Democracy-Based Consensus in Medicine

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Background: **High-quality evidence and derived guidelines, as typically published in major academic journals, are a major process that shapes physician decision-making worldwide. However, for many aspects of medical practice, there is a lack of High-quality evidence or an overload of somewhat contradictory low-quality information, which makes decision-making a difficult, uncertain, and unpredictable process. When the issues in question are important and evidence limited or controversial, the medical community seeks to establish common ground for "best practice" through consensus conferences and consensus statements or guidelines. Such consensus statements are seen as a useful tool to establish expert agreement, define the boundaries of acceptable practice, provide priorities for the research agenda, and obtain opinions from different countries and healthcare systems. This standard approach, however, can be criticized for being elitist, noninclusive, and poorly representative of the community of clinicians who will have to make decisions about the implementation of such recommendations.**

Objective: **Accordingly, the authors propose a new model based on a combination of a local core meeting (detailed review and expert input) followed by a worldwide web-based network assessment (democracy-based consensus). The authors already have applied this approach to develop consensus on all nonsurgical interventions that increase or reduce perioperative mortality in critically ill patients and in those with acute kidney injury.**

Methods: **The methodology was based on 5 sequential local and web-based steps.**

Results: **Both a panel of experts and a large number of professionals from all over the world were involved, giving birth to a new type of "democracy-based consensus."**

Conclusions: **This new type of "democracy-based consensus" has the potential to increase grass-root clinician involvement, expand the reach to less-developed countries, provide a more global perspective on proposed interventions, and perhaps more importantly, increase awareness, ownership, and the statistical likelihood of subsequent implementation.**

KEY WORDS: consensus conference, knowledge sharing, democracy-based medicine, web-based network

PHYSICIANS FACE THE CHALLENGE of making therapeutic decisions every day. They often seek to base their choice on the best published evidence. However, in some cases, there is a lack of high-quality pieces of information from which to draw conclusions. In other cases, an overload of often contradictory information hinders the development of a synthesis even for the experts; in these cases, guidelines are inconclusive or even unavailable because of a discrepancy among experts' opinions. Consensus conferences have emerged as a tool to establish expert agreement on key aspects of clinical practice for which definitive evidence from meta-analyses or large randomized controlled trials (RCTs) is unclear.[1,2]

Although quantitative methods, such as meta-analysis, have been developed to provide statistical summaries of clinical trial findings and to resolve inconsistencies in published studies, they are also imperfect and often contradicted by subsequent high-quality RCTs. Even in their presence, and particularly in their absence or when such meta-analyses are based on poor-quality data, consensus conferences allow a wider range of study types to be considered, providing a practical way to offer a response to identify uncertainty in medical and health services research.[3] In addition, such a consensus process allows a greater role for the qualitative assessment of evidence. Consensus methods respect expert opinion as a result of diverse experience, providing a formal framework for opinion sharing and dialogue. They provide an opportunity to discuss, debate, and endorse proposals, and may facilitate further research and donor investment into potentially life-saving interventions.[4,5]

Consensus conferences may limit some of the detrimental effects of the process of evidence synthesis, including the potential for undue influence on those drafting conclusions. However, the contemporary consensus conferences have several drawbacks that limit their conclusions. Consensus conferences have been conducted for decades within small pools of experts, elitists noninclusive of the whole medical community, and possibly more subject to various influences and biases. They may represent only a specific group of countries, thus representing only the views and the influence of a specific country or society. They may under- or misevaluate problems related to third world or developing countries, specifically

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aspects related to economic and logistic issues. Therefore, to reduce these aspects of elitism and remoteness, a reform of the process of consensus building reasonably can be suggested.

In response to concerns about the usual process of consensus development, a new approach to consensus building was implemented using a web-based technology for data sharing and web-polling.[6] The methodology and the major advantages of this new approach to evidence-based medicine are detailed in the following section.

METHODS

This new type of consensus conference was articulated in a 5-step process. A first phase of systematic data collection and analysis brought a summary of all randomized controlled evidence to participants. This was followed by worldwide contribution through web-polling of the articles selected in the first phase. The results of this web vote were analyzed and each topic was discussed during the third phase: A consensus meeting held among experts. The next phase was dedicated to new web-polling, focused on the results of the consensus meeting. The last phase was devoted to article drafting and publication of results.

The phases of the method are illustrated in Figure 1 and further described below.

