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The new opt-out Dutch National Breast Implant Registry – Lessons learnt from the road to implementation

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Summary An estimated 1–3% of all women in the Netherlands carry breast implants. Since the introduction five decades ago, problems with a variety of breast implants have emerged with direct consequences for the patients' health. Plastic surgeons worldwide reacted through campaigning for auditing on long-term implant quality, surgeon performance, and institutional

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outcomes in implant registries. Especially, the PIP implant scandal of 2010 demonstrated the paucity of epidemiological data and uncovered a weakness in our ability to even 'track and trace' patients. In addition, a recent report of the Dutch Institute of National Health showed a lack of compliance of 100% of breast implant producers to CE requirements. These arguments stress the need for an independent implant registry.

Insufficient capture rates or dependence from the implant producers made the variety of national and international patient registries unreliable. The Dutch Breast Implant Registry (DBIR) is unique because it is an opt-out registry without the need for informed consent and thus a high capture rate. Furthermore, an estimated 95% of breast implants are implanted by board-certified plastic surgeons. Funding was received from a non-governmental organisation to increase the quality of health care in the Netherlands, and maintenance is gathered by 25 euros per implant inserted.

This article describes the way the Dutch have set up their system, with special attention to the well-known hurdles of starting a patient registry. Examples include: funding, medical ethical issues, opt out system, benchmarking, quality assurance as well as governance and collaboration. The Dutch consider their experience and data shareware for others to be used globally to the benefit of patient safety and quality improvement.

Introduction

Breast implants are used routinely for purposes of breast reconstruction and breast augmentation and play important roles in the lives of patients and practices of plastic surgeons. The Dutch Reference Centre for (medical) screening programmes[1] reported a minimum incidence of 1% of Dutch women between 50 and 75 years old in mammogram screening programmes carrying breast implants. Adding the women who refuse mammograms and who are not in a screening programme, an estimated 1—3% of all Dutch women have breast implants. Currently, it is estimated that around 30,000 implants are annually inserted. This equals approximately the annual number of knee arthroplasties being performed.[2] Approximately 30% of all implants are used for reconstructive purposes. From the data of the American Society of Plastic Surgery, it is evident that the number of breast implants that are used is increasing.[3]

Breast implants are considered safe for use in patients,[4,5] although there is a paucity of evidence for detrimental effects on the patients' health. All medical devices are addressed as non-active high-risk implants by definition (category III) by the European Union.[6] This implies that in order to be approved for distribution into the European market (conformité européenne), certain requirements need to be met by the producers,[7] including toxicological and clinical tests in most cases. In addition, companies need to comply with post-marketing surveillance and have an obligation to collect adverse events. Health care professionals may report these events to the respective company on a voluntary basis.

One limitation of the current marketing approval system is that no criteria are set for the quality of these reports[8]; there is no demand for peer-reviewed publications, and reports on diligence and post-marketing surveillance are neither mandatory nor is it well-defined in how companies need to conduct these studies. Finally, incidence reports are typically not open to the public or to the health care professional.

Since the start of production of breast implants, several implant crises have occurred from the Dow-Corning scandal in the 1980s[9] to the more recent PIP scandal[10] that attracted negative media attention worldwide. In June 2016, the Dutch Health Care Inspectorate reported the technical review and chemical testing among all breast implant producers in the Netherlands.[11] All 10 technical files showed flaws. Two out of ten implants were based on a different medical silicone gel, which was not reported to the Notified Body. One implant showed relatively high levels of cyclosiloxanes. Fortunately, all these deviations were not expected to have any negative effects on patients. This example shows clearly that the recent scandals did not result in a flawless production process of all types of implants. Plastic surgeons should attempt to raise the bar for quality monitoring of breast implants, independent from the industry.

