STRENGTHENING THE CENTRAL PROCUREMENT SYSTEM IN THE GREEK HEALTH SECTOR

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The Strengthening Capacity for Universal Coverage (SCUC) action is carried out with funding by the European Union through a grant agreement between the European Commission and WHO/Europe. Its general objective is to contribute to improving health and health equity in Greece, especially among the most vulnerable in the population, by helping the Greek authorities to move towards universal coverage and to strengthen the effectiveness, efficiency and resilience of their health system.

Part 1: Review of specifications for hip and knee prostheses

INTRODUCTION

Procurement of medical devices (MDs) on a national level, is a quite challenging task since it -at the same- time aims in guaranteeing high quality of products and assuring patient safety, with the lowest possible cost for the health care system. The vast variety of MDs, the accelerated pace of appearance of new technologies, the shorter life cycle, the continuous improvement of existing products on the market, are some constrains that make the MD procurement very challenging. This report addresses issues related to the MDs procurement system in the Greek health sector and more specifically in developing in close collaboration with staff in charge in EKAPY, standard specifications for hip and knee prostheses, to be used for tendering purposes.

SOME DATA ON TOTAL HIP & KNEE REPLACEMENT (THR - TKR)

Total Hip and Knee Replacement (THR & TKR), are the two most common operations in orthopedic surgical arthroplasty and many various types of hip and knee implants are available today on the market. Bearing surface combinations such as: metal-on-polyethylene, ceramic-on-polyethylene, and ceramic-on-ceramic; surgical fixation techniques: cemented, uncemented, hybrid, and reverse hybrid; as well as various head and cup diameters or stem sizes.

The selection of an implant type, is determined by multiple factors: patient characteristics, such as age, activity or bone shape; healthcare provider issues, such as cost pressures on hospitals and availability of implant combinations; and ultimately, the available evidence in the literature on their stability and side effects over time or surgeons related issues, such as training and skills; in fact surgeons need specific training for each type of arthroplasty and their experience in individual prostheses influences further the choice of the implant.

In many countries, there are national registries with data from patients who had a hip or knee replacement. These databases provide very useful information on the number of operations, tendencies, and trends, but most importantly, on revision rates. National Joint Registry for England, Wales and Northern Ireland (NJR), the world's largest database, contains over 2 million procedure level records and during the financial year 2015/16 nearly 225,000 were added, what demonstrates the size and growth of this very large dataset (1). Similarly, very reliable registries are maintained in Australia and Sweden.

Studies based on data from such registries on large numbers of THR and TKR, as well as, clinical trials and studies performed by the manufacturers, provide important information for decision-making. For example, a study based on the NJR data, suggests that resurfacing hip replacements and metal-on-metal implant combinations, fail at a higher rate than metal-on-

polyethylene, small head and/or cemented implants (6). Joint registry data also suggest that newer ceramic-on-ceramic, large head implant combinations might improve implant survival compared to standard implant combinations. It was also found that the older the patient group, the more likely it is that the small-head cemented metal-on-polyethylene implant is the most cost-effective choice. This type of implant appears as the most cost-effective choice for men and women aged 65 years and older. At the same time small-head cemented metal-on-polyethylene implants are the cheapest combinations available and display some of the lowest risks of revision surgery for elder patients. For patients younger than 65 years, the small-head cemented ceramic-on-polyethylene implant seems cost-effective, but these results are more uncertain, mainly because of still missing precise estimations of revision risks (7). It should also be mentioned that the number of hip, knee and shoulder replacement surgeries for young people is increasing and the fact that these patients have a high life expectancy, imposes longer periods of proper function for such implants in order to reduce revision surgery and its risks.

REVISIONS

Revision surgery is certainly the most important factor that influences the choice of a combination type or specific products. Complications that may lead to replacement revision surgery, include prosthesis instability, dislocation, aseptic loosening, osteolysis (bone reabsorption), infection and prosthesis failure. These complications cannot be easily attributed on technical factors only. The performance of an implant may be affected by many factors, such as the skills of the surgeons or the types of patients making use of it. Therefore, attributing the cause of the revision to a single cause is a very complex task.

Estimating the hazard of revision surgery is very critical due to the serious consequences that they have to the quality of life of the patient. It is also evident that the lower the revision rates are the more cost effective prostheses become. More specifically, hip and knee replacements are weight-bearing and sophisticated implants, for which the risk of revision surgery is greater than this of other joints. The best way to evaluate the risks of failures is to analyse not only data from clinical trials, but also from big registries for such replacement surgeries, performed on a national level to assure homogeneous samples. The National Joint Registry for England, Wales and Northern Ireland (NJR), and the similar registries of Australia and Sweden, already mentioned above are good examples and sources of valuable information. Additionally, since 2009, all NHS patients who are having hip replacement surgery are invited to fill in Patient Reported Outcome Measures (PROMs) questionnaires about their health and quality of life before and after their surgery. This provide very critical information on cost estimates per QUALY and willingness to pay.

