

In Defense of the International Collaboration of Breast Registry Activities (ICOBRA)

Rod Cooter, MBBS (Adel), MD (Adel), FRACS (Plast); Richard Barnett, MBBS (Syd), FRACS, FACS; Anand Deva, BSc (Med), MS, FRACS (Plast); Mark R. Magnusson, MBBS (UQ); John McNeil, AM, MBBS (Adel), MSc (London), PhD (Melb), FRACP, FAFPHM; Graeme Perks, FRCS, FRACS, FRCS (Plast); Hinne Rakhorst, MD, PhD; and Charles Verheyden, MD, PhD

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The International Collaboration of Breast Registry Activities (ICOBRA) involves the national plastic surgery societies of several countries, including Australia, Austria, Canada, France, Germany, Ireland, Italy, the Netherlands, New Zealand, South Africa, the United Kingdom, and the United States.¹ Its inception was triggered by the Poly Implant Protheses (PIP) crisis in France in 2010. It was clear at this time that no existing or past breast implant registry was in a position to alert government and regulatory authorities.

In Australia, an inclusive approach backed by surgical societies, government and regulatory bodies has now resulted in the design and implementation of what we now believe is an optimal model for a breast device registry.

In 2010, the Australian Society of Plastic Surgeons and the Australasian Foundation for Plastic Surgery, with support from reputable registry scientists, sought to design a “best-practice” Breast Device Registry. Australia’s new national opt-out Breast Device Registry was designed along similar lines to the Australian Orthopedic Association’s National Joint Replacement Registry. The orthopedic experience, with successful detection of clinical failure of metal-on-metal hip joint prostheses provided a valuable and parallel experience of how a device registry could function as an important tool to ensure patient safety.²

The Australian Government tendered for the design and implementation of the registry and the Monash University’s Department of Epidemiology and Preventive Medicine, which has extensive experience with Clinical Quality Registry design, implementation, and ongoing functionality,³ were successful bidders and were therefore engaged.

As joint partners with Monash University, the Australian Society of Plastic Surgeons, along with the Breast Surgeons of Australia and New Zealand, and the Australasian College of Cosmetic Surgery, have now implemented the new Australian Breast Device Registry to improve the outcomes for breast implant patients, both cosmetic and reconstructive, by using international best registry practice with an opt-out model using a minimal core spine of data collected from all breast implant procedures. A successful pilot across seven centers has been conducted, the results of which have yet to be published. Once the data collection

Dr Cooter is Clinical Head, International Collaboration of Breast Registry Activities, and Adjunct Clinical Professor, Department of Epidemiology and Preventive Medicine, Monash University, Melbourne, Victoria, Australia. Dr Barnett is a retired plastic and reconstructive surgeon and Chairman of the Australasian Foundation for Plastic Surgery. Dr Deva is an Associate Professor of Plastic and Reconstructive Surgery, Macquarie University, Sydney, Australia. Dr Magnusson is a plastic and reconstructive surgeon in private practice in Toowoomba, Queensland, Australia. Dr McNeil is a Professor and Head, Department of Epidemiology and Preventive Medicine, Monash University, Melbourne, Victoria, Australia. Dr Perks is a Plastic and Reconstructive Surgeon, Department of Plastic and Reconstructive Surgery, Nottingham University Hospitals, Nottingham, United Kingdom. Dr Rakhorst is a plastic and reconstructive surgeon in private practice in Rotterdam, The Netherlands. Dr Verheyden is a Professor of Plastic Surgery, Baylor University, Scott and White Health, Temple, TX, USA.

Corresponding Author:

Dr Rod Cooter, 360 South Terrace, Adelaide, SA 5000, Australia.
E-mail: rdcooter@plasticsurgeryadelaide.com

forms were tested and proven to be an optimal data profile it was decided to share all aspects of the registry design with international colleagues. ICOBRA was born out of the need to avoid pitfalls experienced by orthopedic registries analyzing metal-on-metal hip joint prostheses where data definitions varied between the United Kingdom and Australia.² To avoid such a fundamental problem for breast devices, an international cohort of surgeons and registry scientists met in Amsterdam to define a core set of minimum data, data definitions, and registry systems for all collaborating countries. ICOBRA has become the vehicle to share all aspects of breast registry science. All information has been provided pro bono to participating nations to ensure future data are harmonized and amplified so any future crises related to breast prostheses can be detected and averted in a timely fashion. The datasets include a wide range of information: device, surgeon and institutional details, device placement, information on the soft tissue envelope, and perioperative strategies to combat infection (Appendix 1, available as Supplementary Material at www.aestheticsurgeryjournal.com). Breast implant registries with the ICOBRA dataset imbedded are operational in the Netherlands and are incorporated into the nascent National Breast Implant Registry in the United States. It is through the ICOBRA network that a psychometrically valid set of Patient Reported Outcome Measures (PROMS) is being assembled in collaboration with international colleagues with high level expertise in that field.