In addition, more recent reports on ALCL possibly being linked to the use of breast implants[12] should make caregivers aware of the need for an optimal, prospective method to monitor performance of breast implants over time.[8] One of the major lessons was that clinics can go bankrupt and implant data can be lost, resulting in large numbers of patients with no implant information. Using a national registry, it is envisaged that recalls are possible after clinics have gone out of business or in case patient charts are destroyed.

Numerous political reports from the European Union,[13] the UK,[14] the Netherlands,[15] the USA and international breast registries attest to the importance of improved data collection systems.[16—18] Unfortunately, the breast implant registries initiated[19—21] were not successful in providing reliable data until today because of the incapacity to capture sufficient implants to draw reliable conclusions, e.g.[22—24] For example, the PIP scandal was not identified on

data from these registries. The Dutch Registry of Implants in Plastic Surgery is an example of the unsuccessful breast implant registry, constructed in 1995 as an opt-in registry. 'Opt-in' implies that surgeons and patients participate on a voluntary basis. Typically, these opt-in systems reach estimated capture rates of just 20% or less of all implants used.[25] Consequently, reliable conclusions on implant performance and complications & hospital/clinic outcomes cannot be drawn because of selection bias and other sources of bias.

In 2012, the International Collaboration of Breast Registry Activities (ICOBRA) was founded on the initiative of Rod Cooter under the auspices of the Australian Society of Plastic Surgeons[26] to establish an internationally agreed comparable minimum data set, using standardized and epidemiologically sound data that reflect global best practice.[18] Although not evidence based, a list of minimum requirements for such a data set was drafted in 2013 during an international meeting in Amsterdam, and its final version is listed in Table 1. Contributing countries include Australia, Austria, Canada, Ireland, Italy, Germany, France, the Netherlands, New Zealand, South Africa, the United Kingdom and the United States. At the heart of the ICOBRA concept resides the core ethic and commitment to improving patient outcomes by using modern audit techniques in an atmosphere of transparency and sharing of techniques and experiences in a non-profit setup.

This article describes the way the Dutch have set up their system being the first opt-out breast implant registry worldwide with special attention for the well-known hurdles[27] that will be faced when starting a registry.

Dataset and registry principles

The ICOBRA initiative developed the dataset. The number of data items was reduced to a minimum, and extra data points were discussed extensively prior to adding them to the database. Patient data including indication for surgery, unique and descriptive implant data and data regarding surgical technique are gathered. Data are collected longitudinally. Surgical revision procedures or any other surgery regarding implants are thus registered into the same patient record (social security number) to be able to measure outcomes such as capsular contracture or explantation rates per implant brand or clinic. Patients and implants are listed by professionals and linked to a hospital or clinic. This means that each surgeon can only access data of his or her own practice or patients.

Table 1 ICOBRA Minimum requirements data registry as determined in the Amsterdam Meeting of ICOBRA, 2013.

Opt-out system, participation unless denied by patient
If no opt-out system is chosen, capture rates should be >95% of all implants
Unique Device Identification (UDI) number
Unique Patient Identification (UPI) number
GS-1 barcode on the implant packing
GS-1 bar scanning module
Minimum data set identical to ICOBRA member countries
Longitudinal setup; multiple entries from one patient
Demographic data incorporation listing death of patients
Respect privacy patient, surgeon, industry and hospitals
Safe data storage

A pilot study using the registry was used to identify faulty or suboptimal data points. A core dataset is permanent (Supplementary data 1&2). Other data points are reviewed on an annual basis to determine which data points can be removed and which can be added.

As administrative burdens in health care rise, care should be taken to register an efficient process. Registration in the DBIR (Dutch Breast Implant Registry) can be done online or using paper versions in theatre so that administrative staff can subsequently register the data online. Data entry takes approximately 5 min in experienced hands.

The industrial parties have agreed to embrace the GS-1 barcode system. Using this barcode, the DBIR has developed a scanning module for bar codes to be used for input in the online system; this prevents spelling errors.

