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Preface

The National Register of Joint Replacements (NRJR) is an overall registry focused on acquiring and collecting information on performed joint replacement procedures during which artificial joint prostheses were used.

The National Register of Joint Replacements has been established by the Ministry of Health of the Czech Republic (MH ČR) and the acquisition of data into this registry is an obligatory component of health documentation.

The Institute of Health Information and Statistics of the Czech Republic (IHIS CR) as the administrator of the National Health Registers cooperates with the Czech Society for Orthopaedics and Traumatology (ČSOT), particularly with its representatives on the Board of the Register. The active approach of authorized professionals ensured that after overcoming the initial problems, the National Register of Joint Replacements (NRJR) ranks among efficient registers and evidence to that is also this bulletin, which keeps to the records of NRJR data and provides an aggregate table of results for the years of 2003 through to 2009. Aside from the credit for putting the register into practice, it is necessary to especially highlight the interest of the orthopaedic community in the outputs and results, their interpretation and presentation. Solely extended utilization of the register's data by relevant specialists vindicates the justification of operating such a register and, at the same time, contributes towards improved quality of the provided health care.

The objective of this bulletin is to acquaint the orthopaedic community with the NRJR development status and to demonstrate on selected outputs from the period between January 1, 2003 and December 31, 2009 the methods of their handling and thus present the register's possibilities.

First part of the bulletin follows the history of origin and development of the NRJR, pays attention to what has been successfully achieved, what are the major problems of the NRJR today and what are the prospects of health registers, including the NRJR, in the future.

Second part is devoted to presentation of results where basic epidemiological data are stated in relation to the individual patient and the respective site, followed by outputs relative to the method of surgery procedure, special outputs with analysis of revision surgeries, outputs relative to implants and materials used and also survival curves of the most used materials. In addition to text section the bulletin contains sixty graphs and eighty various tables.

The objective of IHIS CR as the register's administrator is to increase data utilization both on the national level in terms of joint replacement epidemiology and on the level of clinics in terms of professional and scientific needs and to further improve presentation of results from the NRJR. For data processing and their presentation it is necessary to create relevant tools and conditions. Another goal is to broaden the register out to all types of joint replacements, so as to fulfil the purpose of the register completely and to have its name correspond with its contents.

Mgr. Jiří Holub
IHIS CR

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The National Register of Joint Replacements of the Czech Republic

Hip Joint Replacements
Selected Outputs and Their Analysis for the Period 2003-2009

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SUMMARY

The National Register of Joint Replacements of the Czech Republic was established as part of the National Health Information System in 2002. The register's administrator is the Institute of Health Information and Statistics of the Czech Republic, the Czech Society for Orthopaedics and Traumatology acts as its guarantee for scientific standard. The register is financed from state resources. It was launched into full operation in 2003 and it currently focuses on hip joint replacements. Register of knee and shoulder joint replacements is being prepared.

The register provides aggregate epidemiological data and other statistics, including the Revision Rate – RR and survival curves (Kaplan Meier) for the main monitored groups of patients and implants used. More complex analytical evaluation methods are being set up.

In years 2003-2009 there were 72 hospitals participating in the register's activities, 63 037 primary implantations and 8 931 revision surgeries were registered. In terms of gender share there is a prevalence of females amounting to 59,9% in primary implantations and to 64,7% in revision surgeries. The age structure covers the entire range of adult population, however, more than 50% of the replacements are being implanted between 60-74 years of age. Most frequent indications for primary implantation are idiopathic osteoarthritis 68,6%, post-traumatic conditions 13,53% and post-dysplasia arthritis 9,39%. The most frequent indications for revision surgery are aseptic loosening of acetabular component – 40,9%, aseptic loosening of femoral component – 21,65% and recurrent luxation – 6,37%.

29 650 (47,04%) of primary implantations were cemented, 22 028 (34,94%) non-cemented, 10 924 (17,33%) hybrid with cemented femur and 435 (0,69%) were hybrid with cemented acetabulum. Most widely used is the classic anterolateral approach –77,76% in primary implantations and 52,35% in revision surge-ries. Bone grafts were used in 24,37% of primary implantations and 43,03% of revisions.

Most widely used implants in primary implantations were cemented cup Muller (Aesculap) 10 196 pcs, cemented steel stem Poldi AK (Beznoska) 9 932 pcs, from the non-cemented models the cup Plasmacup SC (Aesculap) 6 738 pcs and stem SL Zweymüller Alloclassic (Zimmer) 2 708 pcs. Most widely used implants in revision surgeries in general are non-cemented oval cup Medin (HA) 740 pcs and non-cemented stem Wagner (Zimmer) 407 pcs.

The Revision Rates of primary implantations indicated for infection in the samples from individual years were at the close of their monitoring in June 2010 as follows: 2003 – RR 0, 37%, 2004 – RR 0,36%, 2005 – RR 0,35%, 2006 – RR 0,28%, 2007 – RR 0,18%, 2008 – RR 0,10%, 2009 – RR 0,10%.

The cumulated survival probability (Kaplan-Meier) in year 8 of the monitoring represent 97,27% for cemented implants, 96,53% for non-cemented, 96,73% for hybrid with cemented femur and 95,08% for hybrid with cemented cup.

Key Words: Czech National Hip Arthroplasty Register- hip joint replacement revisions- hip arthroplasty survival curve - hip joint replacement revision rate

History of Origin and Evolution of the NRJR

First ideas about establishing a register of joint replacements sprang up at the end of the nineties of the 20th century and in year 2000 the Board of the Czech Society for Orthopaedics and Traumatology (ČSOT) charged Ass.prof. Václav Štědrý M.D., PhD. with the guidance of a working group consisting of two more members – Ass. prof.. Pavel Vavřík, M.D., PhD., and Jiří Kubeš M.D. It was resolved to start first by establishing the register of hip joint replacements as these were at that time by far the most frequent implants, and later, when methodology was managed, extend the register to knee joint replacements and perhaps even other implants.

The beginnings were quite challenging because in Europe of those days the experience with longer functioning of similar registers was solely in Sweden and Norway. In other countries registers were still rather being born and at a stage of first data collection.