Phase 1. Review of Literature and Collection of High-Quality Evidence

The main objective of the consensus process was the systematic identification of all interventions affecting mortality in cardiac surgery (2010), in the overall perioperative period of any surgery (2011), in patients with or at risk of acute kidney injury (2012), and in the overall population of critically ill patients (2013). In 2010 and in 2012, because of the paucity of published topics, any kind of evidence was selected; in 2011, only RCTs and meta-analyses of RCTs were included; and in 2013, only multicenter RCTs were considered.

One or more search strings were prepared each time to identify pertinent articles. The search strings that aimed to identify RCTs were based on the largely validated research strategy proposed by Robinson et al[7] in 2011 and 2013; other strings with inferior specificity were prepared to identify meta-analyses, review articles, or nonrandomized trials and are reported in supplemental Table 1.

To increase sensitivity, additional strategies were adopted. Experts and authors of identified manuscripts were contacted, and references of recent reviews and guidelines were searched. In 2010 and 2011, more than 100 international anesthesiologicy and surgical societies and more than 50 patients and nurses' associations were contacted. This process was not carried on in the following years because of the poor response rate. In 2010 and 2011, all editorial offices of peer-reviewed journals relative to perioperative medicine, including surgery, anaesthesiology, critical care medicine, and cardiac or cardiovascular systems, were contacted for further suggestions. This was not carried on in the following years because of the poor response rate. New articles were identified and evaluated until the consensus meeting, always held in Milan, Italy.

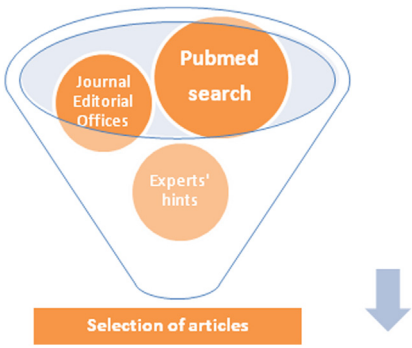

Fig 1. Consensus conference process. Modified from Landoni G, Ruggeri L, Zangrillo A. "Reducing mortality in the Perioperative Period" Book, Springer 2014.

Identified papers were reviewed at an abstract/title level by a trained team of physicians. The following criteria were adopted for inclusion in the next step of the consensus process: Focused on nonsurgical interventions (drugs, strategy or techniques); reporting a statistically significant difference in mortality; published in a peer-reviewed journal; including adult patients. In 2011, a further inclusion criterion was "randomized evidence," and in 2013, only multicenter RCTs were included.

Phase 2. Web-Based Polling www.democracybasedmedicine.org

A web-based poll was conducted with 340, 1,090, 311, and 558 physicians from 65, 77, 62, and 61 countries taking part in this process. They included professional and experts in the fields, covering a large area of medical specialties, especially corresponding authors of recently published articles. The consensus conference was advertised by web, e-mail, and by information spreading through networks of professionals.

In the periods between June 20-28, 2010; June 1-8, 2011, January 1-February 14, 2012, and February 1 to June 19, 2013 participants voted through web-poll their agreement on the beneficial or detrimental effect on mortality of the interventions proposed in the previous phase and had the opportunity to add further topics or write comments. Every opinion was collected and reported to the consensus meeting, along with new articles proposed for inclusion. An example of web-polling is shown in Figure 2.

Phase 3. Consensus Meeting

The meetings of the four consensus conferences were held on June 28, 2010, June 8, 2011, February 14, 2012, and June 20, 2013, at the Vita-Salute University (San Raffaele Scientific Institute, Milan) with a task force of anesthesiologists, intensivists, surgeons, cardiologists, nephrologists, and epidemiologists.

During the meeting, all articles proposed by participants were assessed for inclusion. Each topic/paper was presented by a rapporteur and a discussant. This was followed by discussion through consensus building. A vote was taken if at least one participant was against including the paper in the major topics at the end of discussion, and a position statement was approved describing the intervention, the reasons for the inclusion of the topic, its effect on mortality, and possible challenges in its evaluation (the latter reported only in the consensus on acute kidney injury). Topics were divided between final statements and major exclusions. Different exclusion criteria were adopted in each consensus conference, reflecting diversity in the quantity and quality of available literature and specificity of the consensus theme. These exclusion criteria were specified in the published papers and included, among others, mortality as part of a composite endpoint, statistical significance derived from a subgroup analysis, contradictory evidence found in higher quality studies and evidence on mortality existing but not in that specific setting.

Phase 4. Second Web-Based Polling www.democracybasedmedicine.org

The approved statements were presented online for validation among all participants by a second and more important web-poll. Participants were asked to support or dispute the proposed statements through an interactive web questionnaire. Items under a predefined percentage of support from voters were excluded.

Participants were required to express their agreement, choosing from an ordinal scale for each intervention. In the consensus conference