Every registry needs control systems to check for completeness. The industry has helped in agreeing to share their supply information to hospitals and clinics in a separate industrial registry (Figure 1). If an implant is shipped out of the company to a hospital, it is listed in the industrial registry. This system is a dynamic system in which implants are de-registered if not used and shipped back to the company. This registry is used as a control system to the clinical registry by providing the denominator in the estimation of capture rates at a national level and checking which hospitals or centres perform best in registering their implants. Moreover, in case of a recall, the registry can be used to check what hospital has implants of interest on the shelf, so that these hospitals can be addressed specifically to prevent further implantation of faulty devices.

Funding

After the dataset was developed, the physical registry was built. In addition, compliance and legal issues were addressed, assuring high capture rates. This phase was funded by the grant of 130,000 euros from the foundation 'Stichting Kwaliteitsgelden Medisch Specialisten', a non-governmental organisation to improve quality of health care by medical specialists in the Netherlands.

After the developmental phase, a second phase now needs a healthy funding system for sustainability. An estimated 70% of all implants are used for aesthetic indications. This poses a challenge to funding systems, because the use of insurance money to just maintain the implant registry is debatable from a societal perspective. Sources for funding can be government, industry, insurance money or patients themselves through extra costs added to each device at the point of sale.

One potential downside of government funding is the risk of withdrawal of funding after elections. A downside of funding from industry is the possibility of an unexpected withdrawal of funding. Therefore, it was decided to add 25 euros per implant registered in the DBIR. This additional money is paid either by the national health insurance (ZN) for the reconstructive patients or by the clinics for the aesthetic patients. Thus, all patients will pay for extra

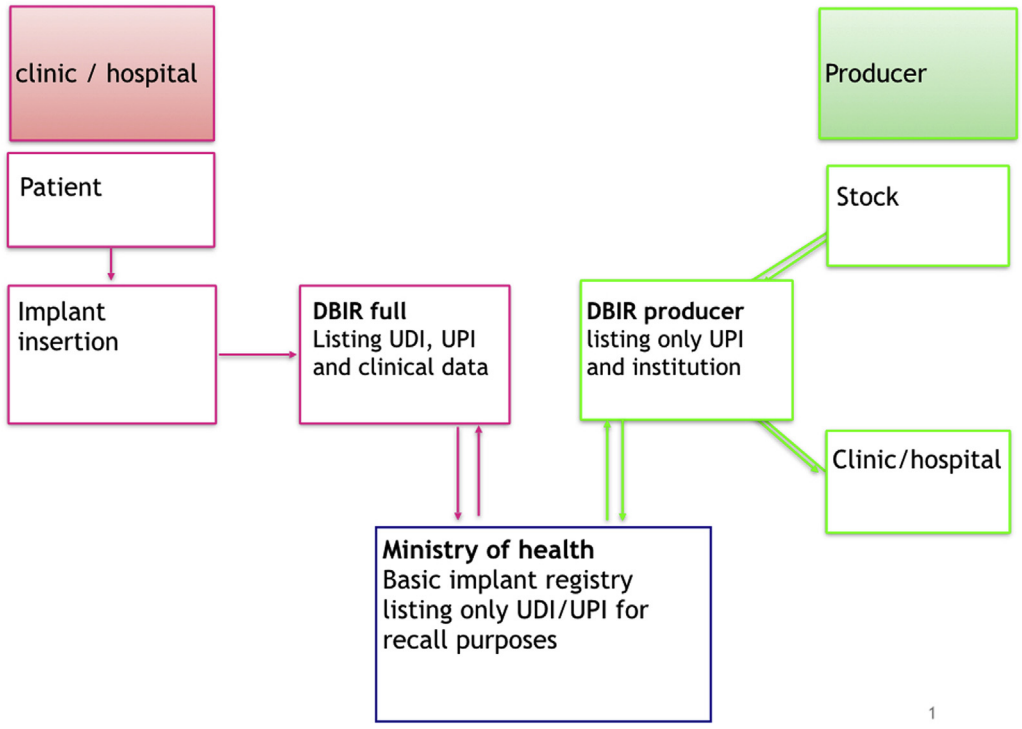

Figure 1 DBIR system as designed. Pink represents the implant that is registered from the clinical side. Green represents the industrial registry that has the goal to check the number of implants that have been sent to the clinic. The industrial system is a dynamic system in which implants are de-registered if not used and shipped back to the company. The annual number of implants delivered to all clinics and hospitals is used to estimate the registration percentage of implants.

