A Scandinavian Experience of Register Collaboration: The Nordic Arthroplasty Register Association (NARA)

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Background: The Nordic (Scandinavian) countries have had working arthroplasty registers for several years. However, the small numbers of inhabitants and the conformity within each country with respect to preferred prosthesis brands and techniques have limited register research.

Methods: A collaboration called NARA (Nordic Arthroplasty Register Association) was started in 2007, resulting in a common database for Denmark, Norway, and Sweden with regard to hip replacements in 2008 and primary knee replacements in 2009. Finland joined the project in 2010. A code set was defined for the parameters that all registers had in common, and data were re-coded, within each national register, according to the common definitions. After de-identification of the patients, the anonymous data were merged into a common database. The first study based on this common database included 280,201 hip arthroplasties and the second, 151,814 knee arthroplasties. Kaplan-Meier and Cox multiple regression analyses, with adjustment for age, sex, and diagnosis, were used to calculate prosthesis survival, with any revision as the end point. In later studies, specific reasons for revision were also used as end points.

Results: We found differences among the countries concerning patient demographics, preferred surgical approaches, fixation methods, and prosthesis brands. Prosthesis survival was best in Sweden, where cement implant fixation was used more commonly than it was in the other countries.

Conclusions: As the comparison of national results was one of the main initial aims of this collaboration, only parameters and data that all three registers could deliver were included in the database. Compared with each separate register, this combined register resulted in reduced numbers of parameters and details. In future collaborations of registers with a focus on comparing the performances of prostheses and articulations, we should probably include only the data needed specifically for the predetermined purposes, from registers that can deliver these data, rather than compiling all data from all registers that are willing to participate.

As the results of hip and knee arthroplasty surgery are generally good, it is difficult and expensive to conduct large enough randomized controlled trials for timely detection of rare events, such as early implant loosening or adverse tissue reactions. Unexpected events have also been discovered in association with hip and knee implants previously approved on the basis of randomized controlled trials after these devices have been inserted into large numbers of patients[1]. Internationally, it has been observed that large register studies sometimes have greater abilities than randomized

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controlled trials to discover rare but serious events such as death. While postmarketing surveillance of hip and knee prostheses is to be recommended[2], a requirement for hip or knee implants to be investigated in register studies before approval would probably be too time-consuming, impractical, and expensive.

On the other hand, as registers sometimes have revealed inferior results after only a few years of observation[3], questions may be raised regarding whether new implants should be introduced only in countries or regions with well-functioning registers, or whether countries where new implants commonly are introduced should create registers.

The Nordic countries, including Denmark, Sweden, Finland, Iceland, and Norway, have a total population of about 25 million people, and there have been arthroplasty registers in Sweden, Finland, Norway, and Denmark for many years[4-9]. However, from an international perspective, the separate registers represent small populations, which may result in statistical problems, especially when they are used to study uncommon events/end points, uncommon implant brands, or otherwise small groups of patients. Furthermore, the methods of publishing register results in journals and annual reports have not been comparable among the registers.

With this background, it was decided in 2007 to improve the opportunities for research by initiating a Nordic collaboration (NARA [Nordic Arthroplasty Register Association]) establishing common databases embracing selected data for arthroplasty surgery that had been gathered by the individual arthroplasty registers. Because of a needed reorganization of their register, the Finnish register representatives postponed participation until 2010, when they were able deliver data to NARA.

Although they are closely related, the countries differed with regard to patient selection and choices of implants and fixation methods. Furthermore, the registers themselves differed with respect to their methods of collecting data, variables recorded, and statistical methods, and their databases were incompatible. In spite of these difficulties, it was possible to produce a combined database and perform relevant analyses.

In 2010, an initiative was taken from the Food and Drug Administration (FDA) in the U.S. to explore the possibilities for a larger collaboration among arthroplasty registers than NARA, and almost all national, regional, and large hospital-based joint arthroplasty registers were invited. After the first meeting, in May 2011, of this organization (the International Consortium of Orthopaedic Registers [ICOR]), we were invited to write about our experiences from our collaboration among the Nordic arthroplasty registers.

The aim of the present article is to explain the NARA system, including its organization, database, methods, and results as well as our experiences in general.

Materials and Methods

The process of making a common database took a few years. Several meetings were held before the databases for total hip and knee arthroplasties could be defined. In addition, statutes and contracts were agreed on and signed.

