Summary HTA

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HTA-Report | Summary

Arthroplasty register for Germany

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Health political and scientific background

Joint prostheses are man-made replacement joints. The hip and knee joint prostheses are commonly well-known. Recently, prostheses are also available for shoulder, ankle, elbow, finger and toe joints. Different prosthesis models and implantation techniques exist: prostheses can replace joint surfaces completely or partially, they consist of high-quality alloys, ceramic or plastic materials. They may be basically divided into cemented, cement-free and composite prostheses.
According to the data of the German National Agency for Quality Measurement in Healthcare, the implantation of hip prostheses ranks as the most frequent joint replacement operation in Germany (152,584 in 2007) and the implantation of knee prostheses as the second most frequent (136,379 in 2007). The number of revision operations both for hip prostheses (21,830 in 2007) and for knee prostheses (9,598 in 2007) is also high.
Special registers, called arthroplasty registers, are introduced in many countries for the assurance of the quality of joint replacements. These registers are aimed to collect the data for all joint replacement operations in a certain region tracking the operated patients up to death and/or up to the migration from this region. Arthroplasty registers are organized as electronic databases. These registers systematically collect data for each patient concerning the implanted prostheses, intervention modifications and the results of the operations (including revisions).
In many European countries arthroplasty registers have already made an important contribution for research and for the improvement of the quality of the patient's care. In some countries, the rates of revision operations in the time after introduction of the arthroplasty register decreased substantially. Moreover, many products were taken from the market or modified, when quality flaws were discovered during the evaluation of the data.
In the German Federal Joint Committee some efforts exist to introduce an arthroplasty register in Germany. Industry, the German society for orthopedics and orthopedic surgery, and others encourage the introduction of such a register. A contemporary decision about an introduction of such an arthroplasty register in Germany is overdue. The presented health technology assessment (HTA) report should provide important details about the organization of the register and contribute to obtain a clear view on the potentials and constraints of such a register.

Research questions

The presented report addresses the questions on the organization and functioning of the arthroplasty registers, benefits and cost-benefits of these registers as well as on their legal, ethical and social aspects.

Methods

Sources of information and search strategy

The literature search was conducted in the electronic medical databases MEDLINE, EMBASE, SciSearch etc., by the German Agency for Health Technology Assessment of the German Institute for Medical Documentation

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and Information (DAHTA at the DIMDI) in September 2008 after an agreement about the search strategy with the authors. The search strategy was restricted to the years beginning from 2003 as well as to the languages German and English.
In addition, a hand search was performed in the reference lists of the relevant articles as well as in the internet pages of the identified arthroplasty registers.

Inclusion and exclusion criteria

The analysis of the identified literature was performed in three steps (titles, summaries and complete publications). Two independent reviewers, both familiar with the procedure of the evidence-based medicine, were involved in the selection of the relevant publications.
In the first two sightings literature citations were excluded from the further analysis only if no relevant description of an arthroplasty register and/or of its relevance was expected in the publication.
In the third sighting literature citations describing arthroplasty registers or their relevance were included in the analysis. Only databases of joint replacement operations collecting data on the type of the implanted prostheses were defined as arthroplasty registers.

Data evaluation and information synthesis

The most important information on the organization, functioning and relevance of the arthroplasty registers was extracted from the available information sources and described. Initially, data concerning arthroplasty registers from internet pages, annual reports and special publications were included. Afterwards, identified articles to certain clinical questions were screened for additional information about these registers.
Data comparing different arthroplasty registers, which were presented in the overview publications, were described separately. Data on the following aspects of the arthroplasty registers were included: organization, documentation and results.

Results

Results of the literature search

The systematic literature search yielded 1,391 hits. A total of 1,391 titles and 155 abstracts were screened. 112 publications were selected for the examination in full text. Two articles were identified listing different arthroplasty registers and 64 articles concerning individual arthroplasty registers.
A total of 24 homepages, 15 annual reports and 36 additional relevant documents concerning 34 arthroplasty registers as well as two articles listing different arthroplasty registers were identified over a hand search.
In summary, data about 30 arthroplasty registers in 19 countries as well as about one international arthroplasty register were identified.

Description of the registers

The identified arthroplasty registers are at different development stages: some registers have already existed for several years, only adapting their practice to the emerging requirements and options, if necessary. Several registers are in early stages of development; their databases are still in the buildup phase.
In most countries only one arthroplasty register is introduced, which collects information about all, several or at least about hip and knee joint replacement operations. In some countries there are different registers for each joint. In two countries only regional registers exist; in two further countries such regional registers were replaced by supraregional ones.
Most of the arthroplasty registers are maintained by national orthopedic societies, others by health authorities or by their cooperation. The financing

support is mostly performed by the government; however different sources such as membership fees of the orthopedic societies, research grants or levies placed on the implant prices are widely used. In some cases several funding sources are employed.
The participation of the orthopedists and/or hospitals in the data collection process of the arthroplasty registers is voluntary in most countries; however, in some countries it is mandatory. The patient`s consent is needed in most countries; but not necessary in some countries. A unique patient identification number is used in nearly all registers.
Each data set used in the arthroplasty registers consist of patient and clinic identification numbers, data on diagnosis, performed interventions, operation date and implanted prostheses. Clinical scores, self-evaluating questionnaires and radiological documentation are conducted in only a few registers.
Arthroplasty registers use one or several methods for data documentation and transfer, which may be selected by each hospital individually. Data communication in paper form is employed by nearly all, electronic data documentation and transfer via Internet and/or via files only by some registers. A clinical information system is rarely offered.
The data validation is being performed manually or electronically. Many registers only assign implants to a certain prosthesis category, some registers record exact implant data (code and lot number), scanning their bar codes.
Nearly all arthroplasty registers offer results of the data evaluation to the treating orthopedists, provide annual reports and publish articles in scientific journals. Online access to the orthopedists' own data is available only in few registers.

