

Proposals and Consensus Views - Provisional Final Release Implants and Human Health Conference

Darling Harbour Convention Centre • Sydney • Australia • Feb. 17-18, 1996

The following are the proposals and consensus statements of the Implants and Human Health Conference. The paper has been circulated over the past 6 weeks to all participants and registrants of the Conference, and there has been approximately a 45% response rate (ie return of questionnaire).

Scoring was done by a "visual analog scale", and the result reduced to one of the 5 categories (*Strongly disagree, disagree, neither agree nor disagree, agree, strongly agree*) which represented the majority view. In cases where the majority view was not clear, or where clear dissension was apparent, the median score was used, and the discrepancies were noted. In the majority of cases, the responses to the questions were remarkable in their consistency of response. The Visual Analog Scales have been removed and replaced by the raw score. This paper now has the status of

"Provisional Final Release of the Conference Consensus Paper and Proposals"

This paper is now available for general distribution, as directed by conference participants, for both public and professional comment by those who did not attend the Conference.

The Consensus Views and Proposals are broken into areas where clear divisions exist, and the remainder are placed under the "General" header. There is an arbitrary division between "proposals" (paragraphs preceded by **Proposal** in the left margin) and consensus statements (preceded by **Consensus** in the left margin). Proposals are made in order to support and implement the consensus statements, and are designed to initiate action. The final form of this document may be changed in the future, although the content is unlikely to significantly alter.

Should you have comments, please return this page (or a copy of it) to the address at the end of this document, or fax ON FINE MODE ONLY to ACMA on the computer fax (to save paper) on 02 9968-4778 (international +61 2 9968-4778). If this fails, use the paper fax number, 02 9968-3378 (international +61 2 9968-3378). Thank you for your time and participation.

Pre-questionnaire (optional):

Name: _____ Contact Number: _____ Fax: _____

Category: Doctor Other Health Professional Public Other _____

Do you, on the whole, tend to agree with the majority of the Consensus Statements? Yes No

If not, which ones do you most strongly disagree with? _____

Do you, on the whole, tend to agree with the majority of the Proposals? Yes No

If not, which ones do you most strongly disagree with? _____

Do you wish to have continued involvement in the Conference and the proposals below? _____ Yes No
(if so, please mark those items which interest you by circling the P or C in the left margin)

Can you help ACMA gain access to resources which could help facilitate the proposals below? _____ Yes No
(such resources may include money, personnel, contacts, access to labs, etc - please mark items)

What help? _____

Other Comments _____

1/ Implants Generally (and uncategorised items) - {results given as the category of the mean response}

Consensus	The Conference agrees that, within the current technology, implants are unlikely to last lifelong. Therefore, all implant recipients, current or prospective, need to be informed of the likely time period to revision, and that these patients receive active follow up to minimise the risk of rupture and its consequences.	STRONGLY AGREE
Consensus	The Conference agrees that there are significant public costs generated as a result of the use of breast implants, and that the extent of these additional public costs are currently unknown in Australia. Based on Canadian information, this figure may be between \$5 and \$25 of extra medical costs over the patient's life for every \$1 privately expended on the original insertion of implants. The Conference agrees that these additional costs need to be carefully quantified in order to assess the true costs of implant insertion	STRONGLY AGREE
Consensus	The Conference agrees that an improved method of post-marketing surveillance be established by implant manufacturers, surgeons and the medical profession generally.	AGREE
Consensus	The Conference agrees that polyurethane implants be explanted from all implant patients as a matter of urgency, and with the support of the profession.	STRONGLY AGREE
Consensus	The Conference agrees that the profession be made aware of the risks of insertion of silicone implants in breast implant patients, especially where cytotoxic medications or radiotherapy are being considered.	STRONGLY AGREE
Consensus	The Conference agrees that preoperative improvement of health status be undertaken in all cases where implants are required, and especially in cancer implant recipients. The focus should be on nutrition, lifestyle, and the use of antioxidants.	STRONGLY AGREE
Consensus	The Conference agrees that the National Health and Medical Research Council is not, in isolation, the appropriate body to provide a definitive assessment of the data related to breast implants. The Conference notes that the NH&MRC is not perceived as independent and trustworthy by some of the major stakeholders, and calls for inclusion of selected Conference delegates to ensure that all scientific evidence is fully assessed.	AGREE /STRONGLY AGREE
Proposal	That ACMA immediately write to the Minister for Human Services and Health, and convey the view that it is inappropriate and unacceptable for the NH&MRC to assess the full range of data related to the safety of breast implants. Further, ACMA should propose that selected Conference delegates be included in the body assessing and reporting on such data. Lastly, should the final report be inadequate in its assessment of risks, that a subgroup must have the right to produce a dissenting report as part of the main report.	STRONGLY AGREE
Proposal	That the Government set up, as a matter of urgency, a consistent national Implant Register, and that technologies as may be appropriate be employed to ensure consistent long term follow up of implant patients. Further, the ultimate fate of all the implants and recipients be kept on this register.	AGREE
NOTES		

