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Construction and content validation of an Advance Directive Document form for advance care planning in Colombia: a Delphi study

Construcción y validación del contenido de un formulario de documento de voluntades anticipadas para la planificación de decisiones anticipadas en Colombia. Estudio Delphi

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What do we know about this problem?

The lack of accessibility, quality content, and legal validity criteria in ADD forms can affect their applicability in clinical settings.

What new elements does this study contribute?

From an interdisciplinary healthcare perspective, an ADD form with ethical, clinical, and legal criteria for advance care planning in Colombia is provided.

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Abstract

Introduction: The advance directive document (ADD) is intended to align medical care and treatment with the person's goals and preferences in clinical scenarios where they are unable to communicate and decide. It is a priority to promote the creation of the ADD in patients with serious illnesses as part of the advance care planning (ACP) process.

Objective: To construct and validate the content of an ADD form with an interdisciplinary approach.

Methods: Qualitative study using the Delphi technique. The study comprised three iterative rounds of online surveys involving healthcare professionals and professors from the country. In round 1, panelists evaluated the components of the sample form and suggested new ones. In round 2, they assessed their level of agreement with the components suggested in round 1. In round 3, using the results from round 2, the final ADD form was developed.

Results: A structured ADD form was developed, containing ethical, clinical, and legal criteria.

Conclusions: A structured ADD form with high-quality content is presented for completion and formalization in the framework of a deliberative process exclusively between the doctor and the patient. It is available for partial or total adoption by patients, doctors, healthcare institutions, and palliative care services throughout Colombia.

Keywords: Forms; Advanced directives document; Advance care planning; Delphi technique; End-of-life care; Advance directives; Colombia.

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Resumen

Introducción: El documento de voluntades anticipadas (DVA) permite alinear la atención médica y los cuidados con los objetivos y preferencias de la persona en escenarios clínicos de incapacidad para comunicar y decidir. Es una prioridad promover la elaboración del DVA en pacientes con enfermedades graves dentro de una planificación de decisiones anticipadas.

Objetivo: Construir y validar el contenido de un formulario de DVA con una perspectiva interdisciplinaria.

Métodos: Estudio cualitativo con técnica Delphi. Comprendió tres rondas iterativas de encuestas en línea en las que participaron profesionales de la salud asistenciales y docentes del país. En la ronda 1, los panelistas evaluaron los componentes del formulario modelo y aportaron otros nuevos. En la ronda 2, evaluaron su nivel de acuerdo con los componentes sugeridos en ronda 1. En la ronda 3, usando los resultados de la ronda 2, se desarrolló el formulario final de DVA.

Resultados: Se elaboró un formulario estructurado de DVA que contiene criterios éticos, clínicos y legales.

Conclusiones: Se presenta un formulario de DVA estructurado con contenido de alta calidad para ser diligenciado y formalizado dentro de un proceso deliberativo únicamente entre el médico y el paciente. Se encuentra disponible para su adopción, parcial o total, por los pacientes, los médicos, las instituciones de salud y de los servicios de cuidados paliativos de todo el territorio colombiano.

Palabras clave: Formulario; Documento de voluntades anticipadas; Planificación de decisiones anticipadas; Técnica Delphi; Atención final de la vida; Directivas avanzadas; Colombia.

INTRODUCTION

Aligning care and treatments with the patient's personal values and life goals is important within the framework of person-centered care. This goal is achieved through sensitive dialogue between the healthcare professional, the patient, and their family about their illness and treatment, intervention, and care options for their current and future health, according to the person's needs, preferences, and values within the scope of advance care planning (ACP). (1) ACP consists of multiple doctor-patient encounters, where dialogue is the primary objective of this process, eventually leading to the creation of the ADD. (1,2) People can start ACP at any time in their lives, but it may be more focused towards worsening health or aging conditions (2). ACP has a positive impact on improving the quality of end-of-life care by prioritizing patient goals, reducing inappropriate treatments, and lowering costs, among other benefits for the patient, family, care team, and healthcare system. (2,3)

Fears when talking about death, as well as deficiencies in the communication and documentation of end-of-life preferences are commonplace in Colombia. (4) Scientific literature highlights that ACP improves open dialogue about end-of-life issues and increases the rate of ADDs generated. (3,5) In Colombia, anyone whether in good health or sick, may write an ADD with or without help from a doctor. Additionally, an advance directive (AD) can be expressed using videos, audios, or in writing, either in a standard form or on a blank sheet of paper, as long as it meets the minimum content criteria required. (6) The ADD can also be formalized before the treating physician, as provided under the law, before two witnesses, or before a notary, each according to the specific requirements to ensure legal validity. (6) This eliminates several barriers and facilitates the development of the document in actual practice.

Alternatively, an advance directive may be drafted by anyone on their own at any time, even in the absence of illness and without medical advice; however, this often leads to multiple future conflicts regarding the binding force of the AD. (2) Research conducted at the international and national level indicates that poor content quality and/or questionable legal validity of the ADD (2,7) on one hand, and on the other, the lack of comprehensive and accessible forms may compromise the applicability of the AD in future clinical scenarios. (7,8) In both cases, this is a setback for person-centered care and affects the quality of end-of-life care. In this regard, the European Association for Palliative Care recommends the development of ACP programs and the provision of a structured ADD form by healthcare institutions and specifies the role and tasks of the physician in producing the ADD. (1,2) Therefore, although in Colombia the individual is allowed to draw up the ADV autonomously, the advice and formalization of the ADV by the physician is indisputable.

