Regulation of medical implants

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Respondent's details

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Respondents

Tom Joyce is a biomedical engineer with almost 20 years of experience specialising in the design, testing, analysis and evaluation of artificial joints including hips, knees, shoulders and fingers. He works extensively with industry and clinicians in order to inform and improve future designs of artificial joints. He currently supervises a number of projects around hip joint failure including: ex vivo analysis of failed resurfacing hip prostheses; improving the metal-on-metal hip prosthesis – a study of failures and wear mechanisms; investigation of failed lower limb arthroplasties; and 'when technology fails patients': engaging with stakeholders on metal-on-metal hip joint failures. He has taken part in recent investigative media programmes highlighting problems with metal-on-metal hip failure, these include Dispatches and Newsnight in the UK, Primetime in Ireland, Four Corners in Australia and Kontant in Denmark.

Pauline McCormack is a medical sociologist who researches social and ethical aspects of treatment, care and research in health. She has interests in disability, notions of power, the patient voice, and how policy serves individuals. As part of the project 'when technology fails patients': engaging with stakeholders on metal-on-metal hip joint failures, she is collecting data from patients and their families about their experiences with a failed hip implant.

Scope

Our submission to the Committee focuses on an area of recent controversy, that of failed metal hip implants, which intersects with our areas of expertise. We will concentrate on:

i) engineering analysis of failed metal-on-metal hips. We have examined components from almost 400 failed hips and published much of our data.

We are the only independent centre in the UK, and probably the world, undertaking such extensive research. We were the only research group in the world to publish critical data on the DePuy ASR metal-on-metal hip prior to its worldwide recall in August 2010.

ii) Qualitative data from patients about their lived experiences. We believe we are the only people in the world undertaking specific, sociological research into current patient experiences with failed metal-on-metal hip implants, gathering data on their daily lives and the impact on their work, families and social activities. We are in the midst of data collection and, while the findings presented here are very preliminary and are unpublished, we are prepared to make them available to the committee as we feel strongly that the patient voice should be audible in these deliberations.

Responses to the Consultation Questions

1. Are current legislation and regulations on safety and efficacy of medical implants fit for purpose?

No. In the case of hip joint replacements we believe that this has been shown in various scientific publications (Langton, Jameson et al. 2008; Joyce, Langton et al. 2009; Langton, Sprowson et al. 2009; Langton, Jameson et al. 2010). To give the Committee a summary idea of the problems, we cite the example of the DePuy ASR hip which was implanted into almost 100,000 patients worldwide (around 10,000 UK) and which is responsible for causing widespread health problems in patients. This has been described as perhaps the biggest disaster in the history of orthopaedics. As international experts in implant design and analysis we have no idea whether this device was tested before it was implanted in patients, as there is no regulatory requirement for such tests. If it were tested in house, we have no idea what the results were as there is no legislative or regulatory requirement for companies to publish data.

For a detailed discussion of the general problems, particularly those of substantial equivalence, we would refer the committee to the work of colleagues who are experts in regulatory affairs (Heneghan, Thompson et al. 2011; Matthew, Carl et al. 2011; Heneghan, Langton et al. 2012).

In engineering terms we believe that the international standard ISO14242, 'Implants for surgery - Wear of total hip-joint prostheses' is not detailed enough and should be amended to include specific guidance on the testing of acetabular cups at various angles of inclination and anteversion. In addition, it should require the smallest and largest sizes of artificial hips to be tested. Had such pre-clinical tests been undertaken on the ASR then the current disaster might have been averted.

Data from patients with failed metal-on-metal hip implants shows they are perplexed, confused and often angry as to why, in their opinion, the regulatory system has not protected them. They query how effective the system is, which allowed hip joints which are failing so disastrously, onto the market in the first place.

> "*...the medical regulatory bodies, they've really got to protect us better and they're not being bold enough in doing that, they're passing the buck*". (Focus Group patient)

2. How effectively does the MHRA implement the Directive in the UK?

This question does not draw attention to the fact that, if the Directive is not fit for purpose, then the effectiveness of its implementation is largely academic.

In our patient focus groups people consistently interrogated the responsibilities of the MHRA and concluded the MHRA do not have a clear remit and lacked sufficient authority to take responsibility over, and act decisively on implant failure. The patients saw the gap in responsibilities as ethically and morally wrong.

> [We] "*were really annoyed that the regulatory body, we felt that they shirked their responsibility and, what is the regulatory body? Has it not got enough teeth*"? (Focus Group patient)

Worryingly, they interpreted the lack of action as evidence that the regulator could not be impartial or independent.

