Requirements for Adequate Arthroplasty Care (Expert Opinions)

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Summary

The previous chapters reviewed the status of knee and hip arthroplasty care based on existing literature. This chapter assesses the current situation from an expert perspective through the examination and analysis of available data. In August 2015, a workshop was conducted in preparation for this chapter, which was attended by a renowned panel of experts and stakeholders who play an important role in shaping the provision of healthcare services in Germany. This chapter presents the results following this workshop, the content of which has been approved by the relevant participants.

The panel of experts (Tab. 6.1) represented the following areas of care:

- Research and Training
- Specialized Clinical Care
- Medical Rehabilitation
- Professional Medical Societies
- Registry
- Statutory Health Insurances
- Medical Technology

Relevant statements regarding hip and knee arthroplasty in the following areas were selected:

- Prevalence of primary and revision arthroplasty
- Healthcare situation for primary and revision arthroplasty
- Health economics

The experts were requested to give their interpretation of the data and discuss the requirements, aims and challenges of joint replacement care as well as potential solutions and future needs for action.

6.1 Prevalence of Hip and Knee Arthroplasty

According to the German Federal Statistical Office, approximately 210,000 primary hip arthroplasty (partial or total replacement) inpatient cases were registered in Germany in 2013. In the same year, approximately 143,000 primary knee arthroplasty (partial or total replacement) inpatient cases (Chapter 2) were recorded. Patients in the 70 to 80

years age group constitute the largest proportion of all hip and knee arthroplasty cases (hip: 41.8 %, knee: 41.0 %). The average patient age for primary total hip arthroplasty (THA) was 69.7 years in 2013 and for primary total knee arthroplasty (TKA) 69.2 years.

Primary hip arthroplasty case numbers recorded by the Federal Statistical Office for the period from 2008 to 2013 show a plateau from 2009 to 2011 with approximately 213,000 operations each year. After a peak in 2011 at 213,935 cases, the case numbers decreased slightly in 2012 and 2013 (▶ Chapter 2). A similar trend is observed in primary knee arthroplasty: A plateau phase can be observed from 2009 and 2011 with a subsequent marked decline in case numbers in 2012 and 2013. While approximately 159,000 cases of knee arthroplasty were recorded in 2009, approximately 143,000 cases of primary knee arthroplasty were recorded in 2013 (▶ Chapter 2).

According to the panel of experts, data published by the Federal Statistical Office was originally collected solely for accounting purposes and is consequently only of limited use in making reliable evaluations in relation to hip and knee arthroplasty case number progressions. Consequently, the data do not permit evaluations of the degree to which government policy or patient-related causes, for example, influence the rate of joint replacements. For reliable assessments of both the prevalence of arthroplasty and potential influencing factors, further data should be used in the future (for example, from the German joint replacement registry »Endoprothesenregister« or the EndoCert initiative). This would enable a comprehensive, quality-assured and cross-sectoral collation of data which would allow reliable and verifiable interpretations.

In previous years, frequent comparisons have been made to international data (for example, OECD comparisons) to evaluate case number development trends for hip and knee arthroplasty. These trends confirmed Germany's alleged top ranking position in this field. However, according to the panel of experts, these comparisons are unfounded owing to several factors such as different patient cohorts, the means by which surveys were carried out, inclusion criteria and, in part, a lack of age standardization. Meanwhile, however, this has