So far, "there are no international guidelines on the content of the ADD". (2) In Colombia, the problem of content quality and legal validity criteria of ADD forms has been previously documented. The justification for this research is the response to the problem statement of the study entitled: "Content of the advance directives document forms in pain and palliative care services in Colombia. Cross-sectional study," published in the Colombian Journal of Anesthesiology in 2023. (8) In summary, this study concludes that: "The ADD forms in the participating

pain and palliative care institutions have a modest content, based on to the rights that can be included in the ADD, according to the available scientific literature. The study summarizes the legal, ethical, and clinical criteria to develop or improve institutional ADD forms. The findings support the development of a structured form, validated by palliative care medical associations in Colombia." Similarly, in Australia, a national framework was published in 2015, to combat threats to the validity, and barriers to the implementation of the ADD. (9) Some of these guidelines indicate that the design of an ADD form should involve healthcare professionals from different disciplines to contribute with their views in a comprehensive and consistent context.

According to the above premises, a structured form may facilitate the discussion about end-of-life issues, and its implementation in institutional ACP programs can increase the rates of development of ADD for everyone, particularly individuals who represent a higher priority in the clinical context, such as patients with serious illnesses. The objective of this paper was to construct and validate the content of an ADD form with an interdisciplinary approach of healthcare professionals using the Delphi consensus methodology. (10)

METHODS

Study design: the development of an ADD form requires constructing and validating its content through a consensus process among "experts," thus fulfilling the primary goal of the Delphi technique, which is achieving consensus. Hence, both the research objective and method converge in consensus building. This study is a qualitative research using a consensus method developed according to the Delphi technique (11,12) through a process of three iterative rounds of online surveys, consistent with the "Conducting and REporting DElphi Studies (CREDES)" guidelines for palliative care. (10).

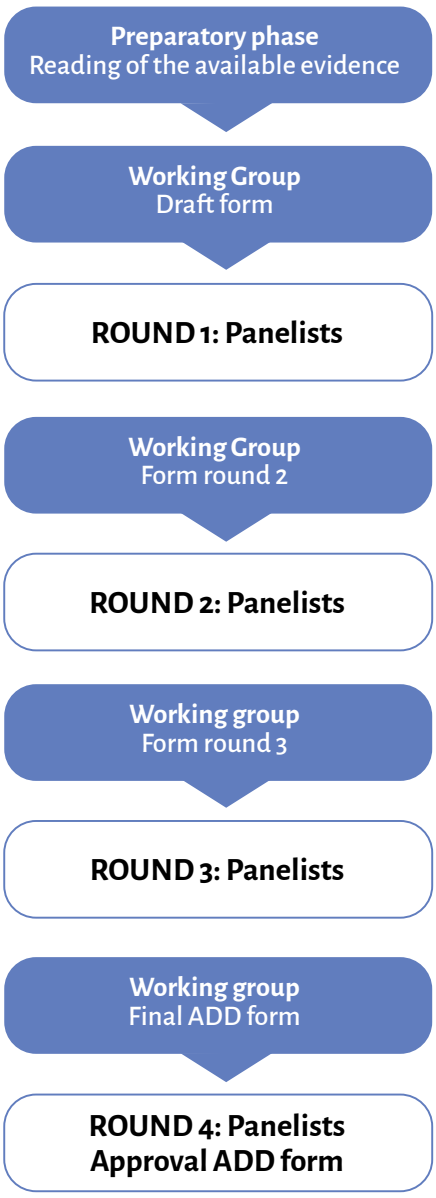
Population, sample, recruitment, and selection criteria: The strategy for selecting participants was open and inclusive, with a view to establishing a national and interdisciplinary working group that included professionals from a wide range of geographical backgrounds, with clinical, research, and teaching experience in the care of patients with chronic, severe, end-stage, critical, and end-of-life illnesses (Complementary material 1 discusses the details of the sampling approach). The invitation included national medical societies of palliative care, psychology, psychiatry, intensive care, geriatrics, internal medicine, as well as national universities with pain and palliative care and bioethics programs. Participation was voluntary, and there was no predetermined sample size. The professional's self-perception of their knowledge and experience in ADD, along with the signed informed consent, were the only inclusion criteria. The exclusion criterion was the professional's desertion or abandonment (defined as non-participation in two of the three rounds). The participant recruitment strategy covered the period from February 1 to March 8, 2024.

There is no definition of "who is an expert" in ADD in the national and international literature. (11) Therefore, in this study, the authors conducting the research were identified as the "working group," and the professionals who provided signed informed consent were designated as "panelists."

Delphi rounds: Three Delphi rounds were planned for this study (Figure 1). All followed the same methodology; however, each round specified details of the form's content domains to reach group consensus. A Delphi round was defined as the written, structured, independent, and anonymous evaluation of the form by each panelist within a specific time frame.

All panelists were educated on the standard Delphi process as follows: the structured rounds were characterized by a written, anonymous, and individual evaluation of the form (to avoid group conformity effects having an impact on the results), repetition (allowing opinion changes in each round), and controlled feedback (communicating the previous round's results through the report and access to the full recording of the virtual meeting).

Figure 1. Consensus process flowchart.



Source: Authors.

Consensus criterion: The a priori consensus criterion for each domain of the form included in the final ADD was defined as follows: 80% agreement in round 1 and 70% in rounds 2 and 3, with a response rate of at least 75% among eligible panelists for each round.

In Delphi round 1, each paragraph of the form was evaluated with one of four options: remain as is; review; delete, and don't know/not sure. The criterion for "deleting" a paragraph from the form was that 10% or more of the panelists requested its deletion. Paragraphs evaluated as "review, don't know/not sure" were included in round 2. Each paragraph had an open space for observations, comments, and contributions. In each round, an additional space was left open for a topic not foreseen in the form, at the discretion of the panelist.

