Correspondence and Communications

High risk device registries: Global value, costs, and sustainable funding

Dear Sir

Globally, clinical registries are progressively being recognised as drivers to improve safety and quality in healthcare.1,2 Medical device registries however, serve an additional purpose, by evaluating the performance of registered devices in vivo. Orthopaedic (OD) and cardiac device (CD) registries have been successful for many years. Additionally, the importance of the second generation breast device (BD) registries (developed after the Poly Implant Prothèse (PIP) crisis in 2010)3 has been highlighted once more by the recent SIILMED affair and Breast Implant Associated Anaplastic Large Cell Lymphoma (BIA-ALCL).4,5 Nowadays, information on how to set up an implant registry is widely available. However, information regarding the sustainability of these registries is scarce. Therefore, we aimed to provide transparency on pivotal issues for the long-term survival of registries, focusing on costs, funding models, and the role of stakeholders.

A standardised, online questionnaire was designed (Supplementary File 1) and sent to designated representatives from OD, CD and BD registries worldwide. Answers were analysed and grouped into three categories: 1) general characteristics, 2) costs & value of investment and 3) funding structures & sustainability. Costs were reported in Euros, using a set currency of €1.00 = $1.14 USD / $1.49 AUD / £0.80 GBP (currency on April 12, 2016; launch of the survey). Uncertainties or discrepancies in provided answers were verified with the participants afterwards.

General characteristics (Table 1). A multinational cohort including thirteen registries originating from nine countries (all seven BD registries, five OD registries, one CD registry) was created. During the study period, ten registries were operational. Two BD were in their start-up phase, and one BD was restructuring an older, paper-based registry. Most registries (10/13) were based on an opt-out system, which means that enrolment is standard unless the physician/patient actively requests not to register. The average number of registered BDs per year (1–4 per 1000 female inhabitants) was surprisingly close to the number of registered ODs (1–7 per 1000 inhabitants per year). Beside plastic surgeons, multidisciplinary BD registries included breast surgeons, cosmetic surgeons, gynaecologists, and general surgeons. Multidisciplinary OD registries included orthopaedic surgeons and trauma surgeons.

Costs & value of investment. In general, start-up costs of all registries were comparable, ranging from €100,000–€350,000. In the Australian and American BD registries however, start-up costs were estimated at €450,000 and €1,500,000, respectively, most likely due to substantially bigger country size and multiple state governments in a federal nation. Annual maintenance costs varied by the type of registry and country, regardless of the type or number of outcome measurements or the comprehensive nature of a registry. With average prices between €5 and €85 per registered device per year, the younger (BD) registries were most expensive to maintain at this point in time. OD and CD registries reported costs of €5–20 per registered device per year. Value of investment was determined by the extent of registry outcomes. Data for post-marketing surveillance of implants were collected by all registries. Benchmark data, quality audit reports, and outcomes per hospital were provided by 12 registries. Outcomes and results per physician, as well as recall information, were present in eight registries. Both participating stakeholders (hospitals, physicians, patients), as well as external stakeholders (government, manufacturers of devices, research institutions, healthcare inspectorates, insurance companies), showed a considerable amount of interest in these data.

Funding structures & sustainability. Whereas over half of the registries were approached by stakeholders for their data, substantially fewer registries received any financial contribution from these parties. Only six registries reported a sustainable funding structure, for a minimum period of two years (Figure 1). No standard, long-term funding model was reported, but there appeared to be two essential elements for financial sustainability. First, funding for core elements such as ICT (information and communications technology), legal issues, governance, recall purposes, and outcome research should be ensured. Preferably, this is achieved through a financial contribution from several large stakeholders, aiming for independence, such as a combination of the government and insurance companies. Furthermore, it is important to attain appropriate funding for innovation, professionalization, and international collaboration, which might be best accomplished using grants and levies from smaller parties.