	Tab. 6.1	Expert pan	el workshop	participants
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Name	Occupation
UnivProf. Dr. Karsten Dreinhöfer	Professor of Musculoskeletal Rehabilitation, Prevention and Health Services Research at the center for musculoskeletal surgery »Centrum für Muskuloskeletale Chirurgie (CMSC)«, Charité – Universitätsmedizin Berlin Medical Director and Head of the Department for Orthopaedics and Traumatology Medical Park Berlin Humboldtmühle Vice-President of the Professional Association of Orthopaedic Surgeons (Berufsverband der Fachärzte für Orthopädie und Unfallchirurgie e. V. (BVOU))
Prof. Dr. med. Klaus-Peter Günther	Executive Director of the University Center of Orthopedics and Traumatology at the University Hospital Carl Gustav Carus of the Technical University Dresden (Universitätsklinikum Carl Gustav Carus an der Technischen Universität Dresden) Past President of the German endoprosthetics society »Deutsche Gesellschaft für Endoprothetik (AE)« Past President of the German Society of Orthopedics and Orthopedic Surgery (Deutsche Gesellschaft für Orthopädie und Orthopädische Chirurgie (DGOOC))
Dr. med. DiplIng. Hans Haindl	Publicly appointed expert in medical technology
Prof. Dr. Karl-Dieter Heller	Head of the Orthopedic Department Herzogin Elisabeth Hospital Braunschweig Secretary General of the German arthroplasty association »Deutsche Gesellschaft für Endoprothetik (AE)« First Chairman of the German association of senior orthopedists and trauma surgeons »Verband leitender Orthopäden und Unfallchirurgen (VLOU)« Vice-President of the Professional Association of Orthopadic Surgeons (Berufsverband für Orthopädie und Unfallchirurgie e. V. (BVOU) Board member of the German Society of Orthopedics and Orthopedic Surgery (Deutsche Gesellschaft für Orthopädie und Orthopädische Chirurgie (DGOOC)) Vice President of the German hip society »Deutsche Hüftgesellschaft (DHG)«
Dr. med. Andreas Hey	Managing Director of the German arthroplasty registry »Deutsche Endoprothesenregister gGmbH (EPRD) «
Prof. Dr. Dr. Reinhard Hoffmann	Medical Director of the BG Hospital Frankfurt am Main (Unfallklinik Frankfurt am Main gGmbH) Secretary General of the German Trauma Society (Deutsche Gesellschaft für Unfallchirurgie (DGU)) Secretary General of the German Society for Trauma Surgery (Deutsche Gesellschaft für Orthopädie und Unfallchirurgie (DGOU))
UnivProf. Dr. med. Rüdiger Krauspe	Director of the Department of Orthopaedics Düsseldorf University Hospital President of the German Society of Orthopedics and Orthopedic Surgery (Deutsche Gesellschaft für Orthopädie und Orthopädische Chirurgie (DGOOC))
N. N.	Statutory health insurance representative
UnivProf. Dr. med. Georg Matziolis	Professor of Orthopedics at the Jena University Hospital, Campus Eisenberg, Department of Orthopaedics and Trauma Surgery Medical Director of the Clinic for Orthopaedics and Accident Surgery at the Waldkrankenhaus Eisenberg (Waldkrankenhaus »Rudolf Elle« GmbH)
UnivProf. Dr. med. Henning Windhagen	Medical Director of the Orthopaedic Clinic of the Hannover Medical School in the DIAKOVERE Annastift Hospital Past President of the German Society of Orthopedics and Orthopedic Surgery (Deutsche Gesellschaft für Orthopädie und Orthopädische Chirurgie (DGOOC)), and the German Society for Orthopaedics and Trauma (Deutsche Gesellschaft für Orthopädie und Unfallchirurgie (DGOU))

also been amended in relevant publications (► Section 2.6).

Nonetheless, despite limitations in the reliability and validity of the data available so far, the panel of experts has observed some obvious connections. In the period from 2009 to 2011, during which a plateau in the number of arthroplasty cases was observed, the necessity of arthroplasty was being critically discussed in the media which consequently led to uncertainty amongst patients. The incorrect assessment, consequently rectified, that Germany was ranked in the top position with regards to arthroplasty rates, led to verifiable confusion and mistrust towards treating doctors. The panel of experts deemed knee arthroplasty to have been affected in an over proportionate manner by these discussions. At the same time, however, the panel of experts indicated that before having to resort to surgery, more conservative treatment alternatives were available for the knee than for the hip and consequently, knee patients have a broader range of treatments to choose from. Additionally, fractures constitute a more frequent indication for hip arthroplasty which could explain the greater decline in knee arthroplasty. In addition, the decline in arthroplasty rates could also be related to an improvement in conservative treatment over the past few years.