In Norway there is one arthroplasty register with databases for hips and knees, while in Denmark and Sweden there are separate hip and knee arthroplasty registers. The national registers were started at different times: the Swedish knee register was begun in 1975; the Swedish hip register, in 1979; the Norwegian arthroplasty register, in 1987; the Danish hip register, in 1995; and the Danish knee register, in 1997.

The hip arthroplasty registers participated in the first study during 2008, and as all three registers had individual-based registration of operations from 1995 it was decided to select primary total hip replacements performed during 1995 to 2006 for this study[10]. Similarly, for the second study—on knees—in 2009, primary knee replacements performed during 1997 to 2007 were included[11].

The different national databases were not directly compatible as they used different ways of collecting data and different registration forms, not always including the same variables and to some extent using different definitions of variables. Therefore, a process of defining a minimal set of parameters containing only parameters and data that all three hip or knee registers could deliver was needed, to determine the maximum possible set of common data.

Variables

Some variables, such as age, date of primary operation, date of revision, date of death, sex, and laterality, were well defined while other variables were more problematic.

For both hips and knees, the registers varied with regard to whether the fixation was registered as one joint implant (e.g., cemented, uncemented, or hybrid variants) or was registered separately for different implant parts. This problem was solved by transforming information for those registering fixation for individual components into one parameter classifying the fixation for the whole implant.

Diagnoses were classified differently among the registers, and the numbers of diagnoses allowed on the registration forms differed as well. Some registers allowed reporting of any diagnosis, while others allowed use of only the diagnoses specified on the reporting forms. As the first hip paper only included data that all of the registers could deliver, there was a reduced list of diagnoses grouping all inflammatory diseases together as well as all childhood hip diseases and all diagnoses related to hip fractures. The first knee article was even more restrictive, as it had only three groups: osteoarthritis, rheumatoid arthritis, and "other." In later hip papers, the solution was to keep the specified diagnosis when available and to keep the summarized groups for data from the registers that could not deliver the specific diagnosis.

With respect to the surgical approach for the hip arthroplasties, one of the registers could only produce data specified as a posterior surgical approach or other approaches, so this became the common classification in the NARA database after reclassification of the data from the two other registers containing more detailed information. Of the three knee registers, only one documented the surgical approach so the surgical approach was eliminated from the common knee database.

Regarding the reasons for revision, the registers had their own classifications, with the number of reasons for revision listed differing among the registers. A common classification was established on the basis of the register that had the fewest available reasons. For example, revisions due to aseptic loosening, wear, damaged polyethylene, and osteolysis were classified together. As a result, the decision was made to use only revision for any reason as an end point in the implant survival analysis in the first two papers. The list of reasons for revision was expanded for later hip studies because the register with the fewest options had been able to acquire more specific information from the patients' records.

There were also differences with regard to classification of the types of revision procedures. One register could not distinguish between exchange of the acetabular cup and exchange of only the liner, or between exchange of the femoral component and exchange of only the femoral head. Therefore, the common hip classification resulted in four types of revision procedures: exchange of the total prosthesis, exchange of the acetabular cup or liner, exchange of the femoral stem or head, and extraction of the total prosthesis (Girdlestone procedure). As a result of the larger number of components often used in knee arthroplasties, the types of revision procedures in the knee are more numerous than those in the hip, and the common classification is not finished.

With respect to catalogue or part numbers, two hip and knee registers recorded all implant parts on a catalogue-number level, while one hip and knee register used brand names and did not have catalogue numbers. Thus,

TABLE I Description of the NARA Data File on Total Hip Replacements

Variable	Position	Label	Measurement Level
Nation	1	Country	Nominal
PatID	2	Patient's unique serial number	Nominal
Age	3	Age at primary total hip replacement	Scale
Gender	4	Gender	Nominal
Side	5	Laterality	Nominal
DiaCode	6	Diagnosis code	Nominal
DatePri	7	Date of primary total hip replacement	Scale
HosCode	8	Hospital code (country-specific)	Nominal
FixType	9	Type of fixation, resurfacing or not	Nominal
Cup	10	Cup component (country-specific)	Nominal
Stem	11	Stem component (country-specific)	Nominal
TrocOst	12	Trochanteric osteotomy used	Nominal
MIS	13	Minimally invasive surgery used	Nominal
PostApp	14	Posterior approach used	Nominal
CemType	15	Type of bone cement (country-specific)	Nominal
DateDis	16	Date of death	Scale
RevCause	17	Cause of revision	Nominal
DateRev	18	Date of revision	Scale
SurgProc	19	Surgical procedure at revision	Nominal

the common database used brand names for the implants as well as for the cement.