From the very outset the register was fumbling with quite a few problems:

1) The first records were processed in paper form with the assumption they would be sent to a computer centre, which would process them furthermore. The reason rested in the non-existence of appropriate computing equipment in a number of hospitals, difficulties with safe activity on the Internet and its general availability, as well as, in many surgeons, their unfamiliarity with and reluctance against computer handling and other office work.
2) It was not clear who would run and administer the database of patients.
3) It was vital to locate finances for operational costs.
4) It was necessary to figure out the legislative coverage of the register, particularly in terms of confidential data collection and its treatment.
5) As rather unexpected appeared the problems with inaccuracies in population statistics related to the division of Czechoslovakia, formation of new regional administrative units and the restructuring of public administration, duplicity in personal identification numbers, unresolved foreigner registration etc., which impeded unambiguous identification of specific cases in terms of computer processing.
6) It was required to determine and define the data to be recorded in the entry form so that these were evaluable, controllable, provided requested outputs and did not overburden the registrar. The opinions on what all are affecting the success of arthroplasty and what the register should pertinently be monitoring vary substantially (6, 8, 10, 11, 12) and are often hardly feasible in practice.
7) Last and the most difficult issue was the creation of proper functional database and system of identification of all implants, their elements and components used.

Following a number of negotiations between the CSOT and the Ministry of Health of the

Czech Republic it was resolved that the NRJR be included in the National Health Information System and financed from state resources. It was officially put into operation on September 1, 2002. The administrator of the register is the Institute of Health Information and Statistics of the Czech Republic (IHIS CR) and its processor the Coordination Centre for Departmental Health Information Systems (CCDHIS). The CSOT subsequently acts, through its representatives, in the role of a scientific guarantee of the NRJR. The register is fully financed from state resources. Its activities are managed by the NRJR Board, chaired by Ass.prof. Pavel Vavřík M.D. PhD., MBA of the 1st Orthopaedic Clinic of the 1st Faculty of Medicine of Charles University and Motol Teaching Hospital, members of the Board being other orthopaedic surgeons – Head of Department of Orthopaedics of the Regional Hospital Pardubice Jiří Kubeš M.D. and RNDr. Martin Biegel M.D. of the Orthopaedic Clinic of the 1st Faculty of Medicine of Charles University and Praha Bulovka Teaching Hospital. Additional 5 members of the Board are delegated on the part of the administrator of the register – IHIS, processor of the register CCDHIS and the Ministry of Health of the Czech Republic.

Ass. Jan Hach M.D. has created a functional and relevant database of implants, which he has been further continuously maintaining and updating. Following a short period of pilot operation, regular operation was launched as of January 1, 2003, with focus on data collection. In the operation of the register initially participated a little over 20 orthopaedic departments which number, however, rapidly grew and currently there are 72 orthopaedic departments contributing to the register. The register's database was interconnected with the database of the Death Register, which provided for developing survival curves. After year 2006 all registers governed by the Ministry of Health of the Czech Republic were switching to a new operating system and their unified operational and organisational platform was being sought. Consequently, software development, data mining from the hip replacement register, and generating the knee replacement register were somewhat slowed down. Nevertheless, the orthopaedic surgeons on the Board of the NRJR in the meantime put together several motions for desired formats of the outputs from the register and Ass.prof. Vavřík compiled the fundamental structure for the inception of the knee replacement register database.

In 2006, in virtue of its readiness and rather sophisticated structure, the NRJR became one of the pilot registers according to which other national health registers

of the National Health and Information System (NHIS) were being set up similarly, of which there are presently next to thirty. The objective is to gradually interconnect these registers into an integrated health information system. In 2006 the works began on modern data mining software on the principle of a "data block" that enables quick multilateral processing of large mass of data. It operates based on the generally well-known program Microsoft Excel and thus allows the users familiar with the basics of work with pivot table to prepare their respective output formats. Moreover, the data may easily be exported and further processed in Excel or other programs.

The data block software is processing data that are further entered on-line to the original database by all users involved. The data on following pages should serve as first presentation of data from the register and illustrate the potential of the new software.

Prepared on the Health portal run by the CCDHIS are also at the same time prearranged outputs (tables and graphs) of the most important indicators from the NRJR, designed for rapid orientation of those users who lack time or opportunity to form the outputs individually. Some of them are intended for the broadest non-professional community and comprise aggregate, nationwide epidemiological data from the area of arthroplasty. There are more detailed, aggregate nation-wide data designed for professional users, extra extended to equally processed outputs from the hospital of a particular enquirer and will thus allow their swift comparison towards the total.

What has been successfully achieved so far?

In the stage of first reflections on the register nobody was able to preconceive the true scope of the problems and difficulties that would have to be overcome, nonetheless, we gradually managed to:

– Ensure organizational and financial background for the establishment of the register
– Determine legal framework for its existence
– Create functional system of on-line data collection with optimized number of parameters entered for primary hip replacement procedures and revisions
– Involve within 9 years of its functioning 72 hospitals, 204 authorized users to whom, in the first place, belongs the credit of more than 71000 relatively quality-recorded entries on primary and revision surgeries
– Generate a correct database of hip and knee implants
– Interconnect the register with the Death Register
– Switch to a new operation system and to integrate the NRJR into the system of health registers without the loss of or the necessity of converting the data already stored
– Prepare, after having developed the first version of data mining software based on the Business Objects program, a modern data processing system based on the principle of a „data block" in Microsoft Excel format
– Publish a compendium of public outputs in 2006 in Czech and English versions
– Prepare this publication with selected aggregate outputs for years 2003-2009

What are the major current problems of the NRJR?

The fundamental problem of the joint replacement register is that so far it has been only a broadly founded multi-centric study from materials submitted by involved hospitals. Giving birth to a veritable register worthy of its name is being inhibited by the incompleteness of entered data of two types.

a) Into the register do not contribute all the hospitals where hip replacements are being performed, although data gathering for the NRJR is in the CR a mandatory component of health documentation upon total hip joint replacement procedure (THR). Yet, no manner and form of control or penalties have been determined for contingent default.
b) It is clearly evident from data analysis and the summary of the number of contributions, that not all the hospitals involved in the register's activity provide all data for the years of their participation. Causes vary from hospital to hospital. As a first step towards improvement we have therefore, for a start and with the consent of the CSOT Board, published two tables showing the particular numbers of contributions into the register from individual hospitals (Tab. 1 and 2). Their purpose is to provide aggregate data that will allow the orthopaedic community evaluate the quality of involvement of a hospital in the register's activity.