However, the panel of experts expects a renewed increase in the number of hip and knee replacements in the future based on current demographic trends and the related increases in degenerative joint diseases. Another factor that could lead to a rise in knee arthroplasty is the fact that joint preserving arthroscopic surgery for osteoarthritis of the knee has been subject to criticism and may no longer be reimbursed as it is not considered a curative procedure. Consequently, joint preserving surgery may be performed less frequently in the future. Softer criteria such as access to care, who makes the indication and the institution in which it is made (primary care physician, specialist physician, hospital) as well as changes in the public perception of joint replacements will influence the development. However the impacts cannot be predicted at present.

6.1.1 Fixation Techniques and Revision Total Replacement

Federal Statistical Office data on the types of implanted prostheses and the fixation techniques used show that the majority of hip procedures (51 % in 2013) are total hip arthroplasties (THA) without the use of bone cement (▶ Section 2.2). In contrast, for the knee, total knee arthroplasty (TKA) with the use of bone cement for fixation constitutes the largest proportion of surgery cases (66 % in 2013) (▶ Section 2.2).

Revisions and revision total replacements over the past few years (2008 to 2013, also based on Federal Statistical Office data) show a marked increase following primary uncemented THA. In addition, there was also a distinct decrease in the number of revision procedures following cemented primary THAs in the period from 2008 to 2013 (> Section 2.3). With regard to knee arthroplasty, the rates of revision total replacement and revision remained predominantly stable. Solely bicondylar surface replacements showed an increase in rates up until 2011 and a subsequent decrease in revision replacements over time.

According to the panel of experts, interpreting the data published for case number trends for revision and revision total replacements is also limited as it involves raw data that were reported to the Federal Statistical Office by the payer institutions. The data included numerous different types of revision and revision total replacement procedures, including surgery without or with only partial replacements of prosthetic components through to revision total replacements. It is unclear to what extent the current documentation, information transfer and analysis routines in hospitals and external institutions (payers, AQUA, Statistical Office) correctly depict the numbers and types of operations actually performed. This could result in misleading estimations of the number of operations performed.

Determining correlations between primary implantation and replacement and/or revision is not possible as existing data do not link cases. Development trends in replacement and revision surgery rates are typically characterized by two peaks. Shortly after primary replacement, renewed surgery may become necessary mainly due to infections and

complications and in rarer cases due to implant-related issues. A second peak occurs after ten years or more and is due in particular to the loosening of the implant. These two peaks overlap in the Federal Statistical Office's cumulative presentation hence making a connection between primary surgery and the need for revision total replacement or revision indeterminable. This will only be possible through future evaluations of data from the German joint replacement registry »Endoprothesenregister«.

6.1.2 Regional Distribution and International Comparison

Analyses of AOK insuree data show that there are regional differences in the rates of primary hip and knee arthroplasty per 100,000 inhabitants (▶ Section 2.4). When observing data within an area from the southeast to the northwest of Germany, it can be seen that in 2013, there was an upward trend in the number of surgeries performed.

The panel of experts considers that the regional distribution shown by AOK insuree data is not entirely representative as varying patients in the cohorts may potentially differ from the patients of other payer institutions. Moreover, in order to make conclusive assessments, other factors that could potentially have an impact on the regional rates must also be taken into consideration. These include potential differences in patient demands and socioeconomic factors (for example, lifestyle habits) as well as differences between urban and rural areas. International statistics also show that social deprivation considerably influences the rate of knee and hip arthroplasty. Lower rates of surgery in areas with high social deprivation can also be observed in Germany. Some of the experts also consider that supplydriven or economic reasons may play a role: Practice-based physicians are also permitted to perform endoprosthetic surgery as visiting consultants with admission privileges or through other contractual agreements with hospitals (for example, as so-called fee-based physicians). According to the panel of experts, an indication of potentially influencing monetary factors could be the considerable differences in the rates of care observed at administrative levels, particularly at the individual federal state borders.

Regional variations in remuneration for surgery performed by fee-based surgeons could be deduced from this observation. Conversely, surprisingly higher rates of surgery were observed particularly in areas with lower numbers of specialist physicians. This might suggest more intensive conservative treatment being performed as an alternative to surgery in regions with higher numbers of practice-based orthopedists. However, from the panel of experts« point of view, regional differences in Germany cannot be conclusively assessed as numerous concurrent influencing factors with largely unclear causal relationships are still a matter of ongoing discussion. Therefore, more funding towards improving healthcare research is necessary.

