

July 2023

To all manufacturers of Total Hip Replacements

Dear Colleague

We would be grateful for your help!

Over the past 2 years the Orthopaedic Data Evaluation Panel (ODEP) has been working with the American Joint Replacement Registry (AJRR) to assess whether it would be possible for AJRR data to be used for ODEP submissions.

There are a lot of gains to be had if this was possible.

- Nowadays more data is being added to the AJRR than to any other registry.
- With the MDR and UKCA there will be more, new TJRs entering the market from the US than any other part of the world.
- Without a benchmark these implants will not easily be available, at least in the UK and probably in the EU and many other parts of the world, as well.
- Obviously, having AJRR data to benchmark them will make it easier for everyone, including purchasers. In Principle this is nothing new; ODEP benchmarks implants from all over the world that are not used in the UK

As you will be aware ODEP accepts applications using data from many of the world's registries but the registries from which ODEP will accept data have to match its agreed standards. Until recently it has been thought that AJRR did not meet the necessary standards, particularly for linkability between a primary and revision surgery. This has all changed and AJRR are keen to make their data available to manufacturers for ODEP benchmarks.

The plan and why we need your help.

There has already been a lot of work done, comparing the results of revision in the AJRR and NJR for a number of prostheses and, by and large, there does not seem to be any unacceptable differences.

Just recently, for ODEP knees, some manufacturers submitted both their "normal registry data" and AJRR data so we could see if there were significant differences. This study was most helpful and although we are still evaluating the study, there did not seem to be any big differences.

Our next step is for manufacturers submitting for an ODEP benchmark for a **Hip replacement** this coming autumn, and who have data in the AJRR, to submit that data as well the data they are using in the application. The standard ODEP form should be used for the additional data.

ODEP will use the non AJRR data to make its decision, but it will give both AJRR and ODEP a lot of important information, notably:

- Whether the process for manufacturers obtaining AJRR data is as we hope.
- So we can again compare revision rates from the AJRR cohort and the cohort from whichever other registry(ies) that is submitted. This information will be invaluable in assessing the use of AJRR data in the future.

The AJRR data, during this “Dummy Run”, will not influence the decision to benchmark.

The “Nuts and Bolts”

We anticipate there will be one or two ways that manufacturers who have data in AJRR can use the data to help us:

- a) As parallel data for a standard submission for a benchmark probably up to ODEP 7, where the AJRR cohort is likely to be a large one.
- b) As additional supporting data for a submission that is for a higher (7-15) benchmark, for us to make comparisons.

The data for the parallel must be supplied using the standard ODEP hip submission form which is downloaded from the website (www.odep.org.uk) and, in scenario (a), cut for the benchmark for which the overall application is being made. (It is important to use the standard form as this is part of the assessment)

For b.)

When the benchmark which is being applied for, is for a time point **past** where AJRR has data available for that implant, we would still be most grateful for sight of the AJRR data. **However**, if the main data could be cut, as well as for the benchmark application, at the highest available (3,5,7 years) from AJRR available for that implant we would be most grateful. That would mean we could make comparisons at the same timepoint.

For example:

- The “XXX” TKS is applying for a 15A* benchmark using NJR data.
- The manufacturer supplies NJR data to meet this benchmark.
- The manufacturer also provides AJRR data at the highest AJRR timepoint (3, 5 or 7 years)
- The manufacturer also cuts NJR data for the same implant match the AJRR timepoint.

We realise that this will increase your workload, but we reckon that for the future using AJRR data for ODEP will be very advantageous for all manufacturers.

What if we find that the revision rates don’t line up satisfactorily? Well, we think they probably will, but we have a cunning plan if they don’t!

You are welcome to contact ODEP or AJRR for further information if you require it.

Kind Regards



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