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Procedures and criteria for the regulation of innovative non-medicinal technologies into the benefit catalogue of solidly financed health care insurances

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Health political background

Many countries have introduced procedures to regulate the adoption of innovative non-medicinal technologies into the benefit catalogue of solidly financed health care insurances in order to guarantee that only effective medicinal innovations and services are introduced into the health benefit basket. The current lack of funds makes it more and more important to decide which medicinal services and innovations should be paid for and which, according to specific criteria, cannot be recommended and therefore not paid for by public health insurance. An important aspect of supporting decision-making is Health Technology Assessment (HTA), which is the systematic and transparent evaluation of health services. The goal of this report is to describe the procedures, prerequisites and criteria of the evaluation process in introducing innovative non-medicinal technologies into the benefit catalogue of solidly financed health care insurances. A representation of the strengths and weaknesses of the German system as compared to other countries (England, Switzerland and Australia) can help in showing where there is potential for improvement.

Scientific background

Health insurance providers are described as solidly financed health care insurances when the individual financial contribution of the insured is not connected to his individual risk of becoming sick. Every insured person has the right to the same medicinal services and the same quality and range of service. The amount of the insurance premiums is immaterial.
The benefit catalogue can be defined as the sum of all the rules which govern which services (e. g. methods, products and procedures) are financed by solidly financed health care insurances. The types of institutions which decide what to include in the benefit catalogue differ from country to country, as does the actual definition of the benefit catalogue.
Diagnosis Related Groups (DRG) are one form of a global billing of health services which are used in differing ways in various countries. In most countries, Diagnosis Related Groups are applied to hospitals and the distribution of federal or insurance-related budgets. Often, the Diagnosis Related Groups are applied only in one part of the billing for the services.
According to the current definition, a technology can be considered innovative when it has been recognized by individuals or groups of users as something completely new. In this report, the term innovation has been extended to technologies which still lie outside the legally accepted benefit catalogue and therefore cannot be calculated according to this benefit catalogue; alternately, the technologies are available but are subject to reevaluation because of new areas of application, changes to effectiveness and/or cost.
In the area of medical care, the term technology encompasses medical products, instruments, procedures and drugs. This report excludes drugs and deals exclusively with non-medicinal technologies, for drugs are subject

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to different cost-coverage regulations in different countries. Also, different institutions are involved in regulation. Many countries have developed specific procedures and criteria for innovative technologies through which the benefit catalogue is put in concrete terms and by which it can be decided whether and how the innovations are to be regulated in the legal benefit catalogue.

Research questions

In this report, which was commissioned by the German Agency for Health Technology Assessment at the German Institute for Medical Documentation and Information (DAHTA@DIMDI), the research question runs as follows: Which rules and mechanisms exist to regulate the introduction of innovative non-medicinal technologies into the benefit catalogue of solidly financed health care insurances in the countries examined? This study analyzes the regulations in Germany, England, Australia and Switzerland.

Methods

In order to find relevant literature and information about this topic, a systematic literature search of 29 data banks in total was carried out by DAHTA@DIMDI according to the prevailing requirements and upon consultation with the authors regarding search strategies. Published literature was searched with synonyms of search terms such as statutory health insurance and benefit catalogue in combination with the names of countries and of the institutions which had already been found. The effective date for the search was April 2006. The search period began in 1998. The selection of the literature found in the search took place in three steps according to previously established criteria for inclusion and exclusion. In the first check, only the titles of the literature were examined. In the second step, the summaries were analyzed before finally, in the third step, the texts were examined in their entirety.
For the description of the regulation of innovative non-medicinal technologies, the common systematic literature research in the data banks made available by the German Institute for Medical Documentation and Information (focusing mainly on journal articles) was not sufficient, therefore an extensive hand search was carried out.
Relevant institutions in the countries to be examined and corresponding helpful documents were identified via the internet. Furthermore, a search was carried out of economics journals and magazines, as well as the data bank ECONIS of the Central German Library of Economics (July 2006). In this step, search terms came under those used in the research of the data banks of the German Institute for Medical Documentation and Information. Additional studies were identified by examining the reference lists of the publications found. With few exceptions (e. g. concerning date of publication), the same selection criteria applied as in the hand search. Furthermore, the literature research was complemented by a written survey of relevant institutions and people in all four countries. A list of questions was specifically developed for each corresponding institution in order to find answers to questions which had not been adequately addressed in the evaluation of the available literature.
All the selected documents were qualitatively evaluated, summarized and presented on a chart using a framework developed for this purpose.