2/ Consistency of Diagnosis and Management - {results given as the category of the mean response}		
Consensus	The Conference agrees that screening examination for all implant patients include full physical examination, especially of the breasts and nervous system, and pathology testing (protocol yet to be determined).	AGREE
Consensus	The Conference agrees that ACMA and other stakeholders look at all proposed tests put forward at the conference, and come to a decision about appropriate screening testing for 1/ pre-implant assessment, 2/ assessment of asymptomatic implant recipients, and 3/ assessment of symptomatic implant recipients.	AGREE
Consensus	The Conference agrees that mechanical problems with implants be separated from systemic problems, and that appropriate strategies for helping each group be identified, and this information disseminated.	AGREE (there was a broad spread of views on this question)
Consensus	The Conference agrees that the essential features of "implant-related illness" be gathered and converted into a diagnostic instrument (in a checklist format) so that all doctors who see implant patients with unusual symptomatology are able to assess them for this proposed disorder (this may be modeled on the Chronic Fatigue Syndrome format of the CDC)	STRONGLY AGREE
Consensus	The Conference agrees that all women wishing to receive implants for aesthetic or cosmetic reasons should receive a psychiatric consultation to exclude psychiatric conditions which may cause them to seek such surgery.	DISAGREE (SEE NOTE BELOW - polarised views on this question)
Consensus	The Conference agrees that mastectomy has no place in the management of most women with breast cancer, and that the most possible breast tissue should be retained, minimising the need for implants.	AGREE
Proposal	That ACMA create and disseminate a standard diagnostic checklist, based on the information presented in this conference, enabling all practitioners to take a consistent and complete history, simply and within the constraints of a normal consultation.	STRONGLY AGREE
Proposal	That ACMA work with appropriate bodies to develop or identify appropriate research instruments to gather the necessary information to make informed judgements about safety of the implants used in Australia, and will distribute these to all stakeholders and the profession.	STRONGLY AGREE
Proposal	That ACMA identify and support effective methods of improving self image which do not rely on surgery. ACMA will help promote such methods as an alternative to aesthetic or cosmetic surgery.	AGREE (SEE NOTE BELOW - polarised views on this question)
Proposal	That the Government ensure the a long term follow up of implant patients, including yearly screening of recipients for rupture, local disease, and systemic disease at least second yearly, using the methods and diagnostic instruments generated from the Conference.	STRONGLY AGREE
3/ Research - {results given as the category of the mean response}		
Consensus	The Conference agrees that research into the technologies and tests presented at the Conference be included for consideration of future research and trials, and that such projects be supported.	STRONGLY AGREE
Proposal	That ACMA gather an appropriate group to establish research priorities related to breast implants. Such studies should involve clinicians and researchers, and should focus on diagnosis, cost-benefit, and outcomes.	STRONGLY AGREE
Proposal	That ACMA and conference delegates support the efforts of those research groups who presented their data and proposals at the Conference, and seek further funding so that they can establish formal research programs involving clinical data collection by practitioners.	STRONGLY AGREE
Proposal	That ACMA work with other groups to collect specific data on breast implants, with a view to establishing the public cost of surgical implants. This may need to be linked to a national register, and performed with the help of the Health Insurance Commission and other stakeholders.	AGREE (Subject to protection of privacy of patients)

