American Association of Endodontists & Foundation for Endodontics Request for Applications (RFA)

DELPHI survey to identify a Core Outcomes Set (COS) in Nonsurgical Endodontic Treatment, Retreatment, Apexification, Vital Pulp Therapy, Regenerative Endodontic Therapy and Surgical Endodontics

Submission Deadline: April 1, 2023
Earliest Award Date: July 1, 2023

Purpose

The American Association of Endodontists (AAE) and Foundation for Endodontics (The Foundation) seek applications that will investigate which outcomes of endodontic management of pulpal and associated periapical diseases should be included in future studies. The intent of these applications will be to use previously published scoping reviews to generate core outcome sets (COS) for endodontic treatment. The intent for this process is to follow the iterative interactive communication process with all stakeholders, commonly referred to as the Delphi approach.

Background

AAE and the Foundation recognize the significant advances in the contemporary practice of endodontics and strive to promote evidence-based practices to achieve optimal health outcomes. The AAE and Foundation also recognize that the determination of outcomes is an effort underway in many health fields, including endodontics (Kenny et al., 2018, Duncan et al., 2021, El-Karim et al., 2021, Cushley et al., 2022, Kirkevang et al., 2022, Shah et al., 2022). As such, the AAE Board of Directors has identified the need to reach consensus on the optimal types of clinical outcomes for endodontic procedures.

AAE and the Foundation will pursue the approach used by the Core Outcome Measures in Effectiveness Trials (COMET) Initiative (http://www.comet-initiative.org/). This approach proposes the development of standardized methods for measuring outcomes, using a process known as “core outcome sets” (COS). This approach generally relies on the development of a scoping review of all previously reported relevant clinical outcomes, as an initial step in the process. This phase of the project was completed in June 2021 (Azarpazhooh et al., 2021, Azarpazhooh et al., 2021, Azarpazhooh et al., 2022).

Phase Two

AAE and the Foundation are inviting applications to conduct an iterative study in which key stakeholders are repeatedly surveyed and interviewed regarding a hierarchy of the identified outcomes, in order to reach the COS. The investigation should address outcomes for the management by type of disease (i.e., pulpal disease vs. periapical disease) as well as the outcomes of specific interventions used to address those pulpal and periapical diseases.

This RFA is for applicants to conduct a systematic and qualitative method of collecting opinions from stakeholder groups (at minimum, practicing endodontists and general dentists, patients, researchers, and educators, but may include other stakeholder groups) through several rounds (2-3) of questions to achieve a consensus on the standardization of methodology and study variables that should be included in published outcome studies related to the treatment of pulpal and periapical diseases in the permanent

dentition. The Delphi study might be conducted as a single or multiple-stage process, depending on the disease or treatment rendered.

Stakeholder participation shall require disclosures of potential conflicts of interest, and the application shall include a plan for management of conflict of interest at each step of the Delphi process.

The investigators conducting the Delphi process should be balanced in terms of skills, knowledge, and experience. Additionally, the Delphi study should include an educational session for participants, describing the online Delphi process and the participants' role in building consensus.

Eligibility Requirements

Proposals may be submitted by U.S. and international public and private persons and organizations, including universities, colleges, hospitals, laboratories, units of State/Province and local governments, consultants, private researchers, and eligible agencies of the U.S. federal government. Any international application should include a co-Principal Investigator based in a U.S. institution. Investigators are encouraged to seek collaboration with evidence-based methodologists.

Funds Available

The total funding available for this RFA is up to $100,000. Direct costs that will be funded include salaries, fringe benefits, consultants, and literature access fees. Indirect costs, commonly referred to as facilities and administration costs, will not be funded.

The total project period for each application submitted in response to this RFA may not exceed eight months.

Mechanisms of Support

AAE and the Foundation intend to support successful grants(s) responding to this RFA beginning in July 2023. Research grants will be awarded to the Principal Investigator (PI) and the Co-Principal Investigator (Co-PI) institutions. Responsibility for the planning, direction, and execution of the proposed project will be solely that of the applicants. Grant awards will be contingent on the receipt of applications that are responsive to this RFA.

The AAE and Foundation may not support any proposal if the applications are not responsive to the purpose of this RFA or do not have sufficient scientific merit to warrant funding. Based on programmatic and scientific review, AAE and the Foundation also reserve the right to fund applications either in part or in whole.

