ODEP and Beyond Compliance

Our response to

The report of the Independent Medicines and Medical Devices Safety Review

FIRST DO NO HARM

We, and the patients we care for, welcome the long awaited Cumberlege review published on July 8th. The Orthopaedic Data Evaluation Panel (ODEP) and Beyond compliance were set up following the use of implants that caused harm, particularly the Capital Hip in 1998 and the global "metal on metal" hip problems the early 2000's (the UK being the first country in the world to issue national patient guidance on metal on metal joint replacement). For all of us it is extremely sad to see other examples of similar problems (albeit outside orthopaedics), with two pharma products and one implant which have caused huge damage and distress to a large number of patients.

So, given these shared experiences and how the Orthopaedic community has responded to and now addresses them, we believe we are in a strong position to offer helpful advice and support in taking forward the Review's recommendations.

By way of demonstrating why we believe we are so well placed to help, we offer a summary of how UK orthopaedics has transformed the way in which it manages patient safety following these and other similar disasters.

- It is generally accepted that UK orthopaedics, as one of the Country's main users of implanted medical devices, is at the leading edge of implant safety assessment. It is seen as a world leader in the breadth and depth of data that is collected, analysed and then used for patient protection and improvement of treatment.
- The Capital Hip disaster of the 1990s led to the National Joint Registry (NJR) and NICE (the National Institute for Health and Care Excellence) recommending the creation of ODEP in 2002. Since then ODEP has evolved and, through its rating system, (built on evidence-based clinical evaluation). ODEP has led the way in informing the purchasing of safe and effective orthopaedic implants. It is supported in its operations by Supply chain Co-ordination Limited (SCCL) and Northgate Public Services (UK) Limited.
- ODEP ratings are used internationally http://www.odep.org.uk/.
- ODEP currently provides ratings to almost 700 Hip, Knee and Shoulder implants and since our beginning has seen over 100 lose their rating and leave the market for one reason or another. (Perhaps it is not coincidental that many of these were also unlikely to meet the ODEP benchmarks).

The problems encountered with metal on metal hip replacements, which caused so much harm to patients, lead to the development of the Beyond Compliance (BC) Programme, as a means of supporting and monitoring the safe introduction of implants new to the British market. This was encouraged by the then minister of state for Health, Jeremy Hunt.

The Programme has been successfully running for over seven years and has closely monitored over 60 new implants. With input from the lay public, BC operates as a

partnership between the profession, the regulators and industry. It supports innovation by rigorously assessing and closely monitoring new devices in "real time". In its short history Beyond Compliance has led to several manufacturers withdrawing their implants from the market (either permanently or in order to make certain modifications as identified by the programme). Our reports and analyses have led to major changes in either IFUs (Instructions For Use) or design changes in at least 3 implants. Through our user group meetings changes in technique and in the instruments for insertion of the devices have also been changed. It is widely acknowledged that this model is sufficiently robust and scalable as to be applied to many other branches of healthcare where implantable medical devices are involved.

https://www.telegraph.co.uk/news/health/news/9629323/Jeremy-Hunt-I-will-not-tolerate-British-patients-being-put-at-risk.html .

Fundamental to orthopaedics in this country is the National Joint Registry (NJR), the largest and most comprehensive registry of its kind in the world with over 3 million patient records. The NJR has no parallel and its data forms the essential platform underpinning the work of both Beyond Compliance and ODEP.

We very much support the recommendation, that collection of data for implant databases should be regarded as a patient safety issue, mandated by government and thus without the requirement for routine patient consent. From our experience, only by monitoring **all** aspects of the performance of an implant will assessments be totally reliable. We completely agree that patient feedback such as PROMS (Patient Reported Outcome Measures) and PREMs (Patient Reported Experience measures) are an essential part of monitoring. The flow of data from these instruments must be unhindered, if we are to ensure patients are at the centre of any surveillance system.
There is world-wide agreement that data alone, although a critical and central element of the process, will not provide all the answers and it will not provide safety for patients unless there is direct involvement of clinicians. (Working in conjunction with manufacturers, data scientists and regulators).

Our concern is that a very simple isolated database linking only implant and patient identifiers cannot deliver patient safety and improved outcome unless the data are securely linked in a guaranteed way to the patient outcomes data and the complete datasets of both kinds made available for analysis by clinical experts in the specific clinical area with patient involvement.

Cumberlege also points out that agencies overseeing the use of implants should link up. ODEP and BC have had close links with all the groups noted below and regularly communicate on formal and informal level, often more than once a week. Orthopaedics has gone a long way towards an integrated implant assessment system but there have regularly been problems caused by failures in data flow arrangements that we hope the Cumberlege report will help solve

We recommend that we should leverage the experience and knowledge gained in orthopaedics and apply it throughout the medical device community. We make the plea that future arrangements must allow for complete capture of data and that this data is easily accessible and widely scrutinized by experienced clinical professionals and data scientists.

All the stakeholders in ODEP and Beyond Compliance have worked hard to establish high standards for the assessment and monitoring of implantable orthopaedic devices. We have been asked to work with other specialities to help design similar systems for their patients. Plans are being drawn up for ODEP to be introduced into Europe and initial steps are being taken in India.

We are a broad church and with any re-organisation of the system for monitoring implants in the UK we are keen to work with all the agencies that will be enacting the Cumberlege Report's recommendations.

The stakeholders with whom we meet and liaise with regularly include:

- Our lay public representative
- SCCL (Supply Chain Co-ordination limited)
- The BOA (British Orthopaedic Association)
- GIRFT (Getting it Right First Time)
- BHS (The British Hip Society)
- BASK (British Association for Surgery of the Knee)
- BESS (British Elbow and Shoulder Society)
- The ABHI (The Association of British HealthTech Industries)
- The MHRA (The Medicines and Healthcare Products Regulatory Agency)
- Notified Bodies (British Standards Institute, representing the Notified Bodies),
- The NJR (National Joint Registry)
- Northgate Public Services (UK) Limited

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