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Developing a decision support tool for the continuation or deprescribing of antithrombotic therapy in patients receiving end-of-life care: Protocol for a European Delphi study

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ABSTRACT

Introduction: To develop a European shared decision support tool (SDST), a Delphi process will be used to reach consensus about aspects relating to the continuation or deprescribing of antithrombotic therapy (ATT) in cancer patients at the end of life. As part of the SERENITY project, this study corresponds to work package (WP) 4. Methods: Findings from SERENITY WPs 1–3 (realist review, flash mob research, epidemiological and qualitative studies) informed the Delphi study. The WP4 steering committee had two objectives. (1) to build a representative expert panel comprising physicians, pharmacists, nurses and psychologists from eight European countries; and (2) to advise on the content of the Delphi form, divided into four sections: context, content, SDST design and trial outcomes. The form was reviewed by the SERENITY patient and public involvement group to ensure that it met patients' needs. The Delphi study will take place in three rounds held at 6-week intervals, involving experts from

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eight countries. Consensus will be reached on items with at least 70 % agreement. The steering committee will review and validate the results across the different rounds.

Results: Through this Delphi study, the following aspects will be defined: characterisation of candidate patients for discussion about ATT deprescribing; healthcare team roles in ATT decision-making; specific information and communication requirements for patients when making deprescribing decisions; SDST content priorities; and optimal outcomes for the planned clinical trial.

Conclusion: This study will feed directly into the development and evaluation of the SDST, aimed at reducing complications and improving quality-of-life in end-of-life cancer patients receiving ATT.

1. Introduction

Due to the progress made in anticancer treatments, cancer patients now have an increased life expectancy of many months and years, leading to a growing number of patients to manage, including those with advanced cancer. People living with cancer are often elderly, have comorbidities and are frequently exposed to polypharmacy. The combination of cancer-related inflammation, treatment toxicity, older age, and comorbidity-related complications results in a high risk of long-term adverse events, particularly cardiovascular outcomes [1-7]. As a result, antithrombotic therapy (ATT) is frequently prescribed in this population [8]. Although ATT helps prevent thromboembolic events, it is also associated with an increased risk of bleeding and reduced quality of life [9]. Consequently, ATT prescription (and long-term ATT maintenance) can be particularly problematic, thus calling into question its suitability in cancer patients at the end of life [7,10-15]. Despite the identified risks, deprescribing ATT remains uncommon in this context due to the difficulty in predicting life expectancy, the involvement of different healthcare professionals, the large variability regarding models of care and access to palliative care teams, the optimal timing (months, weeks, days) of deprescribing and the potential consequences of discontinuing treatment [16-20].

Rationalisation of medication should be common practice for patients with advanced cancer [21,22]. However, no evidence-based guidance specifically addresses ATT deprescribing for these patients in the context of end of life [23,24]. This lack of clarity prevents both clinicians and patients from making informed decisions about ATT prescribing or deprescribing [25], and most patients take their medication until their last days of life, which can result in medical complications, reduced quality-of-life and higher healthcare costs [10,12,13, 17,18,26–31].

The implementation of interventions to optimise medication prescribing can reduce the use of potentially inappropriate medications [31]. An intervention that facilitates a shared decision-making process by integrating evidence-based data, healthcare professionals' expertise and patients' preferences may be best suited to meet this need [32–35]. To address this challenge posed by ATT use in end-of-life cancer patients, the SERENITY project was initiated [36,37]. SERENITY aims to develop, evaluate and implement a European web-based shared decision support tool (SDST) to support patients with cancer, their carers/family and healthcare professionals in making informed decisions about ATT near the end of life.

The present study, which is an integral part of the SERENITY project [36,37], aims to achieve consensus about aspects relating to ATT continuation or deprescribing in cancer patients at the end of life with the broader objective to contribute to the development and evaluation of the SERENITY SDST. In addition, this study will confirm the primary outcome of the randomised controlled trial (RCT), which will evaluate the effectiveness of the tool.

2. Materials and methods

2.1. Scope of the SERENITY project

SERENITY (towardS cancer patiEnt empoweRment for optimal usE

of aNtithrombotIc TherapY at the end of life) is a European project structured around seven work packages (WPs) (see Box1).

The present study corresponds to WP4, which is led, conducted, and coordinated by Assistance Publique-Hôpitaux de Paris (AP-HP), France.

More detailed information about the different WPs can be found in an earlier publication [36].