Sustained efforts must be exerted to secure funding not for ordinary function of the register but for its further advancement, i.e. development and installation of software application enabling the launch of knee replacement register and other joint replacements thereafter.

Another area requiring incessant attention is the improvement of possibilities and quality of mining large mass of already collected data, this to be achieved not only by means of descriptive statistics but by modern analytical statistical procedures that will allow the largest possible objectification of results and will be comprehensible and applicable for the broadest professional community.

Vital is a systematic care for the quality of entered data and error rate control. Presently we are setting and perfecting the mechanisms that will provide for quality control of individual entries, retrieving and correcting defective records, and perhaps even block their insertion upon entering. Some processes are already functional, however new types of errors keep appearing, which require to be resolved in cooperation with the administrators.

Future of the NHIS health registers in the Czech Republic

The establishing of registers in advanced countries is gradually being transferred to a highly sophisticated level of clinical information mining. A general trend in the presentation of its contents rests in the transition

from descriptive characteristics to a dynamic perspective and the feasibility of assessing the efficiency of individual clinical procedures ensuing from direct interaction with the users. The advantage of the situation in the CR rests in centralization of the registers within the framework of the NHIS, with the asset being their uniform concept. Outputs from the registers may thus concurrently be of use in a range of specializations for which they have been established because perspectively they may become interconnected.

The primary requirement for the future is the capability of entering individually defined enquiries from the field of clinical hypotheses, i.e. statistical treatment of information subsets that would provide for verification of results of clinical procedures plus regional and international comparison. Within the framework of register development a laboratory solution is being presently completed, which has been drawn into the following modules:

Public module – is focused on the general public. It provides data intended primarily for the citizens, such as information on current (as well as historical) status of population with a particular disease, general epidemiological parameters and trends, perhaps even the numbers of patients or procedures in aggregate form. Emphasis is placed here especially on user friendliness, lucidity of available data and the mode of their presentation. The input structure and the data presentation mode in this module are pre-defined and the end user has only limited capacity to modify them. Access to this module is unrestricted directly from the environment of the Internet network.

Manager module – is a tool for effective data mining in form of a dynamic perspective and the feasibility of assessing the efficiency of individual clinical procedures. The purpose is partly in detecting the trends and changes, namely the negative ones, that go beyond the framework of statistical error, and then in data assimilation for the creation of forecasting and decision algorithms predominantly instrumental to managerial and decision-making activity.

Expert module – the purpose is to provide wider spectrum of data with the option of their basic export. Data will be set in form of separate summary reports where the user will have extensive means for parameter modifications. Accentuated are the chances of clinical evaluation not merely in terms of descriptive statistics, but also with the aid of all sorts of prearranged analytical methods. Access to this module will be provided solely from „local" intranet network and exclusively for authenticated and authorized users. Basic presentation form is a classic report, in which the user has relatively wide chances of modification or stratified perspectives on the target group.

Analytical module – is designed for scientific and statistical purposes. Technically, data will be accessible practically in the primary form of its acquisition. Its post-processing is a matter of the end-users. Emphasis is placed chiefly on data export options and potentiality of connection to other systems. Access into this module will be subject to a strict process in the course of which, among others, complete history of data handling within the system will be monitored in every user.

Prospects of NRJR development within the NRJR and the NHIS

Specifically for the NRJR in the current year we look forward to the occasion of commencing the works on the knee joint replacement register. Formulation of the structure of entered data, that would encumber the registrar as little as possible but at a later time enable optimum data mining, which is the most difficult phase of the register's preparation, has already come through. Also created has been the database of components of primary and revision knee joint replacements currently available on the Czech market. Now we are entering the phase of software preparation of entry form with active common error protection. This step will permit initiation of data collection, system testing and its opponency from the ranks of orthopaedic surgeons, statisticians and other professionals. Developing the data mining software shall follow. Part and parcel of all the steps is monitoring the connectivity and compatibility of the hip and knee registers. Upon development of knee joint register we go by the experience with the hip joint register, nonetheless, knee issues are specific in many aspect and must be so considered.

At a stage of professional contemplation is the register of shoulder joint replacements, eventually of elbow and ankle replacements. All will depend upon financial capacity and cooperation of the professional community.

The most relevant task into the future is to prepare „data mining" from entered records. The long-term problem of health registers is their low utilization of entered data. Hereinafter published outputs represent only a small example of what may be extracted from already entered data. Current outputs are mostly only very simple descriptive statistical data. The objective is to switch over to more complex systems enabling analysis and statistically correct comparison of various types of files. Selection of suitable methods will require further testing, as well as professional debate that has already been open on the pages of our bulletin (4) and is further extended in our modest output section.

First steps have already been taken (2). A model mining of clinically significant information from primary data has been elaborated within the NRJR with the aim of generalizing and utilizing this methodology also for other health registers in the CR. Created specifically for the NRJR was the scheme of register entries expressing the interdependence and sequence of processes. The result is a structured model with evaluated sessions, for which particular clinical enquiries will be formulated. The said system serves as basis for the selection of relevant hypothesis tests usable for solving individual problem areas. Statistical data analyses will be prepared in two regimes. Initially simpler analyses utilizing the "data block" system, as soon as possible complemented with procedures for statistical comparison of

chosen monitored groups and prepared in second phase will be the multidimensional analyses seeking response to more general questions, requiring skilled data handling that cannot be automated. Emphasis in this phase will be placed on comprehensible user environment. It presumes selection from the menu based on names of clinical hypotheses, not on names of statistical methods; it will further provide means for checking the accuracy of selected statistical methods and comments to results interpretation that serve as prevention of false conclusions. It is a rather ambitious project, solution of which may be anticipated in the horizon of several years. Present means of data mining from the NRJR will not be thereby reduced but, on the contrary, shall gradually be enhanced.

Outputs Section

The outputs section is divided into several theme areas that present selected outputs from the register and demonstrate also various forms and options of their processing. In our annotation we have preferably featured also individual problems associated with data outputs evaluation and the way as to how to interpret them. In years to come we envisage we will reduce the general commentary and will focus rather on the expertise aspect of outputs evaluation.