3. How could the legislation and regulations be improved?

We outline a number of areas where we believe legislation and regulation should be improved, points i) and ii) should be treated as urgent:

i) Testing

> "*The reality is, you cannot test the wear patterns of human joint replacement in any animal species*". (Professor Sir Kent Woods, Chief Executive, MHRA) http://www.bbc.co.uk/news/health-17200330

> "*I cannot believe in this advanced technological age that no-one could design a machine that would replicate the movement of variously fitted hip joints*". (Patient panel participant)

Observations about testing human joints in other species are spurious and the apparent lack of understanding by the regulator on this point is disturbing. Fortunately, machines do exist to wear-test human joint replacements. They originated in the UK in the 1960s (Duff-Barclay and Spillman 1966) and are

validated to international standards (ISO 14242:2000). They have been further developed since then and are now commercially available. It is our view that **stringent, mechanical, pre-implantation, testing should be mandatory for all joint replacement implants and that test data should be publicly available**. Ideally such testing should be undertaken independently by not-for-profit organisations, as designers and engineers working for companies could be subject to commercial pressure which can lead to publication of favourable results (Schott, Pachl et al. 2010). At the very least, if testing is allowed by commercial companies for their own products, test data should be open to scrutiny by independent experts and the public.

We believe that the international standard ISO14242, 'Implants for surgery - Wear of total hip-joint prostheses' is not detailed enough and should be amended to include guidance on the testing of acetabular cups at various angles of inclination and anteversion. In addition, the smallest and largest sizes of artificial hips should be tested.

ii) Explant retrieval and analysis

Examination of explanted joints that have failed or caused problems in the body is one of the most valuable sources of data about how and why implants fail – they can be thought of as the 'black box'. Revision operations, which remove such problem implants have to be reported to the National Joint Registry (NJR) but conservation of the failed joint itself is not required and many are simply thrown away. We have some evidence of surgeons and hospitals disposing of joints even when patients have requested that the joint be kept to be sent for analysis.

We call for the conservation and analysis of explanted joints to be made mandatory as part of the NJR reporting procedure. This analysis should be undertaken by independent, not-for-profit experts. Such a move might be facilitated by the establishment of a national explant retrieval centre and the committee should consider putting in place consultations for how such a centre could be managed and funded. One option might be a universal tariff on all new joints, as currently funds the NJR. Another option would be that a charge is made to the manufacturer for each joint examined – in this way manufacturers would be additionally encouraged to design and produce joints with the greatest longevity.

iii) Symptom reporting

We have repeated reports from patients that their concerns over symptoms from their hip implants were dismissed and/or ignored by medical professionals. We believe that the Yellow Card System, whereby a user of medication can report

side effects directly to the MHRA, could be usefully expanded to include users of medical devices.

iv) Data transparency and results publication

We join the ever-growing body of professionals who are calling for greater transparency of the results of experiments, particularly in medical trials and testing where the results can have profound implications for patients (Groves 2010; Alsheikh-Ali, Qureshi et al. 2011; Ross, Lehman et al. 2012; Wellcome Trust 2012). Research and innovation moves more quickly in a positive direction when data and findings are shared between investigators, meaning they can build on colleague's work. The practice of pharmaceutical companies publishing mainly favourable data means that investigators do not get to learn from the mistakes of others and may waste valuable time repeating failed experiments (Schott, Pachl et al. 2010; Lundh, Krogsbøll et al. 2011).

The NJR is something that this country should be proud of. It is the largest such registry in the world, but we should consider whether the raw data contained in it could be made more readily available. We also suggest that the NJR should be expanded to cover all artificial joints.

The NJR could also provide a publicly available, adverse event reporting website along the lines of the MAUDE (Manufacturer and User facility Device Experience) database offered by the FDA in the USA, so that all interested parties can view this important data (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm).

We believe surgeons should be required to disclose payments received from orthopaedic companies and that such data should be made publicly available as is the practice in the USA. This would free medical professionals from accusations that their choice of treatment or device for their patient is not based on the patient's welfare. Such an observation was made in our focus groups and in a patient panel:

> "*If you can't trust the surgeon who is the expert, to give you the best advice and a device that is suitable for you, not one that has been "sold" to them, who can you trust? Are patients just pound signs at the end of the day*"? (Patient panel participant)

4. How could the European Commission ensure that potential changes to the Medical Devices Directive do not hinder the introduction of innovations in medical implants to the market?

It is a misconception that more regulation hinders innovation. As President Obama said in his 2012 State of the Nation address "rules to prevent ... faulty medical devices don't destroy the free market. They make the free market work

better". As noted above, regulation can aid collaboration and mutual education through transparency and openness, which only helps innovation. In addition, regulating medical devices to ensure that better products reach the market means that devices sold will be more efficient and successful, which will result in better uptake from surgeons and greater trust from patients. Evidence shows that devices in the USA which follow a longer, stricter regulation route are more successful and have fewer recalls (Heneghan, Thompson et al. 2011).

This said, we caution against a constant focus on innovation rather than on patient safety and precautionary measures. Innovation should result in improvement or enhancement – not for their own sake but in order to pass on improved treatments to the patient. The current situation around medical devices is such that not only does the system not guarantee improvements for patients, it hampers them.

The last word in our submission goes to the patients, who are astute in summarising what action they would like to see taken:

> "*We are just saying that the MHRA need to learn and listen to the experts, take action without fear of being sued and the government need to step in and sort out the seeming corrupt practices and hidden and unacknowledged evidence*". (Focus Group patient)

> "*We here on the shop floor are suffering, so everybody should be responsible for bringing this out into the open and making sure it doesn't happen again*". (Focus Group patient)

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