In Delphi rounds 2 and 3, an ADD form with paragraphs that did not reach consensus in the previous round was submitted. Each paragraph was evaluated using a 5-point Likert scale as follows: 1: completely disagree; 2: mostly disagree; 3: neither agree nor disagree; 4: mostly agree, and 5: completely agree. The 70% consensus was reached with the sum of the response percentages of Likert items 4 and 5. Each paragraph had an open space for observations, comments, and contributions.

The panelists written evaluation in the next Delphi round included: a) Any elements on which consensus was not reached in the respective round. b) New elements proposed by panelists in each written round evaluated. 3) Emerging elements expressed by the panelists during the online meeting.

Consensus process: AMÁA conducted a non-systematic literature review from August 1, 2023, to January 31, 2024, selecting relevant articles on the topic of interest and design of the study. (10-12) Before the start of the first round, panelists were provided with an online package of relevant articles and books for reading and consultation, including the CREDES guidelines, to standardize the panelists' knowledge base.

For each round, panelists were emailed the reading and evaluation form of the ADD and the online Google form link to submit their answers. The reading and evaluation forms had the same text, but the latter the text was divided into paragraphs with their corresponding assessment scale. The Google form shared the same design as the evaluation form and was used for submitting and consolidating the answers of the panelists. Each online link allowed a single participation, and all the answers were mandatory in the online form.

The strategy for processing and feedback of results for each round was communicated to panelists through a report that included: the group's statistical response for each paragraph, all qualitative comments (without summary) from each panelist for each paragraph, the results of the paragraphs that reached or failed to reach consensus, and the inclusion of new topics for evaluation during the next round.

As a complement to each Delphi round, a two-hour virtual meeting was proposed for argument deliberation solely among panelists. In the virtual meeting of round 1, a debate on clinical scenarios for the applicability of the advance directive (AD) was scheduled. After providing panelists with the written report and access to the virtual meeting recording link from the previous round, dates for the virtual meetings of rounds 2 and 3 were scheduled.

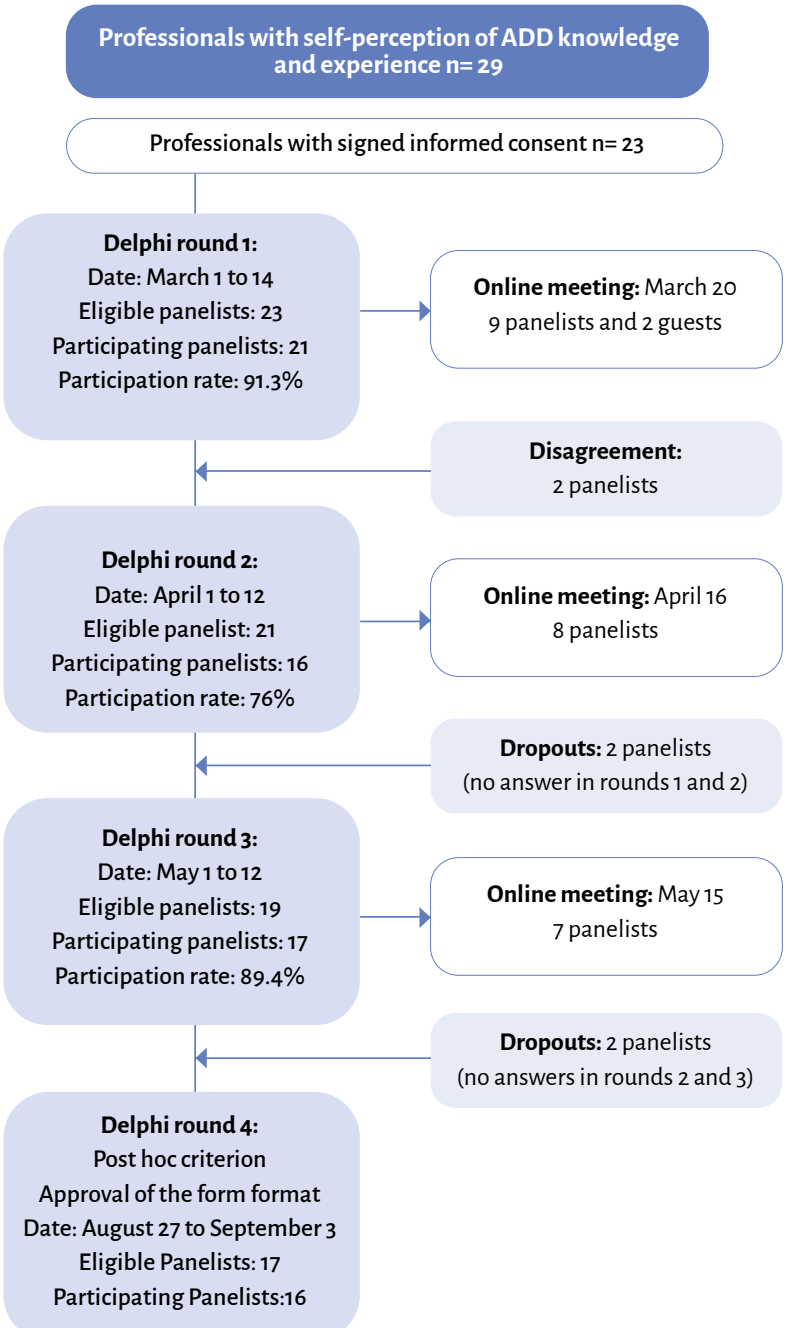
Panelist participation in the online meeting was voluntary considering the difficulty to coordinate work schedules. The working group participation in the online meetings was mandatory and the aim was: a) to submit the round report by the AMÁA coordinator who read each paragraph evaluated, presenting the group's statistical response, and all comments to that paragraph by each panelist; b) to moderate the discussion among the attending panelists by BJPB, and c) guiding and clarifying aspects related to the study methodology and clinical, bioethical, and legal issues related to the ADD. The observations, comments, and contributions made during each online meeting were included in the next Delphi round for written evaluation by all panelists. The Delphi process was supervised and internally audited by an expert in research methodology from outside the working group.

