Quality of Datatsets for Outcome Measurement

Quality of Datatsets for Outcome Measurement, Market Monitoring and Assessment of Artificial Joint Implants

G. Labek, B. Stöckl, W. Janda, M. Hübl, M. Thaler, M. Liebensteiner, A. Williams, W. Pawelka, St. Frischhut, F. Haselsteiner, R. Schlichtherle, M. Agreiter, J. Abel, R. Dorninger, K. Sekyra, R. Rosiek, E. Mayr, R. Hochgatterer, K.-P. Pfeiffer, M. Krismer, N. Böhler

EAR
European Arthroplasty Register
EFORT – JOINT EFFORTS

Contents

Introduction and Background

Due to the large number of confounders, outcome quality is not always easy to measure in the field of medicine. The patients' individuality, differences in surgical procedures, the experience and skills of the surgical team, or the framework conditions of the respective health-care system may considerably influence the final outcomes.

As early as more than 20 years ago in Scandinavia the experience with implants such as the Christiansen Hip, where inferior performance was only detected after a large number of patients had been treated with this implant – and after a considerable number of revisions had occurred, with all negative personal and financial consequences, these countries were induced to go a new and different way. This was achieved by recording all interventions via a register, thus setting up a system of continuous quality control. The advantages of this methodology have meanwhile been scientifically recognised worldwide.

Introduction and Background

For methodological research work several basic prinicples should be taken into account:

1. At present, there is no uniform definition of registers worldwide. Based on the Scandinavian standards, the following definition was determined for EAR:
   Registers are defined by the following criteria:

   - Registration of ALL primary and revision operations in a defined area in a central database.
   - Following the implant until it has to be revised, the patient dies or emigrates.
   - Definition of Revision as 'Failure': at least one part of the implant has to be revised during revision surgery.

2. For sample-based studies the main challenge is to ascertain whether the results are representative for 'the general public'. However, on a worldwide scale 'the general public' is not a homogeneous entity. Hence the crucial question for the readers of scientific literature is to what extent the results and the particular issue are applicable to their own practice, and whether the published results are reproducible.

3. Registers can provide a solution to this problem if the data collection is largely complete. However, this is only true for the system where the data have actually been collected, for instance, in the countries where a register is run. Transferring the results to another country may imply that outcome-relevant influence factors become effective. For instance, in a country with many years' experience in cemented arthroplasty, such as Sweden, one can assume that, due to a great deal of know-how and highly standardised prodedures, the quality of surgical cementing technique is high on average. Such an assumption does not always apply to the same extent to countries having little experience with this technique so that the results achieved with the same implant may be different in another country.

4. This should be taken into account in procedures for data quality assessment, indicator validation and the handling of information. For instance, for sample-based studies it is essential to describe patients and procedures in detail to enable the reader of the study to evaluate the transferability of results to his/her own individual environment. For the assessment of register results within the same system (e.g. a country, or a department) transferability can be expected since the results reflect the circumstances under which they have been obtained. However, when register results are used outside the system, it is essential to verify the backgrounds of the basic data and the methods of data processing, and to adjust the results accordingly. Since the annual reports currently published by National registers are primarily destined for use within the respective system, the backgrounds of the data are usually not described in detail. This may give rise to misinterpretations. A general consensus with respect to essential contents, as used, for instance, in the section 'Materials and Methods' in publications from sample-based studies, does not exist for register publications. Since registers refer to a very broad database, the description of mean values appears to be a feasible option.

Introduction and Background

Arthroplasty and Traumatology differ greatly as regards the datasets available for indicator calculation. In the field of arthroplasty, the first National arthroplasty registers were founded in Scandinavia in the 1980s. Since the year 2000, a marked increase in similar projects has been observed in the majority of EU member states, and also on a worldwide scale. It can therefore be expected that an increasing amount of high quality register data will be available in the future, which will open up additional possibilities in methodological research and allow for inclusion of register data in decision-making processes.

Arthroplasty implantations are characterised by several positive aspects with regard to outcome measurement:

1. As a rule, a serious problem of the implant itself or associated with the intervention sooner or later leads to a revision operation. In those situations where this does not apply, for instance, if the patient's severely impaired general condition does no longer allow such a serious operation, one can assume that in comparative analyses (of various THA products, for instance) these cases are roughly evenly-distributed in the cohorts.

2. There is no direct inter-relation of the event that is to be recorded (revision operation) and unsatisfactory outcome.

3. The end-point to be recorded is a surgical operation, hence good routine documentation from therapy is available, which, when necessary, can also be recorded and controlled retrospectively.

4. The end-point to be documented is a largely standardised, objective parameter.

Similar situations are also found in implanted medical products not pertaining to Orthopaedics, for instance, in cardiac pacemakers. Within the Orthopaedic field, the same positive pre-requisites do not apply to every intervention or pathology. For example, the pre-requisite of 'every serious and unsatisfactory result leads to revision surgery, and every revision operation can per se be rated as a failure' does not apply to spine or traumatological interventions.

Disadvantages and Limits of Registers:

1. Registers are aimed at recording all relevant cases as completely as possible. To achieve this goal, the documentation burden for the clinic staff must be kept at a low level. This either requires clearly structured and short questionnaires, or the use of routinely collected data.

2. Registers are therefore well suited to record clearly structured issues such as the frequency of revision operations, or a rough statement about the reason and the failing component. By contrast, complex issues such as long-term post-operative clinical outcome are less suited due to organisational reasons. However, registers can be used to support the definition of samples or in recording patients concerned, for instance, for retrospective analyses or vigilance control.

Introduction and Background

3. Register collections require well-defined entry criteria (e.g. an operation) and a clearly defined and well ascertainable end-point (e.g. the revision operation). Issues to which these basic requirements do not apply (e.g. adverse effects after drug therapy) can therefore not be recorded using this instrument and should be covered by means of sample-based randomised controlled trials, surveys or incident-reporting systems.

Clinical studies and registers have different prerequisites as regards possible applications and organisation:

1. By referencing to the total population, registers are able to exclude or minimise bias factors. This, however, requires strict control of the boundaries of the area monitored. With National registers within the EU this is at present sufficiently ensured by linguistic and administrative barriers. Along with the increasing practical implementation of a common market for medical services, however, adaptations will be necessary, for instance, the exchange of information and the consideration of Europe-wide identification numbers for data collection.

2. As previously described, registers are applicable in the case of clearly defined issues. Modifications of the recorded contents are associated with considerable expense. Thus, registers are capable of serving as a monitoring tool and providing good, comparable, valid data for analyses. However, they are not very flexible.

3. Sample-based clinical studies are much more versatile with regard to operating procedures, surgical and nursing standards, general influences through the health-care system, as well as the individual objectives of the studies. At the same time, they are considerably more flexible and able to cover individual and detailed issues in study design much more adequately.

When organising an examination, it is essential to use the best tools available. As a basis for further detailed studies, registers are able to provide substantial support, for instance, in defining study cohorts.

Since the specific requirements of arthroplasty registers do not apply in the field of traumatology, the foundation of National registers has proved to be much more complex and considerably more difficult. Up to a few years ago, a corresponding project only existed in Sweden. In recent years, similar projects were launched in Norway and also in other Scandinavian countries.

Clinical Studies versus Register Data

Value of Sample-Based Clinical Studies for Outcome Measurement as compared to Register Data

Methodology

A methodology has been developed that allows for direct comparison of different datasets adjusted for cases included in the study cohorts and follow-up period. It is based on the indicator 'Revisions per 100 observed component years' introduced by the Australian Arthroplasty Register, a variant of the indicator 'Revision Rate'.

The concept of 'Revisions per 100 observed component years' is as follows:

- From the moment of implantation of the implant there is risk for revision. The total number of individual years from implantation (= observed component years) are counted.
- The total number of revisions as the failure endpoint are documented and calculated in 'Revisions per 100 observed component years'
- A value of 1 represents a 1% revision rate at 1 year and a 10% revision rate at 10 years of follow-up.
- The advantage of this method is the possibility to compare datasets adjusted for the two main influence factors on the value of individual cohorts, number of cases and follow-up period.

