privacy regulations and requires extensive data security measures—or it would increase the administrative burden through the necessity to obtain every individual patient's consent and to document the procedure in every single case (EPRD flowchart, NJR Annual Report 2014).

The increasing use of registry data by a growing number of stakeholders demands that the collection of the data must be standardized and harmonized, e.g. regarding uniform product classification or evaluation procedures.

Regulators such as the EU Commission are planning to reinforce the monitoring of medical devices in the future. An essential aspect of this will be the requirement that all the data available should be submitted for examination. Registry data, as a reflection of the reality of patient care, will have particular importance attached to it. Just as is current practice in registries, the intention is to establish a regular accompanying post-marketing surveillance process. Registry experts should take a substantial part in all aspects of data interpretation. This, however, would require formal cooperation with the authorities.

The future regulation will recognize registries as a core facility of market monitoring, assessment of innovations, and improvement of patient care. It is likely that registries will become obligatory in time. Cooperation between stakeholders according to the given legal function of each of them will be essential for the success of the new regulation. Orthopedic surgeons could achieve a position that would have seemed inconceivable only a few years ago.

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