2.2. Study design and justification

A Delphi survey technique will be used to reach a consensus on an unresolved issue (ATT continuation or deprescribing in end-of-life cancer patients). This approach allows for the anonymous collection of expert opinions, thus minimising the risk of group conformity. Through iterative rounds, we will accommodate changing opinions while collecting regular feedback from experts [38,39].

In palliative care research, as in other specialties, clinical trials or large-scale observational studies may not always be feasible or ethically appropriate due to practical, economic or ethical considerations. This limits the ability to generate evidence to inform guidelines [40,41]. Therefore, to facilitate the co-construction of evidence-based knowledge, initial steps are grounded in expert opinions and experiences, frequently captured using consensus-building processes such as the Delphi method [42]. This method is well suited for building systematic consensus around the unresolved concept of care, as targeted in SE-RENITY, with the involvement of many different medical specialties from different European regions known to have different views on the topic [4,23,25,42].

We will follow the ACCORD (ACcurate COnsensus Reporting Document) directives for reporting consensus-based methods in biomedical research [43] as well as the CREDES (Conducting and REporting of DElphi Studies in palliative care) standards given the palliative focus of the study [44].

2.3. SERENITY Delphi steering committee

SERENITY WP4 conduct is led by a steering committee, a multidisciplinary group of experts from eight European countries (Denmark, France, Germany, Italy, the Netherlands, Poland, Spain and the United Kingdom). The committee involves clinicians with experience in ATT therapies, palliative care research, public health, health communication and a public involvement lead. The WP4 steering committee has two main objectives. The first aim is to define the composition of the panel of experts, and the second is to advise on the content of the Delphi form. Each steering committee country leader is responsible for recruiting potential Delphi participants in their own country based on specific selection criteria (see below) under the supervision of the lead team. Further, they will be involved in reviewing the results at the end of each Delphi round and validating the final consensus results.

2.4. Delphi panel composition and selection

As ATT management involves different healthcare providers in clinical practice, a range of healthcare professionals will be included in the expert panel.

2.4.1. Composition of the expert panel

The expert panel will include a multidisciplinary group of healthcare providers from eight countries across Europe to ensure the general-isability of the results and to gather the different views of each group regarding the important aspects to be included in the SDST [45].

The composition of the expert panel in terms of specialties and numbers was discussed during the steering committee meetings. In addition to these meetings that allow all participants to reflect and express their opinions, an online survey was conducted with the steering committee to determine the composition of the expert panel. Finally, for each country, participants in the expert groups were identified on the basis of the eligibility criteria detailed in Table 1.

Exclusion criteria include retired individuals, those unemployed in the previous year, or those with a conflict of interest. In addition, to prevent potential group bias affecting the overall decision-making [44, 46], steering committee members will not participate in the Delphi rounds.

2.4.2. Number of panellists per country

For physicians directly involved in ATT (de)prescribing decision-making, who will be the main users of the SDST, a minimum of four participants per area of expertise is required for each participating country. For other healthcare providers, it is advisable to involve at least one expert from each participating country while ensuring balanced representation of physicians across different practice settings.

2.4.3. Identification of participants in each country

Recruitment of participants will take place in Denmark, France, Germany, Italy, Poland, the Netherlands, Spain and the United Kingdom. The steering committee leaders identified and contacted eligible experts in their respective countries.

The central coordination of the recruitment process will be managed by the lead team, who will collect the information provided by the lead partners and ensure consistency in the panel's composition.

2.4.4. Patient and public involvement

Patient and public involvement (PPI) is integrated throughout the SERENITY project. Two PPI leads will engage with a number of PPI groups to discuss the study methods [47], present initial findings and explore what is important to the patients and public to be included in the SDST. Two public contributors are members of the Delphi steering committee and are involved in preparing the Delphi form (reviewing and suggesting edits and additions) [47]. Their contribution ensures that the content of the form corresponds to patients' needs and perspectives, as direct patient participation in the Delphi process is not possible due to ethical and practical considerations.

In the initial general description of the SERENITY project [36], we planned to perform a Delphi study involving both patients and health-care professionals. The main motivation was to ensure that the views of patients (and their carers) were represented in the statements in the Delphi form. However, we gained many insights from the public across the WPs about what was important to patients and carers involved in the

Table 1 Eligibility criteria for the panel experts.

