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ARTHROSCOPIC SURGERY FOR KNEE OSTEOARTHRITIS: IMPACT OF HEALTH TECHNOLOGY ASSESSMENT IN GERMANY

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Objectives: This study aims to describe how a negative reimbursement decision—based on the health technology assessment (HTA) report of a nondrug intervention—affects healthcare providers in Germany.
Methods: Knee arthroscopy was chosen as an example, because as of April 2016 this procedure is no longer reimbursed for osteoarthritis, but is still covered for other indications, including meniscal lesions. The exclusion followed an HTA report prepared by the Institute for Quality and Efficiency in Health Care (IQWiG). Here, we examine how the decision to revoke reimbursement for arthroscopy was perceived by the surgical community. Information was collected from official hospital statistics, the internet, and informal interviews with orthopedic surgeons.
Results: In 2015, a total of 37,920 arthroscopic procedures were performed for knee osteoarthritis in Germany. Several surgical societies were unhappy with the negative decision, which was issued as a directive in November 2015, and they challenged the decision-making process as well as the underlying scientific evidence. In March 2016, fifteen societies issued joint recommendations on how to differentiate osteoarthritis from other knee diseases and how to document other diseases in a way that inspections by representatives of health insurance funds would not detect any deficiencies. In informal interviews, orthopedic surgeons indicated that miscoding of the principal diagnosis (meniscal tear rather than knee osteoarthritis) is to be expected, especially in the hospital sector.
Conclusions: HTA can have a significant impact on the provision of health services, but various loopholes allow physicians to undermine policy decisions. Therefore, it is important to involve all stakeholders in HTA and to convince them of the benefits of evidence-based medicine.

Keywords: Health technology assessment, Arthroscopy, Knee osteoarthritis

According to German law, every resident is required to have health insurance. Approximately 90 percent of the population in Germany is covered by statutory health insurance (SHI). Insurance benefits include both treatments in hospital and ambulatory care. Decisions on the reimbursement of healthcare benefits are made by the Federal Joint Committee (G-BA), the highest decision-making body of the self-governing SHI system in Germany. The G-BA is under the statutory supervision of the Federal Ministry of Health (BMG) and is constituted by representatives of physicians, dentists, hospitals, health insurance funds, and patients (http://www.english.g-ba.de).

The role of health technology assessment (HTA) in Germany is growing, but there is no systematic way of assessing nondrug interventions, such as surgical procedures, medical devices (except for new high-risk devices), screening, or diagnostic tests. Reimbursement of new nondrug interventions depends on whether a service is provided in the hospital (inpatient) or ambulatory (out-patient) sector. In the latter sector, interventions are not reimbursed by SHI until the G-BA decides in favor of a method ("right to authorize"). A positive decision requires sufficient clinical evidence on the benefit of the intervention. In hospital care, all interventions are reimbursed through Diagnosis-Related Groups (DRGs) by SHI without prior assessments as long as the G-BA does not explicitly ban a method ("right to prohibit"). A negative decision requires clinical evidence demonstrating an intervention is ineffective or even harmful.

The G-BA usually commissions the Institute for Quality and Efficiency in Health Care (IQWiG) to collect all clinical evidence on a nondrug intervention under scrutiny and to summarize its effectiveness (but not cost-effectiveness) in an HTA report (called a "benefit assessment"). In most cases, the results of IQWiG's benefit assessments predetermine the G-BA's decisions. IQWiG is an independent scientific institute (http://www.iqwig.de) and applies the standards of evidence-based medicine (1). It was founded in 2004 and can only be commissioned by the G-BA or the BMG.

Although evidence-based medicine is widely accepted by clinicians, difficulties arise when evidence contradicts common belief, current practice, organizational context, and monetary incentives (2;3). Therefore, the objective of the present analysis was to assess how a negative HTA decision on a nondrug

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intervention is perceived by the medical community and how it affects healthcare providers in Germany.

METHODS

Selection of an HTA Example

In this study, we chose an "impact story" approach to describe how a recent negative reimbursement decision based on an HTA report affects healthcare providers. Once sufficient insurance data are available, a thorough analysis of the impact of HTA on health care in Germany will be undertaken. Knee arthroscopy was chosen as an example for several reasons. First, it represents one of the very few cases in which a well-established procedure was denied further reimbursement in both ambulatory and hospital care. Second, the importance of the decision is inarguable given the high prevalence of knee osteoarthritis. Third, the evidence on arthroscopy in knee osteoarthritis can be considered highly valid and precise, because data from eleven randomized controlled trials were included in the IQWiG report (4;5), even including sham-controlled trials (6).

As of April 2016, arthroscopic surgery is no longer reimbursed in patients with a principal diagnosis of knee osteoarthritis. Arthroscopic lavage ("flushing"), arthroscopic debridement (i.e., removal of tissue fragments), chondroplasty (smoothing of cartilage), synovectomy, and meniscectomy (partial or full) were all excluded (7). However, arthroscopic surgery is still covered for other indications, such as trauma, knee locking, and other meniscal pathologies, if osteoarthritis is a comorbidity rather than the primary diagnosis.

