An International Breast Implant Registry (IBIR) has existed since 2002 to develop a basis for continual discussion concerning the safety of different breast implants.¹ Prior to this, various national bodies contributed to its development, and also maintained their own registries. Thirteen years after its inception, the IBIR remains in a pilot phase, and the data it produces is not robust enough for clinical use.²

The cost of duplicating international and national registries is considerable, and countries such as Australia, which represents only a fraction of the entire international market, have sought to align their data collection with that of the IBIR. This has been recognized by the formation of the International Collaboration of Breast Implant Registries (ICOBRA), which plans to use one standardized data set for registration of all breast implants, to be agreed and reviewed by the group on an annual basis.

In 2011, the American Society of Plastic Surgeons proposed a national registry for breast implants in collaboration with the Food and Drug Administration to respond to concerns over anaplastic large cell lymphoma (ALCL). The registry is a planned, focused clinical quality registry known as the Patient Registry and Outcomes for Breast Implants and Anaplastic Large Cell Lymphoma Etiology and Epidemiology (PROFILE). In addition, there is development of a National Breast Implant Registry (NBIR) to track all outcomes and complications related to breast implants (silicone and saline). Scheduled to launch late in 2015, the NBIR "will benefit consumers and industry and assure that clinical conclusions regarding complications resulting from breast implants are only drawn from unequivocal scientific evidence."³

We believe that there are some significant issues with the proposed ICOBRA plans, specifically those relating to a registry based on the Australian system. In the past, the United Kingdom (UK) Breast Implant Registry took a lot of time and energy to initiate, and even more time to change culture, engage with the users of implants, and collect data. However, it was only when it came to interrogating the data was it discovered that the dataset was so poor that no real benefit could be derived from it.

THE DIFFERENCE BETWEEN A PRODUCT REGISTRY AND CLINICAL QUALITY REGISTRY

From the outset, it is important that a clear distinction is made between types of registry, and the purpose of each. Clinical quality registries (CQRs) follow a protocol to assess the appropriateness and effectiveness of a specified clinical issue, whether it is an implantable device or care pathway. The results are monitored as an ongoing process, and measured against pre-agreed outcome benchmarks, such that subsequent analysis can generate suggested improvements. CQRs rely on those benchmarks being previously defined, based on hypothesis driven research or empirical recommendations derived from collection of appropriate, agreed data sets. As such, they may be interrogated to provide

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meaningful answers to specific questions based on the outcome measures they are designed to examine.

These aims differ dramatically from a product registry, which serves as a repository for information to assist in patient and product recall should an adverse product event occur. Such a product registry is an absolute prerequisite for the development of a CQR. It is not a basis for research except in defining a population which may subsequently be examined in more depth.

The problem arises when a hybrid registry is established which is neither a purpose built CQR, such as the ALCL registry, nor a pure product registry. The temptation to produce “research” and guidelines from the data it generates suffers from the problems of data trawling and does not test a specific hypothesis.

In implant-based surgery of any type, 3 elements influence clinical outcomes: the implant, the surgical technique, and the soft tissue environment into which the implant is placed. The limitation of data collected by implant product registries lies in the presumption that complications are caused by either a fault in the implant design and manufacture, or some basic issue with the surgical technique. This hypothesis, although unstated, is not supported by years of clinical research.

By necessity, there is an assumption that the same criteria are applied by every surgeon to every patient in selecting a given implant, regardless of the soft tissue envelope in which it is placed. The proposed ICOBRA data set contains no information about the soft tissue envelope, and therefore cannot address the context in which complications may arise. Not surprisingly, the manufacturing industry has highlighted this weakness.

Using an inappropriate implant in the wrong patient will inevitably lead to outcome deficiencies, and many research projects over the last half century have been directed towards defining those safe parameters. The implant industry recognizes this basic fact, and attempts to produce sizing systems for their products, such as that developed by Tebbetts and Adams. One of the authors has made the point that within his practice, 28% of implant-based surgery consists of removing and replacing implants that have been undertaken elsewhere, with a perceived poor cosmetic result. Usually, in his opinion, it is because an implant has been used inappropriately for a given soft tissue envelope, within his evidence-based selection criteria. This is not a problem with the implant, but with the match of patient and device, yet within the suggested ICOBRA data set, it would appear to be a device issue. Again, we stress the words “in his opinion,” because it is the assessment by an individual surgeon which is responsible for many reoperations.

These problems do not alter the effectiveness of a product registry, but unless the data set is focused in a manner similar to the ALCL registry, its effectiveness as a CQR is doubtful. Despite the specious logic of using an implant registry to define how a product or surgeon performs, there will inevitably be a temptation for standards to be set from the submitted data.