Contradictory data exist when comparing international surgery rates to those in Germany based on publications using data from other OECD countries. Two years ago, a comparison of endoprosthetic procedures conducted in five EU countries (UK, France, Germany, Italy, Spain) and the USA, based on raw, non-age-standardized data was published and showed there were similar increases in surgery rates in both hip and knee replacements per 100,000 inhabitants in the period from 2000 to 2012. The original database which was published by the OECD at the time, ranked the OECD countries according to surgery rates. In this case, Germany had the highest rate of hip arthroplasty (287 procedures per 100,000 inhabitants in 2012) (▶ Section 2.6) and ranked third for knee arthroplasty following Austria (highest rate) and Finland (second highest rate) (► Section 2.6).

However, when age-standardized data are used for the OECD country ranking, which take into account specific demographic factors per country, Germany's ranking shifts from a top position to 5th for hip arthroplasty. For knee arthroplasty, Germany drops from 3rd to 8th position (▶ Section 2.6).

The panel of experts emphasize that there are serious methodological shortfalls in the OECD's ranking of international surgery rates. The data used are derived from data sources that differ in so many ways that making comparisons is questionable.

International coding systems differ, which therefore do not allow for any direct comparability. The case numbers in the OECD database, for example, are based on ICD codes and do not permit clear differentiations to be made between elective (osteoarthritis-related) arthroplasty and emergency arthroplasty which is performed to treat fractures. They also partly contain both primary and revision procedures. The lack of age-adjusted data, in at least the first publications, has already been pointed out. This is an important point as absolute numbers without appropriate adjustments for demographic criteria lead to significant biases, particularly with regard to the increasing rates of osteoarthritis in older age groups. According to the panel of experts, these biases lead to surgery rates in regions with older populations being over estimated as has been the case in Germany, for example. Finally, virtually no further information exists regarding population groups used for the OECD assessment, i.e. whether the total population or only inpatient cohorts were taken into account or whether the data included information from private payer institutions or not. Major differences in the healthcare systems also do not favor the comparison of figures. Individual countries, for example, may have long waiting lists for the surgical procedures in question.

According to the panel of experts, if all the influencing factors discussed were taken into account, the actual ranking of the rates of care would be considerably different. In addition, there are clear indications to suggest that case numbers correlate with individual gross national products. Consequently, the panel of experts agrees that it can be assumed that financially weaker countries do not meet their care needs.

Need for action and solution approaches

- Fact-based open discussions about the benefits and risks of arthroplasty, drawing on comprehensive quality-assured and cross-sectoral data.
- Revision and harmonization of definitions and coding guidelines for revision total replacement and revision surgery in order to achieve reliable coding for the services provided in hospitals.
- Improving healthcare research in order to gain reliable insights into care needs and care provision at regional and national levels.

6.2 Status of Hip and Knee Arthroplasty Care

Germany seems to offer arthroplasty care nationwide (▶ Chapter 3). This is the case for both knee and hip arthroplasty as indicated by the fact that more than half of all German hospitals perform these procedures, amongst other things (▶ Section 3.3). Primary hip arthroplasty is performed due to osteoarthritis of the hip in 80 % of cases (▶ Section 3.3) and in approximately 12,5 % of cases due to femoral neck fractures. With regard to knee arthroplasty, approximately 96 % of primary surgery is performed due to osteoarthritis of the knee (▶ Section 3.3). Approximately one third of the patients who undergo either THA or TKA also suffer from serious systemic diseases and substantial functional limitations (ASA score 3) (▶ Section 3.3).

For THA patients, the length of stay in hospital is about 4.5 days longer than the average length of stay in a German hospital. Shorter lengths of stay have been observed in the past few years. While the length of stay was in the region of 14 days in 2012, it decreased to 12 days in 2014. A similar trend can be observed for TKA patients.

Treatment begins with the treatment plan before the actual surgery. This includes preliminary examinations, surgery planning and follow-up treatment planning. Numerous aspects therefore have an influence on the treatment and its outcome.