safety, either directly in case of cosmetic patients or indirectly in case of reconstructive patients.

Benchmarking and output

Benchmarking in other areas has led to impressive improvements in quality of care; for instance, a 50% reduction of morbidity of gastric cancer in the Netherlands resulting from benchmarking and centralisation of care after benchmarking.[28] Other countries, such as Sweden, have shown similar results as a result of benchmarking, for example benchmarking treatment for acute myocardial infarction according to the hospital's protocol clearly reduced mortality.[29,30]

The DBIR registry will be used to provide benchmarking data for industry, clinics and surgeons. These outcome measures will be presented anonymously by using funnel plots disclosing only data points of a specific clinic or an institution. Consequently, only their own position relative to others can be appreciated as well as in relation to the group mean and 95% confidence intervals using comparisons with pooled data. These data will provide the best practice and worst practice, which will guide the Dutch Association of Plastic Surgery to recover why these practices stand out.

Output will be generated using indicators, to be defined by the scientific board of the DBIR. After setting up the registry, 3 years will be needed to have a registry with reliable data. For the first 3 years, 'process' indicators are developed such as 'participation in registry' or 'percentage of implants registered'. After 3 years, qualitative indicators can be drawn from the registry such as 'percentage implant rupture/x years', capsular contractures requiring revision surgery or even ALCL incidence rates. These outcome measures with known risk factors for these outcome measures (such as radiotherapy, smoking, age, bilateral surgery and co-morbidity) are registered per patient per surgery. These data will be analysed by using variance analysis to understand the largest effects on revision surgery (patient characteristics, surgery characteristics, surgeon characteristics and/or implant types).

Data governance and research

The Dutch Society for Plastic Surgery (NVPC) owns the data. However, access to all data is restricted to DICA and a scientific board that access and is held to a code of secrecy. In addition, the scientific board reviews proposals for research projects. All participants, specialists and hospitals can submit proposals that require database data. All data are anonymous and can never be used to trace back to hospitals other than their own or individual patients.

Challenges of this breast implant registry

Internationally, the start-up of registries has attracted much interest from various governments and medical specialists. However, the construction phase of robust registries can take considerable time due to a number of factors.

1. Funding

The funding of a device registry is difficult, especially for breast implants that are mainly used for cosmetic reasons. In the Netherlands, two factors helped in starting the DBIR. First of all, funding was provided by a fund issued by the national board of medical specialist (Stichting Kwaliteitsgelden Medisch Specialisten). The programming, a pilot study and a first period of going live prior to setting up a final system for funding the registry in a sustainable fashion had to be accomplished with this fund.

Second, the maintenance of this registry comes from experience from the existing Dutch orthopaedic and Dutch cardiology registries. On the basis of their cost analysis, a price was set at 25 euros per implant.

2. Collaboration

The data used were not newly developed. Instead, collaboration with the international consortium ICOBRA and Monash University Australia led to a significant reduction of time as they developed a data set with a data dictionary that defines each item in the dataset. They considered the data set as shareware and was regarded as a minimum data set for DBIR to pool data in the future for identification of overperforming or underperforming implants. Because all Dutch board certified specialists are fluent in English, the set was not translated into Dutch to prevent differences in interpretation. The datasets are listed in the supplementary data and can also be downloaded at the Medical Research Data Management (MRDM) website (https://www.mrdm.nl/showcase/downloaden).