This concept and the indicator can easily be used for clinical studies, as well.
As to register use, the main limitation is that the reasons for revision and the frequency may differ on the time-line. But since the majority of published data include at least medium- to long-term results, the impact on the final outcome should be low.
For the assessment of clinical studies a linear function of distribution was estimated when a period of follow-up was mentioned instead of a clear cut-off point.

A structured literature review was performed based on electronic libraries such as MEDLINE that was followed by a manual literature research. Conventional meta-analyses were carried out from peer-reviewed journal publications in English and German language. The pooled results were stratified for potential influence factors such as the region of origin, or whether the inventor of the implant was part of the study team. These results were compared to data from worldwide arthroplasty register reports. Statistical analyses were performed calculating confidence intervals.

Clinical Studies versus Register Data

Methodology

To take account of potential confounders such as the impact of the surgeon or surgical techniques, a cut-off point for relevance was defined. A difference factor up to 3 (for instance, the revision rates of a dataset are 3 times as high as in the control group) between the datasets was considered to be explicable by individual expertise, circumstances in the particular hospital and other potential confounders. The value of 3 was selected because this value covers the variability of individual hospitals in countries where National registers publish these data, such as the Swedish and the Danish National Arthroplasty Register, as well as the deviation from the mean of revision rates of individual implants in various National registers.

	Sweden	Norway	Finland	Denmark	Australia	New Zealand	England & Wales
AGC	0.94	0.56	0.76	2.39	0.77	0.38	
NexGen	0.37/ 2.71				1.55	1.66	1.27
Oxford Uni	0.86		1.17		0.97		
Duraloc	1.04			1.02	0.86		1.14
SP II	0.67		2.20	1.60			
PFC	0.91			1.44	1.03	1.02	0.88

To be rated as an outlier, positive results were required in both categories, statistically significant differences by non-overlapping of confidence intervals and relevance by exceedance of a difference factor of 3 between the datasets.

Clinical Studies versus Register Data

Results

The data presented in the clinical literature show a high degree of authors' influence as regards the number of cases published.

Region	Number of Articles	Number of Articles by Inventor	Number of Independent Articles	% Publications by Inventor	Number of Cases	Number of Cases – Inventor	Number of Cases – Independent	% Inventor	CI
EU	72	12	60	16. 67	12,408	908	11,500	7.32	6.78-7.79
GB	30	11	19	36.67	3,974	2,140	1,834	53.85	52.30-55.40
USA	127	36	91	28.35	51,321	30,617	20,704	59.66	59.23-60.08
Total	262	62	200	23.66	79,040	34,521	25,677	43.68	43.33-44.02

This influence is even greater in studies from the USA and Great Britain than in studies from continental Europe, which might be a consequence of the different structures in scientific and public health procedures.

Authors per se show a relevant bias in outcome:

- Of the examples investigated in the project, fourteen had a clearly identifiable individual author or a developing institution.
- Six (=43%) of these developers have published results showing a statistically significant and relevant difference in outcome as compared to comprehensive, non sample-based register data.
- Implant developers have very special expertise and can make use of other particularly favourable conditions potentially resulting in the fact that their results are not representative for the performance to be expected.

» Developers usually deal with a subject matter intensely and in great detail so that one can presume the clinic's high expertise and their fundamental understanding of the product and its handling.

» Developers might be highly motivated themselves to thoroughly examine potential outcome-relevant failures in the entire course of therapy and take the appropriate steps.

» The final result of an arthroplasty implantation depends on a variety of factors, such as the product, instrumentation, surgical approach, patient selection, etc. Since product development is always based on a specific background and pool of experience, a product might reflect the particular consideration of factors prevailing in the developing clinic.

» Implant designers and associated manufacturers pursue their own economic interests, which may have an influence on the communication of results.

Clinical Studies versus Register Data

Results

- Even if one takes all aspects into consideration that might lead to superior outcome when the intervention is performed by highly specialised experts as compared to the average surgeon, the data published by some of the inventors show differences which are difficult to explain by superior surgical knowledge and competence. The most impressive examples are located in the USA.

Implant	Statistically Significant	Factor	Region of Origin
Pappas-Büchel TAA	+	14.31	USA
Taperloc	+	8.19	USA
BHR	+	4.87	EU (GB)
STAR	+	4.63	EU (DK)
Oxford Uni	+	4.37	EU (GB)
AGC	+	4.15	USA
Agility	-	2.43	USA
Avon	-	2.17	EU (GB)
Hintegra	-	1.94	EU (CH)
Conserve Plus	-	1.54	USA
Lubinus SP II	-	0.98	EU (D)
LCS	-	0.86	USA
Alloclassic SL	-	0.76	EU (A)
PFC	-	0,64	USA

- In summary, it has been found that the majority of clinical studies published by the developers of an implant do not allow drawing adequate conclusions or making predictions as to the average performance of an implant. On the other hand, not all implant developers have shown a high deviations from the average. A general impact on the outcome due to the specific expertise of the inventing surgeon can therefore not be declared.

Clinical Studies versus Register Data

Results

The clinical literature shows a high degree of statistically-significant differences as opposed to non sample-based register datasets:

- After exclusion of low volume implants and products where data are exclusively available from the inventor, eleven systems are left for assessment of an individual author's bias and its impact on aggregated literature evaluations.
- In six examples the bias by the author has a significant impact on aggregated data, in 5 implants this bias leads to a significant bias of the entire dataset.
- In three of eight examples even independent studies have shown statistically significant bias. All datasets were compiled in the USA. With respect to AGC, independent literature from the US has shown a significant and relevant deviation while European literature was in line with the register benchmark.

Implant	Significant Bias in Independent Literature	Author Bias	Author Bias leading to Bias in the Aggregated Assessment	Region of Origin
Pappas-Büchel TAA	+	+	+	USA
Taperloc	-	+	+	USA
Accolade/Trident	+	n.a.	n.a.	USA
Duraloc	-	n.a.	n.a.	USA
AGC	+/-	+	+	USA + EU
NexGen	-	n.a.	n.a.	USA + EU
LCS	-	-	-	USA + EU + Asia
PFC	-	-	-	USA + EU + Asia
Oxford Uni	-	+	+	EU
STAR	-	+	+	EU
BHR	-	+	-	EU
Alloclassic SL	-	-	-	EU
Lubinus SP II	-	-	-	EU
Spotorno (CLS)	-	-	-	EU

- When applying the usual assessment procedures based on sample-based clinical studies without taking recourse to comprehensive reference data, one must thus expect a high percentage of results deviating significantly from the actual situation of the population.

Clinical Studies versus Register Data

Results

Structured surveys show better agreement with register data, but are inferior to outcome registers in data quality and organisation.

- Structured surveys are only found in individual cases. All examples available for the issues under examination come from the US, particularly in total ankle arthroplasty and implant fracture. Even though they are more consistent with worldwide reference data from registers, detailed analysis has shown that they are also susceptible to misjudgement.
- In a survey conducted in California (lit. 37)regarding the revision probability in total ankle arthroplasty the benchmark of worldwide register results was underestimated by a factor of 1.9. The difference is statistically significant.
- In a survey recording implant fractures (lit. 37) comparable results were shown for the frequency of cup and head fractures; the reference values of the stem fracture rate, however, has been found to deviate by a factor of 26.

Experimental studies show a low correlation with the clinical outcome.

Conclusions regarding the prognosis of future outcome should not be drawn without support by sufficient clinical outcome data. Since experimental studies are frequently conducted at the beginning of new developments, this information is often also applied in licensing procedures and marketing activities when new products are brought onto the market.

Publications based on randomised controlled trials do not show essential improvement in the quality of the studies in an assessment of patella replacement at total knee arthroplasty.

The usual categorisation appears to be inadequate for endoprostheses and comparable medical devices.