Results

All of the countries examined in this report carry out an evaluation process of some innovative non-medicinal technologies as a prerequisite for adoption into the benefit catalogue offered by solidly financed health care insurances. In each country, this process involves an institution expressly concerned with innovations; each institution has access, either internally or externally, to an expert advisory body. These four central governing bodies are the Federal Joint Committee (Germany), the National Institute for Health and Clinical Excellence (England), the Medical Services Advisory Committee (Australia), which is the only governing body which does not evaluate drugs, and the Federal Commission for General Health Insurance Benefits (Switzerland). The recommendations issuing from these institutions form the basis for later political decisions or are even passed immediately into law.

The institutions are all similar in terms of the size and composition of the governing bodies. England is different in that manufacturers are directly involved in decision-making and sit on the governing body. In all the countries except Germany, manufacturers may file an application for evaluation or suggest a topic to be evaluated. In general, the institutions carry out the desired evaluations. In England, on the other hand, the minister of health makes the final decision. In England and Australia, there is a program to identify topics (Horizon Scanning). The criteria of the prioritization of claims are, except in England, to a large extent unknown. Furthermore, England is a special case in that the assessment of the evidence takes place strictly separate from the appraisal.

There is no time limit on the evaluation process in any country. This means that a wide range of evaluation periods exists. Because of this, average time values are not particularly revealing. In general, Australia can be considered the country in which the governing body has the fastest procedure to introduce innovative non-medicinal technologies into the benefit catalogue. The governing bodies of every country have several alternatives in their decision-making processes (agreement, rejection or agreement with limitations). In this area, the Swiss have the most comprehensive set of alternatives. In all countries, it is possible to lodge an appeal against the decision of the governing body.

In Australia and Switzerland, the evaluation is primarily based on applications from manufacturers. These applications must follow upon systematic literature research and the analysis of clinical and economic studies. Corresponding handbooks are tailored to these requirements and describe, mainly, what is expected of the applicants. In the other countries, the governing bodies carry out, either on their own or by commissioning research institutes, systematic and comprehensive literature research and information synthesis independently of the manufacturers. For literature research, choice of study, analysis of the validity of the study as well as systematic reviews and meta-analyses, Switzerland requires manufacturers to draw up their applications with the assistance of international standards (e. g. the guidelines of the Cochrane Collaboration or the CONSORT and QUORUM Statements). The National Institute for Health and Clinical Excellence also refers to these standards in its handbooks dealing with the submission of applications. The guidelines from England are the most extensive in that they describe the entire procedure and the methods used in the evaluation. The Federal Joint Committee does not have a specific handbook but merely rules of procedures, which allows applicants to draw conclusions. Since, however, the details of the evaluation process are not transparent in any of the countries, it is not apparent to which extent the evaluating bodies carry out their own research and analyses. Apart from the Federal Commission