Proposals involving investigators from different institutions are acceptable. Each collaborating institution in a multi-institutional application must specify a Co-PI; Co-PIs will only be allowed when applications involve more than one institution. Successful applications that involve more than one institution will be funded by separate awards made directly from the AAE to each Co-PI's institution.

Research Objectives

The overall objective of the RFA is to identify and prioritize core outcome measures to guide future research methodologies and study variables in nonsurgical root canal treatment, retreatment, apexification, regenerative endodontic procedures, vital pulp therapy, and surgical endodontics, classified by domains according to those published in Dodd, et. al., J. Clin. Epidemiol 2018. The Delphi process should produce a core set of outcomes, classified by domains.

Outcomes for nonsurgical root canal treatment, retreatment, apexification, surgical endodontic treatment, vital pulp therapy, and regenerative endodontic therapy should include, but are not limited to, the work of Azarpazhooh et al., 2022, Cushley et al., 2022 (1 and 2), Kirkevang et al., 2022, and Shah et al., 2022.

The focus should be on narrowing the list of outcomes to a smaller set with full engagement of all stakeholders. Outcomes should be sorted by priority within their respective domains, and justification should be provided for the prioritization. The outcomes taxonomy used in the Dodd et al, J Clin Epidemiol 2018 article is preferred.

The application should describe details of the methodology to be used in performing the Delphi study. The standards for development of the Core Outcomes Set, as defined by Kirkham et al., PLoS Med 2017 should be followed.

The number of participants and details of their constituencies and methods of recruitment should be described. The sample size of participants in each constituency should be defined based on an appropriate statistical representation of the stakeholders.

The threshold for consensus among participants must be predefined and justified in the application for each iteration of the Delphi process. The process itself must be anonymous to guarantee independent representation and prevent undue influence and coercion.

The methodology outlined in the application must follow the Guidance on Conducting and REporting DElphi Studies (CREDES) published by Jünger et al., Palliative Med 2017, and outlined in the list below:

Rationale for the choice of the Delphi technique

1. *Justification.* The choice of the Delphi technique as a method of systematically collating expert consultation and building consensus needs to be well justified. When selecting the method to answer a particular research question, it is important to keep in mind its constructivist nature

Planning and design

2. *Planning and process.* The Delphi technique is a flexible method and can be adjusted to the respective research aims and purposes. Any modifications should be justified by a rationale and be applied systematically and rigorously
3. *Definition of consensus.* Unless not reasonable due to the explorative nature of the study, an a priori criterion for consensus should be defined. This includes a clear and transparent guide for action on (a) how to proceed with certain items or topics in the next survey round, (b) the required threshold to terminate the Delphi process and (c) procedures to be followed when consensus is (not) reached after one or more iterations

Study conduct

4. *Informational input.* All material provided to the expert panel at the outset of the project and throughout the Delphi process should be carefully reviewed and piloted in advance in order to examine the effect on experts' judgements and to prevent bias
5. *Prevention of bias.* Researchers need to take measures to avoid directly or indirectly influencing the experts' judgements. If one or more members of the research team have a conflict of interest, entrusting an independent researcher with the main coordination of the Delphi study is advisable
6. *Interpretation and processing of results.* Consensus does not necessarily imply the 'correct' answer or judgement; (non)consensus and stable disagreement provide informative insights and highlight differences in perspectives concerning the topic in question

7. *External validation.* It is recommended to have the final draft of the resulting guidance on best practice in palliative care reviewed and approved by an external board or authority before publication and dissemination