Two hip registers had a specific parameter classifying a total hip replacement as either conventional or resurfacing, while the third used catalogue numbers of the femoral components to identify those that were resurfacing prostheses. The structure of the final hip database is given in Table I.

Regulations

In all countries, each patient had a personal national civil registration number and, due to regulations, the patients needed to be de-identified and anonymous. This was achieved by deleting the national civil registration numbers, including the date of birth. Each patient was given a unique serial number in the new database and a code for nationality. Hospitals were also de-identified and given an anonymous serial number. This process had to be performed within each national register, and only de-identified anonymous data were merged into the common NARA database. Data had to be treated with full confidentiality according to the regulations of the respective countries; this included limiting the access to the common database to persons listed as coauthors of the planned papers. Furthermore, in all presentations of results, such as in scientific articles, it is necessary to state that it is not possible to identify patients on an individual level either in the paper or in the database.

The study was approved by the Danish Data Protection Agency, J.nr. 2008-41-2024, and by the Norwegian Social Science Data Services.

Statistical Analysis

The initial two papers mainly focused on descriptive statistics and age and sex-specific incidences in the three countries as well as implant survival statistics with use of revision for any reason as the end point in the analyses. Revision was defined as removal, exchange, or addition of implant components and included an isolated exchange of an acetabular or tibial liner or only a femoral head or patellar button. For survival curves, we used the Kaplan-Meier method, and the curves were cut when the number of patients left at risk was less than 100. Patients were censored at death, emigration, or the end of the inclusion period (2006 for hips and 2007 for knees). Cox multiple regression analysis was used for assessment of survival and relative risks (RRs) for revision with use of any revision as the end point, with adjustment for age, sex, and diagnosis. Ninety-five percent confidence intervals (CIs) were given.

The chi-square test was used to test differences in patient and procedure characteristics.

If the conditions for Cox regression were not fulfilled during the total time period, additional time-dependent survival analyses were performed dividing the follow-up into two time-periods.

The statistical packages SPSS, version 15.0 (SPSS, Chicago, Illinois) and S-Plus 7.0 (Insightful Corp., Seattle, Washington) were used for the analyses.

Results

So far, six articles from the NARA collaboration have been published in international scientific peer-reviewed journals[3,10-14], and several articles are in process or planned. In the more recent hip studies, the inclusion period was expanded, and we have collected more data on the reasons for revisions as well as on the procedures performed at the revisions. The Finnish register joined the NARA in 2010 with its data on hip arthroplasty, and Finland will participate in future studies.

In the first study, on 280,201 hip operations (Denmark, 69,242; Norway, 70,138; and Sweden, 140,821), females constituted 60% of the patients with hip replacements in Denmark and Sweden and 70% in Norway, and patients with childhood hip disease constituted 9% in Norway and 3.1% and 1.8%, respectively, in Denmark and Sweden[10]. The posterior approach was, in the first study, used in 91% of the cases in Denmark, 60% in Sweden, and 24% in Norway, and cemented total hip replacements were applied in 46%, 89%, and 79% of the patients in

