

# 1st EFORT European Consensus “Medical & Scientific Research Requirements for the Clinical Introduction of Artificial Joint Arthroplasty Devices”: Background, Delphi Methodology & Consensus process

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- The objectives of the 1st EFORT European Consensus on ‘Medical and Scientific Research Requirements for the Clinical Introduction of Artificial Joint Arthroplasty Devices’ were foremost to focus on patient safety by establishing performance requirements for medical devices.
- The 1st EFORT European Consensus applied an a priori-defined, modified Delphi methodology to produce unbiased, high-quality recommendation statements, confirmed by consensus voting of a European expert panel.
- Intended key outcomes are practical guidelines justified by the current stage of knowledge and based on a broad European Expert Consensus, to maintain innovation and optimisation of orthopaedic devices within the boundaries of MDR 2017/745.
- Twenty-one main research areas of relevance were defined relying on input from the EFORT IPSI WG1 ‘Introduction of Innovation’ recommendations and a related survey.
- A modified Delphi approach with a preparatory literature review and work in small groups were used to prepare answers to the research questions in the form of 32 draft Consensus statements.

## Keywords

- ▶ 1st EFORT European Consensus
- ▶ modified Delphi approach
- ▶ methodology and process description
- ▶ medical device regulation
- ▶ arthroplasty device registration

- A Consensus Conference in a hybrid format, on-site in the Carl Gustav Carus University of Dresden was organised to further refine the draft statements and define consensus within the complete group of participants by final voting, intended to further quantify expert opinion knowledge.
- The modified Delphi approach provides practical guidelines for hands-on orientation for orthopaedic surgeons, research institutes and laboratories, orthopaedic device manufacturers, patient representatives, Notified Bodies, National Institutes and authorities.
- For the first time, initiated by the EFORT IPSI (WG1 'Introduction of Innovation'), knowledge of all related stakeholders was combined in the 1st EFORT European Consensus to develop guidelines and result in a comprehensive set of recommendations.

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## Introduction

Medical implantable devices provide benefits to patients, while on the other hand may involve potential risks. Thus, the mission for bringing new products on the market must be to protect patients from unsafe products, in balance with a straightforward and transparent introduction in the market, especially of innovative products which can be beneficial to patients (1).

As new medical devices are characterized by a large product heterogeneity as well as a significant diversity of actual innovation level, this can lead to substantial uncertainty about the associated regulatory process of each product. The absence of clear guidelines for evaluating a new product based on its actual level of innovation and product properties leads to uncertainty as to how to present (on the part of the applicant firm) and assess (on the part of the notified body and the clinical study surgeon) the methods and results of the pre-clinical and clinical evaluation (1). This 'regulatory uncertainty' causes a certain discouragement in medical device innovation.

Successful cases of collaboration between manufacturers, academia, health institutions and regulatory agencies for developing advanced medical devices have been reported (2), overcoming obstacles in innovation and enabling focused safety assessment of new devices by coordinated efforts among critical stakeholders. The goal of having safe and well-performing devices can thus be achieved within individual project cooperation, but also by collective participation in scientific activities such as conferences, meetings, etc. to develop practical, multidisciplinary guidelines and recommendations for the safe and efficacious development and introduction of medical devices, such as artificial joint arthroplasty devices.

Barriers to registration and innovation in medical products may be reduced by coordinated activities among key stakeholders, including primarily clinicians, device manufacturers and clinical researchers. But also patient associations, medical societies and regulatory agencies need to commit to working together in a collaborative

approach to ensure the safety and efficacy of devices to improve patient health and quality of life (1).

### Objectives

The objectives of the 1<sup>st</sup> EFORT European Consensus on 'Medical and Scientific Research Requirements for the Clinical Introduction of Artificial Joint Arthroplasty Devices' were foremost to focus on patient safety through performance requirements for medical devices in this specific field. The intended key outcomes are practical guidelines justified by the current stage of knowledge and based on a broad European Expert Consensus, to maintain innovation and optimisation of orthopaedic devices within the boundaries of MDR 2017/745. Open Access practical guidelines based on adequate pre-clinical and clinical evaluation methodologies (state of the art 2021) for the introduction of joint replacements and implant-related instrumentation shall provide hands-on orientation for orthopaedic surgeons, research institutes and laboratories, orthopaedic device manufacturers, Notified Bodies but also for National Institutes and authorities, patient representatives and further stakeholders. To achieve this, a number of questions of importance were defined to be discussed and voted on. The resulting practical guidelines on the identified research topics shall comprise several sections and reflect the consensus of an expert group representing EU, UK, Switzerland and Norway as well as quantify the level of agreement on those results.

