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EDITORIAL



The value of hip and knee arthroplasty registries

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1. Introduction

Almost half a century ago, in 1975, the Swedish Knee Arthroplasty Register was established, which was the first knee arthroplasty registry on a national level. A couple of years later, in 1979, the hip registry was founded also in Sweden, which was the first national hip arthroplasty register in the world. Other countries soon followed [1–3].

1.1. Maturity levels of joint replacement registries

Hip and knee arthroplasty registries are uniquely developed to provide real-world and real-time information about caregivers, hospitals, implants, and surgical techniques [4]. They also allow case identification in the event of product recall or adverse surgical outcomes, they provide insight into practice variation, and they are a valuable data resource for research [1,4]. All these features correspond to different levels of maturity, which are depicted in [Figure 1](#). A classification system on maturity of arthroplasty registries allows measurement of maturity and it could provide valuable insight into the factors and time needed to achieve a particular maturity level. Knowledge on the maturity level may thus provide insight into the present and the future features of a registry: Where is the registry now? What is realistic to expect within 5 years? Is an outlier analysis possible in the future given a certain number of patients (n) and certain number of groups of interest (k)? Maturity may be expressed in the following levels: pre-registration, incomplete registration, early complete registration, and mature complete registration. Most hip and knee arthroplasty registries have obtained high levels of completeness of coverage in excess of 95% and have matured sufficiently to allow assessment of outliers in both caregivers and implants [5]. This corresponds to the highest maturity level of 'mature complete registrations.' When registries are complete and in an early phase, they may be called 'early complete registries.' Although early complete registries do not yet have the capability to perform outlier analyses, they may be used for outcome assessment in more general terms: comparing

implants according to design rationales such as posterior stabilized total knee replacements with cruciate retaining total knee replacements or by determining outcomes according to patient characteristics. When high levels of completeness have not yet been reached, the maturation level may be called 'incomplete registration.' Despite lack of high levels of completeness, arthroplasty registries with this maturity could already be used for gaining insight into practice variation, for tracing patients in case of a recall, and for direct feedback to caregivers through a dashboard. There may be an unaddressed clinical need in a country for a registry and there may have already been some work performed on building a registry, but the registry is not yet working. This maturity level may be called 'pre-registration.' During pre-registration, it is important to consider the desired maturity level that the new registry may eventually achieve as well as the estimated time to achieve this level as this may differ for e.g. registries on elbow arthroplasties when compared to registries on knee arthroplasties.

1.2. Post-market surveillance: metal-on-metal hip implants

An important function of hip and knee arthroplasty registries is the monitoring of implant and surgical performance to enhance patient safety [4]. The importance of this function has become evidently clear with the role of hip arthroplasty registries in the detection of significantly higher revision rates for metal-on-metal hip implants [6]. These implants comprise resurfacing hip arthroplasty with metal-on-metal articulation and total hip arthroplasty (THA) with metal-on-metal articulation. Regarding the latter, studies have shown that metal-on-metal THA with large femoral heads (32 mm or greater) were more problematic than small head THA [6]. In an international registry study, the 10-year risk of revision was 12.1% for resurfacings and 15.5% for stemmed large head metal-on-metal THA compared to 5.1% for conventional THA without metal-on-metal articulation [7]. The