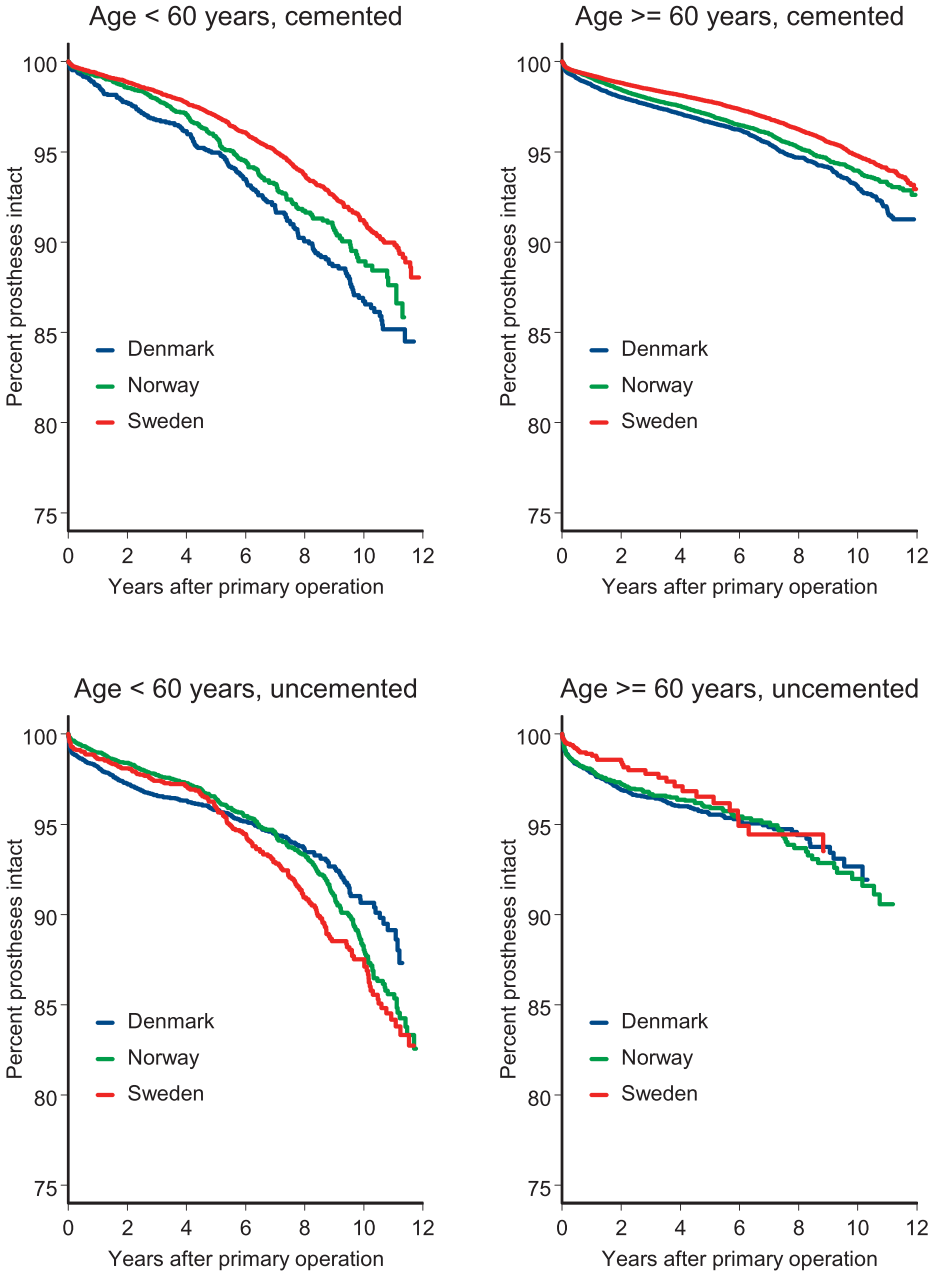

Fig. 1

Kaplan-Meier estimated survival curves, with revision for any cause as the end point, for primary cemented and uncemented total hip replacements in Denmark, Sweden, and Norway from 1995 to 2006. (Reproduced, with permission, from: Havelin LI, Fenstad AM, Salomonsson R, Mehnert F, Furnes O, Overgaard S, Pedersen AB, Herberts P, Kärrholm J, Garellick G. The Nordic Arthroplasty Register Association: a unique collaboration between 3 national hip arthroplasty registries with 280,201 THRs. Acta Orthop. 2009 Aug;80[4]:393-401.)

Denmark, Sweden, and Norway, respectively. The overall national revision rates differed, with the highest revision rate in Denmark and the lowest rate in Sweden (Fig. 1). The longer-term revision rates for the uncemented hip prostheses were lowest in Denmark.

