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Manufacturer submission to:

Total hip replacement and resurfacing arthroplasty for the treatment of pain or disability resulting from end stage arthritis of the hip (Review of technology appraisal guidance 2 and 44)

Executive Summary

With over 80,000 patients in the UK receiving hip replacements during 2011, it is one of the most successful surgical procedures currently undertaken. The procedures are also cost effective, with the health economic data supporting joint replacement equating to a cost of less than £10 per week for sustained relief of pain[1]. In addition there are wider societal benefits including return to work, less demand on social services and family support, and increased mobility and activity/fitness levels.

Total hip replacement (THR), also referred to as Total Hip Arthroplasty (THA), is a well-accepted treatment that it is indicated for people with osteoarthritis (OA) and rheumatoid arthritis (RA) who do not respond to nonsurgical medical treatment. THR is recomended in current NICE guidelines[2].

THR is a broadly established surgical process. In fact it has been referred to as the "operation of the century[3]. Every year about one million patients worldwide undergo this surgery[4]. In the last UK National Joint Registry 2012, data reported that 71,672 Primary Total Hip Replacements were performed in year 2011.[5]

THR is considered a safe and successful surgery with improved outcomes over the past decades. This added to the increasing aging population and the decreasing average age of patient undergoing THR will produce a scenario with an increase demand for this procedure in the coming years.

In practice, THR is not a single technology, but made up of multiple components. These are based on several different types of THR system depending on the cup and femoral component, fixation system used and types of material.

Surgeons make the decision on which type of implant to use depending on a number of criteria including patient anatomy, experience and training in certain methods, clinical data, etc. Stryker therefore produce a wide range of product types and sizes to ensure that there is an appropriate implant for every patient need.

Total hip replacements are extremely successful clinical procedures, as supported by a number of registries and clinical studies. The UK National Joint Registry started collecting data on joint replacements from hospitals in England and Wales on 1st April

2003. As of March 2012 it has accumulated 1.2 million records with between 93% and 100% compliance rate, meaning that all levels of surgeon report their outcomes. The latest Annual Report shows that in 2011, 71,672 Primary Total Hip Replacements were undertaken[5].

The latest UK National Joint Registry indicates that cemented implants have performed better than uncemented in terms of revision rates (defined as the proportion of revision procedures carried out as a percentage of the total number of surgeries on that particular joint), both at short term, and medium to long term revision rates (95% confidence intervals) and resurfacing procedures are more likely to be revised for pain, loosening periprosthetic fracture and other reasons than non metal-on-metal bearing surfaces [5].

Although the NJR shows a shift from cemented implants to uncemented, the revision rates are lower for the former, and the rationale for this shift is unclear based on the clinical data. The latest UK National Joint Registry report shows that at 7 years the Exeter V40, Contemporary has the lowest revision rate at 1.75% (ceramic on poly) and 1.8% (metal on poly)[5].

Total hip replacements have wider benefits than those just for the patient eg relief of pain and improved functionality. In 2009 about 11,000 people in England and Wales were enabled to return to work, saving the UK economy £37.4 million per year of their working lives, or £187 million over the next five years and £374 million over the next ten years[37].

Total hip replacement is also shown to be a cost effective surgical procedure. Different studies have evaluated the cost effectiveness of THR e.g. showing the incremental cost of conservative therapies in terms of the health gain – or quality of life – is sufficiently high to bring the cost per QALY well below the cost effectiveness threshold range usually adopted by NICE.

Few cost-effectiveness studies have been published regarding THR compared to other broadly used surgical interventions. The reason for this might be the generally accepted success and improvements shown during recent years of the operation, the lack of viable long-term management strategy, the low relative cost by the health improvement gained with the procedure, etc. It is clear that the expected increased demand of the number of procedures due to demographic changes and the increased number of revision surgeries observed during recent years and the variability in the clinical results from some new implants, is putting the procedure in the centre of research activity from decision makers to find the most efficient alternative for different patient groups suitable to undergo total hip replacement surgery.

The complexity described above should be taken into consideration in economic model which appropriately inform decision makers in the most efficient use of these technologies evaluated under the scope of the MTA. Stryker is currently working with a group of researchers at UEA and reputed orthopedic surgeons to develop a cost effectiveness model to address the above mentioned issues.