Published in final edited form as:

Plast Reconstr Surg. 2011 July ; 128(1): 13–16. doi:10.1097/PRS.0b013e31821cf88f.

Invited commentary on Managing Late Periprosthetic Fluid Collections (Seroma) in Patients With Breast Implants: A Consensus Panel Recommendation and Review of the Literature

Kevin C. Chung, MD, MS¹

¹Professor of Surgery, Section of Plastic Surgery, Assistant Dean for Faculty Affairs, The University of Michigan Medical School

The recent attention to an extremely rare form of lymphoma known as Anaplastic Large T-Cell Lymphoma (ALCL) has spurred great interest in defining the etiology of this highly unusual malignancy and its potential association with breast implants. Because of the rarity of this disease, data regarding its characteristics can only be gleaned from case reports in the literature and from sporadic unpublished cases from plastic surgeons. Given that the data are too sparse to guide treatment, the Food and Drug Administration has coordinated a registry in order to collect cases prospectively in an effort to better understand this disease. Until better data are available, patients and physicians are seeking guidance from experts. It is generally believed that ALCL associated with breast implants has a more benign course and can be treated effectively by draining the seroma and removing the breast implants.^{1,2} The literature suggests that most women with ALCL who had their breast implants removed can be disease free and do not require more intensive therapy such as chemotherapy or radiation therapy. However, given the uncertainty of this unique disease, the recommendations are based on empiric observations rather than robust epidemiology studies.

Physicians and patients often have to make difficult decisions regarding treatment choices because uncertainties are common and irrefutable evidence for the treatment of many diseases is often lacking. Treatment decisions rely on probabilities of success and failure of the treatments, and frequently rest on the collective experience of experts in the field. The recommendations presented in this expert opinion special article for treating ALCL associated with breast implants are sensible and are derived from the collective experiences of experts who care for women with breast implants. This article provides a timely discussion regarding the expert consensus process that strives to minimize many of the biases inherent in group discussion forums. Because it is natural in a group dynamic for certain members to acquiesce to the will of the group and for others to dominate the discussion, structured consensus expert conferences were designed by the National Institutes

Corresponding author and reprint requests sent to: Kevin C. Chung, MD, MS Section of Plastic Surgery The University of Michigan Health System 1500 E. Medical Center Drive 2130 Taubman Center, SPC 5340 Ann Arbor, MI 48109-5340 Phone: 734-936-5885 Fax: 734-763-5354 kechung@med.umich.edu.

Publisher's Disclaimer: This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final citable form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

of Health and the RAND Corporation to minimize these biases in order to conduct a more scientifically sound inquiry.

In general, there are three popular methods in the consensus building effort: (1) Focus Group, (2) Delphi Method, and (3) Nominal Group Technique. The Focus Group technique is a form of qualitative research in which a group of people are asked about their attitudes toward a product, service, concept, advertisement or idea. The questions are asked in an interactive group setting where participants are free to talk with other group members to generate a list of potential items for future discussion and refinement. The Focus Group procedure is an exploratory phase of an expert consensus effort to sift through the many possible avenues of inquiry.

The Delphi Method was proposed by the RAND corporation in the 1950s based on the dialectical inquiry, which is a philosophical discipline applied to methods of debate or argumentation that seeks to prove or disprove the truth of something by the rules of logic or the laws of reasoning. This form of debate is a structured process in which a thesis is formed to establish an opinion or view, followed by confrontation by an antithesis that presents conflicting opinions or views. By an interactive process between thesis and antithesis a synthesis is formed, which presents a new agreement of consensus to become a new thesis (Figure 1). The history of dialectics showed a consistent theme in Eastern and Western cultures. Asian dialectics consider the idea that everything is made up of opposites, such as Yin that has female connotation and Yang that has male traits. The ancient teachings of Taoism in China expanded on this belief by stating that “Change is the only constant in life.” In ancient Greece, Heraclitus of Ephesus (a pre-Socratic philosopher born off the coast of Asia Minor) believed that all changes come through the struggles of opposites. Socrates argued that only by means of cross examining someone's assertions will the truth emerge. The dialectical intent of the Delphi method was originally used to forecast future technological capabilities that could be applied in the Cold War. However, this methodology has evolved and is channeled into predicting trends in technology and research. The history of the Delphi Method is rooted to the Oracle of Delphi, which was the most revered site in ancient Greece where people sought advice and forecasts from the Gods through intermediary priests. The extension of this mythical belief led to a sequential step-by-step structured Delphi process to formulate an expert panel process (Figure 2). In the initial round of inquiry, a question or statement is posed to an expert panel. The experts then formulate their answers, and the answers are distributed amongst the experts for the panel to consider. Ultimately, the intent of this iterative process is to garner an opinion that is favored by the majority of the expert panelists. However, it must be recognized that the main stipulation of the Delphi Method is not to force consensus but rather for each member to consider the opinions of others in order to revise his/her own opinions based on the best scientific evidence. Ultimately, the considerations from a list of opinions by the experts are collated to formulate the majority preference.