## Background

Formal and systematic group consensus processes allow to include a wide range of expert knowledge and experience. They support interaction between participants as well as constructive debate and can prevent the influential authority of one opinion when addressing specific questions where there is insufficient evidence (3).

The methodology of the 1st EFORT European Consensus process was defined a priori to achieve results (recommendations) of high quality, confirm those by

consensus voting of a European expert panel while still allowing for the possibility of not reaching a consensus, which would indicate the further need of research (4). The reporting of this process includes the standard set of quality indicators proposed for the reporting of Delphi studies by Diamond *et al.*, 2014 (4).

*Delphi method*

The 1st EFORT European Consensus applied a mixed methodology to produce unbiased, high-quality recommendation statements and afterwards define consensus amongst participants. A modified Delphi approach plus additional elements such as a preparatory literature review and work in small groups were used in the first phase. Aim was to generate a solid knowledge base also for questions which cannot (currently) be answered by conventional research methods. Where there is uncertainty about a clinical question with conflicting or insufficient scientific evidence, where accurate published guidance is lacking, or where judgemental information is required, scientific evidence needs to be drawn outside the gold standard methods and consensus expert knowledge must be collected in a structured and systematic way. The Delphi method, for congregating knowledge, is characterised by four methodological aspects which enable the involvement of experts with diverse backgrounds and of different geographical locations: (i) a group of experts is questioned about the topic of interest; (ii) the process is anonymous to avoid conformity to a dominant view; (iii) the procedure is iterative in

nature, comprising several rounds and (iv) the design of subsequent rounds is shaped by the group response of the previous round (5, 6). Thus, it emphasizes structured anonymous communication between individuals or small groups who hold expertise on a certain topic with the goal of arriving at a consensus in a broader group. This mode of controlled interaction among experts attempts to avoid the disadvantages associated with more conventional debates, such as round-table discussions (3, 7).

In the practice of the 1st EFORT European Consensus, identified research topics were first allocated to small groups of experts to independently evaluate the available literature, extract the evidence for current practices and identify areas in need of practical expertise. After the first phase, draft consensus statements responding to each question were made available to all participants with the opportunity to study the information in detail and submit qualitative comments to an Editorial Team, which would then be conveyed as a summary to the authors. This was considered the first Delphi survey round with the second phase including another, more open round of feedback (6).

The core process of the 1st EFORT European Consensus follows the steps detailed in the graphic below (Fig. 1).

*Survey as an additional preparatory stage to the process*

As an additional, preparatory step, a preliminary survey was initiated by the chairs of the EFORT Implant and Patient Safety (IPSI) working group (WG1): ‘Introduction of innovations in artificial joint arthroplasty’ and conducted



**Figure 1**  
 Graphical overview about the main steps of the 1st EFORT European Consensus.

in parallel to the first feedback round of Recommendations from WG1 on ‘Introduction of innovations in artificial joint arthroplasty’ (8). The electronic survey included 12 questions and was sent in October 2020 in a blind fashion to all EFORT National Member Societies ( $n=75$ ; i.e. Presidents, Vice-Presidents, Secretary, Office), EFORT speciality Societies ( $n=3$ ) and the participants of the IPSI inauguration workshop in Brussels ( $n=27$ ) as well as to further stakeholders entitled to give feedback on the Recommendations WG1. The survey questions were developed according to previous topics of discussion in the workshop regarding the introduction of new arthroplasty devices in clinical practice. A cover letter on behalf of the chairs (SO, TGR) which accompanied the survey stated its purpose and ensured anonymity. There was no obligation to participate. The survey was sent out and responses were collected until October 19, 2020. The aim of the survey was to obtain an overview of current opinions and mindsets in relation to IPSI, as well as the clinical introduction of medical devices under the Medical Device Regulation. The results were presented at the 1st EFORT Virtual Congress (Oct 28–30, 2020) and served as input for the definition of focus areas and specification of related research questions for the 1st EFORT European Consensus.

