# Collaboration for Evidence-based Practice and Research in Anaesthesia (CEPRA)

*A consortium initiative for perioperative research*

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RESEARCH ARTICLE

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# Collaboration for Evidence-based Practice and Research in Anaesthesia (CEPRA): A consortium initiative for perioperative research

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## Abstract

Evidence in perioperative care is insufficient. There is an urgent need for large perioperative research programmes, including pragmatic randomised trials, testing daily clinical treatments and unanswered question, thereby providing solid evidence for effects of interventions given to a large and growing number of patients undergoing surgery and anaesthesia. This may be achieved through large collaborations. Collaboration for Evidence-based Practice and Research in Anaesthesia (CEPRA) is a novel collaborative research network founded to pursue evidence-based answers to major clinical questions in perioperative medicine. The aims of CEPRA are to (1) improve clinical treatment and outcomes and optimise the use of resources for patients undergoing anaesthesia and perioperative care, and (2) disseminate results and inform caretakers, patients and relatives, and policymakers of evidence-based treatments in anaesthesia and perioperative medicine. CEPRA is inclusive in its concept. We aim to extend our collaboration with all relevant clinical collaborators and patient associations and representatives. Although initiated in Denmark, CEPRA seeks to develop an international network infrastructure, for example, with other Nordic countries. The work of CEPRA will follow the highest methodological standards. The organisation aims to structure and optimise any element of the research collaboration to reduce economic costs and harness benefits from well-functioning research infrastructure. This includes successive continuation of trials, harmonisation of outcomes, and alignment of data management systems. This paper presents the initiation and visions of the CEPRA network. CEPRA aims to be inclusive, patient-focused, methodologically sound, and to optimise all aspects of research logistics. This will translate into faster research conduct, reliable results, and accelerated clinical implementation of results, thereby benefiting millions of patients whilst being cost and labour-saving.

**KEYWORDS**
anaesthesiology, collaboration, consortium, methodology, perioperative medicine

## 1 | INTRODUCTION

More than 310 million surgical procedures are performed each year, and the number is consistently increasing.[1] Anaesthesia involves several high-risk procedures and exposures to potent agents affecting respiration, circulation, cognitive function, motor function and other aspects of homeostasis. Patients are additionally subjected to the direct consequences of surgery, that is, inflammation, pain, and impaired respiratory and cardiovascular function. Therefore, severe complications directly linked to perioperative patient management may occur from all organ systems.[2–5]

For obvious reasons, the postoperative 30-day mortality varies greatly between types of surgery, that is, from high-risk open thoracic or neurosurgery to minor elective surgery. However, postoperative 30-day mortality for a pooled population of noncardiac surgery is reported to be between 2% and 4%.[6,7]

Additionally, the socio-economic burden of surgical services is substantial and accounts for approximately 50% of in-hospital health care expenses in the United States, with anaesthesia-related postoperative complications being the major contributors.[8]

Preventing or limiting complications will reduce morbidity and mortality. Diminishing acute and chronic pain and physical and cognitive impairment will further facilitate and improve effective rehabilitation. Moreover, it will liberate resources, thus improving cost efficiency.

Anaesthesiology is interwoven in all aspects of patient care. The core role of anaesthesiologists is in perioperative care as well as the treatment of critically ill patients across all specialties.[9] Perioperative anaesthesia practice includes preoperative optimisation, safe handling of patients' airways and respiratory functions, perioperative pain management, and support of haemodynamic functionality and organ perfusion. Optimised prehabilitation[10] and rehabilitation, whilst minimising the surgical stress response and adverse effects of anaesthesia, are essential in perioperative care.[11–13] Safe and evidence-based anaesthesia practice is therefore the foundation for an optimal and safe course for surgical patients.[14,15]

Nevertheless, research funding is scarce in anaesthesia.[16] Anaesthesia care impacts all patients, for example, cancer patients or children, but the anaesthesiologist does not have the overall treatment responsibility for specific diseases or patient groups, perhaps making funding more difficult. Due to the limited use of expensive and novel medication and equipment, there is limited commercial interest in anaesthesia practice and research. Consequently, several of the most used interventions within the field are still based on poor evidence relying on tradition, expert opinions, studies of basic physiology, non-randomised studies, or underpowered trials with poor methodological quality.[17–21] About half of all recommendations in clinical guidelines in anaesthesiology are based on a low level of evidence.[22] This poses a treatment dilemma, since several of these interventions could have no beneficial effects, and some may even be harmful.[23–26]

Differences in perioperative treatments that might seem small or insignificant may have a great impact due to the potency of anaesthetic interventions and the large number of patients subjected to anaesthetic procedures every year. A slight difference in outcomes between two treatments may go unnoticed but can impact a substantial number of patients on a global scale.

