WHO BENEFITS FROM EXPLANT ANALYSIS?

Introduction

In recent years, surgery has benefited from technological breakthroughs with the introduction of successive devices and procedures with improved outcomes. However over time some of these innovative theoretical breakthroughs have had questionable durability in humans and some have led to catastrophic failure (eg Metal on metal hips, Spinal rods, PIP implants and Surgical mesh).

In addition with the increased number of procedures inevitably there has been an increased number of medical devices and number of manufacturers. The burden of regulatory has also undergone reviews in many countries throughout the world and manufacturers are under intense pressure to follow up products as part of their post market surveillance.

The follow up of medical devices should be seen in its positive context since there are huge benefits to improving products, surgical techniques and patient evaluation in real patients in independent centre settings. The analysis of explanted products is useful as an adjunct to the post market clinical studies, research, national joint registries and to dispel myths or rumours and help to defend the NHS in medical legal cases brought about by no-win, no-fee litigation.

Global Issue

Around the world, advanced healthcare systems recognise the need for independent assessment of medical devices pre and post market, for example the Department of Health Australia - which states :-

“It is recommended that all explanted medical devices (not only those associated with fault or adverse events) are sent for assessment to provide an overview of device performance.
• An initial examination is conducted and medical devices are triaged for priority. Devices not marked for investigation are archived to allow future investigation if indicated.
*• Bioengineering will advise the responsible surgeon, the TGA, and the manufacturer of the outcome of medical device analysis in the event of an adverse or sentinel event, or where a device failure is identified.”**

In the USA the FDA requests that all adverse incidents are reported and moreover has started to focus on more in depth reviews in some areas of concern. The FDA is concerned about the biological response to metal implants and makes the point that real world settings are necessary for evaluation and in respect of post market surveillance it states:-

“9.8 POST-MARKET SURVEILLANCE
*The main challenge in both pre- and post-market phases of regulatory review is the lack of adequate study endpoints and diagnostic and/or prognostic tools which reliably predict clinical responses. The threshold for detecting subtle but consequential biological responses which may constitute signals in our post-market surveillance systems remains to be determined. Currently, it is extremely difficult to determine whether symptoms are related to the implanted device or other causes. Predictive assessment of the pro-inflammatory potential and subsequent tissue remodelling remains a major challenge affecting real-world performance of implantable devices and biomaterials. Real world evidence and patient registries may be helpful in this regard.”***

And in Europe there has been focus and support on explant analysis, and in particular a recent paper entitled “What do we learn from explant analysis programme?” Discusses the following areas:-

1. Explant analysis is likely to be the key in improvements in surgery.
2. Failures occur in devices and these are largely under-reported.
3. Reporting of failures is mandatory
4. Explant analysis can help physicians in their choice ie to determine the best indication for a specific device.
5. To highlight major failures of devices
6. Analysis of degradation phenomena
7. Helps to distinguish between sporadic events from general failure

The paper also highlights that sending products back to manufacturers means no open data about the results are available and therefore

*“..explants should be sent to centralised centres dedicated to these issues. Ideally, such centres should be independent from the industry……. Transparency should be based on establishing a strong link between the centres and major scientific societies that could report to health authorities.”****

MHRA

The recommendations for the NHS are set out very clearly on their website and include the following:-

“- An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users (including patients) ……
For example
- a patient’s treatment is interrupted or compromised by a medical device failure
- a misdiagnosis due to a medical device failure leads to inappropriate treatment
- a patient’s health deteriorates due to medical device failure.

Causes may include: design…

- The information from adverse incident reports can help identify faults with medical devices and may prevent similar incidents happening again.

- *Any adverse incident involving a medical device should be reported to the MHRA. Some apparently minor incidents may have greater significance when aggregated with other similar reports.”*

Furthermore the MHRA makes it abundantly clear *“All items should be quarantined if possible. Do not throw them away, repair them or return them to the manufacturer”*****

Direct and indirect effects

The consequences of failed medical devices includes secondary, more expensive medical devices and procedures, a drain on resources, risks of secondary infection, and longer term health risks for patients. Therefore patient safety alone is a very critical part of understanding why an implant has failed.

