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Identifying priorities for cancer caregiver interventions: Protocol for a three round modified Delphi study

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Identifying priorities for cancer caregiver interventions: Protocol for a three round modified Delphi study

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Abstract

Introduction Cancer is often considered a chronic disease, and most people with cancer have a caregiver, often a family member or friend who provides a significant amount of care during the illness trajectory. Caregivers are frequently in need of support, and a range of interventions have been trialed to improve outcomes. Consensus for optimal ways to support caregivers is not known. The aim of this protocol paper is to describe procedures for a modified Delphi study to explore expert consensus about important factors when developing caregiver interventions.

Methods and analysis Online modified Delphi methodology will be used to establish consensus for important caregiver intervention factors incorporating the PICO framework. Round 1 will comprise a free-text questionnaire and invite the panel to contribute factors they deem important in the development and evaluation of caregiver interventions. Round 2 is designed to determine preliminary consensus of the importance of factors generated in Round 1. The panel will be asked to rate each factor using a 4-point Likert-type scale. The option to state panelists reasoning for their rating will be provided. Descriptive statistics (median scores and IQR) will be calculated to determine each item's relative importance. Levels of consensus will be assessed based on a predefined consensus rating matrix. In Round 3, factors will be re-circulated including aggregate group responses (statistics and comment summaries) and panelist's own Round 2 scores. Panelists will be invited to reconsider their judgments and resubmit ratings using the same rating system as in Round 2. This will result in priority lists based on the panel's total rating scores.

Ethics and dissemination Ethics for this study has been gained from (blinded for review) Human Research Ethics Committee. It is anticipated that the results will be published in peer-reviewed journals and presented in a variety of forums.

Strengths and limitations of the study

We adopted the PICO framework for the retrieval of relevant information with which to address the research question and Delphi methodology to explore levels of consensus and assess expert opinion.

Our study methodology can be replicated by other intervention researchers seeking to investigate and design appropriate interventions for varied clinical populations.

A research advisory committee is assembled to inform and guide the purposive sampling of relevant stakeholders with high expertise in relevant fields, which ensures the input of high quality information.

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Given the paucity of evidence with regard to cancer health care professionals' appreciation of the needs of caregivers, this study focuses solely on participants in professional and academic roles. However, data from this study will be used to inform future projects that focus specifically on the views of caregivers.

For peer review only

INTRODUCTION

The growing rate of people affected by cancer and advances in screening, early detection and treatment mean that more people are expected to live longer with the disease [1]. Many people with cancer have a caregiver, often a friend or family member, who undertakes complex and demanding caregiving tasks [2], often without training or resources [3]. Caregiver needs have shown to parallel or even exceed those of the person with cancer themselves [4, 5]. Negative impacts on caregivers have been reported and can include burden of care provision, depression, anxiety, reduced quality of life, loss of self-identity, loneliness, isolation, and a need for more information [6-11], although, some people also experience positives associated with care provision [7, 12]. Two thirds of caregivers, in a study of two hundred caregivers of people with advanced cancer, reported providing over 80% of the care [2]. Reported caregiving tasks included providing emotional support, administering medications, assisting with bathing, toileting and feeding and other daily living and domestic tasks [2].

Several systematic reviews have been conducted summarizing the cancer caregiver intervention literature [13-20]. Northouse and colleagues [21] presented a meta-analysis of the efficacy of caregiver intervention trials, categorising interventions as psychoeducational, skills training and therapeutic counselling. It was concluded that interventions had small to medium effects and were able to reduce burden, improve coping, self-efficacy and quality of life [21]. In a recent update of the Northouse review, Ferrell and Wittenberg [20] identified an increase in trials, noting that more interventions are being conducted in home settings or by telephone. They also found significant diversity in intervention studies for type, dose, format and content of interventions as well as measures and reported outcomes. Furthermore, the need to translate trials into practice was highlighted [20]. These reviews outline substantial variety in how caregiver interventions are delivered.