The introductory tables No. 1 and No. 2 are devoted to the number of primary implantations and revision surgeries that the involved hospitals submitted to the register in individual years. Pursuant to a qualified assessment and comparison with other data sources (IHIS, NRC etc.) they do not, in a number of hospitals, necessarily reflect the actual number of performed surgery procedures. Publication of these tables is the only exception to the applied full anonymity of provided data. The purport is to motivate individual hospitals to continuous data improvement and integrity. Here it is to be remarked that data of a preceding year can be entered retroactively only by the end of February of the subsequent year. The reason is that the data processed in previous years with reference to the NRJR, e.g. for publication purposes or annual reports, remained already stable and did not change any further. Complementary to the data are a table and a graph (Tab. 3 and Graph 1), featuring aggregate figures of primary implantations and revision surgeries as processed by the register in individual years.

Basic epidemiological data relative to the individual patient

The data comprises simple descriptive statistics characterizing the group of patients in the register according to gender, age and basic diagnosis. It is always presented either in form of a table or a simple graph.

Share of gender in primary implantations (Tab. 4 and Graph 2) and revision surgeries (Tab. 5 and Graph 3) is quite as expected markedly in favour of the females. Additional data shows the structure of all patients by age at the time of primary implantation (Tab. 6. and Graph 4) and revision surgery (Tab. 7 and Graph 5) classified into age groups of five years each. Data can be further very easily classified and analysed as indicated by the examples of age structure comparisons in a set of males and females at the time of primary implantation (Tab. 8 and Graph 6), and analogous data for revision surgeries (Tab. 9 and Graph 7). Especially in the graphic form it clearly demonstrates a shift of indications in females to higher-age groups. Accordingly, primary diagnosis and a number of other aspects can also further sort the files.

An overview of basic diagnoses in primary implantations (Tab. 10, Graph 8) and revision surgeries (Tab. 11 and Graph 9) is an important input parameter and may significantly affect survival curves. The occurrence frequency of various causes of hip injuries leading to its replacement is certainly interesting in itself. A certain signal is also the share of the individual groups in the number of primary implantations and whether their share in the number of revision surgeries is the same (Tab. 12, Graph 10). However, most important is the opportunity to use the input diagnosis as a filter. It allows us to separate some risk groups such as rheumatic diseases, posttraumatic conditions, and postdysplastic hip osteoarthritis and the like and to examine them independently.

Interconnecting the NRJR with the Death Register was a considerable move. For the time being, data in both registers is compared and synchronized quarterly. This function in its simplest form allows us to find out how many and what patients of the monitored group died during the entire period of monitoring without association to the surgery, both for variously chosen files of primary implantations and revision surgeries (Tab. 13 and 14, Graph 11 and 12). This information is inevitable for the ascertainment of the number of censored operations upon construction of curves and tables of cumulative survival probabilities (see hereinafter).

Under regular operation this information will be of use for local users with smaller monitored samples e.g. for determining the number of patients that need to be checked or invited. Upon different construction setup of the table it is possible to obtain a printout of particular deceased persons and contingently remove these from further evidence of invitees in the research itself. It stands to reason, that a patient cannot be removed directly from the register.

Natural removal of patients from the register takes place as follows: Provided the time lapsed from the moment the patient deceased exceeds 5 years, his original identification number is, in compliance with the legislation in force, replaced with a random unique code. The patient cannot be thereafter identified but his data remains under the assigned code in the register's database and may be used for cumulative assessments for the next 20 years.

The date of death parameter may be combined with various filters. Used as a filter in the above-presented example, more or less randomly, was the type of fixation.

Quite logically it turns out, that most deceased patients were from the set of cemented implants, because these are universally being used in elderly patients. The Death Register, however, provides the NRJR also with the exact date of the patient's decease and when correct parameter of the data block is set, available is also the major cause of death and further data from the death

certificate. A respective group of operated may be thus examined e.g. in terms of incidence of mortal embolisms and their time interval from the surgery. Examples thereof may be found in other tables (Tab. 15 and 16).

The first shows how many patients of each group of primary implantations operated in particular year died during the entire period of 7 years of monitoring and how many of the deceased had in the death certificate as a cause of death one of the numeric diagnoses for one of the forms of thrombo-embolic disease (TED). But it does not tell us anything about which of the deaths was in causal relationship with THA, and which had other causes. Second table shows us a simplified summary of time interval of dying of TED from the date of operation.

We can see that most deaths of TED in all monitored year groups occur within 1 year from operation. Nevertheless, direct causal relationship with joint replacement would in each individual as well as the entire group require further evaluation.

As well as decreasing figures of the generally deceased and of those dying of TED cannot be interpreted as accomplishments of improving prevention or better operation techniques, but are more likely caused by different time of monitoring the groups from individual calendar years.

We used the data on deaths in relation to TED to illustrate the merits of interconnecting various registers within the framework of NHIS. It enables acquisition of useful data that we have not entered into our own register for a variety of reasons or, which we were not even able to ascertain reliably.

Yet, utilizing so acquired descriptive data does have its boundaries. This data only delimits relevant "suspect" groups of patients in the register and identifies them. Should we need to subject them to further analyses it requires another detailed processing. This procedure is very laborious and necessitates critical assessment of obtained outputs. Perspectively, instrumental in this respect should be the analytical tools referred to in the section devoted to the register's future.

Still, on the set of the operated, the register may provide also different interesting and otherwise rarely featured data. As an example may serve the distribution ratio of right and left hip joint defects in a set of primary implantations and revision surgeries (Tab. 17 and 18, Graph 13 and 14). It is intriguing that even with the application of additional contingent filters the right side is always operated on more often.

Epidemiological and other data relative to the hospital

As an introductory word to this section it needs to be stated that one of the register's principles is data anonymity regarding both the patient and the orthopaedic surgeon, as well as with regard to the hospital providing the data. The surgeon is never mentioned. Only an authorized user of the given hospital who has registered, and after having complied with applicable legal terms has been granted access to the NRJR, holds the authority to access particular records as well as any sub-outputs for a respective hospital. All users have access to anonymized aggregate data for the entire country and their respective data processed in a similar way. That allows all to compare their respective data in all parameters with nationwide data.

The reason for this arrangement is to restrict the efforts for „improving" the outputs on behalf of the hospital. The thing is it misses the point here. He who would not present correct data depreciates the evaluability of data for his own use in the first place, without anybody else seeing his „improved" result. But as we were checking through tests, the aggregate data for the CR in its current volume may be biased by a single person solely in hundredths; or at maximum in tenth of percent.