Randomised Controlled Trials (RCT) are the valid gold standard in clinical research. In the analysis of literature on endoprostheses it is noticeable that such study designs are very rare. That such studies are largely missing in the context of outcome in arthroplasty must also be seen under the aspect that the basic prerequisites for medical devices and pharmaceuticals differ to a relevant extent. In his PhD thesis Prof. Leif Ivar Havelin demonstrated in 1995 that an RCT comparing two implants would require as many as 13,474 patients in order to identifiy a 1% difference in revision rate in compliance with the usual requirements for power analysis. These are more patients than are treated with THA in a country like Sweden per year. Hence such studies encounter organisational limits. Since a minimum of five, typically 10 years follow-up are required for clinical studies, the results of such studies would only be available after a long delay while in the meantime a large number of patients would be exposed to a high individual risk and the public health sector would have to bear considerable financial risks.

Clinical Studies versus Register Data

Results

However, randomised controlled trials are used for clarification of surgical technical issues and for migration analyses. Within the scope of the present project the question was explored whether or not patellar resurfacing should be performed simultaneously with primary TKA implantation – a topic that has been a matter of controversial discussion for years. The reason for choosing this subject was the observation that the majority of medical recommendations are in favour of patellar resurfacing, whereas register datasets from Scandinavia (besides offering epidemiological information about the application of surgical techniques) have been showing a clear trend for over 10 years not to perform patellar resurfacing.

Comparative clinical studies of various designs were collated with register data. In this process a significant bias became apparent in sample-based clinical trials.
Patients not having received initial patella resurfacing were subjected to revision surgery twice to three times more often than those patients who had already been treated with this implant in their primary operation. Hence the recommendations in favour of performing primary patella replacement appear to be justified.
However, these data from sample-based studies could not be reproduced in the reference dataset from worldwide registers, which does not show any major difference between the two treatment groups, the revision rate being close to the values received in clinical studies dealing with primary patellar resurfacing.
The bias is largely independent of the study design with RCTs showing a similar distribution as conventional studies. In review papers the bias is rather re-inforced.
From these data one must conclude that randomised controlled trials do not necessarily protect against bias and are not superior to conventional, non-randomised study designs.

These findings could be interpreted as follows:

- The methodology of RCTs was originally developed for clinical studies in the pharmaceutical area. For organisational reasons, comprehensive monitoring as exercised by arthroplasty registers is not possible in this field.
- It is the objective of RCT procedures to exclude the well-documented bias through individual valuations on the part of the patient and the examiner by means of blinding with regard to the therapy (or a placebo therapy) administered.
- The result of this procedure should be the determination of a preferably unbiased end-point. These end-points often represent subjective assessments. However, the procedure considerably improves the objectivity of comparative analysis.
- If medical devices are concerned, like in patellar resurfacing, the end-point is also a subjectively influenced decision: to perform revision surgery.
- However, a critical factor in this decision, the physician indicating the revision operation, is no longer blinded even if the formal requirements are thoroughly observed. For deciding on and planning an intervention, radiological findings are usually required from which the previous therapy can clearly be derived.

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- Also on the occasion of routine follow-up examinations after TKA implantation x-ray images are usually taken, during which the patient could obtain information about his/her therapy.
- Hence, if the formal RCT requirements are fulfilled (e.g. by identical appearance and packing of the drug) and careful data management provided, one can assume in pharmaceutical studies that secondary deblinding can be avoided. However, these basic requirements are not definitely guaranteed in the case of medical devices such as endoprostheses even if all formal requirements are thoroughly met.
- In the case of endoprostheses, the formal guidelines of study design do thus not ensure that the expected gain in objectivity is actually obtained.

Based on the data available, a modification of the classification of data quality should therefore be taken into consideration.

1. Comprehensive data collections such as registers are to be rated as superior.
2. Randomised controlled trials should be evaluated with respect to the end-point.
    I. In case of objective end-points such as measurement results (e.g. migration of implants as an early indicator of loosening) a randomised controlled study is to be considered equal to the applicable guidelines.
    II. In case of subjective end-points it has to be checked whether blinding could be broken by postoperative examinations. In this case it should be assumed that the results are compromised.

The authors' assessment in the publications evaluated regarding the quality of a product or a recommendation in favour or against its use basically correlate well with the revision rate indicator. However, there is an overlap area where the evaluation turns out to vary in retrospective analysis. Most commonly, this is encountered in a range between 1 and 2 revisions per 100 observed component years, where the majority of those products show inferior performance as compared to competitive products but do not have catastrophic deficiencies. It is in this very range where controversial discussion is also observed in marketing, and where there is ample need for selective and comparable analyses.

In this issue, the subjective evaluations of study authors should not be regarded and used as a reliable parameter for recommendations. Standardised evaluations of the basic data could increase the discriminative power.

Registers monitor considerably larger collectives under better described, standardised and comparable conditions and therefore outvalue clinical studies as a data source.

Clinical Studies versus Register Data

Results

Registers yield valid results much more rapidly than sample-based clinical studies and surveys and are thus able to considerably reduce the periods of time until robust statements can be made concerning the outcome of a medical device or a surgical approach. This refers to periods of several years.

Influence of national circumstances on the outcome of implants:
Even if register data in general have proved superior when compared with other data sources available, some particularities must be considered in the valuation of results.
Arthroplasty registers reflect the conditions prevailing in the regions they cover. This relates, for instance, to the experience with particular medical devices, to surgical approaches, but also to the influence the public health system has on the outcome of a therapy. This allows for comparative analyses and facilitates controlling the effect of modifications. However, this aspect should be taken into account in the comparative evaluation of National register results, and the results should be checked with regard to potential local influence. This should be ensured by involving representatives of the National registers in the evaluation procedure.

In case of comparable circumstances, however, register results are highly consistent.

Without registers it is mostly impossible in an independent analysis to deduce the decisions which have led to a decrease in the use of particular implants or a product recall from the results published in scientific publications. This is usually decided autonomously by manufacturers and physicians in non-public discussions, or by means of a decision-making process at a scientific level. External control or monitoring by scientific societies and public health institutions is thus impossible. The mere access to register data would allow for sufficient control and open up the opportunity of autonomous decisions.

In the organisation of studies and surveys objective end-points are essential. As a rule, subjective end-points entail subjectively biased decisions and results which, without reference sources, may lead to misinterpretations in meta-analyses.

A combination of register data and migration analyses is the most promising basis for evaluating the implant outcomes to be expected.
Migration analyses based on relatively small numbers of cases can provide reliable predictive statements with reference to long-term loosening rates of an implant within a period of about two years. They can thus be integrated in the usual licensing studies and considerably increase the quality of the evaluation of future risks.
Registers can provide statements about potential inferior outcomes and revision rates much more rapidly than any other data source. Contrary to migration analyses they also can detect relevant faults in the production process or in surgical practices.

In combination with registers, patient self-assessment quality-of-life questionnaires can contribute to further improve the quality of statements and reliability of predictions. First projects are currently being developed by National registers.

Clinical Studies versus Register Data

Results

The publication frequency in peer-reviewed scientific journals decreases considerably after a product has been taken from the market or replaced by a succeeding variant. Thus the possibility is lost to detect structural problems of the medical device. This would be particularly important with durable, implanted medical devices such as endoprostheses which mostly fail only after many years. Since the follow-up of implants can obviously not be sufficiently ensured by the publication of clinical studies, this aspect should be covered by means of registers. By this method, this is possible at modest additional expense.

Since clinical studies and arthroplasty registers have different impact factors for the assessment of quality, the project team decided to set up an updated **Proposal for a description of register datasets regarding their quality and validity as a basis of decision-making:**

Comprehensive data collections such as outcome registers or discharge records differ with respect to their validity for particular purposes. A crucial point is to achieve the best possible agreement between the purpose of data-collection and the issue in question. Another essential dimension is data collection completeness. The assessment of the validity of a dataset thus depends on its internal consistence and its suitability for the issue to be clarified.