Therefore, we see is an urgent need for large perioperative research programmes testing and improving existing practice, potentially reducing morbidity and mortality, and thereby improving outcomes for millions of patients.

## 2 | COLLABORATION FOR EVIDENCE-BASED PRACTICE AND RESEARCH IN ANAESTHESIA

With the establishment of Collaboration for Evidence-based Practice and Research in Anaesthesia (CEPRA), a novel collaborative research network is founded to pursue evidence-based answers to major clinical questions in anaesthesia and perioperative medicine.

### 2.1 | Why CEPRA?

Large research collaborations striving to employ the highest standards of methodology are essential to impact patient treatment effectively. Large research collaborations, such as the Australian and New Zealand College of Anaesthetists Clinical Trials Network,[27] The Outcomes Research Consortium,[28] Collaboration for Research in Intensive Care[29] and the Targeted Temperature Management group[30] have succeeded in testing existing treatments, including regimens suspected of having no benefit or even inducing harm. This has led to a change in treatment such as targeted temperature management of patients after cardiac arrest and the European Medicines Agency's prohibition of the use of hydroxyethyl starch.[30,31]

There is a growing need for large pragmatic trials investigating what is insufficiently tested, thereby providing solid evidence for the interventions given to a large and growing number of patients undergoing surgery and anaesthesia.[32]

### 2.2 | Initiation process of CEPRA

A group of trialists and research methodologists acknowledged the need for better collaboration and optimised methodology in perioperative research. An initiative was taken to invite Danish researchers with a known interest in perioperative and anaesthesia research to a meeting to discuss the needs and structure for a large perioperative research collaboration. The Danish Society for Anaesthesia and Intensive Care Medicine agreed to fund a physical meeting in Copenhagen in April 2022. More than 65 researchers covering a broad spectrum of perioperative interests attended the meeting, and a structure built on clusters of common research interests was conceived. The first cluster meetings were held, and each cluster began describing and protocolising research programmes reflecting the most critical clinical questions within their field of interest. A virtual grand meeting including all members of CEPRA was held, and the research programmes from the individual clusters were presented and discussed. A coordinating group undertaking day-to-day management was agreed upon, as well as the structure and composition of the executive board. The clusters collaborate closely with the coordination group to facilitate cross-coordination of the research programmes, to ensure that the programmes pertain to the CEPRA research standards presented in this paper, and to reveal any need for methodological or other support.

CEPRA is growing, and more than 100 researchers from more than 25 hospitals from all regions of Denmark are currently involved (February 2023). Official webpage: www.cepra.nu.

### 2.3 | Aim of CEPRA

- To improve treatment and outcomes and optimise the use of resources for patients undergoing anaesthesia and perioperative care.
- To disseminate results and inform caretakers, patients and relatives, and policymakers of evidence-based treatments in anaesthesia and perioperative medicine.

The collaboration will facilitate cost-effective investigator-initiated research programmes, including randomised trials, to evaluate the benefits and harms of commonly used anaesthesia interventions, thus aiming to secure evidence-based treatment for patients in perioperative care.

### 2.4 | The CEPRA research network

The CEPRA research network consists of collaborators from clinical departments, methodological trial units and departments of biostatistics. CEPRA will serve as the umbrella organisation facilitating collaboration, coordination, funding and academic support for each trial and research programme.

The CEPRA research network currently has seven research clusters focusing on improving different aspects of perioperative care. The current research clusters focus on:

- Airway management
- Cardiovascular function

- Obstetric anaesthesia
- Paediatric anaesthesia
- Pain treatment
- Perioperative course optimisation
- Regional anaesthesia

The Board of CEPRA will be responsible for revising, updating, or replacing these clusters with other research areas in a timely manner to ensure a continuous focus on the most critical clinical questions in anaesthesia and perioperative medicine.

## 2.5 | The organisational structure of CEPRA

Coordination group

- Facilitates coordination between clusters and trials, seeks overall funding, and offers methodological support.

Research clusters

- Each research cluster will have a steering committee with a chairperson.
- Research clusters are open to anyone with an interest in the field of research within the cluster.

Executive board

- The coordination group and a representative from each research cluster will constitute the Executive Board of CEPRA.
- We plan for a future CEPRA board to include representatives from surgical specialties, other close scientific collaborators, and patient association representatives.

Research programmes

- Each trial or interventional programme will have a steering committee.
- Each trial will have a sponsor and coordinating investigator (see Figure 1).