With this background in mind, your journal's editorial "Breast Implant Registries: The Problem with Ambition" is, at best, an error-filled opinion piece.⁴ Importantly, however, we are in agreement that registries must have sustainable funding to be able to audit both completeness of reporting and data accuracy. Also we endorse the need for efficient data collection systems and we aspire to automated data entry technologies. We acknowledge that various registries have failed, but this is typically because of an inadequate funding model or unreasonably large datasets. However, the authors should avail themselves with a better understanding of device registry science before passing their "judgement" on the ICOBRA initiatives using flawed logic.

The most glaring of their errors require strong rebuttal.

- (1) ICOBRA has never duplicated an existing international registry.
- (2) The ICOBRA minimum dataset does include BIA-ALCL and through further collaboration is supportive of the FDA's PROFILE study. We are currently using data from the registry to calculate implant specific risks associated with BIA-ALCL and hope to demonstrate its utility in the next 12 months.
- (3) The Australian Breast Device Registry is most definitely a Clinical Quality Registry. Colleagues at Monash

University are the authors of the Australian national standards for registry design.⁵

- (4) The ICOBRA dataset includes information about the soft tissue envelope (Appendix 1).
- (5) Any opt-out registry is NOT flawed by providing choice for patients to opt-out; it is international best registry practice to allow patients to opt-out.
- (6) It is not appropriate to rely on adverse events being reported to the registry, rather we plan that these will be triggered by regular patient follow up. PROMS are the basis for robust, independent reporting to be integrated into the ICOBRA framework.
- (7) The Clinical Quality Registry design, as proposed by ICOBRA, evolved from an in depth Senate Inquiry recommendation so has close support of the Australian government and the premier registry research group at Monash University.

These major errors were clearly relayed to the principal author prior to this editorial being submitted for publication. Regrettably, the pre-submission advice was not acknowledged, nor incorporated and these factual errors persist in the manuscript which is now published. We are disappointed that such an article has reached print.

Ultimately, we are motivated by ensuring that our patients are given the best advice based on best practice as outlined by solid outcome data. As doctors, we should always strive to put our patients' health and safety first and the establishment of a functional and effective breast device registry is in complete alignment with this goal.

While all aspects of the ICOBRA concept have been extensively examined, we still welcome any constructive criticism that is underpinned with strong evidence based on fact.

Supplementary Material

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REFERENCES

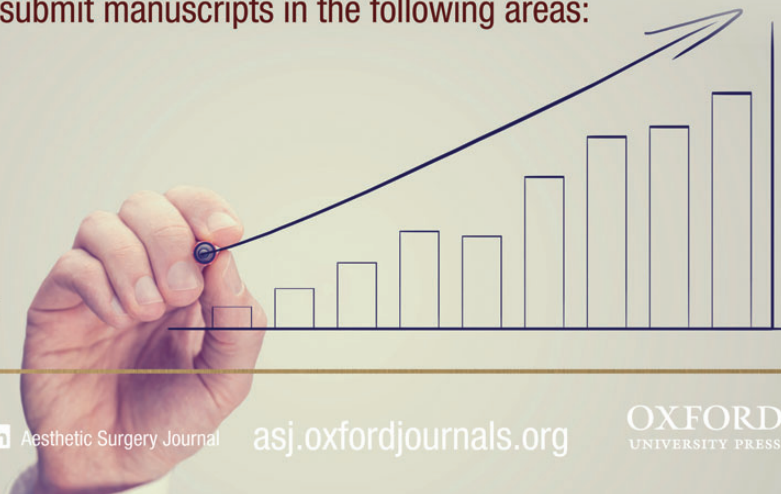
1. Cooter RD, Barker S, Carroll SM, et al. International importance of robust breast device registries. *Plast Reconstr Surg*. 2015;135(2):330-336.
2. Cohen D. Out of joint: the story of the ASR. *BMJ*. 2011;342:d2905.

3. Evans SM, Scott IA, Johnson NP, Cameron PA, McNeil JJ. Development of clinical-quality registries in Australia: the way forward. *Med J Aust*. 2011;194(7):360-363.
4. Brown T, Merten S, Mosahebi A, Caddy CM. Breast Implant Registries: The Problem with Ambition. *Aesthet Surg J*. 2016;36(2):255-259.
5. Australian Commission on Safety and Quality in Healthcare. Operating Principles and Technical Standards for Australian Clinical Quality Registries, 2008. <http://www.med.monash.edu.au/sphpm/creps/docs/operating-principals-and-technical-standards-nov-2008.pdf>. Accessed February 21, 2016.

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