In the second study, concerning 151,814 knee arthroplasties (Denmark, 38,411; Norway, 26,451; and Sweden, 86,952), Norway had a much lower number of knee procedures per hospital than Sweden or Denmark[11]. There were substantial differences in implant selection among the countries, and while a patellar button was used in 76% of the total knee replacements in Denmark it was used in only 11% and 14% of those in Norway and Sweden, respectively. Uncemented or hybrid fixation was also more common in Denmark (22%) than in Norway (14%) and Sweden (2%) (Fig. 2). Furthermore, Sweden had the lowest risk of revision; compared with Sweden, the

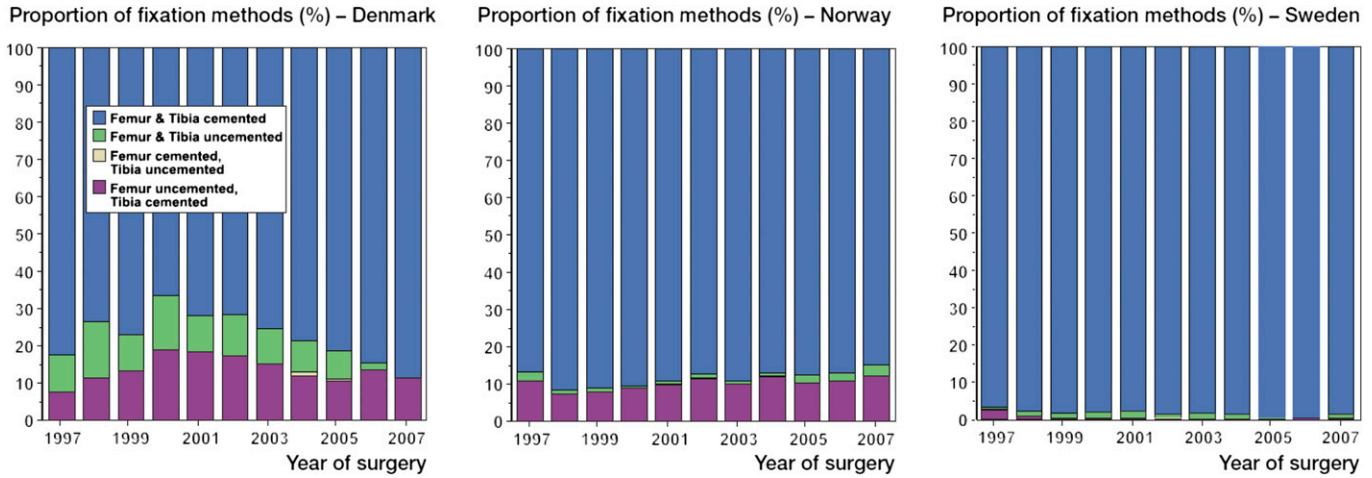

Fig. 2

Proportion of fixation methods for primary total knee arthroplasty in Denmark, Norway, and Sweden. (Reproduced, with permission, from: Robertsson O, Bizjajeva S, Fenstad AM, Furnes O, Lidgren L, Mehnert F, Odgaard A, Pedersen AB, Havelin LI. Knee arthroplasty in Denmark, Norway and Sweden. Acta Orthop. 2010 Feb;81[1]:82-9.)

relative risks (RRs) for revision of total knee prostheses were 1.4 (CI, 1.3 to 1.6) and 1.6 (CI, 1.4 to 1.7) in Norway and Denmark, respectively. For unicompartmental knee replacements, the RRs were 1.5 (CI, 1.3 to 1.8) and 1.7 (CI, 1.4 to 2.0) for Norway and Denmark, respectively.

Since the publication of the initial hip and knee studies, the results of resurfacing hip arthroplasty compared with conventional hip arthroplasty have been studied[3]. In that paper, there was an almost threefold increased risk for revision with resurfacing arthroplasty. Within the resurfacing group, the results were significantly better with the Birmingham prosthesis than with the other resurfacing brands, and the results were also better in hospitals that had performed more than seventy resurfacing procedures than in hospitals with fewer procedures.

The NARA group has also had two publications on statistical analysis of arthroplasty data[12,13]. Standard statistical methods such as life tables, Kaplan-Meier estimates, log-rank tests, and Cox regression analyses are explained in the first article. In the second article, guidelines are given and issues such as competing risks, proportional hazard assumption, and bilateral observations are discussed.

The NARA collaboration has also resulted in a review article on prevention of deep infection in patients treated with joint replacement surgery[14]. In that article, the value of large registers in this field, in which rare events such as infection are the subject, is discussed, and the authors point out the value of including data from other sources, such as hospital discharge data and patient register data.