According to external inpatient quality assurance data, nearly all THA and TKA patients are able to walk independently and perform a daily hygiene routine themselves upon discharge from hospital.

The panel of experts confirms that nationwide care coverage exists for hip and knee arthroplasty in Germany. Consequently, travel times for patients are not problematic. In the opinion of some of the experts, there is even a surplus of hospitals providing arthroplasty services which, however, cannot be confirmed merely based on the number of hospitals offering joint replacement services. Instead, the panel of experts suggests that status of care evaluations should be based on differentiated analyses of certified arthroplasty centers. Only in this way would it be possible to qualitatively evaluate the number of hospitals performing endoprosthetic surgery based on defined quality criteria.

The panel of experts pointed out that patient demands with regard to arthroplasty have noticeably changed in recent years. Patients demand faster recovery for early weight-bearing and mobility as well as being able to resume sporting activities more rapidly. This does not imply that more surgery is being performed but that the expectations of the surgery itself and the outcomes have increased. At the same time, changes in patient expectations have also led to behavioral changes with regard to activities of daily life after joint replacement. This has resulted in implants being subjected to more stress and strain.

The panel of experts has observed marked improvements in the quality of devices used over the past few years. For example, they considered the developments in so-called tribological pairing positive, especially with regard to the different technologies used in the manufacturing of ultra-highly cross-linked polyethylene and new ceramic materials with significantly reduced risks of breakage. These implants are more expensive than implants using conventional materials, but they lead to significantly reduced wear and therefore fewer late stage complications. Other aspects, such as the impact of different implant stem lengths on the treatment outcomes cannot be fully evaluated at present. On the whole, the panel of experts considers the overall situation confusing due to the wide range of devices being used and the data situation unclear with regard to surgery outcomes for the different types of prostheses.

In addition, the panel of experts believes that any modifications in a hospital's administration with regards to purchasing processes could be problematic in practice in that they can lead to changes in implant procurement. For hospital administrations economic factors play a more important role than quality. Repeated changes in the type of implant being used necessitate regular training on behalf of both surgeons and the surgical teams which could increase the risk of complications. According to the panel of experts, it would make more sense if a hospital agreed on a defined set of products containing a few high-quality devices that are quality-assured based on scientific data and for which relevant know-how exists within the hospital.

6.2.1 Medical Rehabilitation

Usually, patients undergo subsequent rehabilitation (AHB) after the acute inpatient stay for the replacement surgery. This rehabilitation aims to generally strengthen and mobilize patients while taking into account their personal and individual rehabilitation goals particularly with regard to the required activities of daily living (ADL) (Section 3.4).

These rehabilitation procedures are financed by different payer institutions which include the German Statutory Pension Insurance (Deutsche Rentenversicherung, DRV), statutory and private health insurances as well as the German employers' liability insurance associations. To date, only limited and unstructured data are available on subsequent rehabilitation (AHB) treatment and a general overview of all the measures provided does not exist.

Furthermore, the depth and quality of the data in most fields is so restricted that only limited differentiated evaluations and interpretations are possible

According to the panel of experts, the data published by the German Statutory Pension Insurance (DRV) on the number and types of procedures conducted during subsequent rehabilitation (AHB) for TKA and THA is limited in terms of representation as it predominantly refers to rehabilitation patients in general and not in particular to total arthroplasty patients. In addition, data publications by some health insurance funds are only very rudimentary and of limited applicability.

The Advisory Council on the Assessment of Developments in the Healthcare System (Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen (SVR)) found that »Even though hardly any evidence pertaining to the effectiveness of rehabilitation under controlled conditions can be confirmed, it may still be assumed that benefits do exist«.

The panel of experts agrees that rehabilitation subsequent to acute inpatient care is necessary for the large majority of patients. Younger and otherwise healthy patients in particular may benefit from ambulatory rehabilitation close to their domiciles and for the growing number of older patients treatment in a rehabilitation clinic is appropriate in most cases.