Implantable device registries are unique in the sense that they evaluate the performance of healthcare providers, institutions, and registered devices. If these implant registries

---

Table 1  General characteristics of included registries (n = 13).

<table>
<thead>
<tr>
<th>Country (establishment(^a))</th>
<th>Development</th>
<th>Current status</th>
<th>Registered implant (per year)</th>
<th>Registered implants per 1000 inhabitants (per year(^b))</th>
<th>Method of enrollment</th>
<th>Capture rate</th>
<th>Mono vs. Multi disciplinary(^c)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Breast device registries</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AUT (1998)</td>
<td>Association of physicians</td>
<td>Restructuring old registry</td>
<td>&lt; 5000</td>
<td>&lt; 1.3</td>
<td>Opt-in</td>
<td>Not yet known</td>
<td>Multi</td>
</tr>
<tr>
<td>SWE (2014)</td>
<td>Association of physicians</td>
<td>Operational</td>
<td>5000-10,000</td>
<td>1.2-2.5</td>
<td>Opt-out</td>
<td>61% – 70%</td>
<td>Multi</td>
</tr>
<tr>
<td>AUS (2015)</td>
<td>University</td>
<td>Operational</td>
<td>10,000-25,000</td>
<td>1.0-2.6</td>
<td>Opt-out</td>
<td>91% - 100%</td>
<td>Multi</td>
</tr>
<tr>
<td>NLD (2015)</td>
<td>Board of registry, Association of physicians, Non-profit organization</td>
<td>Operational</td>
<td>10,000-25,000</td>
<td>1.4-3.5</td>
<td>Opt-out</td>
<td>Not yet known</td>
<td>Mono</td>
</tr>
<tr>
<td>GBR (2016)</td>
<td>Government agency</td>
<td>Operational</td>
<td>25,000-50,000</td>
<td>0.9-1.8</td>
<td>Opt-in</td>
<td>Not yet known</td>
<td>Multi</td>
</tr>
<tr>
<td>USA (-)</td>
<td>Board of registry, Association of physicians</td>
<td>Start-up</td>
<td>175,000-225,000</td>
<td>1.3-1.7</td>
<td>Opt-out</td>
<td>Not yet known</td>
<td>Mono</td>
</tr>
<tr>
<td>NZL (-)</td>
<td>Association of physicians</td>
<td>Start-up</td>
<td>&lt; 5000</td>
<td>&lt; 2.6</td>
<td>Opt-out</td>
<td>Not yet known</td>
<td>Mono</td>
</tr>
<tr>
<td><strong>Orthopaedic device registries</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SWE (1975)</td>
<td>Orthopaedic Association</td>
<td>Operational</td>
<td>10,000-25,000</td>
<td>1.2-3.1</td>
<td>Opt-out</td>
<td>91 - 100%</td>
<td>Mono</td>
</tr>
<tr>
<td>FIN (1993)</td>
<td>Association of physicians</td>
<td>Operational</td>
<td>10,000-25,000</td>
<td>2.2-5.4</td>
<td>Opt-out</td>
<td>91 - 100%</td>
<td>Mono</td>
</tr>
<tr>
<td>NZL (1998)</td>
<td>Few physicians</td>
<td>Operational</td>
<td>10,000-25,000</td>
<td>2.7-6.8</td>
<td>Opt-in</td>
<td>91-100%</td>
<td>Mono</td>
</tr>
<tr>
<td>ROU (2001)</td>
<td>Association of physicians, Board of registry, Non-profit organization</td>
<td>Operational</td>
<td>10,000-25,000</td>
<td>0.6-1.5</td>
<td>Opt-out</td>
<td>91 - 100%</td>
<td>Multi</td>
</tr>
<tr>
<td>NLD (2007)</td>
<td>Board of registry, University</td>
<td>Operational</td>
<td>50,000-100,000</td>
<td>3.6-7.1</td>
<td>Opt-out</td>
<td>91 - 100%</td>
<td>Multi</td>
</tr>
<tr>
<td><strong>Cardiac device registry</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GBR (1980)</td>
<td>Association of physicians, Government agency</td>
<td>Operational</td>
<td>50,000-100,000</td>
<td>0.9-1.9</td>
<td>Opt-out</td>
<td>91 - 100%</td>
<td>Mono</td>
</tr>
</tbody>
</table>