Reporting

8. *Purpose and rationale.* The purpose of the study should be clearly defined and demonstrate the appropriateness of the use of the Delphi technique as a method to achieve the research aim. A rationale for the choice of the Delphi technique as the most suitable method needs to be provided
9. *Expert panel.* Criteria for the selection of experts and transparent information on recruitment of the expert panel, socio-demographic details including information on expertise regarding the topic in question, (non)response and response rates over the ongoing iterations should be reported
10. *Description of the methods.* The methods employed need to be comprehensible; this includes information on preparatory steps (How was available evidence on the topic in question synthesized?), piloting of material and survey instruments, design of the survey instrument(s), the number and design of survey rounds, methods of data analysis, processing and synthesis of experts' responses to inform the subsequent survey round and methodological decisions taken by the research team throughout the process
11. *Procedure.* Flow chart to illustrate the stages of the Delphi process, including a preparatory phase, the actual 'Delphi rounds,' interim steps of data processing and analysis, and concluding steps
12. *Definition and attainment of consensus.* It needs to be comprehensible to the reader how consensus was achieved throughout the process, including strategies to deal with non-consensus
13. *Results.* Reporting of results for each round separately is highly advisable in order to make the evolving of consensus over the rounds transparent. This includes figures showing the average group response, changes between rounds, as well as any modifications of the survey instrument such as deletion, addition or modification of survey items based on previous rounds
14. *Discussion of limitations.* Reporting should include a critical reflection of potential limitations and their impact of the resulting guidance
15. *Adequacy of conclusions.* The conclusions should adequately reflect the outcomes of the Delphi study with a view to the scope and applicability of the resulting practice guidance
16. *Publication and dissemination.* The resulting guidance on good practice in palliative care should be clearly identifiable from the publication, including recommendations for transfer into practice and implementation. If the publication does not allow for a detailed presentation of either the resulting practice guidance or the methodological features of the applied Delphi technique, or both, reference to a more detailed presentation elsewhere should be made (e.g. availability of the full guideline from the authors or online; publication of a separate paper reporting on methodological details and particularities of the process (e.g. persistent disagreement and controversy on certain issues)). A dissemination plan should include endorsement of the guidance by professional associations and health care authorities to facilitate implementation

The study duration should be up to 8 months. The final product must include a manuscript of the iterative process, ready for submission to the Journal of Endodontics (JOE) including the comprehensive listing of outcomes with prioritization, in the different domains with study characteristics. This manuscript must be submitted to the JOE for publication; the JOE retains first right of refusal on all submissions.

Application Contents

The proposal may be up to twelve pages in length and must consist of each of the following elements formatted in 11-point font with one-inch margins. Pages for the appendices listed below will not count toward the twelve-page total limit:

1. **Request for Application Form for each Applicant Institution (APPENDIX A)**

2. **Abstract of proposed Delphi process (300-word limit)**

3. **Introduction**
   Introduce the application including specific aims, definition, and justification of the proposed approach.

4. **Budget (Appendix B)**
   Applications that are received from a single institution and multiple institutions must contain 1) an overall budget for the entire application, and 2) detailed budgets and justification from each collaborating institution. The applications must also indicate if other funding has been received or applied for, and if so, in what amount.
   Co-PIs will only be allowed when applications involve more than one institution; each collaborating institution must specify a Co-PI.
   The following costs should be included in a detailed budget:

   - PI and Co-PI and other personnel costs including:
     - Co-Investigators
     - Research coordinator(s)/consultant(s)
   - Database management
   - Costs for training and calibration of study personnel and costs for quality control monitoring for data collection, data entry and adherence to study protocol
   - Online survey tools and data security expenses.

5. **Biographical sketches of PI, Co-PIs, and key personnel, using the template provided (Appendix C).**
   If a multi-center project is proposed, each center must have a Co-PI. At least one PI or a Co-PI must be U.S.- based. A contact PI must be identified as a single point of contact between the sponsoring organization and the investigative team. The relevant experience and training of the key personnel in conducting similar studies should be highlighted in the biographical sketch and reprints of their relevant publications should be included in the Appendix.

6. **Study Methodology**
   Describe the design, pilot projects or other activities, to implement the Delphi process and any evaluations used to demonstrate the effectiveness of the desired outcomes set. Describe the study samples/population, methodology, experimental format, and research timeline. Include techniques to be used, selection of sample and use of human subjects. Include information on how the sample size was determined.\

7. **Methods for analyzing findings and accounting for heterogeneity**
   Describe methods used to analyze the information elicited by the Delphi process. Provide detailed statistical methodology: including data collection and analysis, power analysis (when indicated), description of statistical tests and the reasons for their selection.

8. **Knowledge and evidence gaps:**
   Describe the most important knowledge gaps/areas of needed research that you have identified as needed or recommended to complete this work. Prioritize these gaps as appropriate.

9. **Resources and Environment**
   Describe the clinical or analytic facilities available for the research.

10. **Time Schedule for Research**
    Provide the approximate dates of the project's duration. The study duration is up to 8 months.