## Consensus process and methodology

### Organisational structure and first stages

The 1st EFORT European Consensus Scientific Committee was formed in February 2020, including clinicians, researchers and medical device manufacturer

representatives. It was chaired by the convenors of the EFORT IPSI WG1 (SO, TGR) and consisted of 11 members from 10 countries (AB, LC, EGR, AG, BG, DJ, MJ, PM, FS). The following European, National or International speciality societies were represented by the members of the Scientific Committee (Table 1).

The Scientific Committee’s tasks were the definition and organisation of the consensus process steps, the definition and decision on the research areas and questions, the appointment of experts and the handling of the decisions in an independent way. In addition, an Editorial team (Sabrina Marchal, Sabine Rusch, Ronja A Schierjott) was established to handle administrative work, assist the Scientific Committee and act as a central point of contact from the EFORT bureau for all participants.

In a meeting of the Scientific Committee on December 18, 2020, a decision for a timeline and all associated process steps was made (Fig. 2).

### Research questions

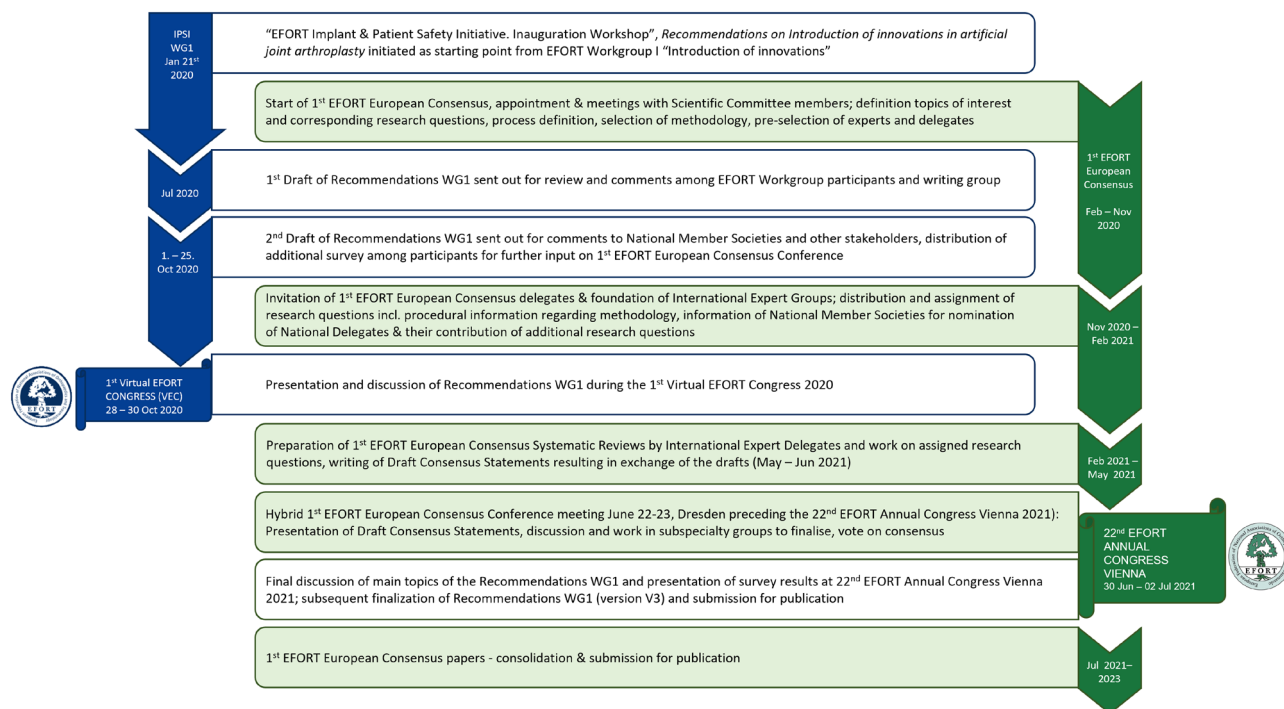
Twenty-one research areas of relevance (e.g. pre-clinical methods, mechanical component testing, evaluation of instruments and usability, short-term postoperative adverse events, pre-CE studies) were defined relying on input from the EFORT IPSI Workshop Recommendations WG1 ‘Introduction of innovations in artificial joint arthroplasty’ and the results of the related survey (8). After contribution, review and discussion from the Scientific Committee and the EFORT National Member Societies which took part in the survey, 40 research questions of major interest were identified to be addressed and answered by expert teams. The complete list of research questions can be found in section VII.