The panel of experts stated that over the last few years, significantly shorter lengths of stay in acute care hospitals together with the higher number of older people undergoing surgery and the number of patients with concomitant diseases have led to patients being more unwell and in greater need of care when they are transferred to rehabilitation establishments. These patients have considerably higher nursing care needs and medical requirements, which, however, are currently not reflected in the remuneration for subsequent rehabilitation (AHB) in orthopedics. Consequently, patients who require higher nursing care are often transferred into geriatric care which does not always warrant specialist rehabilitation care.

The panel of experts sees a need for closer collaboration across all sectors and medical institutions including payers. There is also a need for a graded remuneration system in order to maintain adequate care for the patients.

According to the panel of experts, the fact that subsequent rehabilitation (AHB) does not always take place immediately after discharge from hospital does not imply a lack of care. Many patients request to be discharged to return home to be in their familiar environment after their inpatient stay. In addition, the German Statutory Pension Insurance recommendation stating that that subsequent rehabilitation (AHB) should start within 14 days after discharge from hospital is not evidence-based. Different regulations for this exist when making comparisons at an international level. For example, some countries provide home care without subsequent rehabilitation or provide subsequent rehabilitation at home. Nevertheless, subsequent rehabilitation (AHB) should take place as soon as possible after treatment in hospital. Advantages of this would be that patients recover sooner and gain their ability to work quicker while avoiding complications. Avoidable delays include procedures such as complicated application processes for different payer institutions or arduous transfer processes and arranging for subsequent rehabilitation (AHB). Speeding up these processes would be advantageous.

6.2.2 Service Lives and Revision

To date, the service lives of hip and knee endoprostheses in Germany have not been investigated or any reports on the subject published outside of studies. The German joint replacement registry »Endoprothesenregister Deutschland (EPRD)« is still in the process of being established and it is therefore not yet possible to analyze any registry data. International registries such as the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man, the Scandinavian registries and the Australian National Joint Replacement Registry have been collecting comprehensive data on endoprosthesis service lives for several years (> Section 4.3). However, particularly in the field of hip arthroplasty, insights from these data cannot be directly applied to Germany due to the differing healthcare systems, amongst other things. For example, Scandinavia and England have higher rates of cemented hip arthroplasty.

Conversely, uncemented hip arthroplasty is relatively common in Norway, Finland and Australia, as is the case in Germany, while the implants and surgical techniques differ to those used in other countries.

In addition, the different international registries are very heterogeneous with regard to their data collection. Also, specific outcomes are defined differently, in the case of revision, for example (> Section 4.3). For this reason, considerable efforts are being made in support of standardizing arthroplasty registries worldwide while the German joint replacement registry (EPRD) is being established.

According to the panel of experts, different reasons for revision exist, the most common currently being revision and revision total replacement due to infection. The prevalences of knee and hip arthroplasty differ and are influenced considerably by risk factors such as body weight, diabetes mellitus and other diseases with impaired immune systems. Other reasons for revision and revision total replacements, particularly during early postoperative stages, are luxation and/or instability. In the long term, conditions such as aseptic loosening and particulate wear of a stable fixated prosthesis may deem revision and replacement surgery necessary. Contrary to public perception, revision due to prosthesis

fractures owing to material failure is very rare. Investigations into these occasional ceramic prostheses fractures (less than 0.01 % of all implantations) have shown that they could not be solely attributed to material failure but that the implantation technique may also play a role. For this reason, medical societies collaborate with the manufacturers to conduct intensive training, for example. Prosthesis failure can also be provoked by strain due to excess weight or activity. As is often the case, according to the panel of experts, not enough data exist to conclusively evaluate the situation.

Revision total hip or knee replacement or component replacements lead to longer average lengths of hospital stay than primary arthroplasty (Section 3.3). THA patients who undergo revision total replacement have inpatient stays of almost nine days longer compared to primary surgery. The length of stay for revision total knee replacement patients is four days longer on average than for primary TKA patients. In general, replacement surgery is considered to be technically more demanding and more challenging to perform.