For better idea we will give some examples of anonymized outputs options.

A regular user after enquiring about the number of operations at other individual hospitals or about another parameter and after comparing it with outputs from his respective hospital shall obtain the following output (Tab. 19), which can be processed, for instance, into these graphs (Graph 15a-d). The graphs show the user the evident position of his respective hospital, but not particular names of the others.

A useful function in reference to a particular hospital is also an informative review of correlation between the site (hospital) of primary implantation or preceding revision surgery and the site of the subsequent revision procedure. As illustrates the table (Tab. 20) from a virtual hospital XY, which is accessible only to a registered user from that particular hospital, it is evident how many revisions, respectively re-revision surgeries, were performed on primary implantations and revisions carried out in their respective hospital, how many arrived from other hospitals and how many revisions of operations carried out in their respective hospital were performed elsewhere. Registered in this table format are only revision surgeries of primary implantations or previous revisions that were performed during the existence of the register and were entered therein.

That is to say, that the register also contains files on revisions of primary implantations, which have not been recorded. We will mention this issue in more detail in the section devoted to specific problems of revision surgeries.

Another piece of useful information retrievable from the register is the list of patients from the respective hospital who were re-operated elsewhere. It is again demonstrated on a virtual example (Tab. 21). With respect to the principle of preserved anonymity the enquirer shall only learn about patients originally operated in his respective (XY) hospital, then their identification data, date and mode of re-operation. He shall learn neither who, nor where the operation was performed. The purpose is to prevent patient losses from the research file statistics and complicated, sometimes even bothersome quest for their further fate.

Outputs of that type will be further extended and should become into the future a component part of the upcoming managerial module.

Outputs relative to the method of surgery procedure

The data that fall within this section relate to surgical technique and the method of surgery procedure. It may be used as observed values or as filter for more accurate specification of the monitored set.

Figures and types of used surgical approaches in primary implantations (Tab. 22, Graph 16) and in revision surgeries (Tab. 23, Graph 17) evince the absolute prevalence of classical anterolateral approach (77,76%), with a large gap followed by transgluteal approach (16,93%). In revision surgeries, too, dominates the anterolateral approach (52,35%), followed by transgluteal (42,55%), used here 2, 5 times more frequently than in primary implantations.

According to the type of fixation we classify primary implantations into 4 categories, subdivided in the table by individual years (Tab. 24). Cemented implants continue to represent almost 50%, and approximately 30% of the replacements are fully non-cemented. The share of various fixation types in the total number of implantations in individual years is well demonstrated by column graph (Graph 18). However, times are changing and the trend of gradual decrease in the use of cemented implants in favour of hybrid ones, and particularly non-cemented replacements is well documented by alignment charts of percentage share of used types of fixation in individual years (Graph 19 a-d).

In the case of implants used during revision surgeries the situation is more complex. Here it is necessary to realize that the table and graphs (Tab. 25, Graphs 20, 21 a-d) relate to the final status of the implant after revision surgery and do not say what components have been replaced. About that we get far better information from the outputs focusing on the method of revision surgery procedure set forth below, in the next section, and which can be further processed also with a view to the type of fixation used.

None the less, the column graph presented herein (Graph 20) does show a marked prevalence of non-cemented implants in revision operations. This trend is even more obvious in the alignment charts(Graph 21 a-d), which show progressive interannual growth of percentage share of non-cemented and hybrid implants at the expense of fully cemented ones.

The usage frequency of grafts in primary implantations (Tab. 26, Graph 22) is yet another aspect of operation technique. Grafts are used here approximately in less than a quarter of the cases (24,37%), where practically all used represent autogenous grafts (23,92% of all operations). In revision surgeries (Tab. 27, Graph 23) grafts were used almost in half of the cases (43,03%). More than twice as frequently allogenic grafts were preferred (27,87%) to autogenous (12,51%).

Special outputs and revision surgeries analysis

One of the fundamental questions that demanded to be resolved upon establishing the register was the recording mode for revision surgeries. Two options were being suggested.

First of the options was to enter solely revision operations with relationship to primary implantation kept on the register's file. It means that recorded were only revisions that already have their primary implantations available in the register. Disadvantage of this solution consisted in a considerable time lag in obtaining evaluable outputs from the register because the sample of revision surgeries would be generated with major delay. Another drawback also was that for every revision prior to its entering into the register this approach would solicit seeking out the information whether or not does the given revision already have an existing record of primary implantation. Also possibilities of control, whether and what revisions would have been entered into the register, would not practically exist.

Second option was to enter all revisions. Disadvantage of this policy is that especially in the first years a majority of the revision operations is lacking valid, objective data about previous primary implantation, which inhibits from evaluation of some outputs. We rejected any additional entering of data on medical history because finding it would be laboursome for the registrar and, considering the frequently subjective and inaccurate interpretation of preceding events by the patients, encumbered with large error rate. The drawback of this solution is the necessity of software differentiation of revision operations with a linkage to a registered primary implantation from revisions without such linkage, because upon some evaluations all revisions may be processed, whereas at other times the evaluation necessitates exact knowledge of the primary-implantation data.

In spite of this we eventually acceded to second option because series of data, such as the revision burden of hospitals or revision causes etc., may be processed in high quality even without the knowledge of the primary-implantation data. The assessment of other data, like the time interval from the cause occurrence (luxation, infection), can be processed solely on a revision sub-file containing the surgeries with a linkage to a registered primary implantation. Consequently, the user always has to enter appropriate parameters of the relevant pivot table.

Accordingly, in the text to follow we will distinguish evaluation of revision operations with a linkage (i.e. an existing record of primary implantation or previous revision) and evaluation of revisions without linkage (having no related records of primary implantation) and evaluation of all revision operations as a whole. Happening in time will be size reduction of the revisions file without linkage in favour of revisions with linkage, as the table and the column graph show, which at the same time feature the numbers of individual types of operations by year and the entire period under consideration (Tab. 28, Graph 24).

The situation is farther complicated by the fact that the set of revision operations with linkage includes also a set of re-revisions, which, although they have no record of primary implantation, do have a record of one previous revision or of more repeated revision operations. This group needs to be accurately identified, e.g. in order to research the causes of repeated revisions or the use of

various materials during re-revision operations. Status of the filter settings according to type of evaluation may thus induce slight oscillation in terms of the count of evaluated revisions within large nation-wide samples. Into the future we are seeking ways how to differentiate and specify all these categories with even more accuracy.

