Senate Standing Committee on Community Affairs

INQUIRY INTO PRIVATE HEALTH INSURANCE (NATIONAL JOINT REPLACEMENT REGISTER LEVY) BILL 2009

JUNE 2009

Johnson & Johnson Medical (JJM) wishes to provide comment to the Senate Community Affairs Legislation Committee inquiry into the Private Health Insurance (National Joint Replacement Register Levy) Bill 2009.

JJM is a major provider to the Australian healthcare system through the provision of products and the development and implementation of support services for the medical community. The company is the leading medical device provider in Australia and, as a member of the Johnson & Johnson Family of Companies, is part of the largest medical devices and diagnostics company in the world.

In Australia, JJM works across both public and private sectors, providing the company with a strong understanding of the Australian healthcare sector. Currently JJM has 667 hip and knee items listed on the Prostheses List, representing more than 14% of all joint replacement items.

In principle, JJM supports the Bill however we are disappointed with the lack of consultation in considering the options for cost recovery of the NJRR. As the information provided by the NJRR would help inform a number of stakeholders in both public and private healthcare sectors (surgeons and other health professional, healthcare providers, governments, payers, sponsors, patients), the Committee should have considered a 'user pays' system for access to the data.

The NJRR is an important source of information that contributes to the data set of evidence to 'define, improve and maintain the quality of care of patients receiving joint replacement surgery'. We believe the NJRR data complements clinician expert knowledge and literature provided by sponsors regarding the safety and efficacy of prostheses, along with patient outcomes.

JJM does have some concerns on the intended use of the NJRR dataset. Registries can provide useful generalisable evidence but have many limitations that need to be recognised. The following factors need to be considered:

- Registries generally only measure safety outcomes – the NJRR looks at revisions as a hard end point and does not consider at effectiveness endpoints or any other benefits that might accrue to stakeholders, including reduced length of stay, surgeon training and support, surgical efficiency or instrumentation management. These factors should be included in the overall assessment of a device.

- Registry data can be readily confounded by differing surgical techniques in use with different products. An example is the use of different cementation techniques used by hip surgeons. Fourth generation cementing techniques for hip replacement have been shown to improve outcomes compared to earlier techniques; low viscosity cement has been associated with worse outcomes compared to high viscosity cement; the quality of cement mantle influences aseptic loosening, but registry data rarely accounts for such fundamental surgical technique differences in data analysis. For example, the Muller straight stem prosthesis with an all-poly cup, which at 10-years follow-up had loosened in 15% of cases in the 1980's only loosened in 2.4% of cases implanted in the 1990's. It is thus likely that surgeon-related factors are likely to be more important than fundamental differences between implants.

- Registry results can be very sensitive to performance bias. It has been observed that the apparent success of a particular implant is primarily determined by the whether or not less successful surgeons use the design, not by the its use by the most successful surgeons. The comparison of one particular product implanted by expert surgeons compared to another being used by a wider diversity of surgeons with differing skill levels can thus be confounded. An example from the Swedish Hip Registry was the use of the Spectron hip by skilled specialist hip surgeons in a single teaching hospital being compared to the Charnley hip which was in use across Sweden in all clinical settings, including community hospitals and less expert surgeons - not surprisingly the Spectron performed better in the Swedish registry. However in the randomised controlled trial carried out at the expert centre, there was no significant difference. The most successful clinical units reporting to the Swedish Hip Registry had revision rates of 3.7% less than the national average at 10 years post-surgery, whereas, the least successful reported rates up to 8.2% greater than the national average.

- Registry results can be very sensitive to intensity bias. Some interventions such as unicompartmental knee arthroplasty (UKA) and hip resurfacing arthroplasty are recognised as having an association between procedure volume and outcome. The Swedish Knee Registry has clearly shown this for UKA. Analysis of registry data thus needs to allow for the effect of surgical volumes, both by the surgeon and by the institution when making comparisons between products.

- Registry results can be very sensitive to learning curve effects if products are compared at different points on their users' learning curves. JJM's experience with ASR highlights this issue. Data from the UK National Joint Registry shows comparable safety performance between the Birmingham Hip System and the ASR. The UK is a more mature market for hip resurfacing, THR surgery is certainly more concentrated in terms of surgeon and institution volume. Data from the FDA trial with BHS and the Wright Medical devices shows equivalent learning curve effects with new users as was found for ASR in the NJRR.

- Most registries including the NJRR do not satisfactorily evaluate the root cause of revision procedures and rely on the surgeons making a fair assessment of the reason for failure. It is unlikely that surgeons will expose themselves to potential medical negligence litigation by admitting to technical errors when implanting orthopaedic implants. For this reason, the Swedish registries have central evaluation of all revision procedures but the findings are not in the public domain. This is potentially an additional confounding factor when evaluating new technology, alongside the procedure volume and learning curve issues.

- Simple comparisons using registry safety data alone are not suitable for evaluating products that present a different risk/benefit profile such as the use of conservative hips (e.g. hip resurfacing) where a greater risk of early revision might be justified by better implant survivorship in the future, to the patient's benefit.

We believe the Australian Orthopaedic Association should work collaboratively with all stakeholders including sponsors, to identify the factors that impact the outcomes of joint replacement procedures so that improvements can be made. These may include new product developments or the provision of appropriate training for improvements in surgical technique.

In proceeding with utilising NJRR data to measure the success or otherwise of a procedure, it is important that the following be in place:

- industry and other stakeholders be part of the group that peer-reviews the interpretation of NJRR results.
- clear evidence that performance and intensity bias as noted above have been accounted for and their effects minimised in the data analysis.
- technologies should be reasonably mature and reviewed at comparable points on their life-cycles. Products that are at an early point in their adoption curves can only be compared to other products at the same stage of adoption.
- the final evaluation should be conducted taking into account available clinical effectiveness evidence from other credible sources.

To ensure relevant and accurate information is provided to inform surgeons, other health professionals, governments, sponsors of joint replacement products and patients, requests the following:

- access to up-to-date product performance data –this would be in the form of a monthly report from the registry, regarding all product performance. From an industry perspective, this would ensure that we are able to proactively respond to adverse product performance in a timely manner.
- the ability to request additional information from the NJRR regarding specific product performance (e.g. further expanding on monthly report data; category breakdowns), whereby the information provided back from NJRR represents up-to-date data.
- the opportunity for industry to provide feedback and or input to future improvements to the NJRR

We hope the Senate Community Affairs Legislation Committee considers our request for engagement with all stakeholders to develop the NJRR as part of a robust health technology assessment system for Australia. We would be happy to clarify or discuss this submission with the Committee.

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