Given that interventions are costly, time consuming and challenging to conduct, it is essential that we understand the groups of caregivers likely to benefit from intervention and what to target within an intervention and when to intervene. A recent international Delphi survey set out to identify priority topic areas for cancer caregiver research [22]. Topics achieving high consensus across expert panels included the financial impact of caregiving, routine screening of caregiver-reported outcomes and educating clinicians about caregiver needs. This research presents an important list of broad

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3 priorities, however there is opportunity to build on this work through understanding consensus about
4 how caregiver interventions can be delivered.
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8 The growing number of caregivers and associated burden requires careful consideration of multi-
9 stakeholder views in order to build a comprehensive understanding of the factors that matter most for
10 developing appropriate support interventions. The present study consists of multi-stakeholder enquiry
11 by using a sample of clinical and content experts to determine relevant factors for the practical and
12 clinical delivery of caregiver intervention.
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15 16 17 **Aim**

18 The aim is to solicit knowledge and consensus from relevant cancer-specific healthcare and academic
19 experts in order to develop guidelines for effective caregiver intervention design and evaluation. The
20 study will aim to elicit levels of expert consensus for five factors: 1) views on the caregivers who
21 should be the target of interventions; 2) the content and mode of delivery of the interventions; 3) the
22 potential outcomes and benefits; 4) the appropriate approaches and methodologies to evaluate
23 caregiver interventions and 5) the barriers to conducting caregiver research
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30 **METHOD AND DESIGN**

31 **Study design**

32 Determining critical factors for the design and evaluation of caregiver interventions requires rigorous
33 enquiry into available evidence and relevant expert knowledge. To this end, a new Delphi
34 methodology was developed, which incorporates the PICO framework [23]. PICO refers to Patient
35 problem, Intervention, Comparison, and Outcome and is a framework used to answer a well-focused
36 clinical question by adopting an effective and evidence-based research approach [23]. The PICO
37 framework is used in this Delphi study to focus expert participation on systematically formulating
38 factors that are directly relevant to addressing the question at hand. Delphi research uses a multi-
39 stage, structured and iterative feedback process to elicit levels of opinion consensus on a given topic.
40 The present study uses the PICO framework in combination with Delphi methodology to
41 systematically generate new and translatable knowledge. Applying this method, items under each
42 subject heading will be generated and prioritized based on expert consensus and guidelines for future
43 caregiver intervention development formulated. The study flow is illustrated in Figure 1. The study
44 design follows the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)
45 2013 Checklist [24].
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[INSERT FIGURE 1 HERE]

Figure 1 Design of modified Delphi using a series of three questionnaires (Q1 - 3).

Advisory committee

As recommended for priority setting research, an advisory committee has been established [25, 26] with topic and methodological experts, researchers and healthcare practitioners from a range of disciplines. The advisory committee will contribute to the selection of a sample of experts to be invited to the Delphi expert panel and develop guidelines based on the items that have achieved consensus.

Rounds and timeline

In research areas where little is known, it is recommended to plan up to four Delphi rounds to ensure rigor in the development of items and consensus building [27]. However, where research builds on existing knowledge, a trend is evident toward adopting fewer rounds with successful outcomes. Delphi designs with fewer than four rounds have elicited expert agreement on topics such as the supportive care needs of adult cancer survivors [28], the needs of adolescents and young adults survivors [29] and standardized criteria for automatic referral to palliative care services [30]. The present study requires collection of focused expert knowledge to generate pertinent items and understanding of expert consensus in regards to the importance of items in order to set priorities. A 3-round Delphi is proposed to generate pertinent items (Round 1), explore preliminary consensus (Round 2), and finally rate the short-listed items to determine priorities based on levels of consensus achieved (Round 3). The feedback process will be conducted online in four week intervals [31] accounting for sufficient time to gather input, aggregate and re-circulate group responses, and to stepwise build questionnaires as data are collected and analyzed.

Questionnaires

Delphi is an iterative research methodology that builds upon ongoing data collection. Its primary research procedure is the systematic sequencing of questionnaires. Questionnaire 1 (Q1) will be available for distribution at the start of recruitment and Questionnaire 2 (Q2) and Questionnaire 3 (Q3) will be built based on participants' input. Q1, Section A to E representing five factors are

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3 outlined in the Data Collection section below. Q1 (item generation) will take approximately 15
4 minutes to complete and Q2 and Q3 (rating) are anticipated to take no more than 10 minutes to
5 complete.
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8 9 **PARTICIPANTS**