for General Health Insurance Benefits, all the governing bodies refer to external expertise in the form of official statements when evaluating the evidence. Also, unpublished and confidential information (e. g. from manufacturers) can be used in all the countries for the purposes of evaluation.
The main criteria which the governing bodies use in their evaluations are similar. In this way, the evaluation of the benefits and effectiveness of innovative technologies plays an important role. Cost-effectiveness is also a vital component of the evaluation in every country, although this criterion carries significantly more weight in England. In comparison, the decision for or against adoption into the benefit catalogue is characterized by important criteria such as necessity (Germany), safety (Australia) and appropriateness (Switzerland). Additionally, political and societal aspects also play a role in the overall decision-making process concerning the introduction of an innovation, as do many additional and diverse criteria, such as the availability of alternatives to treatment, social and ethical aspects such as access to innovations, financial consequences for the health system and the nation's overall health or the priorities set by the national health systems.
Randomized controlled studies are considered to be the most reliable type of clinical studies for an evaluation. However, all institutions do allow for other types of evidence (e. g. expert opinion) when no other study types of a higher evidence level are available. Every country has specifications regarding the classification of evidence. Should an improved benefit be shown, every country must also investigate the costs incurred by the innovation. Cost-benefit analyses and the measurement of the health effects in quality adjusted life years take priority in these cases. Explicit cost-effectiveness limitations (as cost per quality adjusted life year, after which an innovation will be automatically rejected, do not exist. Every country requires an account of various types of cost (direct and indirect). England is alone in requiring an account of any modeling which is carried out. In England, Australia and Switzerland, economic studies recommend a yearly discount rate of 3.5 or 5%. In Germany, there are no explicit guidelines for this.
The decisions made by the central governing bodies do not necessarily become conditions for the introduction of innovative non-medicinal technologies. Decentralized decision-makers, or institutions responsible for a certain subject area are also invested with a greater or lesser degree of decision-making power in the introduction of innovations. They may come to a decision autonomously. This is one reason that none of the countries has an explicit benefit catalogue which comprehensively lists all applicable services. Some countries also have specific financial support and instruments such as special regional funds (Australia) or specifically negotiable fees (England, Germany) which facilitate the region-specific introduction of innovations.
Aside from their application in privately financed medical care (self-pay patients or policy-holders of private health insurance) innovative non-medicinal technologies can, once the right to distribution has been obtained (CE-certification or approval by the Therapeutic Goods Administration (TGA)), be distributed in the solidly financed health care system without further evaluation, if the application can be financed due to already existing reimbursement features.

The observation of innovative technologies after they have been adopted into the benefit catalogue takes place, to a certain extent, in registers of certain diseases. The National Institute for Health and Clinical Excellence also reevaluates regularly made decisions. Furthermore, Australia and England have special commissions which regularly re-examine the conclusions drawn by the evaluating bodies.
A tabulation of the results can be found in Tables 17 to 23 (see 6.5.6 Tabellarische Ergebnisübersicht aller Länder) of the main document.

Discussion

This study is a descriptive analysis of the procedures concerning the adoption of innovative non-medicinal technologies into the benefit catalogue of solidly financed health care insurances. The object of the study was not the extent to which innovations, for which the financing is theoretically available, are actually applied in practice. The overall literature research provided a large number of hits, whereas the hand search turned up far more relevant publications and information than the classic literature search in the data banks of the German Institute for Medical Documentation and Information. The limitations which are usually placed on published literature in the preparation of HTA reports were consciously abandoned for this report in order to enable the inclusion of current information from the internet sites of the relevant institutions. It also made the supplementary survey possible. The documents which were selected and analyzed depicted an extremely heterogeneous spectrum of the information and types of publication which are currently accessible to the public. All in all, it can be assumed that this report is based on broad but, because of the above mentioned limitations, not all-encompassing evidence.
The procedures of the governing bodies in the individual countries differ mainly in terms of the accessibility of information and its comprehensibility to the public. The Swiss process is considerably less transparent than the corresponding processed in Australia, England and Germany. The length of the decision-making period, which is difficult to predict, leads to great insecurity in planning for manufacturers. For example, no fixed time limit is set on the decision-making process of any of the governing bodies. Rather, the length of time depends on the individual process and is impossible to predict. The predominant criteria according to which the governing bodies in the countries examined here must make their recommendations are, to a great extent, identical. However, the criteria are still indefinite terms. All the governing bodies have various decision-making options available to them. Switzerland has the most opportunity to differentiate between options and is thus the most flexible in decision-making.
The decision-making process regarding the introduction of an innovation into the benefit catalogue is, however, applied only to part of the innovative technologies. A large part remains, to a great extent, unevaluated, especially in the inpatient sector, and differs from region to region. What the countries examined here have in common is that innovative technologies can be introduced into the benefit catalogue not only through evaluation by the governing bodies, but also by other means (e. g. local decision-makers, regional financing). This way, innovations can also be introduced without the agreement of the central governing body. Obstacles appear mainly in financing the application of the innovation. Apart from the differences in application which result from this problem, manufacturers must deal with the consequence that they will come up against a multitude of decision-making bodies (with introduction on an international scale, this can even happen in several countries) if they try to introduce an innovation into the solidly fi-