Very well structured information on THR & TKR revision rates (RR) and evidence-based evaluation of various products on the market is maintained in the UK, through the Orthopaedic Data Evaluation Panel (ODEP). A major index for these arthroplasties is to

demonstrate the lowest possible RR, over a period of at least 10 years, which should not exceed in any case the 10%. Through this type of evaluation, ODEP provides NHS with an approved list of prostheses that meet revision rate standards of 10 years, set out in the NICE guidance, as suitable for use in primary hip replacement (see Annex 1). For hip prostheses with less than 10 years of clinical data, there are currently 3 entry failure rate standards set by ODEP: 3% or less in 3 years; 5% or less in 5 years; and 7% or less in 7 years, which are considered to be consistent with the 10-year standard. In England, according to the GIRFT report 2015(9) ODEP 10A femoral prostheses are used at 80% of the cases (Range 13% to 100%), in average.

To conclude, it is important to make the best clinical choices for the patients, but at the same time It is preferable to choose the less expensive of two equally good options. For instance, the choice between cemented and uncemented THR, where prices differ significantly, depends mainly on the age of the patient. According to data from the NJR, the average age for a THR is 68 years. Cemented THR has reduced from 54% of THR in 2005 to 36% in 2010 and un-cemented THR increased from 22% in 2005 to 43% in 2010. The current NJR annual report shows that these percentages are being maintained. The use of un-cemented implants in the elderly, with significantly higher costs, is difficult to be justified just in terms of outcome (9).

THE MEDICAL DEVICES DIRECTIVES AND THE NEW REGULATION ON MDS: RECLASSIFICATION OF HIP, KNEE AND SHOULDER JOINT REPLACEMENTS

The Medical Device Directive 43/92 (xx) initially classified the Hip and knee prostheses as Class IIb devices. Due to the complexity of the joint function to be restored and the increased risk of failure, joint replacements have been reclassified in 2005, by a special Directive: 2005/50/EC (12). According to this Directive, hip, knee and shoulder replacements have been reclassified as medical devices falling within class III. This reclassification has been maintained, in the new recent EU Regulation 2017/745 (13), of 5 April 2017, on medical devices, as Class III. More precisely in ANNEX VIII, CLASSIFICATION RULES, CHAPTER III under INVASIVE DEVICES, Rule 8 states that: total or partial joint replacements, are classified as class III, with the exception of ancillary components such as screws, wedges, plates and instruments.

Additionally, the regulation insists in the importance of strict conformity assessment (14), the MDs vigilance and the post market surveillance systems, especially for the implants. Although enforced by law, the MD user reporting system that consists the primary source of adverse events information in Greece remains still rather inactive. The adverse events are in most cases not reported and the recalls are not closely monitored in their implementation. Additionally, since there are no formal nor obligatory national registries, of implant surgeries performed that could reveal problems associated with the devices or procedures, it is not easy to identify problematic implanted prostheses through patients' follow-up in Greek hospitals. Furthermore, the data on the exact models offered by the providers, following the

number of calls for tenders by the hospitals is not known. Therefore, it is advised to prefer well proven cost-effective technologies, with long term follow-up by national registries in other countries, in order to protect patient safety.

PROCUREMENT OF HIP AND KNEE ARTHROPLASTY IMPLANTS

A product with CE mark, can be placed on the market by the manufacturer, in all the EU member states and any unjustified obstacle, in this right, is illegal. However, health care authorities or providers have also the right and duty to assess whether the various products available on the market are fulfilling the requirements and to assess alternative offers based not only on the price base, but also on the quality terms.

In Greece the laws and structures addressing the public procurement of medical devices are not yet very clear and fully implemented. The responsibility to proceed with central procurement of MDs has now been moved from EPY, to the recently established EKAPY. However very few calls for tenders have been concluded so far. For THR and TKR prostheses -in spite of some efforts to proceed with the new system- there has been no conclusive procedure. As a result, hospitals either continue covering their needs based on contracts from their previous call for tenders or proceed to new ones, using in most cases the available specifications created in 2014. The offers should be lower, or at most equal to the corresponding value of the product, in the list of the Price Observatory of the Health Procurement Committee that monitors the prices offered in public procurement all over Greece and maintain these lists. In most cases the final decision is taken on the lowest price offered.

