

Consensus Statement

International Consensus on Periprosthetic Joint Infection: Description of the Consensus Process

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Background

Periprosthetic joint infection (PJI), with all its disastrous consequences, continues to pose a challenge to the orthopaedic community. Practicing orthopaedic surgeons have invested

great efforts to implement strategies that may minimize surgical site infection (SSI). While new discoveries in orthopaedic research allow us to answer more questions each year on the basis of high-level evidence, there remain numerous topics—including many important ones—for which the evidence is limited, contradictory, or absent. For these clinical issues, it sometimes is helpful to know whether general consensus on diagnosis or treatment exists among individuals who specialize in these areas.

Toward that end, we convened a meeting of an international panel of experts during 2 days (July 31 and August 1, 2013) in Philadelphia, PA,

USA. The meeting was the penultimate step of a 10-month-long process to generate a set of best practices for management of PJI through engagement of experts in the field. More than 300 experts from various disciplines including orthopaedic surgery, infectious disease, musculoskeletal pathology, microbiology, anesthesiology, dermatology, nuclear medicine, rheumatology, musculoskeletal radiology, veterinary surgery, and pharmacy, as well as numerous scientists with interest in orthopaedic infections attended. Delegates from 52 countries covering all major regions of the globe participated, representing 160 medical institutions and research centers, having memberships in more than 100 medical societies and boards, and sharing a collective experience of many thousands of cases. The panel undertook this consensus effort to help the global medical community improve the efficacy, lower the complication rates, and move toward adoption of standardized measures and techniques for management of PJI.

As mentioned, the lack of evidence for many aspects of clinical practice

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compels the medical community to seek alternatives for development of best practices. A consensus panel is one such alternative, and the process sought to produce a set of procedures and methods using group judgment on a subject matter for which objective information is lacking [2, 3, 6, 11, 15, 17, 20]. When judgments differ, it is important to understand why, and to develop a process to create, if possible, a common view.

The word consensus has origins in the Latin word *consentire*, which means to give assent or approval or to feel together. A dictionary definition of consensus is “a general agreement” and also, very importantly, “group solidarity or concord of opinion or sentiment” [13]. Consensus, therefore, means general agreement about an idea or opinion among most individuals in a group. Majority support for an idea spans from unanimous support (100% agreement) to a simple majority (greater than 50%). Unanimity has been reported as being difficult to achieve, especially in large groups even when, or possibly because, the consensus process is well run. Unanimity is not always a panacea, as sometimes it may occur as a result of “coercion, fear, undue persuasive power or eloquence, inability to comprehend alternatives, or plain impatience with the process of debate” [8, 14, 18]. Even so, the closer to 50/50

a group is vis-à-vis an issue or opinion, the greater the polarization and conflict around that issue. Usually, consensus is understood as the shared opinion of an overwhelming, or super-, majority of the individuals in a group. A supermajority is a majority substantially greater than a simple majority [8, 9, 14, 18].

Although a specific and widely accepted definition of consensus in exact percentage terms does not exist, one rule of thumb is to define consensus as views shared by more than 75% of a group. A more detailed breakdown may establish three levels of consensus as follows [9, 10]: (1) weak consensus = between 3/5 and 2/3 (60%–66%) of a group agree with a given opinion; (2) consensus = between 2/3 and 3/4 (67%–75%) of the individuals of the group agree; and (3) strong consensus = three or more members of a group agree for each dissenting one ($\geq 75\%$ individuals in a group agree on an opinion). Unanimous support, when everyone in a group agrees, is the strongest consensus.

A consensus process seeks to generate the consent or agreement of all participants around a specific issue, opinion, or recommendation. The consensus process involves a series of steps designed to help individuals in a group deliberate ideas or issues and lead them to agree on a resolution that can be supported by as many individuals in the group as possible, even if

the specific resolution is not the preferred one of every individual.

As noted, many consensus processes attempt to reach a threshold of 75% agreement or greater, that is, a supermajority of 3:1 or better [8–10]. It is important when one refers to a supermajority to take into consideration abstentions and to differentiate between a simple supermajority (based on individuals of a group who are present and have voted) and an absolute supermajority (based on the total number of voters who are qualified or allowed to vote). For example, if a recommendation wins 80% of the vote but only 30% of the eligible voters actually voted, the recommendation is supported by a relative supermajority, but it does not have the support of an absolute supermajority (actually, far from it; that recommendation garnered only 24% of total possible votes). For purposes of our process, we evaluated consensus using both relative and absolute supermajority rules, and more detail on this will follow below, in the Methods section.