Within the context of revision categorization according to whether they do or do not have previous record in the register we will, on two other examples, again get back to the evaluation of revision operations according to hospital. The original aforesaid table (Tab. 20), which registers solely revisions with linkage to a previous operation kept on the register's files we can further broaden with a table of all revision operations that does not give us information on precise revision rates in our own patients as opposed to external patients, but which does reflect better the overall revision burden of a hospital XY (Tab. 29). Revisions without linkage are in this case under section „unknown/respective" and include all revision surgeries without previous record in the register, irrespective of whether previous operation was performed in respective or another hospital.

Dividing revisions according to linkage to previous operation may be used not only in terms of the burden on a particular hospital, but also to assess migration of the population or, if you want, the „loyalty" of revision patients to the original hospital where previous operation was carried out (Tab. 30). Summary of revisions with linkage for the entire CR indicates that contrary to a number of other countries practically three quarters of the patients stay at the original hospital.

We apologize for this intricate explanation but we consider it vital to comprehension and correct interpretation of the results presented hereunder.

The following table and graph (Tab. 31, Graph 25) also show how many or what percentage of patients has undergone repeated revisions in the course of the monitored period. Nearly 10% of patients have undergone a re-revision and 0,12% of patients as many as 5 and more times. Rather sad national record in this respect is represented by 7 operations on a single hip during the monitored period.

For most of the entered revision operations with linkage it is also possible to find out the time interval from primary or previous revision operation (Tab. 32, Graph 26). The cell reading time interval „unknown" comprises surgeries without linkage to previous operation and the rest create incorrect or incomplete entries, which the register's administrator will gradually have to seek out and correct where possible. Time intervals were chosen pursuant to usual scheme used for infections but for future they can be set arbitrarily. Both the table and the graph clearly show that the largest revision risk threatens during the first year after previous operation (upon the evaluation deadline on June 30, 2010 some 95% of patients were monitored at least for one year). In other years the data is with increasing time interval less and less reliable because it is affected by decreasing number of monitored cases existing in the register at that time.

Next information retrievable from the register is the method of the revision procedure. The data entry form allows entering multiple methods in one revision (e.g. ossification removal + head replacement + inlay replacement); so as to intercept all aspects of the operation and so that it could be evaluated from various angles. The consequence is that a simple synoptic table and a graph for the entire register feature 11 485 procedures performed during 8 931 evaluated revision surgeries (Tab. 33, Graph 27). Most frequent is acetabular component replacement (27,44%), followed by exchange of all components (20,43%) and simple head replacement (17,59%). Less frequent is separate replacement of femoral stem(15,52%). The numbers of other operations are by orders lower.

Similarly upon evaluation of the summary of causes leading to revision surgery (Tab. 34, Graph 28) it needs to be noted that here as well the data-entry form allows entering multiple causes because it cannot be always unambiguously determined which one was primary. Obviously, this situation is quite common as here too, the number of declared causes distinctively exceeds the number of revision surgeries. This system has been chosen to minimize subjective approach of the registrar or the surgeon, to prevent data losses and to enable its repeated analyses from a variety of aspects at a later stage. We will come back to this issue in more detail upon material assessment. Most frequent cause of revision is loosening of the acetabular component (nearly 41%) and then, with a large gap follows loosening of the femoral component (21,65%). Worth mentioning is also the third cause in line, i.e. recurrent luxation (6,39%). If we add revisions of non-repositionable luxations (0,98%) and take into account the amount of conservatively performed repositions that are not recorded in the register, here we apparently have by far the most frequent complication of hip replacement ever. In the summary of causes it was noted in total 878 times. Moreover, in 15 cases the surgeon evidently could not determine what cause was major and named both.

Let us take a closer look at this phenomenon and simultaneously attempt to demonstrate possible angles of viewing the data in the register. The number of 863 of all revision surgeries with the cause being one of the mentioned luxations (in 15 cases even both of them) shown in table (Tab. 35) at the same time features the occurrence distribution in individual years and according to time interval from the operation. Since it includes all revisions, i.e. even operations without linkage to previous primary implantation recorded in the register and also re-revisions, the most entries (563) are on line "interval unknown" because the time interval calculation formula lacks the date of primary implantation.

Provided we earmark solely revisions without linkage to primary implantation we get just a simple table (Tab. 36) only with 512 revision operations divided by years of performance where time interval cannot be evaluated as we do not know it. The difference of 51 operations when compared to previous table (Tab. 35) represents re-revisions – indeed without linkage to pri-

mary implantation but bearing relationship to previous revision.

It is also possible to enter revision operations with linkage to previous surgery in the register in general (Tab. 37), where we can see 351 revision surgeries where the last line "interval unknown" again indicates 51 re-revisions.

However, because the luxation issue is somewhat different in revisions the table can be cleared by entering the number of revised primary implantations (Tab. 38). Some registers (5, 6) show also percentage of the revised (revision rate – RR), which is the quotient of the number of revisions/number of primary implantations multiplied by 100.

The result can be summarized that in the entire register during the period 2003-2009 there were altogether 863 procedures performed for either form of luxation, of which in 512 operations we do not have data on previous surgery, 51 operations were re-revisions and solely 300 operations were revisions of some of the sample of 63 037 primary implantations kept on the register's file and fully evaluable from all aspects. The percentage of revised primary implantations (RR) indicated for luxation is 0,48% for the entire period 2003-2009. In terms of time interval distribution between primary implantation and its revision, it is obvious that most luxations occur in all of the above created samples within the first year after primary implantation. This information can be regarded as valid because upon the closing on June 30, 2010 practically 95% of the patients were monitored for 1 year. Subsequent years need to be evaluated with diligence as the total numbers of revisions are affected by the cumulative size of the sample and dissimilar period of monitoring. For more accurate conception of the influence of time interval from the operation on luxation frequency it would be necessary to apply some of the methods for calculation of cumulative probability.

Often discussed is also the influence of the diameter of used head on luxation occurrence. Therefore we have compared the percentage of revisions (RR) in the most common head sizes (Tab. 39). It really seems that the percentage of revised heads is decreasing towards larger commonly used head sizes of 28-36 mm diameter. Yet, the presented data is only informative and no major conclusions may be drawn thereof because the samples are diametrically different in size and the monitoring period is not identical either. Head sizes of 36 mm diameter have so far been represented in the register too little and have been used for a relatively brief period.