Proposal for the structured assessment of data sources for outcome research and structure and process quality issues:

Aim / Purpose	Outcome (A)	Process (B)	Structure (C)
Conformity between aim of data collection and aim of evaluation	Data collection performed for the specific purpose of evaluation (1)	Data collection not performed for the specific purpose of evaluation (2)	
Coverage	Nationwide (1)	Regional (2)	Local (3)
Data collection	Comprehensive (1)	Incomprehensive (2)	Sample-based (3)
Conformity dataset for assessment	Representative (1)	Not representative (2)	

The results can be summarised as follows:
1. the purpose of the data collection in a letter code (A,B,C);
2. internal dataset quality in a descending 3-stage numerical code.

Clinical Studies versus Register Data

Results

Proposal for further improvement of register publications for supra-national purposes:

- To be able to make optimum use of such advantages, the publication procedures of registers should be standardised.

For the performance presentation of medical devices it would therefore make sense to proceed as follows:

- In the general report on a national level and in supra-national reports implant components should be represented separately because the statements have a more general character as well. Evaluations referring to a striking frequency of unusual revision interventions with certain combinations would be a highly targeted approach to be integrated in the annual report, but should only be presented in detail in case of positive results.
- The procedures for confidential departmental reports should not be standardised. In these reports, the additional presentation of particular component combinations –as usual in the Australian Register Report, for instance– could be advantageous.

- There are big differences in the use of implants in the various countries and, by implication, in registers as well. To obtain a comprehensive overview of the products used in the Common Market of the EU, a supra-national evaluation of national results based on a standardised methodology is required.

- At present, there is no standardised designation of the implants recorded in the various national register projects. On the part of the producers no current efforts are made to standardise product designation either. Referencing to the product number can clearly identify the product on a National, but not on an EU level. Since product numbers are also used in administrative processes such as orders, it may occur in a National register that medical devices are recorded differently in different projects at the users' level or due to recording via specific distributors' numbers instead of using the original manufacturer's numbers.

The maintenance of product databases is one of the most complex tasks of an arthroplasty register. Europe-wide standardisation by means of a unitary reference database would economise the operation of registers and lead to an increase in quality.
At the same time, however, it is a pre-requisite for efficient reporting on EU level.

Market Monitoring and Post-Marketing Surveillance

Basics and Background

Increased revision rates and implant failures can have various reasons:

- Failure of the medical device itself, either due to normal wear, premature breakdown, or product deficiencies;
- Failure due to incorrect handling during implantation or use;
- Failure due to employment in situations which overstrain the product in terms of stability, fixation within the body, or with respect to other essential characteristics.

The causes of failure can thus be multi-factorial and, for the most part, are not clearly attributable in a superficial evaluation.

Product deficiencies of significantly increased revision rates causing extensive harm to very many patients are fortunately relatively rare in view of the actual number of interventions. Nevertheless they are a relevant problem.

These circumstances lead to considerable difficulties in the evaluation of individual incidents by a physician or other persons involved. It should also be taken into account that every group affected by product deficiencies and their consequences may suffer individual disadvantages, which in turn may influence individual decisions.

The subject-matter was treated from various perspectives.

1. A structured literature research was performed with regard to the incidence and revision rate of a clearly defined product failure, the fracture of a THA component, and the results obtained from diverse, publicly accessible data sources were compared. The data sources examined comprised publications by public health institutions in charge of market monitoring and the recording of product failure, scientific publications and arthroplasty registers.

2. The processes and available data were evaluated by the example of three recent incidences of product failure:
   - Megasystem C, Implant fracture or conus dislocation, 2006+2007
   - Varicon, Implant fracture, 2004-2007
   - Durom,Suspected high rates of short-term loosening, 2007

Market Monitoring and Post-Marketing Surveillance

Methodology

A series of recent incidents have been identified and decided to be evaluated in detail concerning the access to data and organisation of the procedure. The manufacturers have been contacted and available documents were assessed. The available information was summarised and analysed in order to identify lack of sufficient information, workflow, capabilities of stakeholders to detect the incidents and to extract proposals for improvement.

As additional reference material a structured literature review with comparison to register data concerning fracture of total hip implants was used. The attempt to include data from public health institutions responsible for market monitoring failed due to insufficient published information.

Limitations

Frequently the manufacturers are reluctant to give access to the entire information, so the decision to select a certain incident was dependent on compliance by the manufacturer (Falcon and Link) or published documents. This method of decision-making might lead to limitations in generalisation of the findings. Since examples were evaluated in general no conclusive statements can be made, only starting points for discussion in order to improve procedures and to identify problems are possible.

Market Monitoring and Post-Marketing Surveillance

Results

Quality of the data available

- Considerable differences became evident regarding the incidences of product failure between registers and scientific publications.
- Scientific literature on the basis of sample-based studies is almost exclusively focussed on case reports and therefore is of limited validity in a global evaluation.
- With regard to the validity of statements, structured surveys are superior to clinical publications but inferior to registers. Also due to organisational reasons, registers should be given preference to surveys if there are both options.
- A leading manufacturer of ceramic heads has published incidences of ceramic fractures that were five times below the reference dataset value from registers. The implant manufacturer himself assumes that the numbers recorded only represent a third of the actual numbers of cases.
- The basic data received from market surveillance by the manufacturers seem to be insufficient. The sample of monitored implants is too small and possibly subject to a selection bias.
- In the examined example of the Durom cup a structured follow-up study by the manufacturer yielded the 11-fold revision frequency as compared to the initial value tracked through the regular procedures. However, such measures are only possible in case of substantial reasons for intervention. Yet the results correspond well with reference data from a National register that would have already been available six months before the mentioned survey was initiated due to the complaints of a prominent surgeon in the USA.
- Since the manufacturers' reports represent a main source of information for public health institutions, one must assume that the authorities face similar difficulties with regard to basic data as the manufacturers.

Market Monitoring and Post-Marketing Surveillance

Results

Course of Action in case of the Detection of Inferior Products or High Revision Rates

- In all cases incidences were initially reported by individual users. Due to the specifics of durable implants, however, this is only possible to a user in exceptional cases and when failure patterns are defined quite clearly. It must be assumed that the estimated number of undetected or unreported cases of inferior outcome increases with less spectacular incidents.
- The assessment of observations is restricted due to the lack of comprehensive reference data and subjected to subjective judging. In retrospective evaluations supported by more qualified basic data not all decisions turned out to have served the purpose. This was also true for the passing on of data to central bodies, entailing belated reactions on their part. As a result, the course of action was delayed several times without giving cause for accusing individual decisions of gross carelessness.
- Reporting to the health authorities was handled by the manufacturers. From the part of the users, public health institutions received only insufficient information even though this group is also legally obliged to notify the authorities.
- The present report deals with relatively clear events of damage, which the respective manufacturer and authorities have already recognised accordingly. In less evident incidents, a certain number of belatedly or undetected product deficiencies must be expected.
- In all cases examined, the manufacturers reacted very quickly and in compliance with the relevant regulations.
- In terms of quality, the basic data available for decision-making to both the manufacturer and the health authorities do not always correspond to requirements.
- In all cases examined the stakeholder primarily active in analysis and reasoning was the manufacturer.
- Under these circumstances it is hardly possible to conduct valid and comprehensive risk assessments.
- Due to legal restrictions (data protection) manufacturers are not in a position to collect and administer comprehensive datasets for the individual follow-up of implants or patients as is standard practice in arthroplasty registers. Usually only public health authorities or institutions having a corresponding mandate are entitled to do so.
- Comprehensive analysis would require regular interaction of the various stakeholders (health authorities, manufacturers, physicians) in due consideration of their respective competence and responsibilities.

In summary, it cannot be assumed that the data available from the present sources are sufficient. The present form of market monitoring -be it on the part of the producers according to the Medical Device Directive or on the part of the relevant public health authorities- is not adequate to guarantee sufficient monitoring procedures and ensure safe detection of inferior products.

Market Monitoring and Post-Marketing Surveillance

Results

Proposal for a Future Procedure regarding the Course of Action with respect to the Development and Market Launch of New Medical Devices:

- The standardisation of processes within the scope of the development of medical products should be improved. In addition to the present proceedings the following measures should be introduced:
  - Comprehensive obligation of users involved in development to report undesired events. The notification should be primarily addressed to the manufacturer and also include a commitment by the surgeon to save and return retrievals.
  - The findings of the investigation should be summarised in a report and be linked to the case that is to be reported to the competent authorities for further investigation.
  - Analogous to the regulations for pharmaceuticals, licensing studies should be centrally recorded and the findings be circulated even if they are not published or the development is discontinued.