RESULTS

Figure 2 illustrates the number of participating panelists and the dates specified for each Delphi round of the study. Delphi rounds 1 to 3 defined the form's content with an overall participation rate of 86% and were conducted between March 1 and May 15, 2024. Following are the main findings of each Delphi round, as well as the key points discussed during the online meetings held at each stage.

Delphi round 1: Panelists were provided with an initial ADD form prepared by AMÁA and ACV based on previous research (8). The form was divided into 30 paragraphs. The paragraphs retained in their original format with 80% agreement were: anticipated state of irreversible neurological coma and/or permanent vegetative state; spiritual or religious support; conscientious objection and/or professional autonomy principle; additional end-of-life preferences and instructions, and appointment of representative. The remaining 25 paragraphs received observations, comments, and wording changes. None of the paragraphs reached consensus for deletion from the form. The proposed additions to the form included: personal meaning of "good death"; directive of representation denial and arguments to change the term quality of life to well-being, and addition of the term suffering. Two questions were added to the values history: What do you consider a fate worse than death?

Figure 2. Panelist Participation Diagram per each Delphi Round.



Source: Authors.

And, What would be left for you as unfinished business if you were to die?

Online meeting round 1: A discussion about clinical scenarios related to the applicability of the AD was conducted, with the participation of two experts in bio-law and bioethics, who opened the debate among the members of the panel. Discussion categories focused on the legal construct of informed consent, therapeutic rejection, and the bioethical notion of respect for autonomy. While delving on these concepts, the idea of reversibility or non-reversibility of acute clinical scenarios was also discussed. However, in line with objective and methodology of the research, the focus was directed towards end-of-life scenarios. The final form aims to guide the ACP process, and the end result of this planning effort will be the document's signature.

A reasonable doubt for the doctor expressed during the debate, is the context or the circumstances and timing under which the ADD was developed. For example, a consent drafted 5 or 10 years ago reflected certain motivations, expectations, and desires. All of that may have changed. To address this argument, the standard provides for the possibility of replacing, amending and revoking the ADD. (6) The recommendation is to periodically review the ADD between the doctor and the patient.

Another reasonable doubt raised is that most people make decisions based on common sense, often unaware of technological advances and medical knowledge related to the advance directive (AD). In this regard, it is crucial to provide the patient with a context that integrates the trajectory and functional evolution of the disease. Medical advice is recommended when drafting the AD so that the person has the necessary arguments to make an informed decision, in accordance with the regulatory requirements or the definition of the advance directive document (ADD). (6)

Delphi round 2: A form with 30 paragraphs was submitted, including changes in wording suggested by the panelists: 25 paragraphs from round 1 and five new paragraphs, including the item on acute and reversible medical scenarios proposed in the online meeting of round 1.

The items for which agreement was not reached during this 2nd round and pending for deliberation in round 3 were: " What would be left for you as unfinished business if you were to die?" with 68.8%; "acute and reversible medical scenarios" with 56.3%; "personal meaning of 'good death'" with 68.8%; and "directive of representation denial" with 68.8%.

Online meeting round 2: The content of each paragraph was read and discussed up to paragraph 23 of the form. The paragraphs on other end-of-life considerations were left for discussion in round 3.

The debate clearly stated that the legislation does not mandate an assessment of the individual's mental capacity when requesting euthanasia through an ADD. The reasoning behind this decision is that "when the patient signed the ADD, he/she concretely and specifically declared that they were in full use of their mental abilities and were aware of the implications of their statement," according to Resolution 971 of 2021, article 13, paragraph 1. (13)

Some panelists suggested that based on the complexity and time-consuming exercise of completing the values history, the difficulty to interpret what the patient wrote, and its application in clinical practice, it should be kept as an annex to the form.

In the course of the discussions, the suggestion was made to leave one single blank space in the form for suffering and anticipated medical scenarios, and to include the examples under the instructions, considering the length of the form and the difficulty of including all possible diagnoses.

One panelist suggested to delete the word "dignified" from the expression "die with dignity through euthanasia," arguing that the Right to Die with Dignity (RDD) is different from euthanasia (1). Another panelist suggested removing "dignified" from all the subtitles under the set of RDD rights in the form. During the debate, deontological, philosophical, and legal arguments were submitted to keep the term.

Delphi round 3: This round was intended to decide whether the content approved by consensus should be included in the form or in the instructions. Based on the previous argument, and anticipating the potential loss of four panelists, in addition to preventing a participation rate below 75% and compromising the methodology, a post hoc criterion was used by four members of the working group to assess the form. Two panelist resigned, therefore, the participation rate was 89.4% (excluding the working group evaluation), and it did not compromise the validity of the round 3 results. Again, one of the 30 initial elements and one element proposed in round 1 were presented for evaluation. Consequently, the paragraph on the state of pregnancy in a condition of permanent unconsciousness reached an agreement of 71.4%, and the paragraph on the directive of denial in shared medical decision-making reached an agreement of 66.6%.

Values history was rated at 42.9% so it was adopted as an annex to the ADD form (Table 1). The panelists chose to retain the examples and the blank space for suffering at 66.6%, while anticipated medical scenarios represented 81% of the answers. 52.4% of the panelists selected to inquire about the personal concept of a good death, and 47.6% about the notion of dignified death. Finally, 66.7% of the participants chose to leave the term "dignified" in the subtitles of the powers listed under the RDD in Colombia.