Panel group	Inclusion criteria	Role	Recommended
Physicians	Expertise in the following fields: Oncology Palliative care Cardiology General practice	Directly involved in decision-making regarding the prescription of ATT for end-of-life cancer patients	Four experts per expertise area in each country
	Expertise in the following fields: Geriatrics Haematology Vascular medicine Vascular surgery Neurology Respiratory medicine	Physicians potentially involved in decisions regarding the prescription of ATT for end-of-life cancer patients	At least one expert per expertise area in each country
Other health care providers	Clinical pharmacists Nurses with experience in oncology Psychologists with experience in oncology	Healthcare professionals who could significantly contribute to ATT management for end- of-life cancer patients	At least one expert per expertise area in each country

Delphi study preparations. Furthermore, the results from the qualitative studies in WP3 (patient interviews) provided deep and relevant insights about patients' and carers' views.

An important point relating to the methodological axis and our decision to use the Delphi method to reach consensus (i.e., multi-round process) is that all the experts need to complete all the scheduled rounds. In view of the results of WP1 to WP3, which precisely qualify the target population (i.e., a strict definition of the palliative population), the inclusion of cancer patients at the end of life in the Delphi method with several planned rounds proved to be too complex. These patients may experience health deterioration before completing all three rounds, and due to their health conditions, completing an online questionnaire may also prove challenging.

As we faced multiple major ethical and legal issues related to patient recruitment across Europe with an extended lead time to obtain regulatory opinions, and given that PPI was already established, we ultimately decided not include patients in the Delphi panel.

2.5. Development of the Delphi form

The development of the Delphi form is based on extensive preparatory research. The results of the SERENITY project WP1 to WP3 made a major contribution to the development of the Delphi items by providing a wide range of information on the clinical and social factors to be taken into account when considering continuation or deprescribing of ATT [48–50]. Specifically, the findings from SERENITY WPs 1 to WP3 include the following.

Box 1

List of the work packages of SERENITY project

- WP1: A realist review and flash mob study of current ATT deprescription practices.
- WP2: Epidemiological descriptive studies on ATT complications.
- WP3: Qualitative interviews with patients and healthcare professionals.
- WP4: Consensus building processes to inform the development of the SDST.
- WP5: Development of the SDST.
- WP6: RCT to evaluate the SDST.
- WP7: Implementation of the SDST.

WP1: A realist review [48] and flash mob research to gain an overview of the current ATT deprescribing practices used across Europe [51]:

- WP2: Conduct of several epidemiological studies: one in the UK [9], one in Denmark [8], and three in the Netherlands to examine the incidence of bleeding events and cardiovascular complications related to ATT;
- WP3: Qualitative in-depth interviews held across Europe with patients and healthcare professionals to assess their values, opinions, expectations and wishes regarding the clinical decision-making process for ATT deprescribing [49,50,52].

The Delphi form was then improved through the collective expertise of the steering committee. This multidisciplinary group provided essential advice on the content, structure and progress of the form. Finally, the PPI leads reviewed and approved the final version.

The Delphi form is presented in four sections, each serving a specific purpose: context, content, SDST design and trial outcomes (Fig. 1).

Sections 1 and 2 are dedicated to creating guidance and content for the SDST, comprising 97 and 27 items, respectively, and addressing the following issues.

- Characterisation of the candidate patients for ATT (de)prescribing;
- Roles played by the healthcare team and supportive care professionals in ATT decision-making;
- Appropriate timing for assessing or reassessing patient preferences;
- Specific patient information and communication requirements for (de)prescribing decisions;
- Requirements regarding patient and family empowerment for ATT (de)prescribing.

Section 3 focuses on the design of the SDST and includes 14 items relating to the following aspects.

- Identification of tool users;
- Personalisation of treatment options;
- Consideration of integrating patients' preferences into the tool;
- Content to help guide clinical decision-making.

Section 4 is dedicated to informing about the optimal outcomes for the planned clinical trial of the SDST and includes 16 items.

Participant information, including demographic data, medical specialty, years of experience and practice setting, will be collected. This information will enable a description of the sample characteristics and ensure that the selection criteria are met.

The form includes an introduction explaining the aims and purpose of the study. Each section begins with a brief description of its specific objective. The complete Delphi form can be found in the supplementary material.

The Delphi form was pilot-tested by a group of candidates from AP-HP who are representative of the expert panel.

2.6. Assessing consensus

2.6.1. Delphi rounds

An anonymous three-round online Delphi process will be conducted across eight European countries.