Another much observed item is the infection occurrence in primary implantations. We are often confronted with the enquiry: „What is the infection percentage in this type of surgery?" There is no answer to a query raised this way.

For correct evaluation of infection occurrence we have to define the group of procedures (primary implantations or revision surgeries) and determine the monitored sample by particular time of its creation (2003-2009 or by individual years), if appropriate, we may also apply other filters (type of fixation, age, primary diagnosis, implant etc.) and we have to define the period for which this sample has already been monitored. The table below (Tab. 40, Graph 29) shows the infection occurrence in groups of primary implantations performed in individual years and also collectively in all primary implantations in the register, with indicated time interval of infection occurrence from the date of primary implantation and with calculation of the RR in individual years as well as the entire monitoring period 2003-2009.

The aggregate data monitored in terms of time interval always – as has already been mentioned in case of luxations – suffers from the varying size of the monitored sample and different time of monitoring its segments. Accordingly, it is better to monitor the trend in infection occurrence in the time to come in closed samples of primary implantations performed in individual years. Another option is to use more sophisticated analytical methods.

While the aggregate data on the occurrence of all infections in the register for the period 2003-2009 does not tell us much, as a comparatively correct can be regarded the information that the percentage of revisions (RR) indicated for infection in the sample of primary implantations carried out between January 1 and December 31, 2004 was 0,36% at the time of evaluation (30. 6. 2010). Only with time interval of several years also the representation of late infections in individual samples is gradually becoming more precise and can be mutually compared.

Outputs relative to implants and materials used

Presented in the introduction to this section are summaries of individual types of materials categorized according to application method, i.e. for primary implantation or revision, then according to the type of fixation and component positioning – femoral and acetabular. The names are used as provided by individual manufacturers or suppliers. Inasmuch as the implants can often be with difficulties unambiguously identified by these names, we have also assigned the manufacturer's name. However, it has sometimes changed over time and that is why two or more manufacturers are named. At other times the new company assigned a different catalogue number to an implant and it has been consequently registered separately.

For processing and analytical purposes the individual components in the database are identified with the manufacturer's catalogue numbers, which are the only ones explicitly specifying the component type and size.

Processing a database with tens of thousands items required immense efforts and it took several years. The database has to be continuously maintained (changes in design, manufacturers, and types) and complemented (new implants). Validity of the material results and the possibilities of its detailed analysis further depends on the diligence of the data registrars, id est. so that they always really properly enter the implanted component, its type and size, with correct catalogue number pre-

sented on the label, because in practice error data cannot be identified, searched out and corrected.

What has not been achieved so far, chiefly for economic reasons, is system integration of the option to enter data by means of barcode scanners directly from the labels, which would substantially improve the situation.

Presented first are the summaries of all materials used in the register and their usage frequency in primary implantations – separately cups (Tab. 41) and stems (Tab. 42), then in revisions again divided to cups or – if you like – acetabular components (Tab. 43) and stems (Tab. 44), all without distinguishing the type of fixation. A total of 127 cup types and 136 stem types were used in primary implantations; and 97 cup types and 101 various stem models were used in revision surgeries.

In terms of diameters of modular heads used in primary implantations (Tab. 45) constantly overwhelming lead have the heads with 28 mm in diameter, which were used nearly in 87% of the operations.

Heads used in revision surgeries (Tab. 46) are in addition divided by use in re-revisions. Also in revision surgeries dominates the 28 mm diameter (75,6%) and with totally identical percentage (75,6%) are the head sizes of 28 mm diameter represented when we evaluate collectively the 530 heads used in second and third re-revisions in line. The trend to increase stability by using heads of larger diameter has not so far been in any way marked.

For subsequent more detailed evaluation and further subdivision of the above-mentioned implants it is necessary to realize that the success of a particular acetabular component in consideration of revision rate (RR) or survival curves is significantly affected also by the causes leading to femoral component revision and vice versa. In spite of it, by appropriate settings of the "revision causes" filter, we have attempted to reduce the impact of those causes that are explicitly on the side of the opposite component. Where it cannot be unambiguously determined, we have left the cause in question valid for evaluation of both components (e.g. luxation). These facts are referred-to in tables and graphs. The filter settings for individual groups of components in the outputs presented hereunder is shown in a table (Tab. 47) and can be changed for other evaluations.

Coming next are more detailed evaluations of individual, already aforesaid groups of implants further subdivided by the type of fixation. The items are ranked by usage frequency and each has its own revision rate (RR) calculated. For cemented elements recorded were all replacements of which no less than 100 have been used, and at least 50 for revisions. The thing is that determining and comparing revision rates (RR) in smaller samples does not make sense because the result is overburdened with the error of small numbers. Just as inevitable is to acknowledge that comparisons may be drawn between at least approximately equally large groups (in the tables they are very roughly separated by a bolder line).

The first group constitutes of the most widely used non-cemented cups in primary implantations (Tab. 48, Graph 30), followed by non-cemented stems (Tab. 49, Graph 31), cemented cups (Tab. 50, Graph 32) and at last cemented stems (Tab. 51, Graph 33).

Next group constitutes of similarly classified implants, this time used in revision surgeries. Naturally, they have to be evaluated separately because the risk of their failure is different and the assessed numbers lower, therefore we have included all implants of which more than 50 were used. It is also needful to bear in mind that the presented evaluation does not tell us anything about the conditions, indication and physical status, under which each particular revision implant was used. In revision surgeries they may differ fundamentally. The following tables and graphs may thus be perceived more likely as a summary of usage frequency of various types of replacements in revision surgeries rather than a pronouncement of their success.

Accordingly, the RR value is not provided here but by contrast we have added a summary of implants usage in re-revision surgeries. Implants are ranked in the same way; non-cemented cups first (Tab. 52, Graph 34), followed by non-cemented stems (Tab. 53, Graph 35), cemented cups next (Tab. 54, Graph 36) and lastly cemented stems (Tab. 55, Graph 37).

In the end of the summary of used materials we have placed also two tables presenting the used types of cement and their shares in primary implantations (Tab. 56) and revision surgeries (Tab. 57). The presented values reflect solely the number of records of use of particular cement in individual components, not the amount of packages – thus they may markedly vary from the recorded number of primary implantations and revision surgeries.