Collection of Information on Impact

Insurance data collected by the German Federal Statistical Office were used to estimate the usage of arthroscopy in the year 2009. For the year 2015, we obtained the number of patients with a principal diagnosis of knee osteoarthritis (ICD-10 M17.-), who had undergone arthroscopic surgery (OPS code 5-81) in any German hospital. This information was kindly provided in February 2017 by staff of the Information System of the Federal Health Monitoring in Germany (http://www.gbe-bund.de), which has access to all hospital data. Nevertheless, as such data are not yet available for 2016, no formal evaluation of possibly changed practice patterns was possible. Furthermore, the data do not allow calculating the exact incidences of arthroscopies, because more than just one arthroscopic intervention is likely to be performed in one patient during one surgical session (i.e., double-coding). In addition, no comparative data are available for ambulatory surgery.

To examine how the negative reimbursement decision on arthroscopy was perceived by the surgical community, information was collected from the medical literature (PubMed search and citation crawling), a medical press release service, and the Internet. However, no systematic searches were performed. Searching was restricted to German sources published between 2014, the year when the IQWiG report was published, and the end of January 2017. Sources mentioning either the IQWiG report or the G-BA decision on knee arthroscopy were included.

In addition, informal face-to-face interviews with six orthopedic surgeons were performed to elicit their views and strategies for coping with the new reimbursement situation. The surgeons were selected on an *ad-hoc* basis at three national orthopedic conferences. All surgeons were board-certified and currently working at registrar or consultant level, either in an orthopedic department of a hospital or in an ambulatory specialty practice. The interviews were neither structured nor audiotaped.

RESULTS

According to official hospital data, 18 percent of all 366,182 arthroscopic knee interventions performed in 2009 were in patients with the principal diagnosis of gonarthrosis. In 2015, the number of arthroscopic interventions performed for knee osteoarthritis had already dropped considerably, but still amounted to approximately 38,000 procedures (Table 1). In arthroscopic therapy of the cartilage or menisci, approximately one in five procedures was performed for osteoarthritis rather than for internal knee derangements. Age only slightly affected this ratio. Future studies could use this indicator and these data as a basis to examine the impact of the 2016 reimbursement directive.

Professional societies had extensively commented on the draft versions of the IQWiG report and G-BA directive (five and three public statements, respectively). Nevertheless, some of the societies complained that decisions were made without adequate involvement of stakeholders (8). Various surgical societies uniformly and repeatedly argued that knee arthroscopy: (i) might still be beneficial in certain subgroups of patients with osteoarthritis, (ii) would be at least as effective as other treatment options, (iii) could be better assessed by also including nonrandomized studies, and (iv) should not be excluded, due to the limited number of treatment alternatives.

All these arguments were discussed and refuted by IQWiG and G-BA, but it is clear that some surgeons were unwilling to accept the negative reimbursement decision that was made by the G-BA in November 2015. The press took up the issue widely after the final report by IQWiG was published in 2014. This included articles in newspapers and print magazines (approximately thirty reports) and also coverage by national television and radio (approximately five features). No articles in response to the IQWiG report or G-BA directive were found in medical literature databases, but in March 2016, a day before the directive came into effect, fifteen orthopedic surgery

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Table 1. Arthroscopic Procedures Done in Germany in the Year 2015

Surgical intervention (OPS code)	Procedures done for knee osteoarthritis (ICD code M17)		Procedures done for internal knee derangement (ICD code M23)		Ratio of procedures done for osteoarthritis as opposed to internal knee derangement
	Total number	Mean age (years)	Total number	Mean age (years)	
Diagnostic arthroscopy (1-697.7)	4,109	59.9	7,791	53.5	0.53 (0.30, 0.64, 0.64, 0.71)
Arthroscopic therapy (5-810)	6,518	59.9	25,655	53.3	0.25 (0.14, 0.30, 0.30, 0.38)
Arthoscopic therapy of synovia (5-811)	10,030	59.8	44,183	54.9	0.23 (0.14, 0.26, 0.25, 0.31)
Arthroscopic therapy of cartilage or menisci (5-812)	15,847	59.9	76,389	56.0	0.21 (0.14, 0.23, 0.22, 0.26)
Arthroscopic therapy of knee ligaments (5-813)	868	55.6	9,072	35.9	0.10 (0.04, 0.29, 0.54, 0.74)
Arthroscopic therapy for other reasons (5-819)	171	57.8	1,305	48.3	0.13 (0.08, 0.13, 0.23, 0.27)
Arthroscopic lavage (8-178.h)	377	69.5	149	58.5	2.53 (0.59, 1.11, 3.42, 5.49)
Total	37,920		164,544		0.23

Note. Data provided by the Information System of the Federal Health Monitoring in Germany, http://www.gbe-bund.de. In parentheses, data are split up for different age groups (under 50, 50 to 60, 60 to 70, and 70 years or older).

societies issued a joint statement (9) on knee arthroscopy. They made recommendations on: (i) how to differentiate osteoarthritis from other knee diseases, (ii) how to document other diseases in a way that inspections by representatives of health insurance funds would not detect any deficiencies, and (iii) how to offer arthroscopy as a self-pay procedure.