CEPRA will be inclusive with no collaborator requirements aside from those attributed to the specific trial- or research programmes. The future aims and objectives of the organisation are to:

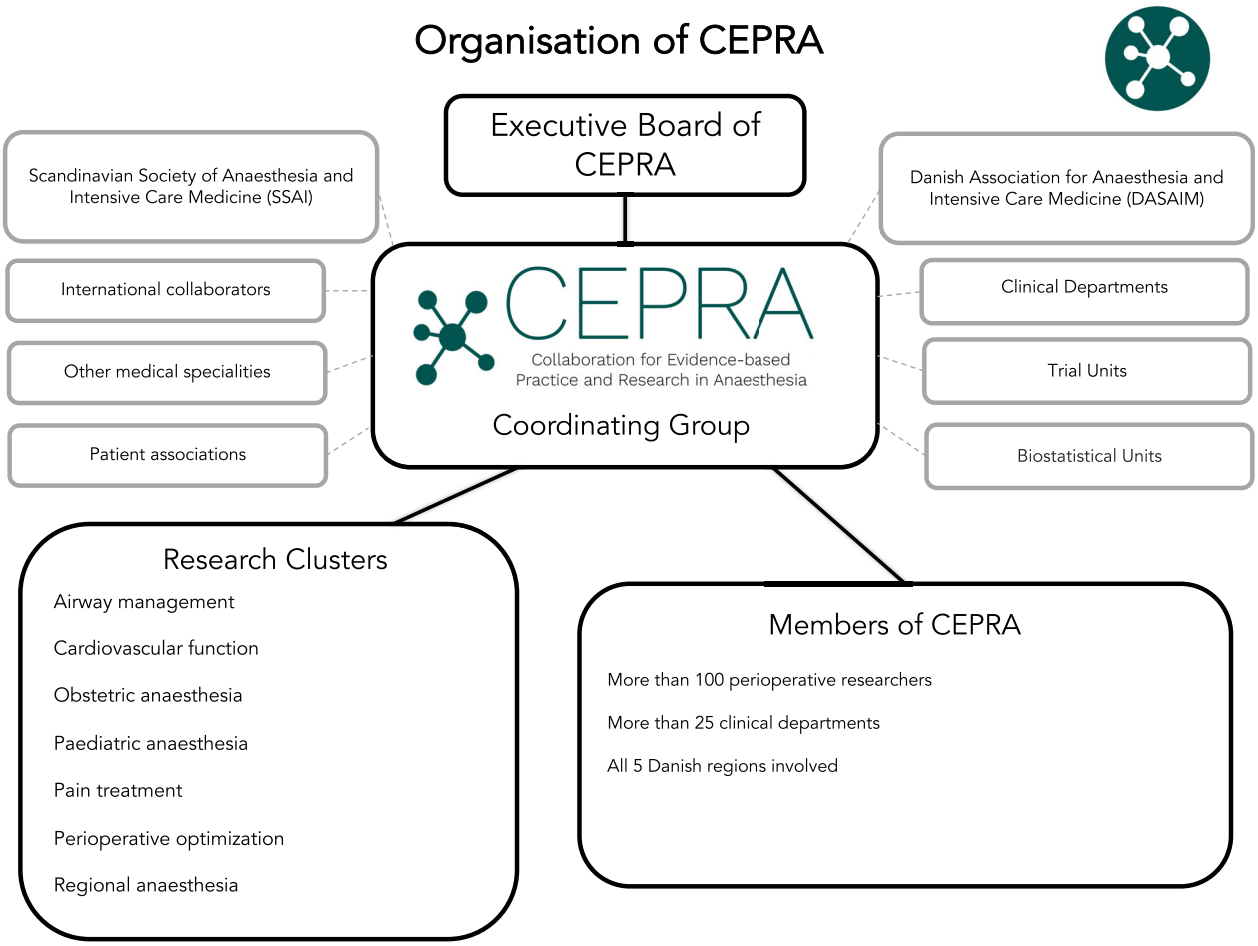


**FIGURE 1** Organisation of Collaboration for Evidence-based Practice and Research in Anaesthesia with present and future collaborators.

- Broaden and extend our collaboration to all surgical specialities and other relevant clinical collaborators, such as paediatricians, emergency medicine physicians, etc.
- Broaden and extend our collaboration to patient associations and relevant patient and relative representatives.
- Consolidate and develop an international network and collaborative infrastructure, for example, with other Nordic countries.
- Continuously identify and define the most pivotal research programmes/areas within the field of anaesthesia and perioperative medicine.

## 2.6 | Research objectives and philosophy

CEPRA will strive to:

- Document or refute the benefit or harm of frequently used anaesthesia interventions.
- Perform methodologically state-of-the-art, pivotal, multicentre randomised clinical trials.
- Perform relevant systematic reviews before initiating the trial to inform the trial design and ensure that the trial is warranted.
- Perform relevant supporting studies such as observational studies, surveys, scoping reviews, feasibility trials, qualitative studies, simulation studies, methodological studies, etc.
- Perform systematic reviews after a trial has finished to relate the new trial results to previous evidence and to present a complete overview of the current evidence.
- Develop and improve relevant methods to evaluate, synthesise and report trial results.
- Perform cost-effectiveness/economic analyses of the consequences of the results of the interventions.
- Monitor clinical practices, for example, through registries, before and after to secure maximal gain.
- Disseminate and implement research results in clinical practice.