Survival curves of the most frequently used materials

Survival probability of an observed phenomenon in time (implant, component) can be processed in a number of methods, each having its advantages and drawbacks (1, 4, 7, 9, 13), and is quite hard to decide which one is to be applied in the register.

Most frequently used in orthopaedic surgery for purposes of registers and professional publications in the field of joint replacements are the calculations of cumulative survival curve by the Kaplan- Meier (KM) (1, 3, 11) or their simplified versions (4, 6).

When applying the original KM method on data from the NRJR we have encountered a problem with calculation complexity and portrayal of the calculated curve in large data files (> 1000 cases). With the original KM method the censored events are always indicated on the curve, even if they do not change the curve continuity, whereas the observed events cause breaks of the curve at given particular exact point in time. The amount of data thus gets cumulated very densely, indicators and breakpoints on the curve coincide, and the curve becomes difficult to read or requires enormous space upon presentation.

When calculating cumulative probability in the format for public outputs with the aid of data block, we

have decided to combine both the observed and censored events into independent annual intervals.

The calculation formula used for individual years is shown in the table below (Tab. 58). By comparing the calculation results with the employment of real data from the register in a simplified procedure selected for the „data block", and matching it with the results obtained after processing identical data by several types of commercial software we have found out that results for larger files vary in hundredths, exceptionally in tenths of percent. Consequently, for all outputs presented herein a simplified calculation procedure was used.

Summarized simplified calculations, however, do not have to be sufficiently precise where it is necessary to process a smaller sample of cases (< 100) with short period of monitoring (< 5 years). For their treatment, needed especially for individual publications, the „data block" will in the future have to enable data export in the Excel table format, applicable in various commercial and freeware programs.

For portrayal of the curves we have in the end selected two slightly different solutions. For scientific outputs reflecting the processing of nationwide data we have used simple black-and-white alignment charts with marked values achieved in individual years because these are easily generated directly by Microsoft Excel and they meet the required informative purpose with low levels of labour input and publication costs.

For public on-line outputs the data was processed by add-on software, which in addition to more sophisticated colour graphics also provides for highlighting the changes in individual years by corresponding step break of the graph.

Detailed analysis of the issue of construction and publication of the KM curves exceeds the framework of this statement and we assume that it will become subject of an independent publication in near future.

As interesting and representative outputs from the register we have selected the tables of calculation of cumulative survival probability (KPP/CSP) always for 3 most widely used components in the following categories – non-cemented cups, non-cemented stems, cemented cups and cemented stems always for primary implantations sample.

First, we present cumulative survival probability and its curves for the most widely used non-cemented cups of the brand Plasmacup SC (Aesculap), 6 738 implantations (Tab. 59, Graph 38), CLS Spotorno (Sulzer), 3 701 implantations (Tab. 60, Graph 39) and ALLOFIT (Sulzer), 3 173 implantations (Tab. 61, Graph 40).

Next come three most widely used non-cemented stems – SL Zweymüller Alloclassic stem (Zimmer), 2 708 implantations (Tab. 62, Graph 41), Bicontact stem (Aesculap), 2 249 implantations (Tab. 63, Graph 42), and third in line the Zweymüller SL Plus stem (Endoprotetik Plus, 2 055 implantations (Tab. 64, Graph 43)

The curves generated for the most widely used cemented cups in primary implantations are for the most widely used component in the register in general, for PE Müller cup (Aesculap) 10 196 implantations (Tab. 65, Graph 44), for SPC PE cup (Sulzer), 5 397 implantations (Tab. 66, Graph 45) and for Müller ZZ cup (Biomet Merck), 2 217 implantations (Tab. 67, Graph 46).

The last group of survival curves is devoted to the most widespread cemented stems, these being the THA stem with cone-shaped neck 12/14 AK (Beznoska), 9 932 implantations (Tab. 68, Graph 47), Centrament stem – newer type (Aesculap), 8 477 implantations (Tab. 69, Graph 48) and Geradschaft konus stem 12/14 cemented (Sulzer), 6 904 implantations (Tab. 70, Graph 49).

Examples of pre-assembled outputs for public web portal

For the prepared public web portal the basic epidemiological nationwide data is processed into coloured on-line outputs in the form of tables and consequential 3D graphs. Control is directly on the portal from pop-up menus enabling easy definition of a time period in years and specification of basic filters.

Similarly prepared will soon as well be the fundamental outputs accessible to registered professionals, which outputs will in addition present data also for their respective hospitals. Of course, pop-up menus do limit the means of precise file specification and these outputs will serve the professionals solely for rapid orientation.

As an illustration we have chosen the following examples of outputs presented here only in black-and-white concept – curves of cumulative survival probability by the type of fixation for cemented implants (Tab. 71, Graph 50), hybrid implants with cemented acetabular component (Tab. 72, Graph 51), hybrid implants with cemented femoral component (Tab. 73, Graph 52) and non-cemented implants (Tab. 74, Graph 53).

Other graphs illustrate the influence on implant survival and survival curves in some basic input diagnoses regarded as hazardous. Presented first for comparison is the cumulative survival probability and its curve in patients with primary osteoarthritis(Tab. 75, Graph 54) and then analogous data for a group of patients with either of the form of congenital hip dysplasia (Tab. 76, Graph 55), rheumatoid arthritis (Tab. 77, Graph 56) and post fracture status (Tab. 78, Graph 57). Appropriate filter settings allow further evaluation of the latter data for males (Tab. 79, Graph 58) and females (Tab. 80, Graph 59).

Indeed, it is possible to examine the groups of patients in the register from a range of other aspects, but detailed presentation thereof goes beyond the scope of this publication.

CONCLUSION

The presented outputs represent a first attempt to process the data collected in the Czech NRJR in a wider degree. In the future, these outputs will need to be further cultivated with care of the input-database quality and with the engagement of modern analytical procedures upon data processing. The structure and character of out-

puts selected for publication in periodical annual reports will also have to be optimized.

Future development will still require considerable professional efforts as well as financial means essential to turn the NRJR into a truly effective, readily available tool, utilizable for the improvement of health care quality and applicable in the management of activities of an orthopaedic department. For the time being, we are at the outset of our journey, however, we believe that solid foundations for further development have been laid.

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