- After licensing, revision operations should be recorded via registers; these data should be made accessible to those legally responsible (manufacturers and authorities).

- In the case of substantial irregularities detailed retrospective analyses of the incidents in question should be provided for. Registers can provide access to basic information such as patients concerned and sources for further information such as X-ray images and patient records. This information can also be used to support potentially required activities in the context of vigilance control or product recalls.

- Reports and evaluations should be interchanged among the stakeholders (registers, manufacturers, authorities, users represented by scientific societies), and the opportunity to comment should be provided for in case of publication.

- The EU should increasingly include autonomous and comprehensive datasets such as arthroplasty registers in accompanying market monitoring, risk analyses, and the handling of damage events. At present a multitude of projects do already exist or are in their developing stage.

- It would make sense to standardise reporting and data supply to authorised bodies in public health. This would require the establishment of supra-national co-ordination.

- To cover risks and handle them as efficiently as possible, it would be reasonable to install standing committees ensuring continuity and professionalism.
  The following parties should be involved:
  - Public health authorities on a National and EU level;
  - Experts from arthroplasty-outcome registers;
  - Manufacturers.

- Increased connectivity between authorities and experts would be sensible to allow for autonomous data evaluation and the option of acting independently on the part of the respective authorities.

- Due to the efficient communication network of these institutions, scientific societies can support the quick circulation of relevant information, its expert assessment and the speedy implementation of measures (e.g. the temporarily restricted use of individual products until an investigation is finished and a final decision has been made).

- The information of physicians and other parties should be improved. Among other things, this could include the special labelling of mail containing important information and summarising information on websites. This could also have positive effects on patient information.

Revision Burden: International Data Sets

International Comparison of Outcome in Arthroplasty by Revision Burden

Methodology

Content from worldwide datasets was collected in order to calculate comparisons between countries by the Indicator Revision Burden. The data were collected in 2008 according to the most recent published data at this time.

Revision Burden

The indicator Revision Burden references to general issues and public health-relevant aspects such as global comparisons of countries and systems.

An essential parameter influencing the result calculated is the development of primary interventions over time. Since revision operations usually occur with a delay of several years, this leads to a decrease in the revision burden in countries with a high increase in the frequency of primary operations; in the rather theoretical case of a decrease in operations frequency the reverse effect would be observed.

In view of an increasingly ageing population, a worldwide increase in the numbers of cases is being noticed; however, the dynamics of this process exhibits considerable differences between the various countries. Within the EU, the Western and Central European countries are comparable, where arthroplasty has nearly uniformly developed into a standard intervention since the beginnings of 1960s. For lack of know-how and adequate implants, this development was not possible in the former countries of the Soviet zone of influence. Since the opening of the borders, rapid development is being observed in this region with country-specific differences. For a comparative evaluation of this indicator within the EU, adjustment should therefore be based on the development of the number of primary operations.

This indicator can be derived from various data sources. The basic quality of the data and the intended purpose of the collection should be taken into account in direct comparisons.

It is therefore recommended to always indicate the sources of the basic data.

In the following, data available for arthroplasty treatment are represented in tabular form.

Revision Burden: International Data Sets

Hip Arthroplasty

Country	Register	Implant	Year	Source	Total Number	Primary Operations	Revision Operations	Revision Burden (%)
Sweden	Swedish Hip Register	Hip	Global	Annual Report 2006	296,015	270,031	25,984	8.78
Sweden	Swedish Hip Register	Hip	2006	Annual Report 2006	15,679	13,942	1,737	11.08
Denmark	Danish Hip Register	Hip	1995-2005	Annual Report 2006	71,900	61,506	10,394	14.46
Denmark	Danish Hip Register	Hip	2005	Annual Report 2006	8,292	7,244	1,048	12.64
Germany		Hip	2007	BQS 2007	218,173	196,391	21,782	9.98
Germany		Hip		DGOOC	215,000	200,000	15,000	6.98

Revision Burden: International Data Sets

Hip Arthroplasty

Country	Register	Implant	Year	Source	Total Number	Primary Operations	Revision Operations	Revision Burden (%)
Italy	ISS	Hip	2005	ISS, ICD-9 Codes (primary 81.51, revision 81.53)	64,180	57,055	7,125	11.10
Norway	Norwegian Arthroplasty Register	Hip	1987-2007	Annual Report 2008	129,481	110,985	18,496	14.28
Norway	Norwegian Arthroplasty Register	Hip	2007	Annual Report 2008	7,486	6,443	1,043	13.93
Australia	Australian Orthopaedic Association - National Joint Registry	Hip	2005-2006	Annual Report 2007	34,211	30,440	3,771	11.02
Canada	CJRR	Hip	2003-2006	Annual Report 2007	42,626	39,162	3,464	8.13
Finland	Finnish Arthroplasty Register	Hip	1997-2005	Yearbook 2006	78,175	65,062	13,113	16.77

Revision Burden: International Data Sets

Hip Arthroplasty

Country	Register	Implant	Year	Source	Total Number	Primary Operations	Revision Operations	Revision Burden (%)
England and Wales	NJR	Hip	2006	4th Annual Report	65,234	58,962	6,272	9.61
Scotland	SAP	Hip	2007	Annual Report 2008	6,891	6,009	882	12.80
New Zealand	New Zealand Orthopaedic Association - National Joint Registry	Hip	1999-2006	Annual Report 2006	48,804	42,421	6,383	13.08
New Zealand	New Zealand Orthopaedic Association - National Joint Registry	Hip	2006	Annual Report 2006	7,319	6,423	896	12.24
USA		Hip	1990-2002	AAOS Publication OKU- Hip and Knee Reconstruction 3, ISBN 0-89203-348-7				17.5

Revision Burden: International Data Sets

Hip Arthroplasty

Country	Register	Implant	Year	Source	Total Number	Primary Operations	Revision Operations	Revision Burden (%)
USA		Hip	2010	The Future Burden of Hip and Knee Revisions, Kurtz et al, AAOS 2006	301,181	253,367	47,814	15.88
France		Hip (THA + Hemi)	2005	PMSI, French National Institute for Statistics	138,713	120,494	18,219	13.13
France	French Arthroplasty Register Pilot			Rapport 2007	2,710	2,332	378	13.95
Switzerland		Hip	2008	Estimation SGO	22,000	19,800	2,200	10.00
Austria	Austrian Health Inst.	Hip Total	2006	Discharge Records	16,352	15,139	1,213	7.42
Austria	Austrian Health Inst.	Hip Partial	2006	Discharge Records	4,532	3,674	858	18.93
Austria	Austrian Health Inst.	All Hip	2006	Discharge Records	20,884	18,813	2,071	9.92

Revision Burden: International Data Sets

Hip Arthroplasty

Country	Register	Implant	Year	Source	Total Number	Primary Operations	Revision Operations	Revision Burden (%)
Austria	Austrian Health Inst.	Hip Total	1997-2006	Discharge Records	145,098	133,496	11,602	8.00
Austria	Austrian Health Inst.	Hip Partial	1997-2006	Discharge Records	38,444	32,721	5,723	14.89
Tyrol	Tyrolean Arthroplasty Register	Hip	2004-2007	Annual Report 2007	6,252	5,411	841	13.45
Tyrol	Tyrolean Arthroplasty Register	Hip	2007	Annual Report 2007	1,573	1,363	210	13.35
Spain		Hip	2005	Hospital Discharges (CMBDAH)	22,036	19,015	3,021	13.71
Romania	Romanian Arthroplasty Register	Hip	2007	Online Statistics RNE	7,105	6,759	346	4.87
Slovakia	Slovankian Arthroplasty Register	Hip	2006	Presentation Cervenanski Days 2007, Activity Report 2006	3,832	3,507	325	8.48