10 **Selection of experts**

11 Expertise is defined as having both knowledge and experience in a given field and an expert is a
12 person with the capacity to articulate informed opinion and provide relevant input about their area of
13 expertise [32]. This study will purposely sample national and international experts in professional
14 and academic roles from relevant backgrounds able to provide salient information about caregiver
15 intervention priorities. The advisory committee will use its own professional networks and seek
16 further referrals for eligible study participants (snowballing). Additionally, authors who have led
17 intervention studies included in a recent caregiver systematic review will also be invited to
18 participate in this Delphi (blinded for review). The following list of inclusion criteria was developed
19 to ensure recruitment of experts with strong understanding of cancer caregiver issues: (1) healthcare
20 or allied health practitioner with extensive clinical practice experience in oncology; or (2) have
21 published in the area of cancer caregiver research in the last 10 years, (3) sufficient written English
22 skills to communicate ideas effectively and capable of contributing relevant input; and (4)
23 willingness and availability to complete all three rounds.
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35 **Patient and Public Involvement**

36 In this study, experts are referred to as professionals and academics with expertise, rather than
37 caregivers. Previous Delphi studies include consumers as experts (e.g. [29]), whereas others do not
38 include the target group (e.g. [28]). While consumer input is known to improve the quality of
39 research [56], it was expected that caregivers would have unique views and perspectives [22] that
40 would benefit from being fully explored with a separate, dedicated and purposefully designed study,
41 incorporating a diverse and representative range of caregivers. This is considered an important
42 avenue for future work. Patients and public are not involved in this Delphi study.
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49 **Sample size**

50 Delphi panel membership is determined by the study purpose and its constraints [33] and can range
51 from single digits to low hundreds [34]. A panel of ten to eighteen experts is recommended to ensure
52 sufficient contributions [27, 34]. However, quality of data and levels of expert census are considered
53 of greater importance than the statistical power of response [35, 36], which distinguishes Delphi
54 research from a quantitative survey [34]. Taking account of the commonly high dropout rate in
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3 Delphi studies, the recruitment target for this study is a maximum of 30 experts to allow for the input
4 of a diversity of views while accounting for expected attrition. A maximum of 100 experts will be
5 invited to achieve the minimum target.
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8 9 **Recruitment**

10 Recruitment will use email invitations containing a short description of the study purpose and
11 participation requirements and Q1. Completion and return of Q1 will be considered implied consent.
12 Participation is voluntary and can be withdrawn at any stage. Participants can request their
13 demographic information and where possible other contributions to be withdrawn; however, due to
14 the study's iterative process not all contributions can be withdrawn once included in previous rounds.
15 If provided, reasons for declining or later withdrawal from the study will be recorded.
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21 **DATA COLLECTION AND ANALYSIS**

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24 The data collection and analysis sequence is illustrated in Figure 2 and the procedures for each round
25 (questionnaire) are detailed below.
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29 *[INSERT FIGURE 2]*
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31 **Figure 2** Delphi data collection and analysis sequence.
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35 **Q1 Generation of items**

36 Q1 aims to elicit relevant issues for consideration (items), before quantitatively rating their levels of
37 importance in future rounds as judged by the expert panel.
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40 Sections A to E represent five different factors, and these sections will invite experts to list at least
41 six items they deem of critical importance to the subject headings introduced. Additional space is
42 provided for detailed descriptions should participants wish to elaborate on their responses.
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45 A. Caregiver characteristics

46 *What caregiver factors are important in cancer caregiver intervention research? Consider*
47 *factors such as demographic, medical, personal or clinical characteristics, to identify high*
48 *priority groups.*
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51 B. Intervention components

52 *What intervention components are important in cancer caregiver intervention research?*
53 *Consider intervention content, and delivery method, setting and doses, for delivery of*
54 *optimal interventions.*
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57 C. Outcomes

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3 *Cancer caregiver interventions can target various outcomes, including caregiver, patient or*
4 *health service factors. Consider what are the important outcomes for cancer caregiver*
5 *intervention, including who may benefit from caregiver interventions and for which*
6 *outcomes.*
7

8 D. Study characteristics

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10 *Cancer caregiver intervention outcomes can be investigated using a variety of approaches.*
11 *Consider which methodologies are important in understanding and evaluating the benefits of*
12 *caregiver interventions.*
13

14 E. Barriers

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16 *What are the most significant barriers to the conduct of caregiver intervention research?*
17

18 Q1 Analysis

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20 All data (items and explanations) will be entered and managed in qualitative data analysis software
21 NVivo [37]. The analysis will involve removing identical responses before subjecting the list of items
22 to interpretive content analysis as is consistent with the exploratory aim of the first questionnaire.
23 Each item will be examined and a broad summarizing label (code) will be assigned. These codes will
24 arise from the data itself rather than be pre-defined. As the analysis progresses and multiple similar
25 and connected codes arise, the analyst will begin grouping them into summarizing categories. Once
26 all items are coded and sorted into categories, the analyst will re-read all data and refine the
27 terminology to ensure all contributions are captured. An inter-rater process will assist interpretative
28 congruity as recommended for qualitative analysis [38]. In this step, a second member of the project
29 team will read all raw data and analytic work and any disagreement about interpretation or category
30 development will be discussed with the analyst until agreement is reached. This generates a list of
31 statements pertaining to each category.
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41 Q2 Rating items