The Nominal Group Technique was developed by Andrew Van de Ven and Andre L. Delbecq in 1971.³ This is a consensus procedure to reach a unified opinion by the expert panel. The use of Nominal Group Technique has been applied by the World Health Organization (WHO) to develop the protocol for public policy in the event of influenza

epidemic.⁴ Similarly, the WHO adapted this procedure to structure the Internal Classification for Functioning, Disability and Health (ICF) for upper limb conditions in Switzerland where representatives from over 20 countries, including myself representing the US, were gathered to establish an international metric for data reporting.⁵ Additionally, the WRIST study group adopted this process to derive a study protocol for a 21-center clinical trial funded by the National Institutes of Health for evaluating outcomes and complications in treating distal radius fractures in the elderly population.⁶ This technique is used when there are concerns that some group members are more vocal than others, some members are not participating in the discussion, there is a scarcity of ideas, or there are controversial issues that require an open dialogue. Use of Nominal Group Technique requires a strong and active moderator who will draft a list of opinions or issues to form the basis of discussion among the group. The moderator solicits participation by all members while controlling the discussion tone in order to prevent certain members from dominating the entire discussion. Ideas are then ranked in the order of importance by all the members, followed by more discussions to formulate a final priority of action items or suitable opinions that form the core of consensus opinions from the expert panel.

The process for the Nominal Group Technique is comprised of several stages (Figure 3). First the moderator writes down the problems on a flip board for all to see. Ideas are generated by the panel independently by asking the participants to write on their cards as many ideas and opinions as they can; there is no discussion at this 1st stage. In the 2nd stage, the moderator asks each member in turn to state their ideas, and the moderator then records these ideas or opinions on the flip board with no more than five ideas on one sheet. Each participant takes a turn until all ideas have been shared, and again no discussion occurs at this stage. In the 3rd stage, the moderator leads the discussion for each idea to clarify these ideas one by one. There is no discussion of each idea's merit or validity at this stage and if a group member begins to lobby for one of the ideas, the moderator will remind the panel that no panel member should attempt to sway others to support any individual member's preference. In the 4th stage, the moderator will instruct each of the members to rank the top 5 preferred ideas on their cards after considering the previous discussions. The moderator then collects the index cards where the members wrote their rank list. The votes are counted and tallied to list all of the ideas on the board for interactive discussion. In this final stage, the group will share their opinions about the top preferences; the final rank list is obtained and a consensus is reached through discussion. The advantage of the Nominal Group Technique is that it generates a greater number of ideas than the traditional group discussion and it facilitates equal participation by all group members. It allows the group to prioritize ideas democratically and provides a sense of closure because consensus is based on the preference of the majority. However, the disadvantage of Nominal Group Technique is that it is a lengthy process that requires a great deal of preparation, can only address one problem at a time, and the ideas may not be fully developed because lengthy discussion may be curtailed.

There are similarities between the Delphi and the Nominal Group Technique. Both involve panels of experts working individually to develop a group consensus. Both processes require experienced moderators who should not be biased in the issues at hand. The input of all participants is used to arrive at a final group consensus. However, the Delphi Method does prevent bias because in the traditional Delphi method, the ideas are presented anonymously

and in certain cases, the Delphi technique can even be used without a face-to-face meeting among the participants who are scattered geographically. The Nominal Group Technique mandates a face-to-face meeting.

Given the intense national attention placed on the issue of ALCL, the RAND Corporation was commissioned to conduct a consensus conference where experts from various disciplines were convened in Washington, DC, using the Delphi Method. This conference has generated two manuscripts in *Plastic and Reconstructive Surgery* to help define the current knowledge regarding ALCL associated with breast implants.^{1,2} Of course, more work remains to be done to provide a better understanding of this vexing disease. However, the uncertainty relating to ALCL is a perfect forum for the use of consensus panel methodology that is ideally suited for situations when the data are sparse, opinions vary, and the stakes are high. The ALCL condition is the type of problem that requires careful consideration for the use of structured consensus methodology in order to minimize biases and to reach the most suitable consensus opinions by a scientific process.

Acknowledgments

With thanks to Pouya Entezami for helping with the preparation of the manuscript.

Supported in part by a Midcareer Investigator Award in Patient-Oriented Research (K24 AR053120) from the National Institute of Arthritis and Musculoskeletal and Skin Diseases (to Dr. Kevin C. Chung).

References

1. Kim B, Roth C, Chung KC, et al. Anaplastic Large Cell Lymphoma and Breast Implants: A Systematic Review. *Plastic and Reconstructive Surgery*. 2011 In press.
2. Kim B, Roth C, Young VL, et al. Anaplastic large cell lymphoma and breast implants: Results from a structured expert consultation process. *Plastic and Reconstructive Surgery*. 2011 In Press.
3. Van de Ven AH, Delbecq AL. Nominal Versus Interacting Group Process for Committee Decision-Making Effectiveness. *The Academy of Management Journal*. 1971; 14(2):203–212.
4. Timpka T, Eriksson H, Gursky EA, et al. Population-based simulations of influenza pandemics: validity and significance for public health policy. *Bull World Health Organ*. 2009; 87(4):305–311. [PubMed: 19551239]
5. Chung KC, Burns PB, Reichert H, et al. Properties of the international classification for functioning, disability and health in assessing hand outcomes in patients with rheumatoid arthritis. *Journal of Rehabilitation Medicine*. 2011; 43:292–298. [PubMed: 21267527]
6. Chung KC, Song JW, The WRIST study group. Guide on Organizing a Multicenter Clinical Trial: the WRIST study group. *Plastic and Reconstructive Surgery*. 2010; 126(2):515–523.

Figure 1.
The philosophy behind the Delphi method.

Figure 2.
The Delphi method for reaching expert consensus.

Figure 3.
A schematic of the Nominal Group Technique.