Online meeting round 3: The meeting began with the reading and debate of the items assessed in the round 3 form, followed by the paragraphs pending from round 2 listed under "other end-of-life considerations."

The participating panelists suggested that for the physician responsible for implementing the ADD in the future, the prevailing criteria should be suffering, understood as the loss of quality of life and well-being according to the patient's perception, regardless of the specific disease or clinical condition. This interpretation gave rise to a reasonable doubt regarding how to apply the concept of suffering in the light of uncertainty of prognosis and clinical sequelae resulting from acute events, such as stroke. To address this concern, the panelists clarified that some diagnoses require stabilization, observation of evolution, and waiting for rehabilitation and the definition of potential sequelae. Acute events are changing conditions that demand prudence.

Most panelists argued in favor of using the term "good death" to differentiate the personal opinion from the frequent association of "dignified death" with euthanasia, often disseminated by the media. However, since the ADD is an informed consent focused on the future, the panel decided to keep the term "dignified death" in the form to maintain consistency with the legal terminology used in legal documents and avoid its invalidation by third parties.

Although the hypothetical scenario of a state of pregnancy in a condition of permanent unconsciousness reached 71.4% consensus, the final conclusion was that this is a rare event to be included as a standard element in the form. Further inquiry was suggested on this particular issue and to include it under the "other end-of-life instructions" domain.

The directive of representation denial (round 2, 68.8%) or in shared medical decision-making (renamed in round 3, 66.6%), intended to exclude a family member with conflicting views about medical and vital care, or in case of conflict of interests or ill will, was not approved in two consecutive rounds. With regards to this argument, the debate clarified that, according to Resolution 229 of 2020 (articles 4.2.4.4 and 4.2.4.5) (14), the representative of the individual who is unconscious or unable to communicate —in the absence of an ADD— must make decisions within the framework of the best interest, that is, considering the patient's

Table 1. Values history.

Of the activities you perform in your daily life, what makes your life worth living?
What health situations would make your life not worth living?
What do you consider a fate worse than death?

Source: Authors.

fundamental rights. If a representative's decision is disproportionate, out of context, or is a violation of the rights of the patient, then it becomes not applicable. This begs the question: "what are the patient's rights"? If there are reasonable treatment options available for the patient, the best interest is the treatment; in the absence of reasonable treatment options, the patient's best interest is palliative care (support and symptoms control); in case of doubt, intervention is required and then the patient's evolution, clinical data, and prognosis will guide the medical approach.

Delphi round 4: A post hoc criterion was adopted by the panelists for the final approval of the form format for publication, as well as the selection of the title and the conclusion of the article. Finally, the panelists conducted an open and optional satisfaction survey on the research work and the result expressed in the ADD form.

DISCUSSION

To the authors' knowledge, this is the first study that has developed a structured ADD form using the Delphi technique to achieve interdisciplinary health consensus at a national level. The form includes all the elements comprised in the RDD in Colombia (14), which was approved by consensus from the panelists. Agreement was reached for most of the elements in the first round with suggestions for wording changes, improved in subsequent rounds. An agreement was made to include the terms, definitions, and references of the national legislation since this is an informed consent oriented towards the future. The form is intended for both healthy and sick individuals, aged 14 and older, to be completed at any time in life during the relational and deliberative encounter between doctor-patient and/or family. "Formalization before a doctor" is emphasized, rather than the treating physician covering all levels of care, both primary and specialized, with a predominance of ACP in primary care as explicitly stated by international associations and publications. (1,2)

Countries around the world, and Colombia is no exception, face educational, cultural, and social barriers that unavoidably lead to a low level of health literacy. (15,16) Unfortunately, this reality restricts the ability of the people to understand and autonomously complete standard forms with complex medical and legal terminology. Therefore, graphic forms emerged as a solution to the hurdle of poor health literacy. (17,18) A previous study in the United States (18) found that the graphic form for a reading level appropriate to fifth grade is easier to understand and use, and more helpful for discussions and treatment decisions, and of greater value in ACP versus the standard form. However, this research reports low rates of ADD implementation by patients six months after receiving the standard form or the graphic form; 8% versus 19%, respectively. (18) These results validate that, regardless of the form design, patients with lower health literacy levels need a thorough discussion in the framework of a good doctor-patient and family relationship to understand the content, make informed decisions, and draw up an ADD. Publications also confirm that if the ADD comes from an ACP program, that increases the confidence and validity of the ADD. In turn, this leads the doctor to respect and comply with the ADD. (2,19,20) Ultimately, the unequivocal international guidelines advocating for the adoption of structured forms and the creation of the ADD with medical advice within ACP are legitimate. (1,2)

At first glance, the ADD form may seem like a lengthy document to the physician. However, several observations should be made. First, the form is the result of a rigorous academic and research process, aimed at providing the most relevant and complete content to facilitate future medical decisions. Second, it has been designed in accordance with the current national regulatory provisions to ensure its future legal validity. (13,14,21-23) Third, the ADD is the final expression of a process of deliberation during the Advance Care Planning exercise. Multiple variables influence this process, leading to its completion upon one or several doctor-patient clinical encounters. (2,18) In this sense, high-quality conversations require doctors to have communication skills, willingness to engage in emotionally challenging discussions, and enough time for debate, which demands organizational efforts to facilitate the process. (2,24,25) Finally, end-of-life decisions are complex and influenced by multiple factors affecting the patient, family, representative or care-giver, and healthcare professionals; all of these factors are subject to change based on the particular clinical scenario. (26) Therefore, approaching the ADD form with the rigor and dedication it deserves is not only a guarantee for respecting the person's autonomy and dignity but also a commitment to the quality of end-of-life care.