A robust consensus process has the following characteristics [5, 8–10, 12, 18], which we sought to incorporate in the process used here:

- Inclusive: The consensus process involved all relevant stakeholders and included as many different views and perspectives as possible.

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- **Comprehensive:** An effort was made to present all available relevant data (eg, sharing of literature references and studies) for all participants in the process to be thoroughly informed.
- **Participatory:** The consensus process actively and repeatedly solicited the input and engagement of all participants.
- **Egalitarian:** Individuals were given equal opportunity to voice their views and those views were given equal weight and efforts were made to mitigate the potential effect of differential status of participants (eg, comments were depersonalized).
- **Credible:** Broad and representative participation is key to ensure widespread acceptance of recommendations. Invitation to participants in the process was extended without bias other than selecting individuals with relevant expertise.
- **Collaborative:** Participants were encouraged to contribute to a common set of recommendations by adding their thoughts to what other members of the group had suggested. The process offered the means (eg, resources, time, technology) to facilitate a sense of working together and in collaboration.
- **Cooperative:** Participants were reminded multiple times that the goal was to reach a set of recommendations that had the support of

most of the members of the group rather than the views of specific constituencies or their own.

Voting through a consensus process is an alternative to other commonly used decision-making processes such as Robert's Rules of Order, which are designed to pass resolutions based on a majority vote [16]. This type of decision-making process typically is faster than a consensus process, but its adversarial dynamics often undermine the ability of a group to successfully implement a contentious decision. One major criticism of consensus processes that seeks the input and collaboration of a large number of participants is that it is time-consuming and that the time commitment required of every participant to engage in the process is so substantial that it actually may decrease participation. However, the time invested in creating consensus pays off as implementation of the group's recommendations tends to be much smoother.

The arguments in favor of well-designed and managed consensus processes are that these processes lead to the following benefits [5, 8–10, 12, 18, 19]: (1) better decisions (by including the input of a large number of varied participants, the resulting recommendations will represent more varied and richer views); (2) better implementation (by including views from as many

relevant participants as possible and by encouraging as much agreement as possible, the process makes participants more engaged and responsible in implementing the resulting recommendations); and (3) better group relationships (by creating a cooperative, collaborative, inclusive group atmosphere, the process fosters greater group cohesion and interpersonal connections).

Methods: The International Consensus Meeting on PJI

The consensus process at the International Consensus on Periprosthetic Joint Infection was designed specifically to address as many issues surrounding the management of PJI as possible. The process engaged a large number of individuals from many countries and from various specialties to agree on what is known about PJI (based on available literature) and lead to identification of areas in need of further evidence. The process had three phases: (1) a phase when participants in the process worked remotely and exchanged ideas through a modified Delphi process [1, 7, 12]; (2) a phase when participants worked face-to-face to address and resolve final issues and details and voted on resolutions; and (3) a dissemination and publication phase.

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The first phase of the process lasted more than 9 months and consisted of identifying the issues and writing position papers or recommendations. This phase was done by conducting a comprehensive review of the available relevant literature. The evidence for current practices, whenever available, then was summarized and presented to the participants. An opportunity was provided to the members to voice their opinion collectively and anonymously.

The second phase of the consensus was done in a face-to-face meeting during 2 days in Philadelphia. On the first day of the meeting, delegates of each workgroup convened in individual rooms to discuss their recommendations and disagreements. Once their recommendations were finalized, members of all workgroups convened in a general assembly and shared their recommendations with all the delegates. Importantly, all delegates were likely to have seen the recommendations of other workgroups during the previous months as the recommendations of all workgroups were posted on the social media website that the consensus used for communications, and numerous opinions were exchanged. In the general assembly, further discussions occurred and suggestions were made. The final set of recommendations was loaded onto the electronic audience response system at the end of the first day to be

presented the next day for voting by the delegates. The electronic audience response system displays the recommendations on a giant screen one recommendation at a time, pauses for a set amount of time to give the audience a chance to read the recommendation, think about it, and vote by pressing a “yes”, “no”, or “abstain” button on hand-held units. The following day, all voting delegates were given the opportunity to read the posed questions and recommendations on a large screen and cast their vote. During the day-long meeting, all 207 questions and recommendations were presented and voted on.