Revision Burden: International Data Sets

Knee Arthroplasty

Country	Register	Implant	Year	Source	Total Number	Primary Operations	Revision Operations	Revision Burden (%)
Sweden	Swedish Knee Arthroplasty Register	Knee (TKA)	1996-2005	Annual Report 2007	63,133	60,936	2,197	3.48
Sweden	Swedish Knee Arthroplasty Register	Knee (UKA)	1996-2005	Annual Report 2007	11,535	9,894	1,641	14.23
Sweden	Swedish Knee Arthroplasty Register	Knee	2006	Annual Report 2007	11,149	10,544	605	5.43
Denmark	Danish Knee Arthroplasty Register	Knee	1997-2006	Annual Report 2006	33,681	30,611	3,070	9.11
Denmark	Danish Knee Arthroplasty Register	Knee	2006	Annual Report 2006	5,138	4,659	479	9.32
Germany		Knee	2007	BQS 2008	145,837	136,262	9,575	6.57

Revision Burden: International Data Sets

Knee Arthroplasty

Country	Register	Implant	Year	Source	Total Number	Primary Operations	Revision Operations	Revision Burden (%)
Germany		Knee		DGOOC	105,000	100,000	5,000	4.76
Italy	ISS	Knee	2005	ISS, ICD-9 Codes (primary 81.54, revision 81.55)	47,574	45,049	2,525	5.31
Norway	Norwegian Arthroplasty Register	Knee	1994-2007	Annual Report 2008	32,292	29,649	2,643	8.18
Norway	Norwegian Arthroplasty Register	Knee	2007	Annual Report 2008	3,855	3,556	299	7.76
Australia	Australian Orthopaedic Association - National Joint Registry	Knee	2005-2006	Annual Report 2007	36,466	33,737	2,729	7.48
Canada	CJRR	Knee	2005-2006	Annual Report 2007	18,055	17,082	973	5.39

Revision Burden: International Data Sets

Knee Arthroplasty

Country	Register	Implant	Year	Source	Total Number	Primary Operations	Revision Operations	Revision Burden (%)
Finland	Finnish Arthroplasty Register	Knee	1997-2005	Yearbook 2006	68,512	63,266	5,246	7.66
England and Wales	NJR	Knee	2006	4th Annual Report	65,425	62,105	3,320	5.07
Scotland	SAP	Knee	2007	Annual Report 2008	6,678	6,291	387	5.80
New Zealand	New Zealand Orthopaedic Association National Joint Registry	Knee (only TKA)	1999-2006	Annual Report 2006	31,204	28,705	2,499	8.01
New Zealand	New Zealand Orthopaedic Association National Joint Registry	Knee (only TKA)	2006	Annual Report 2006	5,490	5,140	350	6.38
USA		Knee	1990-2002	AAOS Publikation OKU Hip and Knee Reconstruction 3, ISBN 0-89203-348-8				

Revision Burden: International Data Sets

Knee Arthroplasty

Country	Register	Implant	Year	Source	Total Number	Primary Operations	Revision Operations	Revision Burden (%)
USA		Knee	2010	The Future Burden of Hip and Knee Revisions, Kurtz et al, AAOS 2007	718,257	663,007	55,250	7.69
Switzerland		Knee	2008	Estimation SGO	13,000	11,700	1,300	10.00
Austria	Austrian Health Inst.	UKA	2006	Discharge Records	1,267	1,004	263	20.76
Austria	Austrian Health Inst.	TKA	2006	Discharge Records	14,304	13,387	917	6.41
Austria	Austrian Health Inst.	All Knee	2006	Discharge Records	15,571	14,391	1,180	7.58
Austria	Austrian Health Inst.	UKA	1997-2006	Discharge Records	7,970	6,275	1,695	21.27

Revision Burden: International Data Sets

Knee Arthroplasty

Country	Register	Implant	Year	Source	Total Number	Primary Operations	Revision Operations	Revision Burden (%)
Austria	Austrian Health Inst.	TKA	1997-2006	Discharge Records	103,393	97,179	6,214	6.01
Tyrol	Tyrolean Arthroplasty Register	Knee	2004-2007	Annual Report 2007	4,678	4,329	349	7.46
Tyrol	Tyrolean Arthroplasty Register	Knee	2007	Annual Report 2007	1,296	1,184	112	8.64
Spain		Knee	2005	Hospital Discharges (CMBDAH)	34,504	32,076	2,428	7.04
Romania	Romanian Arthroplasty Register	Hip	2007	Online Statistics RNE	1,099	1,074	25	2.27

Revision Burden: International Data Sets

Other Joint Arthroplasties

Country	Register	Implant	Year	Source	Total Number	Primary Operations	Revision Operations	Revision Burden (%)
Norway	Norwegian Arthroplasty Register	Ankle	1994-2007	Annual Report 2008	454	380	74	16.30
Norway	Norwegian Arthroplasty Register	Ankle	2007	Annual Report 2008	72	58	14	19.44
Norway	Norwegian Arthroplasty Register	Finger (MCP)	1994-2007	Annual Report 2008	2,946	2,460	486	16.50
Norway	Norwegian Arthroplasty Register	Finger (MCP)	2007	Annual Report 2008	145	89	56	38.62
Norway	Norwegian Arthroplasty Register	Handrot (CMC I)	1994-2007	Annual Report 2008	412	365	47	11.41
Norway	Norwegian Arthroplasty Register	Handrot (CMC I)	2007	Annual Report 2008	27	23	4	14.81

Revision Burden: International Data Sets

Other Joint Arthroplasties

Country	Register	Implant	Year	Source	Total Number	Primary Operations	Revision Operations	Revision Burden (%)
Norway	Norwegian Arthroplasty Register	Hands sledd	1994-2007	Annual Report 2008	211	169	42	19.91
Norway	Norwegian Arthroplasty Register	Hands sledd	2007	Annual Report 2008	31	16	15	48.39
Norway	Norwegian Arthroplasty Register	Shoulder	1994-2007	Annual Report 2008	2,648	2,425	223	8.42
Norway	Norwegian Arthroplasty Register	Shoulder	2007	Annual Report 2008	341	308	33	9.68
Norway	Norwegian Arthroplasty Register	Shoulder (Hemi)	1994-2007	Annual Report 2008	2,088	1,976	112	5.36
Norway	Norwegian Arthroplasty Register	Shoulder (Hemi)	2007	Annual Report 2008	225	215	10	4.44

Revision Burden: International Data Sets

Other Joint Arthroplasties

Country	Register	Implant	Year	Source	Total Number	Primary Operations	Revision Operations	Revision Burden (%)
Norway	Norwegian Arthroplasty Register	Shoulder (Total)	1994-2007	Annual Report 2008	560	449	111	19.82
Norway	Norwegian Arthroplasty Register	Shoulder (Total)	2007	Annual Report 2008	116	93	23	19.83
Norway	Norwegian Arthroplasty Register	Hallux	1994-2007	Annual Report 2008	1,043	924	119	11.41
Norway	Norwegian Arthroplasty Register	Hallux	2007	Annual Report 2008	67	47	20	29.85
New Zealand	New Zealand Orthopaedic Association - National Joint Registry	Shoulder	1999-2006	Annual Report 2006	1,746	1,641	105	6.01
New Zealand	New Zealand Orthopaedic Association Nat. Joint Registry	Ankle	1999-2006	Annual Report 2006	317	298	19	5.99

Revision Burden: International Data Sets

Other Joint Arthroplasties

Country	Register	Implant	Year	Source	Total Number	Primary Operations	Revision Operations	Revision Burden (%)
New Zealand	New Zealand Orthopaedic Association - National Joint Registry	Elbow	1999-2006	Annual Report 2006	222	191	31	13.96
New Zealand	New Zealand Orthopaedic Association National Joint Registry	Knee (TKA + UKA)	2002-2008	Online Statistics (20080818)	41,548	39,881	1,667	4.01
New Zealand	New Zealand Orthopaedic Association National Joint Registry	Knee (TKA + UKA)	2002-2009	Online Statistics (20080818)	4,405	4,323	82	1.86
New Zealand	New Zealand Orthopaedic Association National Joint Registry	Knee (TKA + UKA)	2003-2006	Presentation Cervenansky Days 2007	3,832	3,507	325	8.48
New Zealand	New Zealand Orthopaedic Association National Joint Registry	Knee (TKA + UKA)	2002-2006	Annual Report 2006	34,731	30,067	4,664	13.43

Discharge Records and Outcome Register Data

Methodology

Discharge Records are one potential dataset for outcome measurement. Experts working on the interface between arthroplasty registers and discharge records were invited to contribute to a statement concerning the potential use of these datasets and added value by linkage or other ways of co-operation.