When the NHS purchases a primary implant at a particular price and it fails, the true cost if the medical device becomes primary cost plus revision device (in addition to the other resources

mentioned). Therefore when discussing the cost of implants with companies, this provides opportunities. Having the data available which clearly shows whether the implants are performing as expected, or better than expected, or worse than anticipated, assists in making a judgement on whether value for money is being obtained from the supplier, in tandem with the contractual context.

Revision surgery - choice

At the time of revision surgery, an informed choice can be made of which there are three main option:-

A. Have the implant independently assessed
B. Throw the explant into the waste
C. Return the device to the manufacturer

Taking each of these scenarios in turn:-

A. Explant analysed independently

1. The independent testing allows the explant to be considered in line with patient safety concerns.
2. The MHRA recommendations mean this should be standard practice in the UK NHS
3. As many manufacturers are US based this appropriate post market follow up under FDA guidelines also come into play.
4. The standard practice of analysing explants has already been introduced in many other markets and other specialities behind orthopaedics.
5. If hospitals are purchasing products, it is only appropriate they ensure they are getting value for money and those products are manufactured within the manufacturers own tolerances.
6. History has shown us that litigation can sometimes take time. If an explant is made available for analysis the wear data can be captured and macro analysis can be conducted and captured which may latter be related upon in the case of
    1. Product complaints
    2. Product recalls
    3. Patient litigation
    4. Determine
1. Independent assessment means the unbiased assessment which can help capture data and the explants can be made available for more in depth analysis if warranted.
2. Independent analysis still provides the opportunity for the manufacturer to be informed of potential product concerns and gives a basis for which any other assessment can be measured.
3. Data from explant analysis can assist with patient safety, diagnosis and treatment.
4. Data from explant analysis can help determine the appropriate treating different patient groups. An implant may behave differently in different patient groups.
5. Getting it right first time (GIRFT) expresses concerns about litigation for the NHS and orthopaedics is one of the biggest areas of defence spend. Explants subject to litigation clearly need to be available if the device failed or has contributed to failure.
6. The independent testing allows the explant to be considered in line with patient safety.
7. The MHRA recommendations mean this should be standard practice in the UK NHS
8. Analysing the explants allows potential product issues to be captured as an early warning system ahead of and as an adjunct to the National Joint registry.
9. Issues around products being analysed help assess good and bad results to help determine future patient pathways.
10. Takes orthopaedic service to a higher level and gives true outcome measures beyond a label.
11. Can provide real clinical research of medical devices in a clinical setting.

12. The information and data provided can assist with negotiating with Medical device suppliers and in particular where primary implants fail earlier than anticipated inn requesting assurances, discounts, refunds or resources and other training support requirements.

B. Explant disposed of at source

1. This adds to environmental waste
2. There is a cost of disposal
3. This could be challenged at a later date
4. The opportunity to learn and develop clinical practice is lost
5. Loses transparency

C. Return to the manufacturer

1. The manufacturer may not be able to process the implant to clean and analyse
2. The NHS MHRA advises against this
3. The opportunity to re-analyse after the event may be lost
4. Argument that manufacturer sold the implant and therefore cannot own the explant

Summary

As the number of medical devices, procedures and manufacturers increases, the likelihood of more adverse events affecting patient safety is likely to climb. At the same time there is a drive within the NHS to make clinicians aware of the litigation through clinical governance and multi-disciplinary meetings*****.

Explants thrown in the bin end up as landfill which impacts the environment and adds to the costs of hospitals waste disposal. At the same time, denying the opportunity to learn more about the true performance of medical devices and use the data to drive change.

Many other countries have already recognised the need to analyse explants and adopted this work. The need for truly independent testing is critical rather than centres established through money supplied from the industry. Furthermore the various health authorities in the world also acknowledge work in this area is critical including the NHS, the FDA and the Australian department of health.

Explant analysis helps to drive best practice, ensures an early warning system for poor performance of implants, provides data to assist in patient /implant profiling, and drives down costs through value for money.

Medical Explants Ltd. are extremely excited and proud to work with the NHS, Researchers, Explant labs and other interested parties to assist in collecting, logistics, packaging, documentation and advice in this data driven service.

References:-

Guideline for the release of an explanted medical device - State of Western Australia 2020
***Biological responses to metal implants FDA September 2019**
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*****MHRA Adverse incident reporting website 2020*
******Professor Tim Briggs- BOOS meeting presentation November 2020*