After the second day of the face-to-face meeting, the final document was assembled and sent to all delegates for their final review during a 2-week period. Numerous communications were exchanged during that period leading to generation of the final document. The third phase will involve dissemination of the produced document to orthopaedic and musculoskeletal infectious disease specialists, and other disciplines. The consensus document and its supplemental material, including this document, are being made available through open access. The consensus document will be posted on the websites of numerous societies, will be published as PubMed cited material, and will be published as an electronic

book and a paper book. We also intend to have the document translated into numerous languages.

The process by which the PJI consensus was generated is described below (Fig. 1).

Step 1: Establishing a Steering Committee

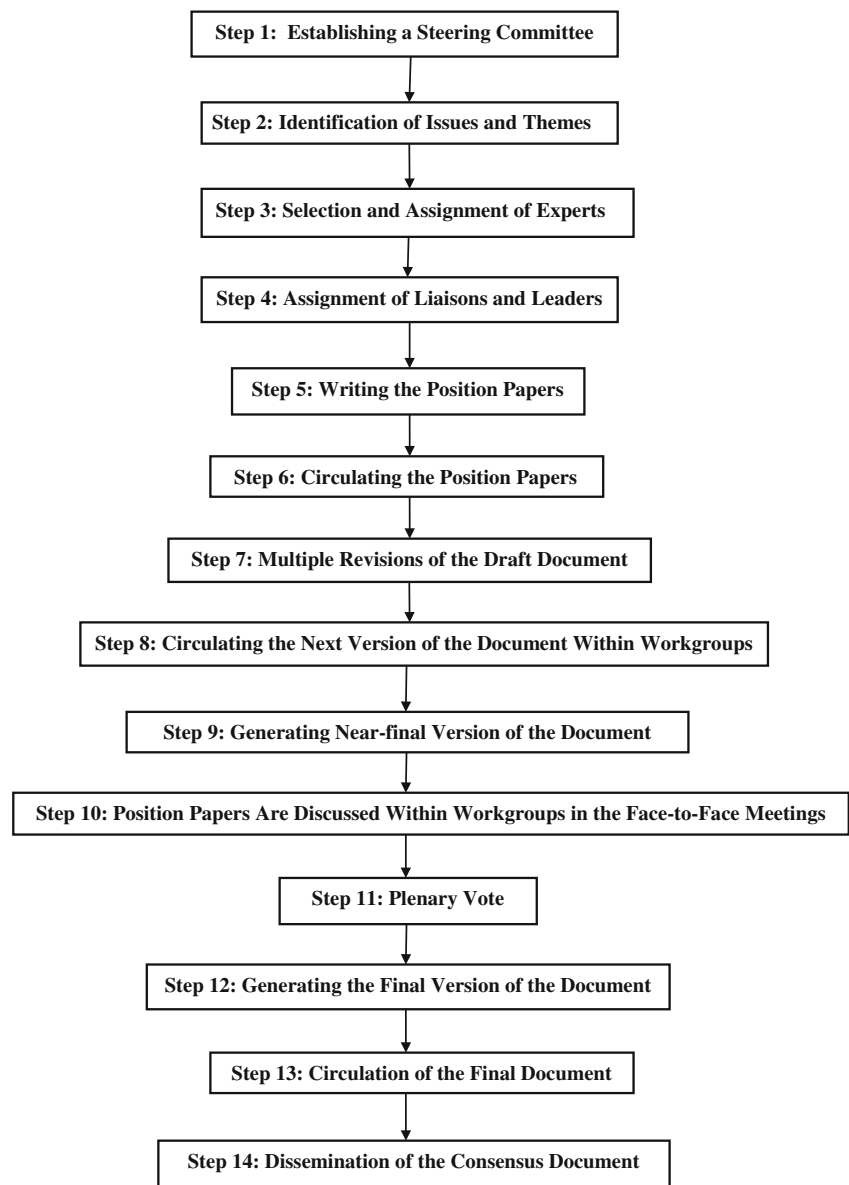
In September 2012, the idea of conducting an international consensus on the topic of PJI was conceived by two authors of this article (JP, TG). Soon after these discussions, a steering committee consisting of those authors, 17 liaisons, a biostatistician, and a medical editor were assembled. The time line for the entire process was determined and the main objectives were set. At that point, it was intended that the face-to-face meeting of delegates would take place during the annual meeting of the Musculoskeletal Infection Society in August 2013.