Limitations

Reports and statements by definition are subjective and starting points for discussion.

Introduction

Outcome-oriented, comprehensive data collecting systems via arthroplasty registers have resulted in considerable increase in the quality of medical treatment during the past decades. In Sweden, for instance, the revision rate was reduced by half since the National register has been launched while in other countries the outcome has remained nearly unchanged within the same period of time.

In almost all countries discharge records are regularly used for evaluations, i.a. also in outcome-relevant issues.

Discharge Records and Outcome Register Data

Results

Possible evaluations from discharge records for outcome measurement

An important factor for evaluation options for outcome measurement is whether longitudinal analysis is possible or not. Discharge records are usually primarily collected for accounting or other organisational purposes and therefore document a code for in-patient stay as the primary case identification. For the chief purpose of recording services, this is an optimum approach. For outcome measurement, however, personal data linkage and evaluation whether an intervention (e.g. primary operation) has led to a defined secondary event (e.g. revision operation) are essential.
At least in Austria, direct linking is currently not feasible for lack of accurate personal identification, as well as for data privacy reasons. The manual assignment of individual cases based on redundantly-stored data may be conceivable but is hardly practicable in daily routine.

The Annual Reports of the Scottish Arthroplasty Project allow for deriving the following possible calculations:

- Epidemiological calculations such as incidences and probabilities of diagnoses and complications (however, without direct assignment to important variables such as the implant);
- Market data regarding the range of services in the medical field;
- Length of in-patient stay; where the patients were discharged to; whether the patient made use of aftercare in some institution; whether the intervention was performed on an out-patient basis or was connected with an in-patient stay;
- Longitudinal economic data;
- Waiting list management and other activities important for the public health sector;
- Revision burden;
- Descriptive presentation of patient profiles such as age, sex or indications.

Apart from personal identification, discharge records sometimes fail to provide important data for outcome measurement:

- The implant, as one of the most essential factors for the outcome;
- Information about the therapy with respect to both primary operation and revision; to a relevant extent, the documentation of diagnoses in the ICD system does not suffice to clearly discriminate the medical reason for an intervention. Since the DRG system was originally developed for clearing purposes, interventions involving similar expenditure are occasionally pooled, which leads to a loss in discriminative power in outcome measurement.

Personal identification in a register pre-supposes unambiguous assignment to the individual person. Therefore, person-specific codings are required that are unequivocal and stable for a lifetime.

Discharge Records and Outcome Register Data

Results

Discharge records have some undeniable advantages for evaluations:

- They are usually complete.
- They are easy to access.
- They are standardised to a high degree, which is helpful in interdiscinplinary evaluations (in an SAP report, for instance, the consideration of anesthesia as an outcome-relevant factor).

For outcome measurement, however, discharge records also have disadvantages:

- The quality of data is often unchecked. A phenomenon observed in large-scale data collections is the inferior quality of data that are not in the focus of the evaluations primarily intended.
- Discharge records are not primarily collected for outcome measurement. Internal data consistency should therefore checked for each data source before including it in evaluations.
- Outcome analyses incorporate a large number of variables depending on the treatments under examination. Missing data or lack of discriminative power of data thus lead to a considerable reduction in final results, since relevant factors influencing the primary end-point cannot be checked and adjustments can only be made to a limited extent.
- Data fusion on an individual level is a pre-requisite for the stratification of groups in the database and for direct comparisons, thus representing one of the essential requirements for the computation of long-term outcome.
- If the outcome of a primary end-point is calculable on the basis of discharge records (e.g. mortality, infections, etc.), usually insufficient data is available with regard to specific therapies or procedures. Therefore, inferential statistics or evaluations are not always possible in the quality required.

Discharge Records and Outcome Register Data

Results

Differences as compared to register reports:

- Evaluations in National register reports feature a more comprehensive coverage of all relevant information for patient treatment. This enables the physician –or other persons in charge– to obtain a comprehensive overview of the respective situation by means of a bench-marking system, and make target-oriented decisions which, in turn, can be checked for their impact in the following years.

- Thus, register reports allow for the efficient implementation of continuous quality monitoring and quality improvement projects.

- Discharge records can also contribute to quality improvement, but have other priorities.

  - Indicators and evaluations based on discharge records are rather focussed on structure and process quality.
  - Drawing conclusions from structure and process indicators to outcome is possible to a limited extent.
  - For organisational reasons the questionnaires of outcome registers must be concise. One of the main reasons for this is that the work load for the hospital staff caused by documentation constitutes a critical factor for compliance and hence for the completeness of the register dataset. Discharge records contain information potentially offering essential contributions for outcome analyses, for instance:
    - Co-morbidities of patients;
    - Services exceeding the primary intervention;
    - Information about the process of medical service (e.g. waiting times, follow-up, etc.) that might have a relevant influence on the outcome but cannot be included at present for lack of possibilities of overall analysis;
    - Economic data that could be used in cost-efficiency analyses.
      At present, this is only feasible to some extent in well-developed register systems such as Sweden or Finland.

Discharge Records and Outcome Register Data

Results

Pre-requisites for the Linking of Discharge Records and Register Data and Potential Added Value for Outcome Measurement

- The basic data for case identificaton must be synchronisable. Synchronisation could be performed via a trust centre. Similar aspects have been widely and intensely discussed for years within the scope of the introduction of electronic health records or electronic storage media (e-Card) containing medical basic data. A trust centre has also been planned in Austria for quite some time now, but has not been implemented yet.

- The introduction of a standardised personal identification (European Medical Code or National equivalents) as reference data in various datasets would make sense with regard to the additional information gained for quality development in health-care. However, clarification is needed concerning data protection in data collection, data processing, and the subsequent procedures.

- Outcome data involve a very complex process with many variables and including factors that are changing rapidly. Selective and detailed information is therefore required allowing for target-oriented decisions in support of quality improvement.

- This process, in turn, requires a core dataset in the form of an outcome register modelled on arthroplasty registers.

- A Link with further data from routine data collections such as discharge records will then allow additional applications and adjustments covering the following topics and respective areas:

  - Influence of structural and procedural changes on the outcome;
  - Linking of outcome data and economic data for further and more detailed cost-benefit analyses than common at present;
  - Influence of co-morbidities on outcome and proposals for the adaption of interventions based on individual risk profiles.

Discharge Records and Outcome Register Data

Summary and Recommendations

- Discharge records alone are not comparable in quality with outcome registers specifically designed for this purpose.
- Target-oriented measures require a great wealth of information and detailed evaluations.
- By focussing on specific, central outcome indicators and longitudinal analyses, outcome registers such as arthroplasty registers offer an adequate basis.
- The inclusion of discharge records and other data regularly collected in the health-care system in evaluations of outcome registers allows for essential and additional evaluation options.
- A pre-requisite for this, however, is to enable dataset assignment at a personal level, which is currently not possible in all EU member states on the basis of a routine procedure since the basic data for personal identification are not congruent or even not accessible at all.
- In this respect, it is also essential to clarify the regulatory framework (data protection) of such procedures. This could be integrated into current efforts for further data networking in health care, electronic health record, etc.
- The consideration of standardised datasets for personal identification, such as the European Medical Code, might substantially simplify technical solutions.

Summary and Conclusions

Outcome Registers

In terms of outcome measurement there is a fundamental difference between pharmaceuticals and medical devices.