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43 Q2 will list all generated items according to subject headings they were submitted under and panelists
44 will be asked to rate each item's importance in order to establish preliminary levels of consensus.
45 Each item will be presented with a corresponding 4-point Likert-type scale (1 = Very unimportant, 2
46 = Unimportant, 3 = Important, 4 = Very important) and an option to indicate "No judgment" will be
47 provided including space for panelists to state their reasoning. To minimize response bias, Q2 will
48 list the items generated in Q1 without response statistics (number of experts who contributed to each
49 items).
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55 Q2 Analysis

Statistical analyses will be performed using IBM SPSS Statistics [39]. Descriptive statistics (median scores and IQR) will be calculated to indicate each item's relative importance based on the full response sample. Delphi studies use variable definitions and thresholds for determining opinion consensus [27]. For purposes of assessing levels of consensus, this study will use a predefined rating matrix, adapted from Meskell and colleagues [40], which is illustrated in Table 1.

Q3 Prioritizing items

Q3 will be designed to provide panelists the opportunity to reconsider their responses in light of preliminary levels of consensus achieved about the importance of each item. Additionally, the panel will be presented with summary comments about the reasoning for judgments made by other panelists. To assist clarity and consistency, Q3 will follow the same layout as the previous one. All items will be relisted under their respective subject headings with corresponding 4-point Likert-type rating scales. Additionally, this questionnaire will include aggregated statistical group responses generated for each items including: the level of importance of each factor based on group consensus thus far, a summary of group comments and reasoning for ratings of each item, and individual panelist's own Q2 response.

Q3 Analysis

Analysis for data collected in Q3 will use the same strategy as in the preceding round. The study aims to explore and quantify levels of agreement rather than achieve consensus, therefore this Delphi has been designed to progress through a pre-defined number of three rounds rather than continue until consensus is reached. Statistics will be calculated (median scores and IQR) to describe each item's importance and group consensus will be determined based on the consensus rating matrix. A final priority list of items will be generated.

Table 1 Consensus rating matrix.

Importance level	Numerical category of importance rating	High consensus	Moderate consensus	Low consensus	Direction of consensus
Very unimportant	One	70% or more in category one	60% or more in category one	50% or more in category one	Low importance
Unimportant	Two	70% or more in category two	60% or more in category two	50% or more in category two	
Important	Three	70% or more in category three	60% or more in category three	50% or more in category three	High importance
Very important	Four	70% or more in	60% or more in	50% or more in	

		category four	category four	category four	
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ETHICS

The study was approved by the (blinded for review) Human Research Ethics Committee. All consented participants will be assigned a unique identification code. Collected demographic information and contact details will include: name, contact phone number, e-mail address, description of professional role, years served in field of expertise, country of professional residence/affiliation. Participants' identifiable information will be matched with their unique identification code in one digital masterfile only. All data collected will be stored safely and securely in locked filing cabinets and in password protected folders on a secure drive (electronic data) that can be accessed only by the study investigators. Data will be kept for 5 years as per local ethics guidelines.

DISCUSSION

Combining the PICO framework and Delphi methodology

It is recommended that evidence-based medicine include a rigorous process for the formulation of clinical questions to find precise answers [41, 42]. Research shows that clinicians cross numerous questions in their practice and that up to two thirds remain unanswered [43, 44]. It is held that better question formulation and search process can lead to better solving unanswered questions [42, 45]. To this end, the PICO framework was developed to facilitate focused formulation of answerable clinical queries [23]. PICO is designed to elicit and precisely articulate the elements contained in clinicians' queries, which is considered key to efficiently retrieving relevant evidence for making evidence-based clinical decisions [46, 47] and for guiding searches and content for systematic literature reviews [48, 49]. The PICO framework lends itself to addressing questions such as caregiver intervention priorities, which require collection of items relating to caregivers themselves (P), the types and content of effective interventions (I) and the expected outcomes (O). While the study's information needs does not include a Comparison/Control (C) component, we are additionally interested in discerning the appropriate methodologies for evaluating and researching intervention outcomes. Huang and Demner-Fushman's [42] investigation of the PICO's suitability for clinical queries found that not all questions necessarily utilize all PICO components; in their study of 59 real-world clinical questions only two contained all four PICO elements. While the findings affirm the usefulness of PICO overall, it was noted that complex, real-world questions not always fit its formula squarely and may require modifications [42]. Our research question is focused on the need for healthcare response to the detected lack of appropriate caregiver support.