Step 2: Identification of Issues and the Themes

The steering committee then met in person or conducted conference calls on numerous occasions to identify the issues that surround the medical community regarding management of PJI. The issues were organized under the chronologic stages of patient care. Fifteen major areas were identified:

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Fig. 1 A flowchart shows the 14-step consensus process.



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(1) mitigation and education on comorbidities, (2) patient preparation, (3) perioperative antibiotics, (4) operative environment, (5) blood conservation, (6) prosthesis selection, (7) diagnosis of PJI, (8) wound management, (9) spacer, (10) irrigation and débridement, (11) antibiotic treatment and timing of reimplantation, (12) one-stage versus two-stage exchange, (13) management of fungal or atypical PJI, (14) antimicrobial therapy, and (15) prevention of late PJI.

It was decided that 15 position papers summarizing state of the knowledge and experience would be written, one on each topic, as the basis for achieving consensus.

Step 3: Selection and Assignment of Experts

At this point, a list of potential worldwide experts was identified. The selection of experts was based on two criteria: (1) publication record and/or (2) clinical interest in management of PJI. A list of 446 such experts was generated and an electronic invitation was issued to these individuals. The consensus group included orthopaedic surgeons, infectious disease specialists, scientists, musculoskeletal pathologists and radiologists, pharmacists, rheumatologists, and experts in many other disciplines. The intention was to make this process as open and inclusive as possible while

ensuring a deep base of knowledge. A total of 438 individuals could be reached, of whom 432 individuals accepted the invitation to participate in this initiative. The experts were given the option of choosing the workgroup dealing with issues of interest to them. For those not expressing a preference, the experts were assigned to a workgroup that dealt with issues related to their expertise. The steering committee reviewed the assigned participants to themes using, as criteria, the stated interest of the participants but also balancing views and countries of origin to ensure maximum debate and exchange of ideas and to accommodate discussion of minority views. (An effective consensus process encourages dissenting views to come out early so that they can be addressed and overcome as soon as possible [5, 10, 18].)

Step 4: Assignment of Liaisons and Leaders (US and International)

The steering committee appointed for each workgroup a liaison and two co-leaders. It was ensured that each workgroup had a leader from the US and also another leader from a different part of the world for balance. To help with writing the position papers and support the coleaders, an individual (liaison) was appointed to each workgroup. The purpose of the leaders was to anchor each theme by providing undeniable

expertise and ability to exert leadership with writing the position papers. The liaisons were responsible for conducting a comprehensive literature review and writing the first draft of the consensus statements based on the available literature. We created forums (or chat rooms) to exchange ideas and comments on a preexisting social media website (www.forMD.com) specifically for this project, and the liaisons were responsible for monitoring this website for comments from experts and incorporating them into the evolving document whenever possible. In addition, they worked closely with conference organizers (JP, TG), who provided guidance and ensured that there were no contradictions between statements made in each position paper.

Step 5: Writing the Position Papers

After the comprehensive literature review, the first draft of the consensus document on state of the knowledge was generated. To supplement the literature review performed by the position paper, authors and those associated with the consensus process, an independent senior expert (MM) also performed a literature search. The generated position papers were intended to anchor the consensus process by serving as the templates to frame conversations in each of the 15 workgroups. The format of the position papers consisted of an

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introduction of the theme, an overview of the available literature, a conclusion, and a list of recommendations for practitioners. In addition, gaps in the available evidence were identified during this process.

Step 6: Circulating the Position Papers

The generated document consisting of 15 position papers was sent to leaders and members of each workgroup for review and comments. In addition, the entire document, consisting of the 15 position papers, was posted on the social media website (www.forMD.com) for review by all experts. Although members used email and the forMD website, as they preferred, an advantage of forMD was that new participants could log in and see all discussions before their involvement. Two hundred thirty-six workgroup members used the forMD website.