Discussion

The NARA collaboration, with its systems for selection, transformation, and merging of data, has been functioning. The basic requirements for the collaboration were good data quality, >90% coverage and completeness, and validated data, to obtain reliable results. The collaboration was only possible because of trust, agreement, and cooperation as well as a serious purpose to work for improved outcomes after hip or knee arthroplasty surgery.

The first two articles concentrated on the development of methods and comparison of the overall results of total hip arthroplasty and knee arthroplasty among the national registers. The main findings in these papers were the large differences among the countries concerning preferred prosthesis brands, fixation methods, and surgical approaches. The best overall hip prosthesis survival was in Sweden, where arthroplasty with cement had been more commonly used than in the other countries, and the lowest overall prosthesis survival was in Denmark, where hybrid and uncemented prostheses had been more common than in Sweden and Norway. The differences among countries with regard to prosthesis survival were minor, but the reasons for revisions and the procedures performed at the revisions seemed to be related to the dominating surgical policies on implant fixation and surgical approaches in the countries. We were also able to confirm inferior overall results of resurfacing hip prostheses, and we could differentiate between the results of the brands within this group of implants.

There is a tendency for orthopaedic surgeons to follow the most accepted surgical policies in their respective countries. Because of the small numbers of patients given other treatments, it might be difficult within one national register to compare mainstream treatments with alternatives. As the surgical policies differ among countries, collaborations of national registers could make it possible to compare, with sufficient statistical power, implants and techniques that would have too small numbers in one register. In the more recent publications, as in the ongoing and planned projects, we concentrate on comparing methods and implants, rather than countries.

As one of the main aims of the first project of the NARA collaboration was to compare the countries' results, we included only parameters and data that all of the three countries

could deliver, and a database not as rich on parameters and details as each separate register was the result. In addition, only replacements inserted in 1995 and later were included. On the other hand, the strength of the NARA project was that we could compare directly the descriptive statistics and the survival results among the three countries. Furthermore, it allowed for better understanding of the discrepancies between the registers and will probably facilitate future standardization of registration methods and analyses. The strength of using the larger common database was also that we, in a situation with different treatment traditions among the countries, could compare results of treatments across the countries' borders.

To estimate prosthesis survival and relative revision risk, we used Kaplan-Meier and Cox multiple regression analyses with adjustment for differences in the patient materials, sometimes also with subanalyses within more homogeneous subgroups of patients. However, there are other choices. In a collaboration of many large registers, we could also consider use of aggregated data. The groups must be prespecified, and each participating register must deliver only aggregated data after these specifications. As no individual data are delivered, this would also be a practical way to act according to the regulations in the respective countries.

The complexity of arthroplasty surgery is increasing as new techniques, materials, and designs continuously are introduced, and others are abandoned, and this problem should be addressed in the future. Large registers should collaborate to identify inferior implants and techniques as early as possible, before they have been used in large numbers of patients.

The technology in the 1970s, 1980s, and 1990s, when the Nordic registers were established, allowed only limited data on each patient. As the data technology has developed, probably only the workload for the reporting surgeons and hospitals will limit the number of variables registered. However, because of the complexity, the general experience has been that large databases should include as few parameters as possible, and include only the data that are needed to fulfill the predecided aims of the projects. In future collaborations among large registers, we therefore need to make careful decisions about which data we need for adjustment for differences in the patients, and for identification of implants. Most likely, we will need catalogue numbers on all implant parts, as only with catalogue numbers will we be able to identify, within brands, variations in material, geometry, size, surface coating, surface structure, and chemistry. Similarly, we will need exact data on the bone cements, if used, as the choice of cement sometimes has a larger impact on the results than the choice of prosthesis brand[15,16].

For a still larger collaboration than NARA, a discussion of strategy is needed. Our common database resulted in a reduced set of details and parameters because it only included data that all of the involved registers could deliver and only after the data were explored was it decided what to study. A larger collaboration should start at the other end, by first defining the aims and subjects for the studies and then including only the data needed to fulfill the aims, from those registers that are able to deliver those data.

Conclusion

With the collaboration of Nordic national registers, we were able to show differences among the countries concerning demographics, prosthesis fixation, prosthesis survival, and revision patterns. In a large future collaboration of registers, with a focus on comparing performance of prostheses and articulations rather than countries' results, we should probably include only the data specifically needed for the predecided aims and purposes, rather than compiling all data from all registers that are willing to participate. ■

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