6.2.3 Adherence to Indication Criteria

In Germany, the rates of adherence to medical indication criteria for both primary and revision THA and TKA are recorded during external inpatient quality assurance procedures. The indication criteria are defined by a federal expert group (▶ Section 3.5). From this quality assurance data, the adherence to indication criteria for primary THA showed an increasing trend nationally over the past few years with 95.8 % in 2014. For individual federal states, the data published showed significant differences in adherence to indication criteria. Revision total replacements had an adherence to indication criteria of 93.1 % on a national level in 2014. At federal state levels, the differences observed are similar to those observed for primary arthroplasty.

The results are comparable for TKA. In 2014, the adherence to indication criteria at a national level was 96.9 % for primary TKA and 92.3 % for revision TKA. Here again, federal state levels show marked differences between individual states (> Section 3.5).

From the panel of experts« point of view, adherence to indications is generally poorly documented. At present, there are no guidelines on the time points for when arthroplasty should be performed and the data collected for external quality assurance (stage of osteoarthritis visible in x-ray, pain and mobility indicators) is only questionably suitable for determining »appropriate indications«. According to the panel of experts, some indications cannot be portrayed on the basis of the AQUA data as they do not necessarily correlate with arthritic changes as observed in x-rays (for example, aseptic necrosis or tumor near the joint). Particularly necrosis of the femoral head which is relatively common accounting for approximately 3 % of endoprosthetic surgery is generally assessed incorrectly as it is not coded separately With regard to this indication and others, the data generated do not correspond to the actual healthcare situation and incorrectly suggest that indications are not being adequately adhered to. In addition, current data collection procedures do not include other factors that have been shown to influence indications, such as prior treatment, comorbidity, problems with other joints, quality of life and expectations prior to surgery. Consequently, a group of experts is currently working together with professional associations to develop indication guidelines for joint replacements. Regardless of these contentual issues, service providers« reliability with regard to the use of the actual coding has also not been assessed, therefore indicating that data quality on the whole is not reliable.

However, the panel of experts say, it should not be assumed that regional differences in the prevalence of the provision of care are generally due to the issue of documentation of »appropriate indications«.

Registry data would provide a suitable approach for improving quality assurance. Registries contribute to the collection of information and data according to standardized criteria. A prerequisite for this is that all patients are recorded in the registry. This is why the panel of experts believes that private payer institutions should also submit their patient data to the registry. Private payer institutions are currently not participating in the reporting process. In addition, reporting should not only be made mandatory but should also be remunerated. Making

reporting mandatory would be a prerequisite for improving care especially for multimorbid patients. In addition, sufficient funding should be made available to subsequently enable evaluations of the registry data.

6.2.4 Minimum Volume Regulations and Increasing Case Numbers

Minimum volume regulations for primary TKA were introduced at a hospital level in 2006. According to this regulation, a hospital may only be reimbursed for TKAs by the SHI if it performs at least 50 TKAs per year. Analyses conducted by the Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)) show that the introduction of minimum volumes has led to increases in case numbers (> Section 3.5).

According to the panel of experts, the minimum volume regulation could lead to an increase in case numbers during the transition period as some of the care providers operating below the thresholds may still perhaps attempt to meet the requirements. However, after the introduction of the regulation, no further increase in case numbers can be expected for to this reason as larger centers with higher case numbers are not affected and hospitals that had had case numbers below the threshold are subsequently no longer included.

However, other factors may also play a role in increasing case numbers. For example, when the minimum volume regulation was introduced, the remuneration for conservative therapies was simultaneously reduced, which may have influenced the decision for joint replacement therapy.

Meanwhile a positive correlation between case numbers and the quality of service provision has been shown in many fields, for which reason the panel of experts consider the minimum volume regulation to be a positive step on the whole. However, there are certain issues with regard to the actual implementation of such regulations in endoprosthetic care. On the one hand, there is sufficient evidence to show that hospitals operating as centers have low rates of morbidity and/or mortality in addition to a decline in complication rates alongside

the increasing experience of the surgeons. On the other hand, no reliable data-based thresholds exist for individual surgeons or for hospitals in which several surgeons perform arthroplasty. Consequently, the thresholds which were determined in the Endocert® procedure are subject to further modification. Some experts consider the current threshold of 50 arthroplasties per year per surgeon to be too low. The panel of experts state that there is no danger of the minimum volume regulation jeopardizing nationwide coverage of endoprosthetic care. However, the aim of healthcare policies to provide care close to patients' domiciles will always be in conflict with the desire to establish specialized treatment centers that are located further apart.