Step 7: Multiple Revisions of the Draft Document

At this stage, members of workgroups were encouraged to read the posted document and send their comments by whatever means they found convenient. Using a revised Delphi process [1, 7, 12] to achieve consensus, each participant was asked to anonymously comment on the following seven

questions: (1) Are there published articles or bibliographic sources that you believe are important and that have not been included in the literature review? If yes, please list. (2) Do you agree with the main conclusions of the position paper? If no, please explain. (3) Do you agree with the main recommendations of the position paper? If no, please explain. (4) Would you like to add one or more recommendations? If yes, please list. (5) Do you agree with the suggestions for new studies? If no, please explain. (6) Would you suggest one or more study or studies? If yes, please add. (7) Is there one or more specific controversies around the theme addressed by this paper that you would like to highlight or reiterate? If yes, please list.

The numerous comments and suggestions that were generated during these few months were carefully evaluated and implemented into the document. The consensus position papers underwent many revisions during this period. We sought to engage as many workgroup members as possible, as much as possible, to create participant ownership in the position paper recommendations. We also insisted that participants explain their opinions by giving detailed reasons and, when possible, references to the literature. Each member of the workgroup also was encouraged to actively state their agreement with the proposal to avoid

interpreting inactivity and silence as a mistaken agreement.

Step 8: Next Version of the Document Is Circulated Within Workgroups

Step 6 above was repeated here. By iterating drafts of the respective position papers, we were aiming at converging toward consensus within each of the 15 workgroups. The experts were given until 2 weeks before the face-to-face meeting to provide any additional comments or suggestions they had regarding the position papers.

Step 9: Near-final Version of the Document Is Generated

All the comments and suggestions generated as a result of soliciting further input from the members were incorporated into the document until 2 weeks before the meeting in Philadelphia. The near-final document was loaded onto slides in preparation for voting. The draft of the document that would be discussed in the meeting of Philadelphia was emailed to all members in the proceeding days of the face-to-face meeting. An electronic version of the entire document was also placed on flash drives and handed to the members on their arrival to the meeting. All members were encouraged to

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bring personal computers to the meeting.

Step 10: Position Papers Are Discussed Within Workgroups in the Face-to-face Meetings

All participants had been invited to attend the 2-day consensus meeting in Philadelphia in person, if possible. The goals of this conference were (1) to finalize the consensus on each topic through discussion of remaining issues in a face-to-face meeting and (2) to vote on every recommendation in a plenary session using an audience response system that allowed delegates to vote electronically and anonymously.

On the evening before the plenary voting, the workgroups were given the opportunity to come together in a face-to-face meeting for the first time. Using a modified nominal group technique process [4, 5, 19], the workgroups reviewed the document as it stood and discussed any outstanding issues. After the initial meeting, all members came together in a general assembly and presented their recommendations as they would be voted on the following day. Opportunity for discussion by all members was provided at this stage. These two sessions the day before the plenary voting session were designed to bring out any last-minute disagreements.

Step 11: Plenary Vote

The voting session took place on the second day of the meeting. In line with the philosophical underpinnings of the process—egalitarian, inclusive, and participative—an automatic, electronic voting system was used. The voting system allowed all participants to vote, allowed every participant one vote, and allowed the vote to be given anonymously. The voting in this particular case was used to measure the extent of agreement with each of the recommendations and not to make binding resolutions. Also, given that there were 207 resolutions and up to 236 delegates voting on them at any given time, voting was deemed to be a more efficient and accurate way of determining the extent to which the full assembly of delegates agreed or not with each of the recommendations.

The voting was carried out in a large auditorium providing the proper environment to minimize the fatigue and discomfort of an all-day voting session. To minimize tedium and maximize concentration on the task at hand, the working day was broken down into four voting sessions of 2 hours each. The voting session was led by one of us (WCB), whose special expertise is in the development and implementation of consensus processes.

The instructions given to the delegates before the vote were the following:

- We will vote today:
 - on what best practices are (what we know)
 - on what we do not know; and
 - on what we need to do to know more
- There will be no discussion today—only voting (and there will be LOTS of voting)
- Only clarification of language will be allowed before a vote
- If you do not agree with the proposed consensus statement or recommendation, vote accordingly (don't argue it)
- We will use the following definition of consensus:
 - Simple majority: no consensus: 50.01% to 59%
 - Supermajority: weak consensus: 60% (1.5:1) to 65% (1.9:1)
 - Supermajority: consensus: 66% (2:1) to 74% (2.9:1)
 - Supermajority: strong consensus: \geq 75% (3:1 or better)
 - Unanimous: 100%
- We will have time at the end of the day to debrief on the issues that did not gain consensus. Interventions that do not reach consensus will be discussed and revised, if feasible. Repeat voting will be performed if any clarification of a statement was made.
- If strong consensus is achieved, the version of the consensus statements

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and/or recommendations on which vote was taken will be published.