THE PROBLEM OF COMPLIANCE

Collection of partial data sets for a population can produce misleading trends (is it 30% or 95% data capture?) and the place of a product registry therefore should be to define what makes up the whole population. Unless managed independently by the physician, it is possible that registries would attract participation from more committed, conscientious surgeons who have good results, and discourages those who may be less diligent, so skewing the data. Similarly, there may be reticence to submit data for fear of being classified as producing results lower than the “defined standard.”

Various methods have been tried to ensure compliance, including surgeon incentives and patient self-registration. Despite these attempts, there remains no reliable indication that all the implants in any one geographical area represent a true and accurate reflection of what is actually used. Compliance in Austria is amongst the highest reported, but compared with neighboring Germany, the estimate is that less than 50% of the implanted devices are registered. The only way of obtaining a true indication of implanted device numbers is to institute mandatory reporting centrally by a hospital, surgeon, distributor, or manufacturer. In its new initiative, the Australian implant registry hopes to capture over 93% of data, yet relies on patients selecting not to opt out, and therefore remains essentially flawed by providing choice.

The information concerning implant and patient details are already available from the suppliers of implants, most of whom maintain these details and are capable of submitting them to a surgeon on request. It would seem to be relatively simple to have this information submitted to a central location to form the basis of a product registry at best, or at the very least to use as a cross-check on those patients submitted to the registry, so that the accuracy of data capture can be cross-referenced.

BREAST IMPLANT REGISTRIES SO FAR HAVE NOT BEEN SHOWN TO BE EFFECTIVE

Current breast implant registries failed to identify the problems associated with the 2010 Poly Implant Prothèse (PIP) scandal. Initial concerns surfaced in France during 2009 when surgeons started to report an abnormally high rupture rate in this product, and a series of legal challenges resulted in the company’s bankruptcy. In a subsequent inspection of the manufacturing site, the company was found to use unapproved, industrial grade silicone, with a cost of only 10% of an approved gel.
It should be pointed out that this was a case of criminal manufacturing fraud, and as such, was a regulatory rather than a surgical issue. Whilst the problem was detected due to a high number of reported ruptures with the product, a more stringent manufacturing monitoring protocol by the relevant regulatory authorities may have highlighted a quality issue at an earlier date. As PIP implants were supplied internationally, it relied on one regulatory body accepting another jurisdiction’s manufacturing controls. Ultimately this was the source of the system failure; each national regulatory body assumed the French system was adequate, and so there was little local verification of the product.

A registry would only have closed the stable door long after the horse had bolted. The fact that none of the existing implant registries were able to detect the PIP quality issue highlights the point that they failed as clinical quality registries. However, a comprehensive product registry that had captured the patient’s details and those of the implant would have allowed product recall.

THE PROBLEM OF REPORTING

In order to report on adverse events, there is an assumption that all complications will be reported to the registry. There is little incentive for a surgeon to report on their own complications and many may be treated elsewhere. In addition, some silent complications such as rupture may never be reported, and a poor cosmetic result is so subjective that classifying it as a complication would be problematic.

Without a robust independent protocol for reporting back to a registry at specific time points over the lifetime of an implant, there is no reliability regarding the quality of the data. If industry experience is to be believed, this is very difficult to achieve. The approval given to Allergan (Dublin, Republic of Ireland) and Johnson & Johnson’s Mentor (Santa Barbara, CA) implants was conditional on following 40,000 women over 10 years, in addition to the pre-approval studies. By August 2011, Allergan reported collection of 2-year data for 60% of participants, while Mentor only had 3-year data for 21%. Allergan offered patients US$20 to participate in the study and US$100 for each office visit, while doctors were paid US$200 for enrolling each patient. Mentor did not offer any cash incentives to patients but gave doctors US$100 for each participant. We believe that a proposed voluntary registry is likely to have greater problems without incentives of some sort, or penalties for non-participation.

THE ISSUE OF PRIVATE VS PUBLIC INSTITUTIONS AND CROSSING BORDERS

In the UK central data collection is relatively comprehensive for the National Health Service but this has been more difficult to achieve across the private sector, where the majority of breast implant procedures are carried out. The UK now has the Private Hospital Data Bureau (PHDB) which contains de-identified information on all private hospital separations, including patient demographics, hospital episode, and clinical information (ICD-10-AM). These institutions are inspected by the Care Quality Commission (CQC) and compliance with quality data collection is required for maintenance of their operational license. As very few doctor’s offices undertake surgery in a manner similar to the United States, it is doubtful that a similar system would be easy to set up where there is a diversity of surgical facilities.

In the UK, failure of breast prostheses should be reported; but compliance with this requirement is very poor. We do not believe that there is any publication on this issue and there is a huge lack of knowledge by breast, cosmetic, and plastic surgeons about how to register the information and how to liaise with the manufacturers regarding return of failed implants for laboratory testing. Even if the implants are returned, the testing often fails to provide useable information. Handling and sterilization procedures may well interfere with the shell and gel before reaching the laboratory.