Need for action and potential solutions

- Optimizing cross-sectoral care concepts.
- Systematic establishment and development of a relevant database, i.e. the German joint replacement registry »EPRD«, which includes all patients. This entails mandatory registry participation including patients with private health insurance. At the same time adequate funding for data collection and evaluation is required.
- Developing appropriate indication criteria and improving data collection in order to gain reliable information for developing relevant needs-based care.
- Developing suitable criteria for determining ambulatory and inpatient rehabilitation needs. Correlating these criteria to future new phases in orthopedic rehabilitation to determine the degree of comorbidity and nursing care assistance required.
- Emphasis on requirements for and the importance of specialist rehabilitation for older patients.
- Accelerated application processes and arrangements for subsequent rehabilitation (AHB).
- Developing and recording suitable quality criteria to appropriately depict the complex influence that physicians, patients and the implants have on quality.

- Improving knowledge regarding patient preferences and expectations paired with higher patient involvement in the decision-making process.
- Concentrating on providing care through experienced surgeons in certified arthroplasty care centers.
- Intensifying care research to gain reliable information about care requirements at regional and national levels.
- Supporting rehabilitation research independent of care providers in order to develop needs-oriented and optimized care.

6.3 Health Economic Aspects of Arthroplasty

From a health economic perspective, the direct costs arising from endoprosthetic care need to be taken into particular consideration. Results from AOK data were published with regard to patients suffering from osteoarthritis of the knee who underwent TKA in Germany. Not taking into account the costs for the TKA surgery itself, the data analysis showed that the costs for the period of 12 months after surgery (for example, for therapeutic products, drugs, contract physician care) are higher than those for the period of 12 months prior to surgery. The costs for younger patients were considerably higher than for older patients (▶ Chapter 5). Nonetheless, several studies have demonstrated the definitive cost efficiency of endoprosthetic care and of different rehabilitation procedures in Germany (Chapter 5).

A cost and remuneration comparison of inpatient primary THA cases (i. e. hospital cases) in nine EU countries conducted in 2005 showed that even after adjustments for purchasing power parity, Italy has the highest costs followed by Germany. Cost comparisons become difficult when an individual country's« purchasing-power parity has not been adjusted for. This can be demonstrated by using non-adjusted average costs of hip and knee joint replacements in Switzerland as an example. In this case, after simple currency conversion, the costs of

the most common DRGs are more than double than those in Germany (> Section 5.2).

The overall costs have risen over the past few years as becomes apparent when considering the most common DRG case fee calculations for hip and knee arthroplasty. Costs for physician treatment make up the largest proportion. The average costs for implants have either remained the same (hip) or decreased (knee).

Meanwhile, the relative proportion of overall costs per case is markedly below 25 %.

Treatment of infected hip endoprostheses in particular presents an economic challenge for hospitals. According to certain publications, deficits (higher costs versus remuneration) caused by this are on average over 12,000 euros per case per hospital.

Osteoarthritis is of particular economic importance. In 2011, osteoarthritis of the hip or knee resulted in approximately 7.6 million days of incapacity to work (osteoarthritis of the knee: approximately 5 million days, osteoarthritis of the hip: approximately 2.6 million days) (> Section 5.1). In addition, in 2011, almost 80 % of all retirements due to osteoarthritis were due to osteoarthritis of the hip or knee.

The panel of experts clarified that the higher costs for younger patients can be explained by the different indications related to this age group. »Normal« patients within this age group with osteoarthritis of the knee are unusual. Instead, patients usually suffer from more complex and cost-intensive general diseases (for example, joint damage due to hemophilia).

Need for action and potential solutions

- Fact-based discussions on the costs of diseases from a social perspective, irrespective of payers, type of service or individual aspects of care provision.
- Potentially involving patients financially, for example with fixed, diagnosis-dependent additional surcharges that guarantee basic care. This issue should be the subject of further open and straightforward discussions. This would also necessitate improving patient information and getting patients more involved in their treatment.

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