In the Netherlands, a growing number of national audits are performed and registered in a national registry through the Dutch Institute for Clinical Auditing (DICA), a non-profit organization founded and boarded by surgeons and other specialists. The DICA has developed the infrastructure for online data entry through secure data transfer and storage with the highest levels of security; this is managed by MRDM. The use of the existing infrastructure decreased the time to develop the DBIR dramatically.

The DBIR will be linked to our national breast cancer audit data, which collects oncological data of breast cancer treatment and is required for all caregivers in breast cancer. The link will use raw datasets from both registries and compares registry of all direct implant-based breast reconstructions.

3. Compliance

When a new registry is introduced, it can be challenging to motivate patients to cooperate and caregivers to register, as compliance is the key for success. This is especially challenging in the case of breast implant registries as in many countries breast implants are used by different surgical specialties, and sometimes 'cosmetic' doctors without proper training or qualification can undertake surgical procedures.

In the Netherlands, an estimated 95% of all breast implants are inserted by certified plastic surgeons. Of all plastic surgeons in the Netherlands, 95% are members of the national, Dutch Society for Plastic, Reconstructive and Hand surgery (NVPC). Board-certified plastic surgeons are quite aware of the importance of the registry as PIP implant legal claims are still undergoing legal scrutiny.

Compliance to the registry was made a requirement for membership of the NVPC, resulting in high member participation rates. Moreover, registration is the legal responsibility of institutions and professionals by the national government in new laws for private clinics and general hospitals providing additional compliance from hospitals and clinics.

4. Privacy and legal issues

Respect for privacy and dealing with informed consent within the governmental legislation is of vital importance.[31] An opt-out consent is not an informed consent, but a legal basis for consent is needed to streamline registry inclusion.[32] Interestingly, legal issues vary between countries, member states of the European union and sometimes even between states within a country. This slows down the process of organizing registries with an opt-out system to reach capture rates of above 95%, such as the orthopaedic patient registries.[33]

In the Netherlands, the use of registries is treated as part of the patients' treatment protocol for which assumed informed consent is given by the patient by means of willingness to undergo treatment. This implies that no additional specified informed consent is required to register the patients' implant(s) in a registry, which automatically makes it an opt-out system. A prerequisite of the registry is that patient data are anonymous and encrypted according to the latest and highest standards. Close collaboration with the government, orthopaedic surgeons and cardiologists paved the legal way developing an opt-out registry for breast implants.

Current status

The DBIR project started in June 2014. A pilot study was completed by using a preliminary dataset from September 2014 to October 2014 in a limited number of clinics or hospitals. After analysing results and refining the datasets, the DBIR went live nationally in April 2015. Since then, all board certified plastic surgeons are required to register their implants in the system. At the end of December 2016, 17,237 surgeries were registered and 28,278 implants were embedded. This implies that since the official start of the registry, within 12 months, 10,295 surgeries with 17,231 implants were registered (Figure 2).

Almost 30,000 implants in 2 years is unmet by any existing registry neither from smaller nor from larger countries than the Netherlands. This shows that all plastic surgeons in the Netherlands embrace the importance of this registry and its dataset, and they approve of the concepts and principles it used to reach its present status. From this, the DBIR is hopeful to reach its goal to increase the capture rate of implants to rise to over 95% within the next 3 years.

Moreover, during the 2016 withdrawal of the CE mark of Silimed implants, the power of a running registry was shown clearly. Within a few hours, the number of implants in the registry was determined. This provided clarity to patients, institutions and governmental organizations.