Interviews with orthopedic surgeons clearly showed that miscoding of the principal diagnosis (traumatic or degenerative meniscal tear rather than knee osteoarthritis) is to be expected, especially in the hospital sector, where inspections are less stringent compared with ambulatory care. One surgeon for example described that a surprisingly large proportion of his patients reported knee locking when specifically asked. Two surgeons, on the other hand, spontaneously conceded that arthroscopy is not beneficial in the majority of patients with knee osteoarthritis.

DISCUSSION

Compared with other countries, Germany has been rather slow in implementing the new evidence on knee arthroscopy. Following the publication of the pivotal trial by Moseley et al. in 2002 (6), in 2004 the United States was among the first to revoke reimbursement of arthroscopy for osteoarthritis. In the United Kingdom, the decision to exclude arthroscopic debridement for osteoarthritis (unless knee locking is present) was made in 2007 (10). However, the majority of surgeons still believed that it would be better to keep arthroscopy as a treatment option (3). In Germany, a large proportion of the nearly 38,000 arthroscopic procedures performed for knee osteoarthritis can be estimated as not being evidence-based. However, it is not possible to calculate the number of patients, who undergo surgery for indications according to the new directive, because neither the severity nor the causality of meniscal lesions is recorded in national health statistics.

The impact of HTA depends on how strictly and unequivocally the rules governing healthcare policy and reimbursement are formulated and implemented. Medical conditions, however, sometimes tend to be a matter of both definition and interpretation. In knee osteoarthritis, the borders between indications are based upon judgment and are thus open to criticism in each individual case. The effectiveness of arthroscopic surgery is also uncertain in patients suffering from degenerative meniscal tears without osteoarthritis (11–14). In Germany, patients with meniscal lesions can receive arthroscopic therapy if osteoarthritis is either absent or not considered to be the underlying reason for the meniscal lesion. Because degenerative meniscal lesions frequently coexist with knee osteoarthritis, it is challenging to tell which of the two disease entities is responsible for the patient's symptoms. This opens an opportunity for miscoding, especially because a "culture" of upcoding is already prevalent in Germany (15).

The problem of miscoding, which is to be anticipated for arthroscopic surgery in Germany, has also been reported in other countries. In Finland, where arthroscopy is covered neither for osteoarthritis nor for degenerative meniscal lesions, the proportion of meniscal tears coded as traumatic is almost twice as high as in Sweden. From the patients' mean age, one can assume that many of the Finnish patients actually had degenerative lesions and knee osteoarthritis (16). In the United States, where Medicare restricted reimbursement of arthroscopy for osteoarthritis in 2004, the number of arthroscopies performed for traumatic knee lesions increased drastically (17). As it requires medical expertise and considerable time to carry out detailed checks of patient records, no good solution exists for effectively preventing intentional miscoding. To some

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extent, however, inspections by representatives of health insurance funds (i.e., the Medical Review Board of the Statutory Health Insurance Funds (MDK)) will detect and prevent miscoding (18).

HTA in Germany allows stakeholders to comment on scientific assessments and policy documents. Without a good understanding of evidence-based medicine, however, it is difficult for them to accept the reasoning leading to policy decisions. Financial conflicts of interest may also be an issue. Still, it is important to promote the concepts of evidence-based medicine as the common tenet in health care. The German Society for Orthopaedics and Orthopaedic Surgery (DGOOC) is currently preparing a guideline on knee osteoarthritis, which will show how great the divide between clinicians' beliefs and evidence-based medicine is. Patients also need to be informed, as they rightfully claim a more active role in selecting their treatments.

Being only an "impact story," the current analysis has several shortcomings. Most importantly, no actual data on arthroscopy numbers were available to assess the impact of the G-BA directive in 2016. Thus, miscoding can only be anticipated rather than proven or measured. Using published reports and statements, together with a few face-to-face interviews, allowed us to obtain only a superficial idea of clinicians' views. It is also possible that the majority of orthopedic surgeons oppose arthroscopic surgery for knee osteoarthritis, but that we did not record their views, because these surgeons had not commented on the G-BA directive.

Over the past decade, HTA has found its way into the German healthcare system. The example presented in this study demonstrates that benefit assessments of nondrug interventions conducted by IQWiG play an important role in the G-BA decision-making process and can have far-reaching consequences for reimbursement. However, loopholes can weaken the implementation of healthcare policy. Only the future will show whether arthroscopic surgery for knee osteoarthritis has been effectively banned from medical practice in Germany.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

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