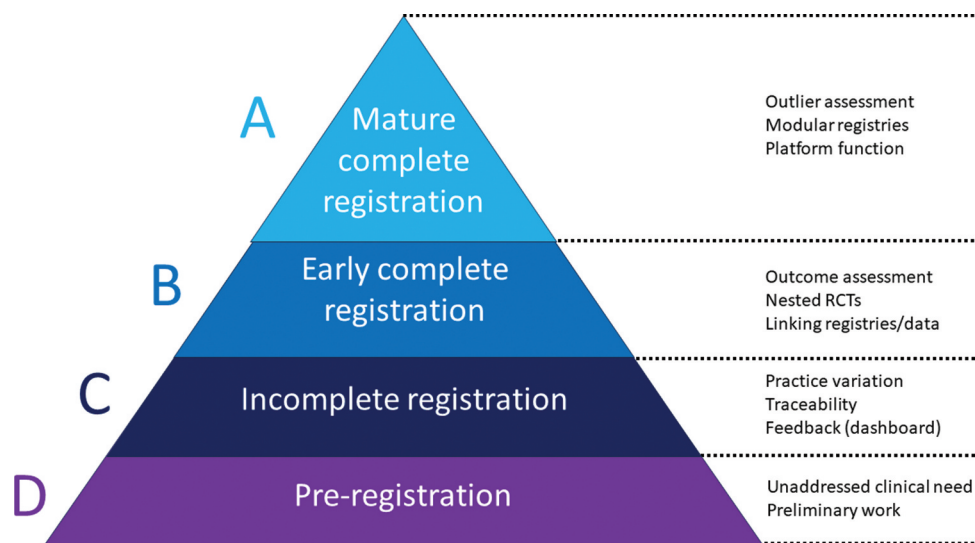


Figure 1. Schematic representation of the maturity levels of joint replacement registries and features associated with each level.

Australian Orthopaedic Association National Joint Replacement Registry has been the first hip arthroplasty registry to identify the problems with metal-on-metal hip implants and this was later confirmed in other registries [6].

1.3. Post-market surveillance: influence of manufacture and packaging process

While post-market surveillance of implants by hip and knee arthroplasty registries has historically focused on implant types and systems, a recent recall of a total knee arthroplasty (TKA) systems has shown that changes of the manufacture and packaging process may also introduce unexpected higher revision rates [8]. In case of this TKA, the poly-ethylene inserts were packaged without a protective oxygen-resistant barrier layer starting in 2004 [8]. This package without a protective layer may lead to oxidation of the poly-ethylene inserts in the period between manufacturing and implantation during surgery [8]. Oxidation of the poly-ethylene insert prior to surgery may predispose these implants to increased poly-ethylene wear and osteolysis, which could lead to higher than expected revision rates for aseptic loosening [8]. Indeed revision rates of 14% have been reported for the re-called TKA at 10-year follow-up compared to expected revision rates of 5% [8]. This increased revision rate of this TKA was mainly driven by revision for aseptic mechanical failure with in some cases implant debonding from the cement [8]. Prior to the recall, this TKA has been identified as an outlier implant with higher than anticipated rates of revision by several knee arthroplasty registries including the Australian Orthopaedic Association National Joint Replacement Registry, the National Joint Registry (covering England,

Wales, Northern Ireland, the Isle of Man, and Guernsey), and the Dutch Arthroplasty Registry [9]. Identification of the re-called TKA as an outlier implant by these registries has contributed to discovering that the failure mechanism was related to the package method. This package method was not only used in poly-ethylene insert of this TKA, but it was also used in ankle arthroplasties and total hip arthroplasties of the same company. Hence, these ankle and hip poly-ethylene components also became part of the recall. The issues with the re-called TKA underline the importance of longitudinal post-marketing surveillance and outlier analyses by hip and knee arthroplasty registries. At the same time, the issues with the packaging of the re-called TKA serve as a reminder that unexpected failure mechanisms do happen.

1.4. The value of hip and knee arthroplasty registries

It has been shown that the activities of the hip and knee arthroplasty registries have reduced the revision burden with approximately 20% compared to the non-registry period, when the registry did not yet exist [10]. This estimate has been controlled for spillover and technological progress effects [10]. While this temporal relation does not necessarily imply a causal relation, reduction of revision rates in time has been reported by several arthroplasty registries [6,11–13]. For a more detailed example, one could have a look at the results from the Dutch Arthroplasty Registry [11]. The 5-year revision rate for primary unicompartmental knee arthroplasty (UKA) has dropped from 9.7% for patients who received UKR in 2009–2010 to 3.9% for patients who received UKA in 2017–2018, see Figure 2 [11]. With 7000 patients receiving a UKA annually in the Netherlands, this