### Appointment of experts

Sixty-two international expert delegates from 13 European countries were proposed and appointed by the Scientific Committee to form the expert groups and were allocated to address the 40 research questions (Scientific Committee Meeting January 18, 2021). The experts represented orthopaedic surgeons, researchers with clinical, biomedical, biomechanical or biomaterials background, experts from medical device industry (areas research & development, regulatory & medical scientific affairs), Notified Bodies, joint registries and EU scrutiny board members. The composition of the group was considered important to achieve high-quality recommendations, provide thorough expertise and, finally, lend appropriate weight to the consensus agreement and vote (3). Criteria for the selection were as follows: Participants should be experts and have credibility in the appropriate field providing validity and support dissemination of consensus results. There was no financial compensation for any participants; therefore, only motivated individuals

**Table 1** Medical and Scientific Research Societies represented by members of the 1st EFORT European Consensus Scientific Committee.

Medical and Scientific Research Societies	Society Member represented in the Scientific Committee
European Federation of National Associations of Orthopaedics and Traumatology (EFORT)	SO
European Orthopaedic Research Society (EORS)	AB, BG, EGR, TGR, LC
European Society of Biomechanics (ESB)	LC, DJ, TGR
European Hip Society (EHS)	EGR, SO, DJ
European Knee Society (EKS)	PM,
International Combined Orthopaedic Research Society (ICORS)	AB, BG, TGR
Orthopaedic Research Society (ORS)	DJ, TGR
Société Française de Chirurgie Orthopédique et Traumatologique (SOFOT)	PM
Deutsche Gesellschaft für Orthopädie & Unfallchirurgie (DGOU)	MJ, TGR
Österreichische Gesellschaft für Orthopädie & Unfallchirurgie (ÖGOuT)	AG
Nederlandse Orthopaedische Vereniging (NOV)	DJ
International Society for Technology in Arthroplasty (ISTA)	DJ
Virtual Physiological Human Institute for Integrative Biomedical Research (VPHi)	LC



**Figure 2**

Overview of key tasks and major steps in preparation of the 1st EFORT European Consensus on Medical and Scientific Research Requirements for the clinical introduction of artificial joint arthroplasty devices (green) and interaction with the ‘EFORT Recommendations WG1 on Introduction of innovations in artificial joint arthroplasty’ (blue).

took part. Participants with different backgrounds were proposed to provide more integrity to the methodology and achieve a more robust, universal outcome through heterogeneity (3).

**Process part 1: draft consensus statements (modified Delphi approach)**

In the first phase, the appointed International Expert Delegates of the clinical and pre-clinical groups as well as EFORT National Delegates from the National Member Societies were invited and offered the chance to participate in the EFORT European Consensus. Those participants who accepted the call were then assigned research questions to be addressed based on their specific area of expertise and were informed about their group members. For each of the 37 working groups consisting of between three and seven experts, one coordinator was named, who was responsible for the organisation of the task and for completing their subspecialty’s consensus questions. All participants were informed about the process, the expectations and the objectives by means of detailed information material. Process guidelines, a step-by-step methodology as well as templates for the preparation of the Draft Statements addressing the research questions were provided.