In summary, the structured ADD form reflects the state of the art in research and represents an academic guide for the development of high-quality institutional forms. This form has been developed with an interdisciplinary approach and represents a first step towards the implementation of ACP.

The following lines of future research are suggested: First, in the short term, determine the value of the form to support communication in ACP through the evaluation of the perceptions and experiences of patients, families, and doctors after completing the tool. Second, in the long term, to assess the clinical effectiveness of the form in clinical practice; in other words, the impact of the ADD on the quality and concordance of actual medical decisions during acute episodes of a serious illness and end-of-life care. Third, the deliberations during round 1 provide the opportunity to elaborate on and clarify the clinical scenarios of ADD applicability. Fourth, construct and validate the content of a values history form.

This study presents several strengths. First, although the CREDES guide (10) provides guidelines on the Delphi

technique for developing best practice guidelines, AMÁA chose it due to its methodological rigor for achieving consensus in the development of the form, improving the quality of the results and the presentation of the study report. Second, an additional contribution of our study to the Delphi technique was the availability of online meetings because new perspectives emerged among the panelists, Third, the heterogeneity of the sample of participants from diverse settings (clinical, research, and teaching) strengthened the validity of the form. (11) Fourth, according to the literature, the participation of 20 panelists fulfilled the requirement of a reliable sample size for the validity of the consensus among the panelists. (11) The authors attest to the transparency of the Delphi technique, avoiding directly and indirectly influencing and biasing the panelists' judgments both in the delivery of evidence on the subject and in the submission of the report to the panelists. The report was submitted with all the comments, observations, and contributions from the panelists. No summaries were ever used. Likewise, each panelist had access to the video recording of the online meeting for the evaluation of the next round. The study herein discussed rigorously followed the methodology outlined in the design to ensure the validity of the results. (10-12)

The following limitations inherent to any Delphi technique are recognized. The national and international scientific literature fails to provide an established definition of "who is an expert" in ADD; no definition is available regarding the level of knowledge or expertise required and how it can be identified. (11) In a Delphi consensus, there is no criterion for the number of participant dropouts or how to replace them. This is important because first, it limits the participation rate and compromises the methodology, and second, it may compromise the validity of the results due to bias, i.e., if those who do not participate are different from the sample. (11) In following up with non-participants, lack of time was the reason argued for the four dropouts and the two dissenting panelists, which led to the loss of representation from the critical care, psychiatry, and pediatric disciplines.

CONCLUSION

This Delphi study has generated a structured ADD form based on ethical, clinical, and legal criteria, thus ensuring high-quality content. The form should be completed and formalized through a discussion between just the doctor and the patient in ACP. The form is available for partial or total adoption by patients, doctors, healthcare institutions, and palliative care services throughout the national territory.

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ETHICAL RESPONSIBILITIES

Endorsement by the ethics committee

The Ethics Committee and the Research Committee of the School of Medicine of Fundación Universitaria de Ciencias de la Salud (FUCS) approved the study by Act 728 of January 29, 2024.

Protection of humans and animals

The authors declare that no experiments were conducted on humans or animals for this research.

Data Confidentiality

The authors declare that they have followed their workplace protocols regarding the publication of data from the participants.

Right to Privacy and Informed Consent

The authors declare that no patient data are disclosed in this article.

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Author contributions

AMÁA: original idea and study design, coordination of rounds, preparation of Delphi reports, contributions to the manuscript and critical review, and drafting of the initial manuscript.
BJPB: coordinator of online meetings.
BJPB, PPM, ACV: contributions to the manuscript and critical review.

All authors have read and approved the final manuscript.

Conflict of Interest

None declared by the panelists and authors of the manuscript.

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None declared.

Availability of complementary material

The dataset supporting the analysis and results of this study is available upon reasonable request. The data is not publicly available due to ethical or privacy restrictions.

Presentations

None declared.

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Advance Directive Document

Formalization before the doctor

City: _____Day: ____Month: _____ Year: _____

Exercising my right to subscribe and sign an advance directive document pursuant to Resolution 2665 of 2018 of the Ministry of Health and Social Protection, I hereby declare that my physician and/or the treating healthcare team has given me clear, sufficient and objective information about my current health condition, to ensure that my will is respected and implemented upon a future loss of my capacity to decide and/or to communicate my preferences or wishes related to my personal care and medical assistance in the context of a given clinical condition.

I, _____, identified with citizenship id/foreigner card number_____ issued in _____, hereby declare that I am of sound legal and mental mind, free from duress, and that I understand the nature and consequences of the contents of this legal and clinical document. Accordingly, I specifically, clearly, expressly and unequivocally state the following preferences regarding my future health care and medical assistance, as well as my end of life wishes for a given clinical condition.

Underlying pathologies

Section A: I do not suffer from any disease. ___
Section B: My treating doctor and/or clinical team has explained the natural course of my disease(s), as well as the severity, treatment, and prognosis. I have the following disease(s):

_____
_____
_____

Section I. Values

Concept of well-being or quality of life

What do I value most in my life or what does quality of life means to me?