4/ Health Profession & its dealing with implant patients - {results given as the category of the mean response}		
Consensus	The medical profession generally, and surgeons in particular, need to provide honest and complete information to all patients who have, have had, or are considering having implants. Informed consent depends upon open and complete access to such information.	STRONGLY AGREE
Consensus	That the profession be prepared to involve consumers in discussion and decision making on matters related to implants. In particular, that all professionals involved in implants participate in independent conferences and seminars which involve consumers and those who propose damage from implants.	AGREE
Proposal	That a body of information derived from this conference and from the medical and scientific literature be gathered by ACMA and others involved in the conference, and that this information be disseminated widely through all means to the profession, and to the community.	STRONGLY AGREE
Proposal	That ACMA compile a register of medical practitioners with an interest and experience in dealing with implant related health problems be established, and that this list be made available to primary care practitioners throughout Australia, as well as to those seeking such care	AGREE
Proposal	That ACMA establish a register of plastic surgeons who are aware of the risks of silicone implants, and that these surgeons be supported through patient referral and through funding to develop and train in cosmetically acceptable alternatives to artificial implants, especially silicone and saline implants.	STRONGLY AGREE
Proposal	That doctors adopt a pro-active approach to assessing possible rupture and/or leakage of implants, and that ACMA work with appropriate practitioners and stakeholders to develop an appropriate protocol for assessing such leakage or rupture.	STRONGLY AGREE
5/ Education - {results given as the category of the mean response}		
Consensus	The Conference agrees that accurate and unbiased information regarding adverse effect of the various types of breast implants is needed for the best decisions to be made regarding their use. At present, much of that information is either gathered by, controlled by, or disseminated by groups with a clear vested interest in the outcome, or with the public perception of such a vested interest.	AGREE
Consensus	The Conference agrees that the information gathered (q.v.) needs to be distributed widely to the primary care practitioners so that a balanced view of the issues surrounding implants, and their risks can be gained by all.	STRONGLY AGREE
Proposal	That ACMA work with appropriate groups to create information sheets on breast and other implants. These should cover all major issues raised in the Conference, especially the effect of implants on pregnancy/breast feeding, and that the recommendations be distributed to prospective parents through the profession and generally.	STRONGLY AGREE
Proposal	That ACMA gather and disseminate the information from the Conference, especially regarding the adverse effect of the various types of breast implants, to the primary care practitioners and the medical profession generally, so that a balanced view of the risks of implants can be gained by all.	STRONGLY AGREE

6/ Regarding Plastic Surgery - {results given as the category of the mean response}		
Consensus	The Conference deplors and condemns the decision of the Australian Society of Plastic Surgeons and the implant manufacturers to refuse participation in the Conference. The Conference notes that the best outcome and education is served by wholehearted participation of all stakeholders. The Conference seeks the reconsideration of this refusal by these groups, and their input into the processes and proposals emanating from the Conference.	STRONGLY AGREE
Consensus	The Conference agrees that currently, the surgical specialty of plastic and reconstructive surgery generally is insufficiently responsive to the needs of implant patients and their peak body representative groups.	AGREE
Consensus	The Conference agrees that there is a need to establish a specific body within the surgical specialty which is responsible for training, accreditation, peer review and quality assurance for aesthetic and cosmetic surgery in Australia.	STRONGLY AGREE
Consensus	The Conference agrees that there is a need to promote the highest standards of care and continuing education for all plastic and aesthetic surgeons, and calls for the establishment of an appropriate independent body to create and develop such standards, and ensure their adoption. This body would need to be inclusive, rather than exclusive, of all stakeholders, including regulators and consumers.	STRONGLY AGREE
Proposal	That ACMA, consumer peak bodies, and government promote the adoption of, and training in, the use of grafts using the patient's own tissue in place of foreign body implants, where possible.	AGREE
Proposal	That ACMA works with registrants, consumer groups and other stakeholders to establish and publish a register of plastic surgeons, including their qualifications and information about post-graduate training within the surgical specialty.	STRONGLY AGREE
Proposal	That ACMA make this register (q.v.) available to all GPs Australia wide, and distribute it to consumer groups and individuals with an interest in this area	STRONGLY AGREE

Notes:

- 1/ The Visual Analog Scale used in each question on the original questionnaire: Strongly Disagree _____ Strongly Agree N/O
- 2/ The consensus point and proposal in section 2, relating to prior psychiatric referral and identifying alternatives to cosmetic surgery for improving self image, drew an extreme polarisation of views. The prior psychiatric referral had less support than the proposal for identifying non-surgical ways of improving self-image, but unlike most other questions where there was close concordance of views, these questions received responses ranging relatively evenly from strongly disagree to strongly agree.
- The original proponent of the proposal had sought to ensure that women did not undergo unnecessary surgery for a problem (ie poor self-image) which may have been better and more safely handled by conservative means. There was no intention to attribute a psychiatric diagnosis to women who sought cosmetic or reconstructive surgery.

This list is now complete as at Wednesday, 1 May 1996 , and is to be considered "Provisional Final Release of the Conference Consensus Paper and Proposals" .

Further comments are invited, and should be passed on to the

Australian Comprehensive Medicine Association (ACMA), PO Box 328 MOSMAN NSW 2088 AUSTRALIA
 Fax: 02 9968-4778 or 9968-3378 Int. Fax: +61 2 9968-4778 or 9968-3378 Email: <mark@geko.com.au>