*Systematic review and preparation in the expert working groups*

The process should be as evidence-based as possible. Although group consensus participants were recruited on the basis, that they have superior knowledge of the published literature in the field, it was thought essential to supplement the process with up-to-date literature. The amount of information from literature pertaining to the different research questions varies from no information, because the available evidence is weak, to a comprehensive synthesis of relevant research, when there is abundant information in literature but no consensus. Each expert group was therefore expected to perform a systematic review of the specific literature basis as a preliminary step for the preparation of their draft consensus statement. The identified information was to be included in the answer to the research question to provide a solid basis and allow to assess the level of evidence related to each ‘recommendation’ by future readers (Fig. 3).

The collaboration and preparation of the draft consensus statements by each working group mostly took part through multiple video calls and review/feedback rounds due to the various geographical locations. The experts had the opportunity to direct questions regarding the process or the format to the Editorial Team and thus, the chairs and Scientific Committee at all times

or request clarification or modification of the research question itself. The expert groups were dedicated to work on the draft consensus statements from February to May 2021 and to integrate incoming feedback until the Consensus Conference (deadline June 21, 2021). The short papers (draft consensus statements, 3–4 pages) were then submitted to the Editorial Team for review and countercheck in regard to their recommendation, format and level of evidence. Where modifications were required, those were requested from the authors.

## Process part 2: 1st EFORT European consensus conference and voting procedure

### Consensus conference

In the second phase, a Consensus Conference was organised to further refine the Draft Statements and define consensus within the complete group of participants. A final vote determining percent agreement (e.g. 81%) amongst participants was intended to further quantify expert opinion knowledge. In a 2-day meeting, the complete Consensus Conference, that is, the expert panel consisting of the international experts plus a broader community of stakeholders would hear the scientific data presented by the experts as well as ad-hoc comments in a plenary session followed by discussion. In practice, the draft consensus statements prepared within the first phase were presented and were subject to discussion, review and comment by conference attendees. Two moderators (SO, TGR) were responsible for guiding and controlling the procedure as well as helping to reach an agreement on topics where the experts differed in their opinion. Following the discussion, the Conference had the chance to demand modification of the Statements, if appropriate. The chosen format allows the participation of the audience (participants) in an open meeting and allows

to ask questions to the experts or demand clarification (3). In a next-day session, all Consensus Statements were again recalled one after another, changes made the previous day were again highlighted and each Statement was voted on anonymously by the complete audience of stakeholders.

The Scientific Committee, 62 international expert delegates from 13 countries, plus 42 National Societies and 3 Speciality Societies members took part in the 2-day meeting to finalise the Consensus Statements by means of review and discussion and finally vote for Consensus (Fig. 4). The meeting took place in a hybrid format, on-site in the Carl Gustav Carus University of Dresden, Germany with also the option of virtual participation (via MS Teams dial-in link) on the 22nd/23rd June 2021 to allow for broad participation also in times of the COVID-19 pandemic travel restrictions.

### Tuesday, 22 June 2021

The 1st EFFORT European Consensus was introduced and opened by the EFORT President Klaus-Peter Günther and the sessions were chaired and moderated by the convenors of the IPSI WG 1 (SO, TGR). The agenda consisted of the presentation and discussions of all prepared Consensus Statements. Each expert team coordinator or one of the team members briefly presented their research question ( $n=36$ ). A time slot of 10 min was allocated for each question: 3 min to present the topic (maximum 4–5 slides) while the remaining 7 min were used for discussion. As mentioned, there was the chance to modify the consensus statements in specific points, if appropriate and consented by the expert panel. All changes were documented during the Conference, the sessions were also recorded for later verification of discussion points.

### Wednesday, 23 June 2021

All Consensus Statements were again recalled, pointing out any changes agreed on during the previous day. Each Statement was then voted on anonymously (agree/disagree/abstain) by the complete audience of stakeholders. The definition for consensus within the 1st EFORT European Consensus was conceptualised by pre-defining cut-off values for (non)-consensus based on the percentage of agreement. Those values were oriented on Cats-Baril *et al.*, 2013 (9) and their adaptations during the II. International Consensus on Periprosthetic Joint Infection in Philadelphia 2018 (10) (Fig. 5). This means consensus was not defined as a full agreement among the participants but the percent agreement, allowing also for disagreement, was determined. A 2:1 majority, however, was determined as an established consensus.