Data on medical benefit, cost-benefit as well as on the legal, ethical and social aspects of the arthroplasty registers

The prolongation of the implant survival, change of the joint replacement strategy (e. g. selection of implants) and learning curve effect is documented in some countries in the time after the introduction of the arthroplasty register. An influence of the results on cost savings for the health services is also reported.
The most important legal and ethical aspect is the patient`s data protection and, therefore, the requirement of a patient’s consent. The involvement of the physicians in the data collection process is a further organizational and legal challenge.

Discussion

Literature search

The data sources identified by the literature search have mostly been written some years ago and rarely represent the current state of the arthroplasty register. Many internet pages and annual reports of the arthroplasty registers also provide no relevant information. Such additional information can probably be gained only via questionnaires sent to the individual registers.
To obtain exact data concerning the effects of the arthroplasty registers on clinical practice and health-political decisions, direct communication with the appropriate register representatives and decision makers is advisable.

Potential benefit of the arthroplasty registers for clinical practice and for health-political decisions

Whether documented changes in joint replacement strategies were initialized due to the results of the analysis of the register data or due to other reasons (e. g. results of primary clinical studies) remains unclear.
Further questions are whether there is further potential for the improvement

of the results of the arthroplasty registers apart from the effects mentioned and whether the introduction of registers in each country is of benefit. The observed rate of revisions can also be additionally reduced. Reducing the rate of revisions operations by only about 1 % can cause substantial cost savings on a national level.
The impact of the arthroplasty registers as an early warning system as well as a mechanism of quality assurance will be relevant so long as new products appear on the market and/or procedures will be performed by different surgeons.

Organization of the arthroplasty registers

Especially for the proof of small clinical effects, an almost one hundred percent completeness of the registration of joint replacement operations is required. Thereby, a very important point is the patient`s consent for the registration of their personal data. An obligation and/or financial incentive for the participation of the orthopedists in the data collection process can also improve the completeness of the registration.
The unique patient identification number is a very important method for the linkage of primary interventions with the revisions and with the data in other registers. The problem of patient identification is not yet solved in Germany because of the legal aspects of data protection and primary requires legal changes.
Both, interests of the orthopedic societies and health authorities are to be considered for a successful functioning of the arthroplasty registers. The financial support of the register should be independent from industry and/or health insurance companies and stated on a long-term basis.

Registered data in the arthroplasty registers

Which data are to be collected by the register, can principally be defined by each register. The data collection process can rely on the recommendations about the "Minimal Datasets". In order to compute the number of patients under risk correctly, it is important to accurately consider the deceased and the emigrated patients.
Revision is the most easily measurable, but not an ideal parameter of implant failure. Further clinical, radiological and patient-reported data are also necessary. The collection of patient-reported data can ensure a high data completeness in case of a good cooperation with the patients.
Code and lot numbers of the implants are other important parameters. It is problematic that established implants are often replaced by new products and, sometimes, the same products are coded differently for sale in different countries.

Data handling in the arthroplasty registers and results availability

The methods of the data documentation and communication can be selected by each hospital individually. Data scanning using bar code and optical mark reader systems clearly simplifies the handling of the data. Further useful options are electronic data entry via internet pages and the use of the clinical information systems.
Regular feedback of the registers improves the compliance of the physicians and/or the hospitals. If information about individual physicians and/or the hospitals become publicly available, reduced data completeness and data quality as well as a cautious strategy concerning joint replacements in high risk patients are to be expected. Publishing the evaluations of the registers may facilitate an international discussion of their results as well as changes in the joint replacement strategies.

Registers vs. randomized clinical studies

From a methodical point of view, the difference in the groups of compared patients is a hardly solvable problem within the registers, which can lead to bias of the results. A further methodical problem is the exclusive observation

of the prostheses actually used and not of the prostheses planned for implantation (intention to treat aspect).

Conclusions

Arthroplasty registers are an important additional instrument for the quality assurance of the prostheses implantation and have a large potential regarding the prolongation of implant survival, improvement of the patient's quality of life and cost savings in the health care system.
The most important features of a good arthroplasty register are the completeness of the data collection by the patients and the orthopedists, a unique patient identification number, the collection of the minimum data sets, simple data handling, examination of the data completeness and quality, correct data analysis and interpretation as well as long-term financial support of the register.
Aspects of the patient's data protection and the guaranteed financial support should be clarified before the introduction of a register.