REVIEW OF THE EXISTING SPECIFICATIONS

The specifications used up to now, in almost all procurement processes of THR & TKR are rather general descriptions of the type of implants, the way they are fixed and the sizes requested, than technical specifications. This is due to the fact that once an implant bears the CE mark and fulfils the requirement of the intended use, on the basis of the above characteristics, any additional specification should be sufficiently justified in terms of quality, cost effectiveness and patient safety, which is quite difficult to document. For that reason, the specifications used so far in Greece, are similar to those used in other countries that apply the same approach.

One meaningful criterion that could be used in the selection of an implant, is its expected lifetime, usually expressed in terms of average time for revision. However, as stated in the harmonized standard EN/ISO 21534:

> *"The lifetime of an implant depends on the interaction of various factors; some are the responsibility of the manufacturer, some, such as the implantation technique, are the responsibility of the surgeon in conducting the operation, and some relate to the patient, for example, the biological and physiological response to the implant, the*

medical condition of the patient, the conduct of the patient in respect of increasing body weight, carriage of heavy loads and adopting a high level of physical activity".

This makes difficult to conclude that the origin of a higher revision rate is due to the implant itself, unless this is based on evidence from very large number of cases.

Therefore, the answer to the question whether it is possible or not, to define justified detailed technical specifications for hip and knee replacement arthroplasty, without excluding products that fulfil the relevant harmonized EN standards and directives or regulations, is difficult. For example, due to the different, surgical approaches and technical features of the implants, a total hip arthroplasty can be concluded through four different surgical approaches (posterior, lateral, anterolateral and anterior). An anterior approach requires completely different surgical skills and instruments than the posterior approach. Regarding the technical features of the implants, the femur implant (stem) can be designed as a central or peripheral stabilization stem, which requires again different surgical skills, while the different stem design is based on different concepts. The aforementioned is a small part of the research that is further required in arthroplasties resulting to "followers" and "non-followers" of the different techniques and technologies. As a result, room should also be left for surgeon decisions, according to his knowledge and skills, but according to general rules based on best practices. In all cases, specifications should allow different types of hip and knee prostheses to be specified separately and not in general disease based terms.

Given the above, the proposed modifications in the existing technical description of the items for a potential call for tenders for Hip and Knee arthroplasty implants, are focusing in restructuring the way they are presented in order to better specify them. There are some technical specifications added, but it is considered that trying to be more specific could narrow down the number of products to be offered, in a nonevidence-based approach, without any clear benefit in terms of quality, patient safety or cost. The proposed additions are relevant to the EN/ISO standards that are in fact mandatory and they are not expected to provoke a real obstacle in the procedure, since all CE marked devices should normally comply with these standards. This aims in protecting from small changes in certain models that may not be disclosed by the manufacturers and although minor, could lead to unexpected adverse events (). There is also a number of proposed steps to be followed in the whole procedure, so as to improve these sets of specifications, before starting the procurement procedure, in order to be proactive. Apart from the standards, other sources for these proposed modifications are the recent technical specifications for THR from the "Haute Autorite de Sante" (HAS) of France ( ) and the 13th NJR report(1). The approach of HAS is to define the specifications on an item-by-item basis for the different components and then provide tables of possible combinations among them. The same approach is also followed by other countries. However, since the compatibility between products from different manufacturers is rarely possible, the proposal in this report is to maintain the "holistic" approach.

PROPOSALS

A consensus building procedure should be conducted, with meetings between EKAPY and the stakeholders (providers, orthopaedic surgeons societies, EOPPY), to better define the description of each item group, in order to avoid unnecessary exclusions and to potentially identify new groups to be added, or others to be modified or eliminated. As a first step an advisory expert group of orthopaedic surgeons should be created, to revise in detail the specifications and improve them, taking into account the situation in Greece. Then the representative of the providers could express their general points of view and concerns, before going to public consultation.

A quality criterion could also be introduced, based on the British ODP database information. A review of the items proposed by the providers, in the call for tenders by Greek hospitals, shows that about half of the manufacturers have products in the ODEP database. It is therefore advised to examine this as a criterion in the evaluation procedure.

Concerning the call for tender itself, the extend of the central procurement approach for hip and knee replacement implants, should be reconsidered. The use of the observatory prices, as a maximum for new offers, could be enough as a price control tool, although a renegotiation should be considered in some cases.

Additionally, the costs associated with the transport of the products and the tools, should be evaluated and agreed on a separate basis. The same holds in case the presence of a technical person is required. This is justified by the difference in the related cost, as distance increases or if access is limited.