In the morning, the chairs of IPSI WG1 explained the voting process. Based on the discussions from the previous day, each research question and its conclusion

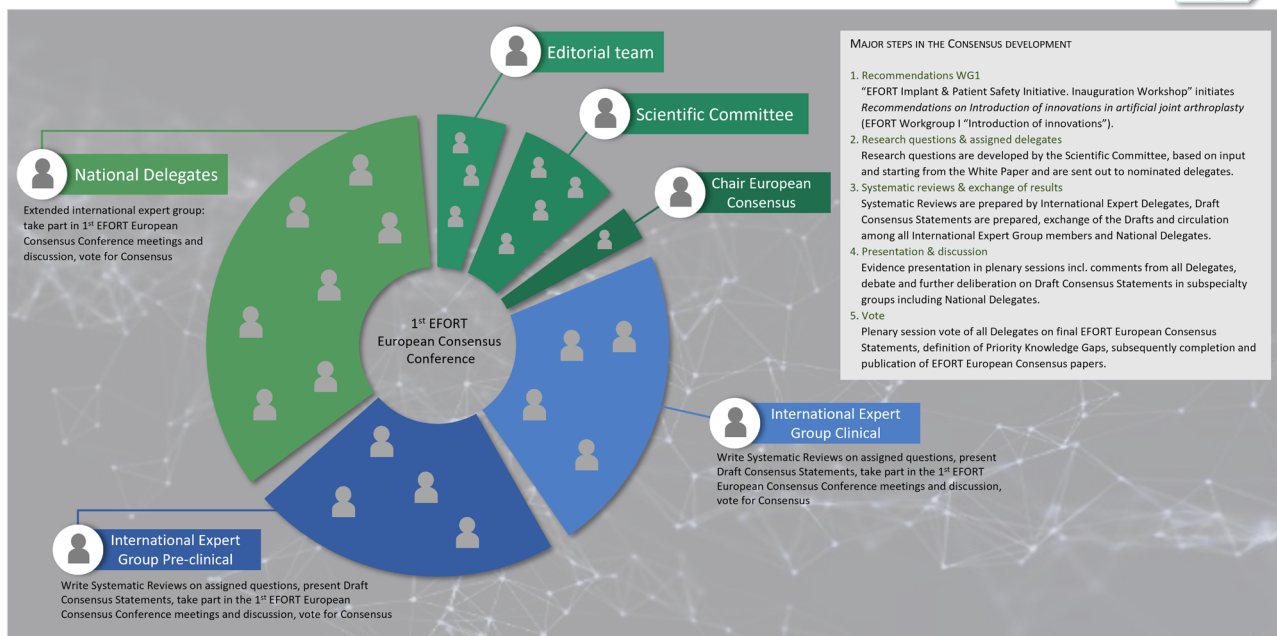
Quality +	Very High	High	Moderate
Quality o	High	Moderate	Limited
Quality -	Moderate	Limited	Low
Quantity +	Quantity o	Quantity -	Quantity -

**Figure 3**

Assessment of the level of evidence related to each ‘recommendation’.

# 1<sup>ST</sup> EFORT EUROPEAN CONSENSUS

on Medical & Scientific Research Requirements for the clinical introduction of orthopaedic joint replacement devices



**Figure 4** Plenary structure and responsibilities during the 1st EFORT European Consensus Conference.

were briefly displayed on a screen and presented by the chairs along with a link for virtual real-time voting (1 link per question). Voting for each Consensus Statement was based, however, on the complete consensus paper of each question. Voting results for each question were shown electronically immediately after each vote was taken. For participants who were not able to attend the voting day

session, there was the possibility to transfer their vote to another participant who would act as their elected, trusted proxy.