nanced health care insurances without direct evaluation by the central governing body. The entire process of adopting innovations in this area is not particularly transparent, since, on the local level for example, it is generally unclear how and according to which criteria the decisions are made.
All of the countries are faced with the problem that some services are evaluated by the governing bodies only when they have already been established in practice via decentralized paths. When this is the case, increased pressure is put on the governing bodies to make a positive recommendation in their evaluation, which may take place later on. In addition the private health insurance sector exerts pressure in all the countries when it has refunded the cost of the innovative technologies at an earlier time.
Introducing an innovative technology is usually straightforward when the technology is effective and able to lower the cost of treatment. It is the overall fees that provide the incentive to introduce and apply the new technology. Introduction is more difficult when the innovation leads to an increase in the cost of treatment. In these cases, it is necessary to adjust fees or to create new ones. If this is not done then the danger arises that the innovation will not be used in practice, or used only in a limited way. Also, other services, which may have more benefits, may be suppressed. A possible rationing of health services can proceed not only from the central decision-making bodies, but also from existing budgets.
Every country has established a system of observation and registration for medicinal products. These systems are meant to document any incidents with the innovations and to confer responsibility on certain organizations. On top of this, every country has registers for specific illnesses. These registers keep track of data regarding various forms and processes of therapy. Surgical processes are evaluated and observed only in Australia. All in all, except where safety is regarded, no country has a central authority which systematically investigates the effects of newly introduced innovative non-medicinal technologies on medical care in general. In England and Australia, however, a reevaluation can take place with some of the innovative technologies which have been introduced, for example via special commissions.

Conclusion

What all the health systems examined here have in common is that there are many determining factors involved in how to regulate innovative technologies. There is no uniform international standard. At the international level, there is no unified method for the governing bodies to carry out their evaluations. However, it has been agreed to align HTA standards.
Many innovative technologies are applied across the board without evaluation from the central governing bodies. Evaluation often takes place only when the innovation has been established by other means. None of the countries has a central authority which carries out thorough evaluations of innovative technologies in all areas. Decentralized decision-making bodies can decide whether or not to introduce a particular technology in a particular area. This leads to regional differences in all the countries. Manufacturers must turn to several contact partners when the adoption of an innovative technology by the central authorities does not seem practicable to them (because of a lack of evaluation processes, long waiting times, many demands on the evidence, etc.).
In principle, the starting point for improving regulations of innovative non-medicinal technologies lies in the extension of transparency, the shortening of decision-making time (especially the central decision-making processes), the further development of evaluation methods, more flexibility and increased capacity in the governing bodies' decision-making processes and

also, if needed, in the creation of a single authority to act as contact person for people who are interested in introducing an innovation into the benefit catalogue. Binding regulation of decision-making time could enhance the process, as could improved opportunities for the manufacturers to be involved. Moreover, it would be a good idea to continue to develop methods and procedures in such a way that an estimate of the benefits of innovations can be produced sooner and faster. A possible solution could be to include more decision-making options, as is usually the case in Switzerland (e. g. introduction only in certain centres or approval of an innovation only for a certain time). All the countries agree that regulation is necessary, for technological progress will make financing more difficult in the future. Established services which have come into the health system without being evaluated could be examined.

More research is required, especially in the area of decentralized decision-makers and how they actually decide whether or not to introduce innovative technologies (methods, criteria, etc.). In view of this, it would also be interesting to see how the application of innovations actually happens in practice once their adoption has been approved by the corresponding governing bodies. This report demonstrates the theoretical ways that an innovative technology can make it into solidly financed health care insurances. However, neither the application nor the impact of HTA has been adequately examined in the adoption of innovations.