11. **Proof of initial application for IRB approval.**

12. **Conflict of Interest Declaration.**
    Applications will not be considered or receive scientific review without this document. Please see **Appendix D,** print, and have all research participants sign. All investigators must disclose any conflict of interest that they might have with respect to any grant. Having an interest in a product, service, course, or company does not necessarily impact an applicant's status. Applicants should exercise particular care that no detriment to the American Association of Endodontists or the Foundation for Endodontics will result from conflicts between self-interest and those of the Foundation or AAE. Any potential or real conflict of interest (see below) should be disclosed, and the project should be independent of any self-interest.

Applications should be sent via email to advocacy@aae.org. Sign the application form, which can be scanned and included with your proposal as a PDF file. Applicants are notified that their proposal was received.

Chair, Special Committee to Develop an Outcomes Consensus Conference

c/o Assistant Executive Director for Advocacy & Professional Affairs

via email to: advocacy@aae.org

Proposals must be received by April 1, 2023. If a proposal is received after that date, it will be returned without review.

Review Process

Proposals will be reviewed for responsiveness to the requirements of this RFA by the Special Committee on Outcomes Consensus along with representatives of the AAE Research and Scientific Affairs Committee. Consultants in clinical research and others as appropriate may be included in the review process. Incomplete and/or non-responsive proposals will be returned to applicants without further consideration. All responsive proposals will undergo full committee review using the review criteria given in this RFA. All applications will be reviewed, scored, and ranked, and a recommendation will be made for funding. Reviews along with the committee's funding recommendation will be forwarded to presidents of the AAE and the Foundation, for final approval. Committee members are excluded from the review process of any application with which they may have a conflict of interest.

Review Criteria

The reviewers will evaluate the applications in the following areas to determine merit for possible funding.

Proposals shall first be evaluated from a methodological standpoint based on the technical proposal and the scientific evaluation criteria defined below without regard to proposed budget. For those proposals determined to be scientifically acceptable, the budget will be evaluated.

Applications will be evaluated based on:

1. **Approach**
    a. The understanding of the project goals, and on the approach the applicant proposes to conduct the Delphi process.
    b. The approach used for statistical analysis.
    c. The process by which the applicant will translate the results of the data analysis into a Core Outcomes Set (COS).
    d. The outline of the final report.
2. **Past Performance** (include a list of publications and funding history as appropriate)
    a. The applicant's and co-applicants' experience in conducting work in the content area.
    b. An assessment of the applicants' experience of completing similar scopes of work within a similar time frame.
3. **PI (and Consultant(s)/Staff, if any) Capabilities**
    a. The qualifications and experiences of key person(s) who will be working on this project and associated project role(s) and responsibilities.
    b. An assessment of the person(s) to complete the scope work in the prescribed time frame.
4. **Production of a timeline outlining completion dates of interim deliverables to assure completion of the project by the timeframe proposed.**

Award Criteria

The earliest anticipated date of award is July 1, 2023. Applicants should be aware that, in addition to scientific merit, the total cost of the proposed project and the availability of funds will be considered by the AAE in making funding decisions. In circumstances in which proposals have similar scientific merit, but vary in cost-competitiveness, the AAE will likely fund the more cost-effective proposal.

Reporting and Funding Milestones

Progress reports shall be reported at project milestones. Continued funding will be based on the timely submission and approval of these reports:

- Study initiation, including final IRB approval: 25% of funding
- Completion of Delphi process: 25% of funding
- Completion of project and submission of a final report and a manuscript for publication in the JOE: 50% of funding.

The reports must contain the following information:

- Research Progress – a summary of the overall status of the project should be given.
- Budget - budget reports should specify actual expenditures to date.
- Future plans – future plans should be summarized. Changes or modifications to the original research plan or approach that are needed to address unforeseen events or challenges should be given. The final report should include a recommendation on whether a Consensus Conference should be held.

Reports will be reviewed by the Special Committee on Outcomes Consensus.

Inquiries

E-mail inquiries are encouraged. The opportunity to clarify any issues or questions from potential applicants is welcome.

Direct inquiries regarding programmatic issues to:

Chair, Special Committee to Develop an Outcomes Consensus Conference

c/o Assistant Executive Director for Advocacy & Professional Affairs

via email: ***advocacy@aae.org***

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