AUS indicates Australia; AUT, Austria; FIN, Finland; GBR, United Kingdom; NLD, The Netherlands; NZL, New Zealand; ROU, Romania; SWE, Sweden; USA, United States of America.

\(^a\) Year of establishment was defined as the first year of actual device registration.

\(^b\) Breast device ratios were defined using the female population, whereas orthopaedic and cardiac device ratios were calculated using the general population. (The World Bank, population 2015, ≥ 15 years of age)

\(^c\) Multi indicates multidisciplinary; Mono, monodisciplinary.
are to realise their full potential, a steady governance structure and autonomous, sustainable funding models are essential. All involved registries in this study provided important information, of value for multiple stakeholders. Yet, only half of the registries received sustainable funding and thus were certain of their future existence. If implant registries are not sustained, our society loses highly important information, including the traceability of all former registered and implanted devices, leading to decreased patient safety. Therefore, we feel it is important to bring this to the attention of all parties involved.

**Conflict of interest**

None reported.

**Funding**

None reported.

**Acknowledgements**

The authors especially thank all registries’ representatives for their participation and highly appreciate their transparency:

H. Klein - Breast Implant Registry, New Zealand.

T. Latham - Breast and Cosmetic Implant Registry (BCIR), United Kingdom.


A.G. Rothwell - The New Zealand Joint Registry (NZJR), New Zealand.

O. Robertsson - Swedish Knee Arthroplasty Register (SKAR), Sweden.

D. Dragomirescu - Romanian Arthroplasty Registry (RAR), Romania.

K. Mäkelä - Finnish Arthroplasty Register (FAR), Finland.

A.D. Cunningham - National Audit of Cardiac Rhythm Management (CRM), United Kingdom.

**Supplementary materials**

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.bjps.2018.05.048.

**References**


Babette E. Becherer

Dutch Institute for Clinical Auditing (DICA), Poortgebouw Zuid, 2nd floor, Rijnsburgerweg 10, 2333 AA, Leiden, The Netherlands
Andrea L. Pusic
Department of Plastic and Reconstructive Surgery, Brigham and Women's Hospital, 75 Francis Street, Boston MA 02115, United States of America
National Breast Implant Registry (NBIR), 444 East Algonquin Road, Arlington Heights, IL 60005, United States of America
David B. Lumenta
Division of Plastic, Aesthetic and Reconstructive Surgery, Department of Surgery, Medical University of Graz, Auenbruggerplatz 29-34, A-8036, Graz, Austria
Ingrid Hopper, Rodney D. Cooter
Department of Epidemiology and Preventive Medicine, Monash University, 553 Saint Kilda Road, Melbourne, Victoria 3004, Australia
Australian Breast Device Registry (ABDR), Level 2, 553 Saint Kilda Road, Melbourne, Victoria 3004, Australia
Hinne A. Rakhorst
Dutch Breast Implant Registry (DBIR), Poortgebouw Zuid, 2nd floor, Rijnsburgerweg 10, 2333 AA, Leiden, The Netherlands
Department of Plastic, Reconstructive and Hand Surgery, Medisch Spectrum Twente/ Ziekenhuisgroep Twente, Koningsplein 1, 7512 KZ, Enschede, The Netherlands
E-mail address: h.rakhorst@mst.nl

© 2018 British Association of Plastic, Reconstructive and Aesthetic Surgeons. Published by Elsevier Ltd. All rights reserved.

https://doi.org/10.1016/j.bjps.2018.05.048