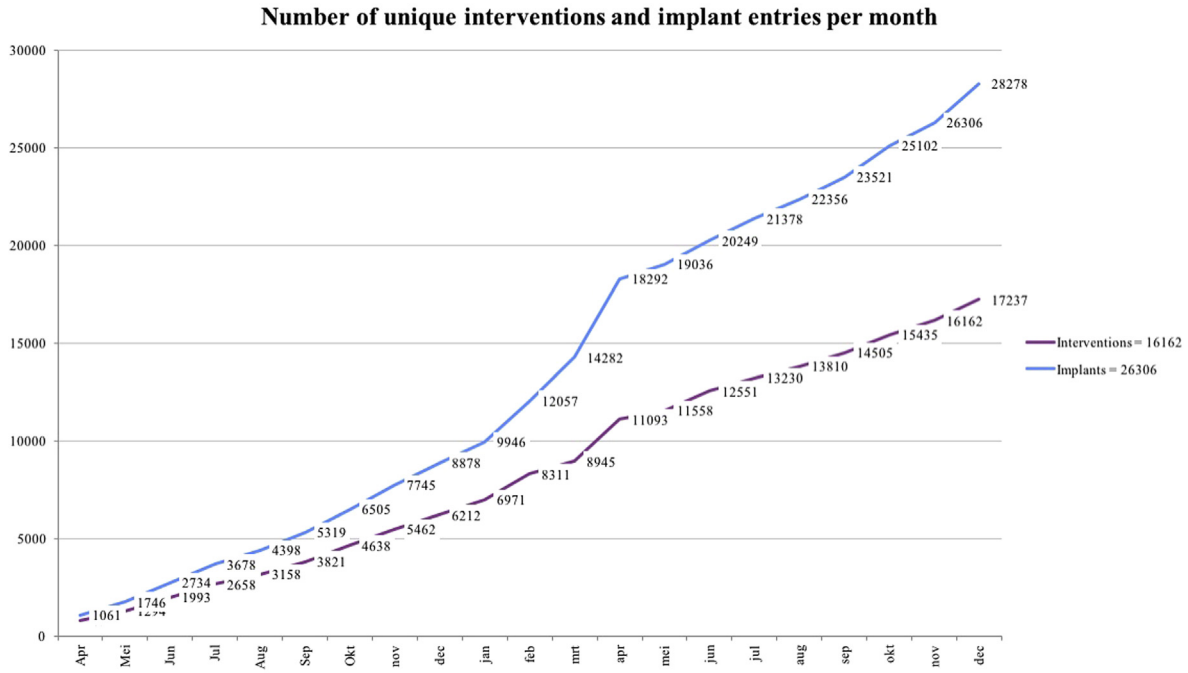

Figure 2 An overview of the number of patients and implants registered in the DBIR per month since the start of the DBIR.

Conclusions

Breast implants are considered high-risk medical devices. The plastic surgery community and current literature shows that breast implants are safe for use in breast reconstruction or cosmetic augmentation. However, currently, still no longitudinal long-term epidemiologically sound data are available on many important issues regarding implants such as long-term implant revision rates for ruptures, capsular contractures or pain symptoms, ALCL or immune responses that might result in silicone-induced diseases.

This registry is anticipated to push rapidly towards better patient safety, better implants, better information about risks of breast implants and reduction of complications for women receiving breast implants. In addition, its track and trace abilities will prove cost-effective when compared to doing recalls by using local patient or hospital files.

The registry is embraced by all national plastic surgeons showing the importance that professionals adhere to the initiative. This resulted in a number of implants registered that have not been met by any other registry.

For the future, working on international collaborative efforts to pool data is the next challenge. Other challenges include issues surrounding data transparency and addressing under-performing parties to aim for better results. Close collaboration with professional societies and governmental agents will be pivotal to successfully meeting these challenges.

Disclosure

All authors have made a substantial contribution of the conception and design of the study, drafting and revising the article and approving the final version.

None of the authors has a financial interest in any of the products, devices, or drugs mentioned in this manuscript. Prof McNeil chairs a safety board for a drug (Eprex) sold by Janssen-Cilag, a subsidiary of Johnson & Johnson. Johnson & Johnson owns Mentor breast implants.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at http://dx.doi.org/10.1016/j.bjps.2017.04.003.

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