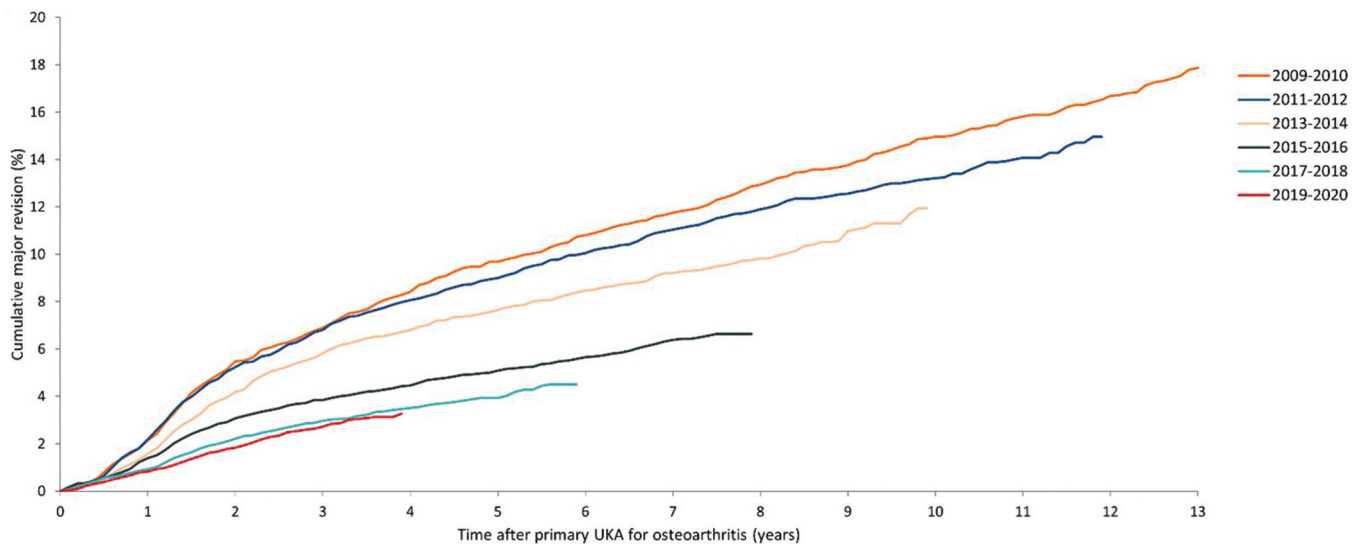


Figure 2. Graph showing cumulative major revision percentage of UKA for primary osteoarthritis by procedure year in the Netherlands. The revision percentages decrease with procedure year showing an overall improvement of safety for patients in time.

risk reduction of 5.8% may result in approximately 400 patients annually who do not have to undergo revision surgery compared to patients who received UKA in 2009–2010. For TKA and THA, the revision rates have also decreased in time. For instance, the 5-year revision rate for primary TKA has dropped from 2.40% for patients who received TKA 2009–2010 to 1.88% for patients who received TKA in 2017–2018 [11]. With 26,700 patients receiving a TKA annually, this risk reduction of 0.52% may result in approximately 139 patients annually who do not have to undergo revision surgery compared to patients who received TKA in 2009–2010. Finally, the 5-year revision rate for primary THA has dropped from 2.71% for patients who received THA in 2009–2010 to 2.18% for patients who received THA in 2017–2018 [11]. With 36,700 patients receiving a THA annually, this risk reduction of 0.53% may result in approximately 195 patients annually who do not have to undergo revision surgery compared to patients who received THA in 2009–2010. Taken together, these observations suggest that for approximately 734 patients, revision surgery may be prevented annually. Assuming that revision surgery costs 20,000 euro [14], this translates into an annual cost reduction of approximately 14.7 million euro in the Netherlands alone. These numbers are not a formal cost-effectiveness study and should be interpreted as an indication of the cost-saving potential of hip and knee arthroplasty registries. Nevertheless, they clearly show that the devotion of hip and knee arthroplasty registries to patient safety results in decrease of revision rates and costs in time.

It is also important to consider the limitations of hip and knee arthroplasty registries. These registries play a crucial role in post-market surveillance, and the data generated in their databases has been gathered for this reason. Therefore, hip and knee arthroplasty registries could have limited data for some research purposes when particular prognostic factors are missing [4]. Additionally, it is uncommon for hip and

knee arthroplasty registries to contain information on the clinical decision process, which could lead to problems for certain analyses due to confounding by indication [4]. This is apparent, for instance, when evaluating mortality in patients with metal-on-metal THA compared to patients with nonmetal-on-metal THA, because the former could be fitter and living healthier leading to confounding by indication [15].

As types of prostheses, manufacturers, orthopedic surgeons, surgical techniques, hospital policy, patient populations, and legislation are never constant and such changes may positively or negatively impact patient safety, hip and knee arthroplasty registries continue to be vital for the monitoring of implant and surgical performance to enhance patient safety.

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Declaration of interest

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