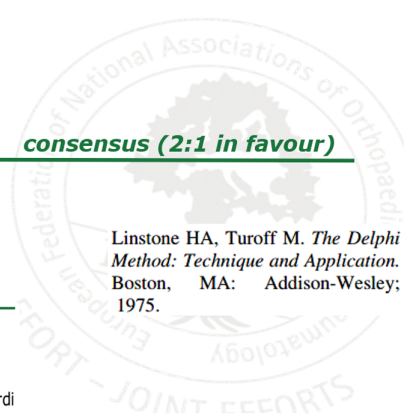
### Consolidation of results

After the conference, exemplary results were presented at the 22nd EFORT Annual Congress on June 30, 2021, and all

**In the spirit of the consensus process according to the Delphi method, the following definition of consensus levels have been agreed by the Scientific Committee and have been used for the plenary delegate vote.**

Delegates Vote	Level
95% to 100%	<i>unanimous, strongest consensus</i>
75% to 94%	<i>super majority, strong consensus</i>
66% to 74%	<i>two-third majority, consensus</i>
60% to 65%	<i>majority, weak consensus</i>
50.1% to 59%	<i>simple majority, no consensus</i>
0% to 50%	<i>no majority</i>

**consensus (2:1 in favour)**



Linstone HA, Turoff M. *The Delphi Method: Technique and Application*. Boston, MA: Addison-Wesley; 1975.

Plenary Delegate Vote

**Chairs:**  
 Søren Overgaard & Thomas M. Grupp

**Scientific Committee:**  
 Ashley Blom  
 Luca Cristofolini  
 Eduardo Garcia-Rey

Alexander Giurea  
 Bernd Grimm  
 Marcus Jäger

Dennis Janssen  
 Philippe Massin  
 Francesco Siccardi

**Figure 5** Definition on 1st EFORT European Consensus levels according to Cats-Baril *et al.* 2013 (9).

authors were asked to finalise their Consensus Statements according to the pre-defined format template. If minor modifications were agreed upon during the conference discussion, authors were requested to incorporate those into the final documents and the results were again reviewed by the Scientific Committee members and the Editorial Team to determine, whether the changes reflected the decision during the conference. The final Consensus Statement papers were then consolidated and published online Open Access to provide easily accessible direction and guidance for clinicians, researchers, manufacturers, Notified Bodies, EU scrutiny board members and European & national authorities.

### Consensus outcome and results

From the 40 research questions assigned to Expert delegates, 37 draft consensus statements were received (92.5 %). There had been no pre-defined criteria to be used to determine which items to drop. However, one Statement was afterwards withdrawn during the Conference by agreement of the Scientific Committee members, as it did not meet the requirements for discussion and voting. Three questions were not addressed in the first place due to organisational complications in the allocation of experts. The experts had been free to combine sub-questions or also slightly reformulate or modify the questions based on their specific expertise, knowledge and findings during the process. Draft consensus statements were made available online during May and June 2021 on the EFORT website. All participants were then informed and provided with the access information to be able to review and give feedback.

### Discussion and conclusion

For the first time, knowledge of all related stakeholders within the field of implantable orthopaedic devices was combined to develop guidelines and recommendations. It was initiated by the EFORT IPSI (WG1 'Introduction of Innovation') and this international, Europe-based consensus process resulted in a comprehensive set of recommendations on 'Medical and Scientific Research Requirements for the Clinical Introduction of Artificial Joint Arthroplasty Devices'.

Of the 32 research areas with 36 items included in the final recommendations for voting, 22 reached a unanimous vote with the strongest consensus ( $\geq 95\%$ ) and 14 achieved a super majority with a strong consensus ( $\geq 75\%$ ). An overview of the detailed voting results for each of the 32 research areas are presented in the [supplementary materials](#) (see section on [Supplementary materials](#) provided at the end of this article).

The advantages and strengths of this process are considered the robust mix of practising physicians,

researchers, experts from manufacturers, Notified Bodies & implant registries, patient representatives and EU scrutiny board members to come together and jointly evaluate this complex topic (3). In the process, the inclusion of experts from across Europe and their congregated, interdisciplinary discussion and collaboration to include different points of views and foster solid results which consider the interests of different groups of stakeholders, are one of the major strengths of this project. Furthermore, all 42 EFORT National Societies as well as 3 Speciality Societies were involved in the process. Due to the COVID-19 pandemic, the use of modern means of communication and conference methods allowed the inclusion and participation of geographically dispersed panellists while on the other hand not allowing for face-to-face meetings. The process as such did not lead to a forced consensus among all participants but the result allows also conflicting views, which indicates topics where further work or discussion is necessary. Transparency of the process, the obtained results and subsequent publication led to reproducible and strong results. Proposed key methodologic criteria to report in publications of Delphi studies (4) were included in this paper to allow for transparency of the approach.