The issue of healthcare governance will be incredibly difficult to agree internationally. As part of the National Mastectomy and Breast Reconstruction Audit in the UK, all data was submitted to the Patient Information Advisory Group (PIAG). They were responsible for Section 251 of the NHS Act 2006 which permits the common law duty of confidentiality to be set aside in specific circumstances for medical purposes. The PIAG was replaced by the National Information Governance Board for Health and Social Care (NIGB) under section 158 of the Health and Social Care Act 2008. The challenge is then “who, when and why?” should gain access to the data once it has been safeguarded by a Governmental legislation in the interests of patient’s privacy. There is certainly the potential to end up with a comprehensive, clean databank but no access! As for sharing this on an International Platform – to say it is a challenge is an understatement.

THE PROBLEM OF DATA INTERPRETATION

Data trawling, which is not hypothesis driven, can lead to spurious results which may not have a clinically-based rationale. For example, the 2013 Sientra (Santa Barbara, CA) pre-approval study by Stevens et al\textsuperscript{10} shows statistical significance of a low capsular contracture rate in patients who had implants greater than 420 cc who did not wear a bra postoperatively. Is wearing a bra going to become a negligence issue post-augmentation? Should manufacturers remove capsule warranties on smaller implants? Obviously not, but it emphasizes a weakness of this study in that it does not examine the context of a soft tissue envelope to which the implant was introduced.

These issues are further highlighted by Adams\textsuperscript{11} in his commentary on the Largent et al\textsuperscript{12} pre-market approval.
data study concerning complication rates in high and extra high profile Allergan breast implants. He states, “While data mining is always possible, it is important to understand that ‘over-mining’—although easy to perform with the right resources—results in scientifically invalid data.” The article goes on to make the point that unless tissue-based planning of implants is adhered to, complications will inevitably occur.

**THE UK ORTHOPAEDIC EXPERIENCE**

By comparison, since 2002 the UK instituted a National Joint Registry that has been well resourced and had good engagement from the orthopedic membership, with 2 million patient records included. It has been financed by a levy on sales of joints. Every operating room complex that undertakes hip and knee prosthetic implantation has a hand-held scanner which allows data capture from a bar code on the packaging. This hardware and software have been installed without cost, and the data is analyzed by a group which contains surgeons but is independent of the craft group. The orthopedic surgeons have ownership of the data and they are professional in ensuring that data is captured and uploaded. Data concerning outcomes are triggered and collected via Patient Related Outcome Measures (PROMs) at regular intervals and reminders are sent to each participant, increasing data collection. The surgeon and his team have no input into collecting outcome measures which is outsourced to a group experienced in data collection. All of this needs to be verified, cross-checked, and often additional information collected to complete the record and is meticulous work if a clean and useful data set is to be obtained. The data is robust enough to publish funnel plots in an annual report and allow individual surgeons to be identified as outliers.

Every patient in the UK has a single unique National Health Service number connected to a central data system which enables record tracking. Unfortunately, most other countries (including the United States and Australia) do not have the benefit of such a system and it is unlikely that without some way of monitoring all implant-based patient episodes, any accuracy could be assured. Whilst the orthopedic registry may seem to be an ideal model for breast implants, there are obvious differences which make direct mimicry impossible. All orthopedic prostheses are utilized in a hospital environment for example, providing an excellent opportunity for data capture, whereas many breast implants are used in the relatively unregulated environment of a doctor’s office or even overseas. In addition, the financial aspects of the orthopedic market dwarfs the breast market by many-fold, raising question about who would possibly wish to fund such a small niche sector.

Nevertheless, the UK National Joint Registry has been a success story as a clinical quality registry and should provide lessons for future medical implant registries. It produces annual reports and research based on the ever increasing, high quality data set and seems capable of examining both implant longevity and the context in which they are used. Only time will tell if it is capable of identifying long-term issues with orthopedic prostheses.

**CONCLUSIONS AND RECOMMENDATIONS**

Breast implants are one of the most frequently used, and intensively studied of all medical devices, which have known and predictable complication rates if used appropriately. When there are problems with their manufacture, they represent an issue which returns to public consciousness.

A simple product registry derived from mandatory reporting of what device is implanted into which patient is to be encouraged as a sensible use of resources, particularly if it traverses international borders. However, unless data concerning the soft tissue envelope into which it is placed is collected, abstraction of additional information is likely to be misleading when it is used as a clinical quality registry, and it has been shown to fail in the past.

The issue of how such registries will be funded has not been explored in this article, but as breast implants represent a very small market compared to orthopedic implants, it is unlikely that that model can be followed. Perhaps one of the lessons from the UK orthopedic registry is that unless there is significant recurrent funding, ambitions should be kept modest.

Taking things one step at a time, producing a simple, compulsory product registry for each country, is more likely to succeed and can act as a solid foundation for a future clinical quality registry that is fit for purpose. Currently we believe that there is an insufficient legislative or research basis on which to develop a clinical quality register in the manner proposed by ICOBRA.

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