The expert panel will be invited to evaluate items as 'Yes/No' or using ranking and rating scales with five options: essential, important, moderately important, less important and not important. They will also be asked to provide feedback in text boxes about items of interest or to suggest additional items.

Responses from the first round will be analysed by the lead team. Aggregated results will be communicated to the panel members in the introductory materials for the second round. Items with a consensus to be included in the SDST will be clearly identified, and the level of agreement will be indicated. Similarly, items with a consensus to be excluded will be highlighted along with the reasons for their exclusion.

Panel members will then be invited to review the results of the first round and to reconsider the items without a consensus; panel members may also evaluate any new items and provide feedback. Items that remain undetermined after the second round will be reconsidered in the third round. If there is still no consensus after three rounds, and no request for modification has been submitted, the decision will be made solely by the steering committee. Conversely, a next round will be omitted if a consensus is reached on all the items at the end of the last round.

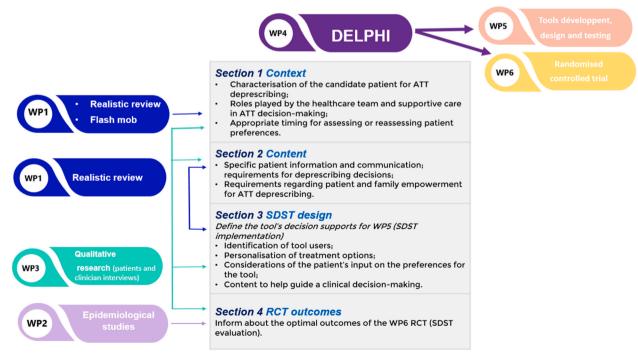


Fig. 1. Methodological framework of the SERENITY project.

During each round, experts will have 3 weeks to complete the Delphi form. We anticipated attrition by recruiting more experts than needed, and to minimise this risk, a clear explanation of the Delphi method and the importance of engagement in all three rounds will be provided according to the iterative process. Several reminders will be sent 1 week before the start of each round and regularly thereafter. Experts can only take part in the next round if they took part in the previous round.

2.6.2. Definition of consensus

Consensus will be defined as \geq 70 % of panellists voting an item as 'essential' or 'important'. Once this threshold is met, the item will not be reconsidered in the next round unless two or more similar requests to modify the item are received (Fig. 2). In this case, the steering committee will decide whether or not to approve the modification. If approved, the modified item will be discussed in the next round during which participants will choose between the previous version and the revised one.

Additional items may also be added to the Delphi form if the steering committee deems them relevant and in line with the study's objectives. Items with $<\!20$ % agreement in the first round will be excluded.

2.7. Data analysis

Quantitative and qualitative analyses will be performed. Descriptive statistics such as response rates, level of agreement for each item, median levels of agreement and interquartile ranges will be used to describe agreement rates between rounds. The same measurements will be used to evaluate consensus stability across rounds [53].

Qualitative analysis will examine comments and suggestions provided by experts, with identified patterns presented alongside the statistical summary for each corresponding item.

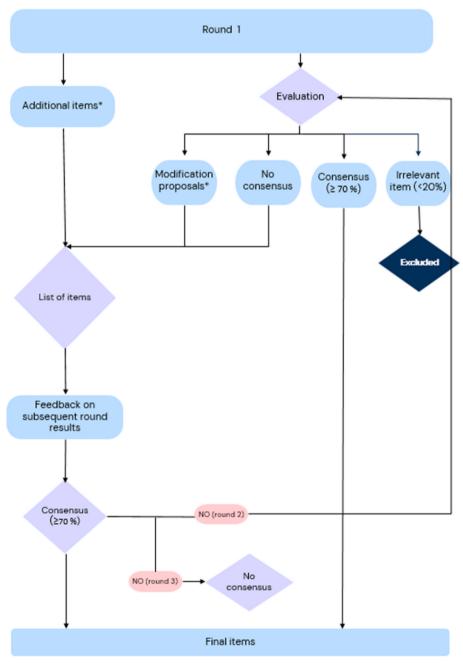


Fig. 2. Flow chart of the Delphi consensus process and decision rules.

2.8. External validation

Prior to dissemination, including using the output in the design of the SDST, the tool concept will undergo testing with patient representatives and general practitioners as part of WP5. The results of these tests may provide additional insights that could differ from the findings of the Delphi study. To ensure consistency, the final results of the Delphi study will be validated by an external board prior to the SDST's implementation, as recommended by CREDES [44].