#### *Limitations*

Modifications from the formal Delphi method were made. There is no standard definition as to what a 'modified Delphi approach' exactly entails (6). Since a range of methodological variations does exist in the application of the Delphi technique, the use of the term is critically reconsidered. In this context, the process tried to incorporate the most valuable features of the method while including also further steps to add quality to the content and the result by introducing more open discussion. The mixed methods approach tried to include advantages of different approaches, that is, detailed, focused work in the first phase, anonymous feedback possibility as well as broad, open discussion to include different points of view in the second phase. Further changes to the traditional approach were that only one round was included and that the work was done by small expert groups, not individuals. The research topics were also defined by the Scientific Committee based on the survey and the IPSI workshops but not elaborated by all participating experts in iterating rounds. A possible bias in the selection of experts, as those were recommended by the Scientific Committee, might be included; however, due to the diversity of the Scientific Committee, this may be mitigated to a certain extent. The task required a lot of time from the participants and considering their occupation, it may not have been enough time. Yet, the process was constantly accompanied by the chairs and Scientific Committee to activate and support



the participants. One missed opportunity may be that currently no future research topics were defined from the results and the further proceedings of the Consensus (frequency of update, inclusion of further fields of interest, for example, devices for spine and trauma surgery) have not yet been elaborated.

Where recommendations are based on expert knowledge rather than empirical data, it is necessary to further interpret and review them in the light of possibly emerging evidence. To a great deal, the results are about trust in the specific knowledge and long-term experiences of the international expert delegates.

## Perspective

The process has shown that there is a need for an alternative or complementary view of evidence-based methods which highlight the value of expert knowledge, including implicit knowledge, for example, based on clinical and practical expertise, that may not directly be accessible through clinical trials or published literature. However, this requires that the choice of the methodology for the systematic collection of such knowledge, the incorporation of actually existing evidence and the building of a consensus needs to be well considered. This 1st EFORT European Consensus on 'Medical and Scientific Research Requirements for the Clinical Introduction of Artificial Joint Arthroplasty Devices' is considered a suitable and well-prepared fundament to start with. It achieved practical guidelines for the pre-clinical testing and clinical introduction of orthopaedic joint replacement (implants as well as related instruments) to act as an orientation for surgeons, research institutes and laboratories, orthopaedic device manufacturers, authorities, Notified Bodies, EU scrutiny board members and patient representatives.

Due to the absence of definitive evidence and product-specific guidance in this area, final recommendations based on literature and expert consensus provide a first, useful resource for helping to guide decision-making for stakeholders in the clinical introduction of artificial joint arthroplasty devices. However, these recommendations will need to be interpreted and reviewed as necessary considering new evidence in a period of 4 to 5 years.

### Supplementary materials

This is linked to the online version of the paper at <https://doi.org/10.1530/EOR-23-0054>.

### ICMJE conflict of interest statement

SO is a board member and Scientific Chair of EFORT and also a chair of the EFORT Implant and Patient Safety Initiative (IPSI) WG 1 'Introduction of innovation'. TGR is a chair of the EFORT Implant and Patient Safety Initiative

(IPSI) WG 1 "Introduction of innovation". TGR, PM, AB, EGR, LC, DJ, BG, AG, MJ, FS and SO are Scientific Committee members of the 1st EFORT European Consensus. TGR and SR are employees of Aesculap AG Tuttlingen. FS is share holder and CEO of Medacta International SA, Castel San Pietro. SO, TGR and SR all received logistic help and staff support for organization of the consensus conference from EFORT and support from the Medical Faculty at the University of Dresden for infrastructure (room and audio-visual cost, staff support) for the organization of the consensus conference (unrestricted educational grants). The authors declare no conflict of interest relevant to this work.

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