The results presented below describe the voting patterns on each consensus statement. The actual statements and their justification and the evidence and literature used to articulate them are provided (Appendix 1; supplemental materials are available with the online version of CORR[®]).

Step 12: The Final Version of the Document Is Generated

After the meeting in Philadelphia and incorporation of the changes that were generated, the next version of the document was sent to all delegates, including those who could not attend the meeting in person but had been involved in every step of the way. The document was emailed to all by one of us (JP) and members were encouraged to send their comments to him directly so that he could monitor the changes. The intention was to ensure that the questions and recommendations that were voted on did not undergo any changes that may have altered the meaning of what had been voted on by the delegates.

Step 13: Final Document Is Circulated to All

Approximately 2 weeks after the meeting in Philadelphia, the final

document was sent to all delegates who were asked to state their agreement and endorsement of the document. The majority of the delegates provided their endorsement of the final document. A few (minor) comments were provided and incorporated into the document. The final document was created at this point.

Step 14: Dissemination of the Consensus Document

The generated consensus document has been submitted to orthopaedic journals for publication and citation. The involved journals know that the material will be published in more than one journal, and copyright laws are being respected in this publication process. The document has also been posted on numerous websites of various societies. The document is also being translated to various languages and will also be published as an e-book and a paper book. It is our intention to provide this document to all interested parties free of charge and in any form they prefer.

Results

Participants engaged avidly in the process; over the 10-month course of the project, participants exchanged more than 25,000 emails. Two hundred

thirty-six participants signed into the social media website that was made available for this process (www.forMD.com); and 185 of them used the website more than once. There were more than 25,000 page views on the website and 31 discussion forums were spontaneously formed. The process was comprehensive as 3500 different publications were reviewed and cited across all 15 workgroups.

Full consensus was obtained for a large majority of the recommendations across all 15 themes. Using a relative supermajority rule, strong consensus ($\geq 75\%$) was achieved for 195 of the 207 proposed recommendations (94%). Under the same rule, only two recommendations fell below an agreement level of 60%. Using the more stringent absolute supermajority rule, strong consensus was achieved for 115 of the 207 proposed recommendations (56%) and consensus (agreement scores $> 65\%$) in 86% of the recommendations.

The voting results on all 207 consensus statements were ranked by “% of agreement” (Table 1; supplemental materials are available with the online version of CORR[®]); that is, the consensus statements were ranked by the percentage of agreement of the delegates that actually voted. Under this consensus rule, there were 195 of 207 consensus statements (94%) with

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consensus scores of more than 75%, eight statements (4%) that had an agreement score between 66% and 75%; two statements that scored between 60% and 65%; and only two statements (< 1%) that had scores of less than 60% agreement.

The voting results on all 207 consensus statements ranked by “absolute supermajority” (Table 2; supplemental materials are available with the online version of CORR®); that is, the consensus statements were ranked by dividing the number delegates that agreed with the consensus statement by the total number of delegates that were allowed. Under this more stringent consensus rule, there were 115 of 207 consensus statements (56%) with absolute supermajority scores of more than 75%, 62 statements (30%) that had an agreement score of between 66% and 75%, 15 statements (7%) that scored between 60 and 65%; and 15 statements (7%) that had scores of less than 60% agreement.

Discussion and Next Steps

The present consensus report represents the best practice guidelines for PJI consisting of 207 recommendations organized under 15 themes. More than 400 individuals participated in a multistaged consensus process designed to maximize inclusiveness

and participation. Two hundred thirty-six delegates from 52 countries representing 160 different medical institutions voted on those 207 recommendations. This massive and global effort resulted in generating overwhelming support for a large number of recommendations, with 86% of all recommendations reaching a supermajority of 66%. The results of this consensus process represent a significant step toward a better understanding of PJI, the standardization of techniques and adoption of best practices, a more reasoned and cost-effective approach to the management of PJI, and identifying further clinical research to improve patient care.

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