Editorial

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ArthroplastyWatch.com three-year follow-up: where do we stand now?

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Introduction

In the wake of the Poly Implant Prosthèse breast implant and the metal-on-metal incidents, the inherent flaws of European regulatory systems for medical products and devices have been highlighted once again.[1] In lieu of the approximately 70 notifying bodies largely setting their own regulatory standards in the European Union,[1] the US has one central regulatory authority to approve medical products and devices.[2] According to Samuel et al, between 1982 and 2014, 70 original orthopaedic devices were approved through the US Food and Drug Administration's (FDA) premarket approval pathway (PMA).[3] The PMA, which requires clinical data, is the most rigorous pathway that high-risk medical devices can undergo prior to being introduced on the market. Despite this, of these 70 devices, 12 were subsequently subjected to FDA recalls during their lifespans, and no less than 765 post-market modifications were recorded.[3] Twenty-two percent of these post-market modifications either significantly altered components or the device design. Class III devices (which include metal-on-metal hip implants) were intended to undergo PMA. However, because of a legislative loophole, metal-on-metal implants until recently usually only underwent 501(k) clearance, meaning that they did not have to undergo studies showing safety or effectiveness.[4]

Partly caused by the challenges in the regulatory processes, a substantial number of recalls and warnings are issued annually by medical companies, notifying bodies, governments and others. Although bad news allegedly travels fast, it has been difficult to reach practicing surgeons or operating rooms with recall and safety information.[5] Few surgeons have the time to actively stay on top of the many sources that provide information on recalls or field safety notices. To assist with this predicament, ArthroplastyWatch.com (www.ArthroplastyWatch.com) was launched on 1 February 2013 in Lund, Sweden. An independent (funded by a university grant) web service based on an electronic system which scans relevant sources of information on the Internet and disseminates safety information on implants, ArthroplastyWatch.com is now celebrating its third birthday. Originally focussing on joint implants, the service has now been expanded to include devices in the orthopaedic field. Those interested in the service may subscribe free of charge and receive push email notifications when new information is published. Links to the original sources are always provided.

The underlying five-step process behind the service is outlined in Fig. 1. In short, a number of sources (e.g. health authorities, notifying bodies, national governments, medical companies, national quality registers, PubMed, professional societies) are continually searched for specific keywords through a computer system tailor-made for ArthroplastyWatch.com. Next, the information retrieved undergoes a two-step screening procedure to determine which information is relevant and should be disseminated. The information is then drafted into a short alert and reviewed and cleared by at least one orthopaedic surgeon and a medical statistician for accuracy. After being given the go-ahead, the alert is posted on the webpage and subscribers will receive the information on their smartphones or computers.

To date, more than 100 alerts have been published, averaging about one serious warning being published per week, and ArthroplastyWatch.com has had more than 16 500 views since it was launched. An advisory board consisting of 23 leading experts from 17 different nations is available.* The vast majority of the information that is released as alerts comes from the medical companies themselves, often in collaboration with government agencies or notifying bodies. However, the information that is identified by the ArthroplastyWatch.com system primarily comes from government agencies in the US and Europe. In Table 1, the distribution of the different sources is outlined under the categories of literature (PubMed), medical company, government or notifying body, national registries, or other.

The serious problem of spreading pertinent information to those involved with implants in order to remove faulty products from the market is still a reality. ArthroplastyWatch.com is one tool that may help to facilitate the dissemination process. Equally important is the responsibility that each individual surgery unit has to act on a recall, as this might require increased patient surveillance. Sometimes only a specific batch or certain lot numbers are affected by a recall. To identify patients who should be informed and eventually

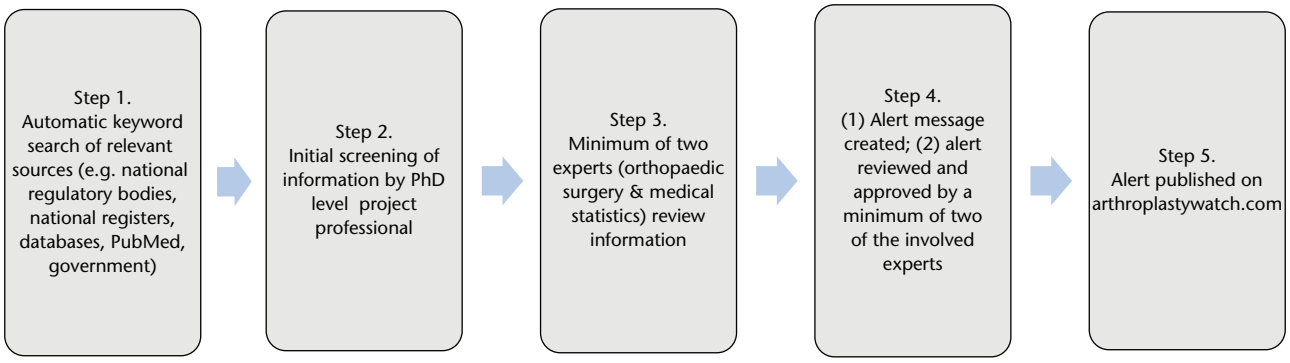

Fig. 1 Five-step process used in ArthroplastyWatch.com.

Table 1. Original sources from which alerts originate (%)

Source/s**	Literature (PubMed)	Government or notifying body	Medical company	National register	Other
Number (%)	6 (5%)	86 (78%)	13 (12%)	2 (2%)	3 (3%)

**This table represents the sources from which ArthroplastyWatch.com received information. The data that caused the government/notifying body to issue an alert generally came from medical companies, registers or literature.

called back for additional examinations or even revision surgery currently requires cumbersome, time-consuming and costly reviews of medical records. Furthermore, only some of the orthopaedic implant registers contain lot-specific information on the individual patient – yet this type of information is highly valuable in assisting orthopaedic units in an expedient recall process, and it should be considered when building an implant registry.[6]

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CONFLICT OF INTEREST

LL is a member of the Board of Bone Support SE, Orthocell AU, and adviser to SKAR and WOA. AAS, JR, and OR have no conflicts of interest to declare.

NOTES

* www.ArthroplastyWatch.com advisory board:
Prof Johan Bellemans, Belgium; Prof Nikolaus Böhler, Austria; Prof Fabio Catani, Italy; Prof Michael Dunbar, Canada; Prof Ove Furnes, Norway; Prof Stuart Goodman, US; Prof Stephen Graves, Australia; Prof Joachim Hassenpflug, Germany; Prof Hirokazu Lida, Japan; Prof Pierre Hoffmeyer, Switzerland; Prof Joshua Jacobs, US; Prof Per Kjersgaard Andersen, Denmark; Prof David Lewallen, US; Prof Lars Lidgren, Sweden; Prof Henrik Malchau, US; Prof Jonas Ranstam, Sweden; Dr Otto Robertsson, Iceland; Prof Alastair G Rothwell, New Zealand; Prof Thomas Sculco, US; Dr Bart Swierstra, The Netherlands; Mr Keith Tucker, UK; Prof Yan Wang, China; Prof William Walter, Australia.

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