## 2.7 | Research methodology

When conducting randomised clinical trials, the choice of methodology and statistical analyses will influence the results.[33] To improve treatment and patient outcomes we must trust the results coming out of the CEPRA network. A premise of CEPRA is that its research should adhere to the highest methodological and statistical standards for the benefit of patients. Examples include:

- Identification of knowledge gaps through systematic or scoping reviews.
- Detailed protocolization made publicly available prior to study initiation.
- Identification of existing best practice as the comparator for testing interventions.
- Identification, recruitment, and inclusion of study participants that are representative of the population of interest.
- Identification and measurement of outcomes clinically relevant to people representing the population of interest.
- Engagement of relevant stakeholders representing the population of interest, patient associations, etc.
- Description of all statistical methods in a publicly available statistical analysis plan before data extraction.
- Protocolizing subgroup analyses and Studies Within a Trial in detail and making it publicly available before the initiation of studies.
- Adherence to relevant planning and reporting guidelines, for example, from the EQUATOR Network, to allow for assessments of internal and external validity.[34]

## 2.8 | Research structure

The CEPRA organisation will aim to structure and optimise any element of the research collaboration to reduce economic costs and harness benefits from established, operational, and well-functioning research infrastructure, without unnecessary loss of time or resources. Examples include:

- Harmonisation of outcomes: The same outcome measures can be collected for several independent trials whenever possible and meaningful. Thus, relevant core outcome measures will be developed. This will streamline the registration process, allowing less training and requiring fewer resources.
- Co-enrolment: A factorial trial design will allow patients to participate in more than one randomised trial, thus optimising enrolment and reducing trial inclusion time and cost. Co-enrolment requires that the interventions are perceived to be uncorrelated.
- Randomisation and data management: Alignment of data management systems across all CEPRA research programmes will streamline pivotal elements of the research process, ameliorating local frustrations, and making it both time-, cost- and labour-saving.
- Continuation of studies: The organisation will structure each research programme so that a new trial or study is initiated whenever the structural resources are available at the individual clinical trial sites. In practice, this would ensure a smooth transition from one trial to another, utilising an operational infrastructure and reducing costs, whilst preserving knowledge and competencies.

Furthermore, CEPRA will establish specialised groups across the network (e.g., working with the development of specific methodologies, systematic reviews, trial designs, and statistical methods) further ensuring that all trials are conducted with the highest possible methodological quality.

## 2.9 | Anticipated patient and cost-related benefits of CEPRA

CEPRA will enforce and strive to ensure that important new evidence will be disseminated to clinicians, patients and policymaker as soon as available and facilitate fast implementation into clinical practice.

- If the results of a trial show that an intervention has no effects, then this intervention may be excluded from daily anaesthesia practice, thereby saving resources that ultimately may be used to improve patient outcomes elsewhere.
- If the results of a trial show that an intervention has harmful effects, then this intervention may be excluded from daily anaesthesia practice for the benefit of patients whilst also saving resources.
- If the results of a trial confirm that an intervention is beneficial, then this intervention may be implemented more systematically in daily clinical practice for the benefit of patients.
- If the results of a trial show that an intervention causes both harm and benefit, weighing these against each other will allow for a more informed decision about whether to implement the intervention more systematically, implement it on an individual patient basis, or exclude it.

## 3 | CONCLUSION

This paper presents the initiation and visions of the CEPRA network, an initiative focusing on collaboration and the improvement of the quality and implementation of anaesthesia and perioperative care research, including large pragmatic randomised clinical trials. The collaboration is currently organised in seven clusters each with a specific research focus within perioperative medicine and anaesthesiology.

CEPRA aims to be inclusive, patient-focused, methodologically sound, and to optimise all aspects of research logistics. This will translate into faster trial conduct, reliable results, and accelerated clinical implementation of results, thereby potentially benefiting millions of patients whilst being cost, and labour-saving.

### AUTHOR CONTRIBUTIONS

AKN, JCJ and OM took lead on terms and conceptualization. AKN wrote the initial draft with inputs from JCJ and OM. JCJ, AA, KHWL, LN, PJ-O, MV, MV-A, AW and OM revised the initial draft. All authors revised, contributed to, and accepted the final version of the manuscript. All authors and collaborator group contribute to the Collaboration for Evidence-based Practice and Research in Anaesthesia (CEPRA).

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## APPENDIX

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