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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 SILIMED 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

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

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

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.

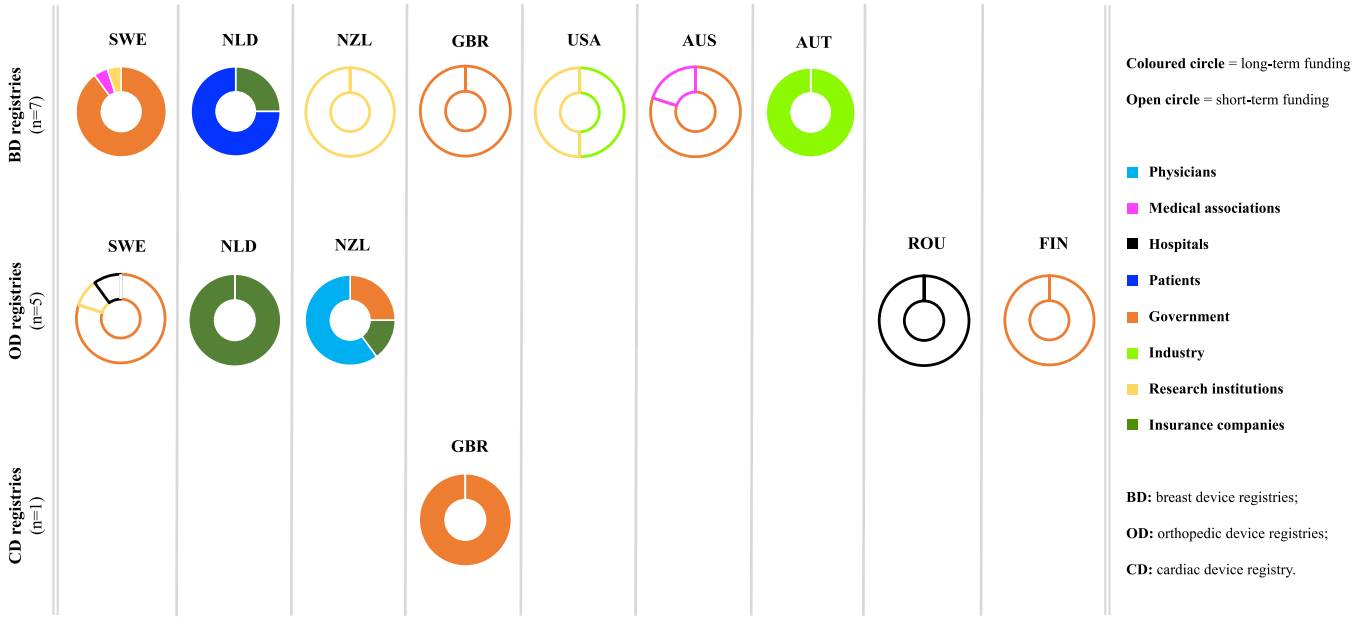

Figure 1 Funding models.

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.

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Supplementary materials

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References

[1]. Cooter RD, Barker S, Carroll SM, et al. International importance of robust breast device registries. *Plast Reconstr Surg* 2015;**135**:330–6.

[2]. Porter ME. What is value in health care? *N Engl J Med* 2010;**363**:2477–81.

[3]. SCENIHR (Scientific Committee on Emerging and Newly Identified Health Risks). Scientific opinion on the safety of Poly Implant Prothèse (PIP) Silicone Breast Implants (2013 update). 2014.

[4]. Silimed medical devices (all - including breast implants). Australian Government, Department of Health, Therapeutic Goods Administration. https://www.tga.gov.au/node/709665. Published 24 September 2015. Updated 26 September 2017. Accessed November 2017.

[5]. Swerdlow SH, Campo E, Pileri SA, et al. The 2016 revision of the World Health Organization classification of lymphoid neoplasms. *Blood* 2016;**127**:2375–90.

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