As to pharmaceuticals, the initial record of a potentially occurring side-effect is sufficient to inform physicians and patients and to allow for corresponding action in the individual case. Most commonly, the adequate reaction is to cease the medication and initiate symptomatical therapy of the side-effects. Due to the short periods of time between the intake of the medication and its effects, the retrospective analysis of damage events appears to be reasonable. Rare, severe side-effects such as embryonic damage (e.g. Thalidomide/Contergan) are exceptional and should be handled in a similar way as implanted medical products.

With implanted medical products such as endoprostheses this does not suffice. In most cases serious side effects lead to revision operations. Often years pass by between primary surgery and product failure, during which further patients do not receive optimum treatment. It is therefore essential to record the side effect profiles to be expected as soon and as exactly as possible in order to allow for target-oriented reaction in primary implantations. This requires very accurate dataset analyses preferably covering all important factors of influence, which in turn necessitates specific data collections carried out prospectively. In this process, registers have proved a useful tool.

Outcome registers for implanted medical products such as total endoprostheses are defined by the following:

1. Registration of ALL primary and revision operations in a defined area in a central database.
2. Following the implant until it has to be revised, the patient dies or emigrates.
3. Definition of Revision as 'Failure': at least one part of the implant has to be revised during revision surgery.

The main advantage of registers is their potential to enable systematised longitudinal analyses as well as a multitude of data linkages which, after expert analysis, may lead to clear recommendations for action.

Analysis and discussion are most efficient when carried out via medical specialist societies. Apart from a democratic decision-making procedure on a high professional level, this ensures the disclosure of information to physicians and hence the consideration of the results during the treatment process.

Summary and Conclusions

Quality of Datasets

Outcome Measurement

- Sample-based clinical studies exhibit highly relevant and significant bias factors and thus have only very limited usability as a data basis for evaluations and conclusions.
- The data are highly influenced by the authors of the clinical literature as regards the number of cases published.
- Publications by implant designers in many cases show a relevant bias in outcome per se, thus leading to a distortion of results. This influence appears to be stronger in publications from the USA than in publications from continental Europe.
- Structured surveys show better compliance with register data, but they are inferior to outcome registers in data quality and organisation.
- Experimental studies show only low correlation with the clinical outcome and are thus not a suitable basis for outcome assessment. This also applies to issues such as the licensing of medical devices.
- Registers monitor a considerably larger collective under more specified, standardised and comparable conditions and are therefore superior as a data source.
- Registers yield valid results much more rapidly, by periods of several years, than sample-based clinical studies and surveys and are thus able to considerably reduce the periods of time until robust statements can be made concerning the outcome of a medical device or a surgical approach.
- In the context of surgical interventions involving the implantation of medical devices, randomised controlled trials yield no essential improvement in the quality of publications. Compared to pharmaceuticals, medical devices show relevant differences affecting the organisation of studies and their quality. For organisational and methodological reasons outcome registers, which can provide highest-quality data in the area of arthroplasty and similar medical devices, do not make sense for pharmaceuticals. In this field RCTs are still to be regarded as the gold standard.

Summary and Conclusions

Quality of Datasets

- At present, the usual categorisation regarding the quality of the literature and bases of evaluations appears to be inadequate for endoprostheses and similar medical devices.

- Therefore, based on the data available, a modification in the classification of data quality should be taken into consideration.

  1. Comprehensive data collections such as registers are to be rated superior.
  2. Randomised controlled trials should be assessed with respect to the end-point.
     a. In the case of objective end-points, such as measurement results (e.g. implant migration as an early indicator of loosening), a randomised controlled study is to be regarded as equal according to the relevant guidelines.
     b. In the case of subjective endpoints it has to be checked whether post-operative examinations could possibly break blinding. In such a case, a compromising of results should be assumed.

- To be able to make optimum use of the advantages described, publication procedures and basic data such as implant recording in registers should be standardised.

- There are big differences in the use of implants in the various countries and, by implication, in registers as well. To obtain a comprehensive overview of the products used in the Common Market of the EU, a supra-national evaluation of national results based on a standardised methodology is required. This would necessitate standardised designation of the implants recorded.

- Without registers it is mostly impossible in an independent analysis to deduce the decisions which have led to a decrease in the use of particular implants or a product recall from the results published. This is usually decided autonomously by the manufacturers and physicians in non-public discussions, or by means of a decision-making process at a scientific level. External control or monitoring by public health institutions is thus impossible. The mere access to register data would allow for sufficient control and open up the opportunity of autonomous decisions.

- In the organisation of studies and surveys objective end-points are essential. As a rule, subjective end-points entail subjectively biased decisions and results which, without reference sources, may lead to misinterpretations in meta-analyses.

Summary and Conclusions

Quality of Datasets

Market Monitoring and Post-Marketing Surveillance

- The data currently available from manufacturers and public health authorities are insufficient for the handling of outcome measurement issues, market monitoring, and the detection of serious product deficiencies according to the material analysed in this project.

- The process is poorly structured and comprises a series of subjective valuations based on insufficient data.

- Public health authorities are highly dependent of the manufacturers' reports, while users only barely meet their legal obligation to report.

- For the user it is difficult to decide whether or not the revision of a product is to be rated as a relevant case, since the assessment of relevance largely depends on the calculation of the frequency of an event with a specific product. This, however, necessitates the access to a comprehensive data collection such as a register.

- Even the manufacturers, who rely on their sales representatives' recordings, are not in a position to guarantee adequate safety. In the cases examined the manufacturers have complied with the legal regulations. However, the decisive step towards improvement, the access to comprehensive data and their retrospective analysis, is made impossible to them for reasons of data protection. This would require a database comprising the personal data of all patients treated with a certain medical device.

- It would thus make sense to consider arthroplasty registers as an additional tool in market monitoring and post-marketing surveillance.
  - The data should be examined retrospectively with regard to irregularities, such as a striking frequency of revision operations with certain medical devices or a cumulation of certain reasons of revision such as implant fracture clearly indicating product failure or requiring measures to be taken with respect to the application guidelines.
  - Manufacturers should be involved in the process, either directly or by means of requesting for statements.
  - Information would be available about patients and departments concerned, for instance, in the case of product recalls, or for vigilance control.

- Information procedures should be improved in detail, for instance, by
  - Improved labelling of letters referring to product problems;
  - More precise regulations for products in the trial stage, e.g. by the users' obligation to report revision operations to the manufacturer, including the preservation of retrievals.
  - Improved and standardised access to information, e.g. by setting up respective websites.

Key-findings

Quality of Datasets

Outcome Registers are the most important factor in Outcome Research, in terms of a

- **Core Dataset and a**
- **Reference Source of other data sources with respect to validity**

Abbreviations

• **TAA**	Total Ankle Arthroplasty
• **THA**	Total Hip Arthroplasty
• **TKA**	Total Knee Arthroplasty
• **RCT**	Randomised Controlled Trial
• **EFORT**	European Federation of National Associations of Orthopaedics and Traumatology
• **EAR**	European Arthroplasty Register, an EFORT-affiliated, non-profit scientific society focussed on outcome research in Arthroplasty and Arthroplasty Registers

References and Literature

This list is designed to present key publications. It is not meant to present the entire material available.

National Arthroplasty Register webpages are listed on the EFORT web portal:
http://www.efort.org/getdoc/1b923b01-41d2-4587-bac2-7ca7a11e613e/Arthoplasty-Registers.aspx

Annual reports, contact information and publications (in some countries like Norway in full text when possible in terms of copyright) are available in up-dated versions and in a user-friendly way.

Information concerning the use of indicators and background information are available from Annual Reports from Sweden, Norway, Denmark, Australia and Canada.

Some recommended journal publications with respect to the validation of datasets, value of datasets and indicators:

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Contact:

Innsbruck Medical University
Dept. for Orthopaedic Surgery
Anichstrasse 35
6020 Innsbruck, Austria

Phone +43 (512) 504 22695
Fax +43 (512) 504 22701
gerold.labek@efort.org
www.ear.efort.org

EFORT Central Office
Technoparkstrasse 1
8005 Zurich, Switzerland

Phone +41 (44) 448 4400
Fax +41 (44) 448 4411

office@efort.org
www.efort.org