_____
_____
_____

Concept of suffering

Considering my values, beliefs and opinions about what I enjoy and gives me satisfaction in life, the following situations would affect my well-being and cause me suffering:

1) Experiencing an irreversible state of unconsciousness. Yes__ No__
2) Being permanently unable to communicate my needs, relate to, and/or recognize my family or friends. Yes__ No__
3) Being permanently unable to make decisions for myself, maintain my autonomy, and be in control of my life, even if I have no physical limitations. Yes__ No__
4) Being permanently unable to provide for my basic self-care, including bathing, dressing and undressing, feeding myself, going to the toilet, and taking medications without being bedridden. Yes__ No__
5) Other considerations that would affect my well-being and cause me suffering are: _____
_____
_____

Concept of dignified death

According to my values, beliefs, and personal appreciation, a dignified death for me is:
_____
_____

Section II. Anticipated medical scenarios

I want my advance directive to be respected when my concept of suffering as described under Section I is met, regardless of any disease or clinical condition I may have. Some scenarios I consider possible, but not limited to these, are as follows:

1) Irreversible neurological coma and/or permanent vegetative state. Yes__ No__

2) Brain injury or disease without reasonable potential for recovery of function and/or well-being. Examples: dementia, thrombosis, ischemia, hemorrhage, tumor, trauma. Yes__ No__

3) Acute disease in an irreversible clinical condition; i.e., without reasonable potential for recovery of function and/or well-being. Examples: refractory septic shock, multiple organ failure. Yes__ No__

4) Terminal disease meaning advanced, progressive, and uncontrollable disease, without reasonable potential for a positive response to treatment and with physical and/or psychological suffering, with a life expectancy of less than six (6) months (Law 1733 of 2014, Article 2). Yes__ No__

5) Therapeutic refusal to the indicated treatment of a potentially reversible clinical event in a chronic disease with a high impact on quality of life (Article 3 of Law 1733 of 2014). Examples: heart failure, chronic obstructive pulmonary disease (COPD), renal failure, pulmonary fibrosis, autoimmune diseases (such as systemic lupus erythematosus [SLE]) or infectious diseases (such as human immunodeficiency virus [HIV]). Yes__ No__

The therapies I refuse to receive include: _____
_____
_____

6) Other diseases or clinical conditions that would cause me suffering are:_____
_____
_____
_____

Section III. Advance Directive

My advance directive is as follows: if my health condition deteriorates to the extent that it leads to a clinical condition that affects my well-being and/or quality of life and causes me suffering according to my own judgement (as described under Section I) and, in the light of the anticipated medical or clinical scenarios mentioned above (as described under Section II), I hereby declare:

1) My right to die with dignity through the readjustment of therapeutic objectives or redefining care measures (Judgment T-060 of 2020)

I understand and accept the concept of "readjustment" as the act of withdrawing or not initiating potentially inappropriate procedures, treatments, or other interventions that the medical team considers for my specific clinical condition and that only aim to unnecessarily artificially prolong my life and interfere with the process of a natural death.

Similarly, I understand that this decision means adjusting all medical decisions to minimize suffering and contribute to symptom control and comfort, without the intention of shortening life. I understand that only the medical team defines which therapies may be potentially inappropriate and that there may be disagreement within my family. Consequently, I request that this right be considered whenever my medical condition warrants it (Judgment T-060 of 2020 of the Constitutional Court).

2) My right to die with dignity through palliative care

I understand "palliative care" as the comprehensive care provided to an individual of any age, who experiences health-related suffering due to a serious illness and, especially, those approaching the end of life, when controlling pain and other symptoms involves not only medical support, but social, spiritual, psychological and family support during the course of the illness and bereavement (International Association for Hospice and Palliative Care, 2020; Law 1733 of 2014, Article 4). I accept: Yes__ No__

I understand that "palliative sedation" is indicated in end-of-life scenarios or in the presence of a poor short-term prognosis (two weeks); it involves the administration of medications to reduce my state of consciousness as much as necessary, to adequately relieve one or more symptoms refractory to medical treatment that would otherwise be intolerable. I accept: Yes__ No__

3) My right to die with dignity through spiritual and/or religious accompaniment

In case of terminal illness or agony, or even after my death, I request spiritual and/or religious care. Yes__ No__.

If the answer is Yes, following are the contact details of the person I wish to provide that spiritual and/or religious care (name of the spiritual or religious leader, community or belief system, phone number[s], address, email, etc.):

_____

_____

In case of terminal illness or agony, or even after my death, my preferences regarding special visits, type of religious service, option of wake, cremation, burial, place where my remains or ashes will rest, etc., are as follows:

_____

_____

4) My right to die with dignity through euthanasia.

I have been informed by the medical team that the “euthanasia procedure” refers to a medical procedure in which a person's death is actively induced in advance, respecting the right of voluntary, informed and unequivocal request, in accordance with the clinical scenarios established under the national legislation. (Article 6 of Resolution 971 of 2021 of the Ministry of Health and Social Protection). Hence, I request the euthanasia procedure in case of having:

1. *A terminal clinical condition; that is, an advanced incurable disease, a terminal illness, or agony that causes suffering (Judgment C-239/1997 and Judgment T-970/14 of the Constitutional Court). Yes__ No__*

2. A bodily injury or a serious and incurable disease that causes suffering (Judgment C-233/2021 of the Constitutional Court). Yes__ No__.

I hereunder list such potential injuries or diseases: _____
_____
_____

3. In the event that I am in the protocol of dignified death by euthanasia, if I deteriorate and become unconscious as part of the end of life and/or dying process, my wish is:

Option A: ___ That the protocol should be continued and the euthanasia procedure be administered to me.
Option B: ___ Cancel the euthanasia protocol and let natural death occur.

Other end-of-life considerations

1) I prefer to spend the last days of my life at home or, if not possible, in a hospice, if my health condition allows for out-of-hospital care. Yes__ No__

2) I wish to be accompanied by a family member and/or close people in the last moments of my life, if allowed by clinical and biosafety conditions authorized by the medical team and the health institution. Yes__ No__

3) I wish to participate in clinical research or scientific protocols duly approved by institutional ethics and research committees. Yes__ No__

4) I wish to donate my organs and/or tissues. Yes__ No. If affirmative, I wish my organs and/or tissues to be donated for: transplants, scientific research, teaching. (More than one option may be selected).