Since the development of new designs, materials, and manufacturers is expected to increase in the coming years, and the related expenses will certainly follow the same trend, it is important to invest on related HTA studies, as well as, in relevant national registries that will allow -at a later stage- to take more evidence-based decisions.

Total joint replacements can be subject to multiple modifications following their introduction into clinical use and placing on the market. However, experience has shown that what appears to be a minor post-marketing change, can lead to unintended adverse consequences. Therefore, it is recommended to be rather conservative in accepting new designs, before enough evidence on benefits is gathered.

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ANNEX I

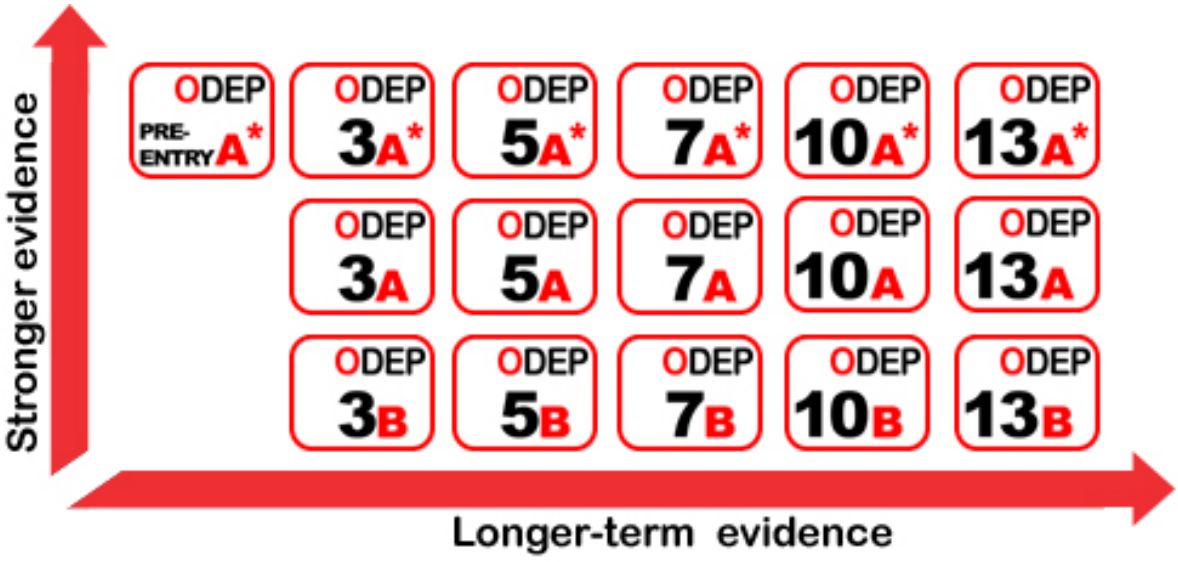
ODEP Rating

An ODEP Rating consists of a NUMBER and a LETTER, and a STAR (optional)

e.g. 

The **number** represents the number of years for which the product's performance has been evidenced.

13	thirteen years of evidence.
10	ten years of evidence - full compliance with NICE benchmark.
7	seven years of evidence - product is on-track to achieve the 10 year benchmark, but has not yet got sufficient data to evidence performance at 10 years.
5	five years of evidence - product is on-track to achieve the 10 year benchmark, but has not yet got sufficient data to evidence performance at 10 years.
3	three years of evidence - product is on-track to achieve the 10 year benchmark, but has not yet got sufficient data to evidence performance at 10 years.



The **letter** represents the strength of evidence (data) presented by the manufacturer.

A strong evidence - generally higher numbers of patients (giving greater confidence in the results presented), with all patients being subject to follow-up (their outcomes recorded).

B acceptable evidence - smaller numbers of patients than the A rating (giving less confidence in the results than A), but sufficient data to demonstrate compliance.

The **star** has been added to the rating system following revised guidelines from NICE in February 2014, in which a benchmark replacement rate of less than 1 in 20 (5%) at 10 years was defined. The **star** is awarded where products are evidenced to comply with this benchmark. **A*** represents very strong evidence above **A** and **B**. Ratings without a star signify compliance to the prior NICE guidance of a replacement rate of less than 1 in 10 (10%) at 10 years.

It must be always remembered that once a product has a CE mark the manufacturer has the right to market it in all the EU states. Essentially this means that if anyone should stand in the manufacturer's way is acting illegally. It can be also said that any organisation that sends out an edict which makes it difficult for the manufacturer to reach a market would also be acting illegally. This is one of the reasons why ODEP does not make recommendations. We simply assess the quality of the submissions that a manufacturer makes in support of the ongoing use of their product.