The external board will include oncology palliative care specialists, shared-decision making digital health specialists (to validate the results related to the usability of the future SDST) and methodologists with research experience in oncological outcome measurement. This will ensure that the outcomes of the RCT, as determined by consensus, align with the research objectives.

3. Discussion

The European SERENITY project aimes to address a challenging issue, namely the therapeutic inertia surrounding ATT deprescribing in cancer patients at the end of life. The present study proposes to build consensus on key aspects of ATT continuation or deprescribing. This consensus is important to ensure the successful development, evaluation and eventual implementation of the pan-European SERENITY intervention, a tool called CoClarity, to support informed shared decisionmaking in this population. Achieving a broad consensus through the Delphi process enables the informed views of experts from various specialties and regions of Europe to be collected, each potentially offering different perspectives on the topic. This collaborative effort is essential to establish clear guidance where evidence on the optimal content for (de)prescribing SDSTs is lacking in this context. The findings of the Delphi study will shape the content of the future SDST and therefore promote its usability in palliative care clinical pathways across Europe.

The methodology of this Delphi study is supported by the robust integrative approach of the SERENITY project. The Delphi form is based on the findings of the previous WPs, including a realist review, flash mob study, large-scale epidemiological research and qualitative studies. These findings were enriched by the contribution of the steering committee that included experts from various fields. As public involvement is a central component of patient-centred projects such as SERENITY, the Delphi form was validated by the PPI panel of SERENITY, which includes patient representatives, to ensure that it meets patient needs.

The findings of this study will directly inform the development and evaluation of the SERENITY SDST in subsequent WPs. Key elements for the SDST will be defined, including identifying which patients are candidates for ATT continuation or deprescribing, clarifying the roles of the healthcare team in the decision-making process and addressing the specific information and communication needs of patients. Additionally, the study will confirm the optimal primary outcomes for the clinical trial evaluating the SDST.

Ultimately, the SERENITY tool will support clinicians and end-of-life cancer patients across Europe in making evidence-based decisions regarding ATT continuation or deprescribing, with the goal to reduce complications and improve quality of life in this population.

Ethics and dissemination

This study does not require ethical review approval, as it does not involve patient participation or recruitment through healthcare services. All participants will receive an invitation to participate in the study along with relevant information and will be asked to give their agreement to participate.

However, the project has been approved by the local ethics committee (IRB) (IRB 00006477).

The findings of this study will directly inform the content of the SDST

and will also provide essential information for the clinical trial regarding the optimal outcomes.

The findings will be disseminated at conferences and published in a peer-reviewed international journal specialising in thrombosis or oncology research, with a publication scheduled for late 2025.

CRediT authorship contribution statement

Imene Deneche: Writing - original draft, Methodology, Conceptualization. Camille Couffignal: Writing - review & editing, Supervision, Conceptualization. Nassima Si Mohammed: Project administration. Anette Arbjerg Højen: Writing – review & editing, Conceptualization. Carme Font: Writing - review & editing, Conceptualization. Stavros Konstantinides: Writing - review & editing, Conceptualization. Marieke Kruip: Writing - review & editing, Conceptualization. Luigi Maiorana: Writing – review & editing, Conceptualization. Sebastian Szmit: Writing – review & editing, Conceptualization. Denise Abbel: Writing - review & editing. Laurent Bertoletti: Writing - review & editing, Conceptualization. Adrian Edwards: Writing - review & editing, Conceptualization. Michelle Edwards: Writing – review & editing, Conceptualization. Alessandra Gava: Writing - review & editing, Conceptualization. Jacobijn Gussekloo: Writing – review & editing, Conceptualization. Miriam J. Johnson: Writing - review & editing, Conceptualization. Rashmi Kumar: Writing - review & editing, Conceptualization. Johan Langendoen: Writing - review & editing, Conceptualization. Kate Lifford: Writing - review & editing, Conceptualization. Simon Mooijaart: Writing - review & editing, Conceptualization. Mark Pearson: Writing – review Conceptualization. Johanneke Portielje: Writing - review & editing, Conceptualization. Kathy Seddon: Writing - review & editing, Conceptualization. Stella Trompet: Writing - review & editing, Conceptualization. Frederikus A. Klok: Writing - review & editing, Conceptualization. Simon Noble: Writing - review & editing, Conceptualization. Isabelle Mahé: Writing - review & editing, Supervision, Conceptualization.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.tru.2025.100209.

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