Specifications for the destination of my organs and/or tissues:_____ _____
_____
_____

6. Additional preferences and instructions for my end of life

(e.g., presence of pets during my end of life or wishes I want to have fulfilled):

_____
_____

Section IV. Support Persons

(Article 47 of Law 1996 of 2019 and Articles 4.2.4.4 and 4.2.4.5 of Resolution 229 of 2020 of the Ministry of Health and Social Protection).

I hereby authorize _____, identified with citizenship card/foreigner card number _____ issued in_____ kinship _____, to have access to my medical record verbally or in writing, receive the necessary information to make decisions not considered in this document, serve as a guarantor of the fulfillment of my will, and be considered a valid and necessary intermediary before my treating physician of healthcare team. To contact them, the following phone numbers are available: _____ and _____.

Sign in agreement:

_____
Support person's signature

If the aforementioned support person resigns, becomes unavailable or dies, I hereby appoint a second support person with the same powers as the first, identified with citizenship card/foreigner card number issued in _____, kinship_____. Contact phone: _____ and _____.

Sign in agreement.

_____
Second support person's signature

Section V. Formalization

Name and signature of the person granting this advance directive

In witness whereof, I hereby execute this legal and clinical document in_____ City, on the _____day of the month, year _____.
Signature: _____

Fingerprint

Full name: _____
Citizenship id _____ /foreigner card _____ number, issued in _____
Address: _____
City: _____

I acknowledge that I have been informed of my right to amend, replace, or revoke this advance directive document at any time and that this decision will not affect the quality of medical and health care to which I am entitled. I understand that there is no expiration date for the advance directive document.

Name and signature of the physician

Signature: _____
Full name: _____
Citizenship id _____ /foreigner card _____ number, issued in _____
Physician's license number: _____
Contact phone (optional): _____

I understand and accept that the health professional providing me with medical care may invoke his/her right to conscientious objection and/or the principle of professional autonomy to not act according to my will expressed hereunder. In this case, I request the clinical institution to assign another professional willing to comply with my wishes.

Note: It is advisable to inform your close relatives or caregivers of this advance directive so that they are sufficiently aware of it.

It is also advisable to leave a copy of this advance directive in the medical record and provide a copy to the support persons and/or the family member(s) you appoint.

COMPLEMENTARY MATERIAL

Complementary material 1. Recruitment strategy.

The collection strategy comprised two phases. In the first phase, following a letter of authorization from the ethics committee, an invitation to participate was sent by email to the directors of the following Colombian medical associations:

- Asociación Colombiana de Cuidados Paliativos (ACCP).
- Asociación de Cuidados Paliativos de Colombia (Asocupac).
- Observatorio Colombiano de Cuidados Paliativos (OCCP).
- Asociación Colombiana de Gerontología y Geriatría.
- Sociedad Colombiana de Medicina Interna (ACMI).
- Asociación Colombiana de Medicina Crítica y Cuidado Intensivo (AMCI).
- Asociación Colombiana de Psiquiatría (ACP).
- Dirección de la Especialización en Psicología de los Cuidados Paliativos Universidad San Buenaventura.
- Asociación Colombiana de Facultades de Psicología (Ascofapsi).
- Colegio Colombiano de Psicólogos (Colpsic).

And university professors from institutions with programs in pain and palliative care and bioethics:

- Coordinación de Especialización en Medicina del Dolor y Cuidados Paliativos, Universidad de La Sabana.
- Coordinación de Especialización en Medicina del Dolor y Cuidado Paliativo, Universidad Pontificia Bolivariana.
- Coordinación de Especialización en Medicina del Dolor y Cuidados Paliativos, Fundación Universitaria Sanitas.
- Coordinación de Especialización en Dolor y Cuidado Paliativo, Universidad CES.
- Dirección de Especialización en Dolor y Cuidado Paliativo, Universidad El Bosque.
- Dirección de Maestría en Cuidados Paliativos, Universidad Antonio Nariño.
- Coordinación de la Especialización en Medicina del Dolor, Universidad de Antioquia.
- Coordinación de la Especialización en Medicina del Dolor y Cuidados Paliativos, Pontificia Universidad Javeriana.
- Facultad de Educación y Humanidades, Universidad Militar Nueva Granada.
- Director Departamento de Bioética, Universidad El Bosque.
- Programa Especialización en Bioética, Universidad de La Sabana.
- Programa en Bioética, Universidad CES.
- Coordinación de Maestría en Bioética y Bioderecho, Universidad Pontificia Bolivariana.
- Programa Maestría en Bioética y Ética de la Investigación, Universidad de los Andes.

The above medical associations and university institutions sent the written invitation twice to each of the health professionals or university professors to their personal and institutional email addresses, with a one-week interval between each email. Likewise, the invitation was posted on the official websites and social media of the medical associations and universities. The invitation included an online link where the professional interested in participating completed the following data: full name, email address, phone number, profession, and institutional affiliation. Then, the first database was created with 29 professionals.

During the second phase, each of the respondents received the consent form to be read and signed, via their institutional and/or personal email. Only 23 professionals returned the signed consent to the institutional email of the corresponding author. Then, a second database was developed, and the participating professionals were then identified as the "panelists." These two phases were conducted from February 1st to March 8th, 2024.

Academic consultation material for the preparatory phase of the Delphi rounds

Round 1: Reading form round 1, evaluation form round 1, panelists report round 1, online meeting video round 1.

Round 2: Reading form round 2, evaluation form round 2, panelists report round 2, online meeting video round 2.

Round 3: Reading form round 3, evaluation form round 3, panelists report round 3, online meeting video round 3.

Round 4: Evaluation instructions, panelists report round 4.

Instructions for the ADD Form. Definitions