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3 The present study aims to not only collect high quality evidence and expert knowledge but
4 also prioritize areas of intervention and elicit levels of consensus amongst experts. The findings will
5 be placed into context with current research priorities and a growing body of work aiming to improve
6 cancer caregiver outcomes [22]. The Delphi method is well suited to solicit knowledge from varied
7 expertise and delineate degrees of (dis)agreement [34, 50] and alignment with other work. Delphi
8 studies are particularly effective in investigating areas where little prior knowledge exists [51], where
9 empirical data is lacking [52] and, where priority setting is desired [34]. The specific advantages of
10 the Delphi method adopted in our research include: the ability to collect expert opinion from diverse
11 disciplines [27], rapid communication processes [53]; overcoming peer-pressure and power struggles
12 through providing an anonymous forum [54], and the ability to coordinate multi-disciplinary
13 participants across countries [33]. The present paper aims to illustrate our study design clearly in
14 order for other intervention researchers to replicate the approach for answering similar questions for
15 different clinical populations or healthcare contexts. The combination of PICO and Delphi
16 methodology presents a novel and promising approach to rigorously and rapidly generating
17 instructive answers to complex healthcare problems.
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29 **What is an “expert”**

30 The success of a Delphi study is contingent on participants who are able to provide relevant input on
31 the research topic. The absence of specific guidelines for identifying experts challenge Delphi
32 researchers to seek suitable participants with appropriate expertise [34, 55]. “Informed advocates”
33 [34] and “specialist in their field” [33] are terms used by Delphi researchers, but there is little about
34 the specific qualities needed. In the absence of clear guidelines, the current study will follow the
35 definition adopted by Blaschke and colleagues [32], which describes the prerequisite qualities of
36 merited Delphi panelists, “individuals who possess both knowledge and experience representative of
37 the capacity to articulate informed opinion and provide relevant input about a given topic” (p. 2 – 4).
38 Consumers are not included in this research with the aim to conduct further work dedicated to
39 exploring their views.
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48 **The Delphi expert panel**

49 Depending on the research objectives, Delphi panels may comprise of experts from a single
50 discipline or represent a broad mix. A heterogeneous pool of experts may serve innovation and
51 creative, combinatorial insights into unexplored questions through crosspollination of expertise.
52 When a research question is already well-focused, a homogeneous panel of experts may serve
53 addressing an identified research need. The present study requires focus on the singular task of
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determining priority items for developing future caregiver support intervention. It is necessary to engage those who contribute to healthcare decision-making, policy development and provision.

Issues of anonymity in Delphi research

Providing participant anonymity distinguishes online Delphi studies from other research methodologies that involve expert participation, for example, in focus groups. Ensuring experts' anonymity can mitigate the potentially negative impacts relating to different power relationships and expert status [34], and individuals may feel more confident to submit their views openly and freely without group pressure or judgment [33]. There is no agreement upon level of anonymity or de-identification [34]. Advantages of not providing anonymity are noted to promote recruitment due to association with other experts and introducing greater accountability for considered responses [34]. While balancing advantages and disadvantages and also recognizing challenges relating to a small but well-established cancer caregiver research community, the present study will preserve participant anonymity.

DISSEMINATION PLAN

A lay summary of results will be sent to participants on completion of the study. Results will be presented as the total number of factors generated in Q1, a summary of factors taken into Q2, and the final results from Q3. Expert recommendations will be drafted for refinement and verification in ongoing research. It is anticipated that the results of this research project will be published in peer-reviewed journals and presented in a variety of organizational, conference and social media forums.

Contributors SB, SDL, PL, SA, AU conceived the study and drafted the initial protocol manuscript. SB, SDL, PL, SA, AB, PS, SC, MK, AU are responsible for the design of the study and SB, SDL, PL, SA, AB, PS, SC, MK, AU critically revised the manuscript and related study materials. All authors have read and approved the final manuscript.

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Competing interests None declared. All authors have completed the ICMJE uniform disclosure form.

Figure 1

Figure 2

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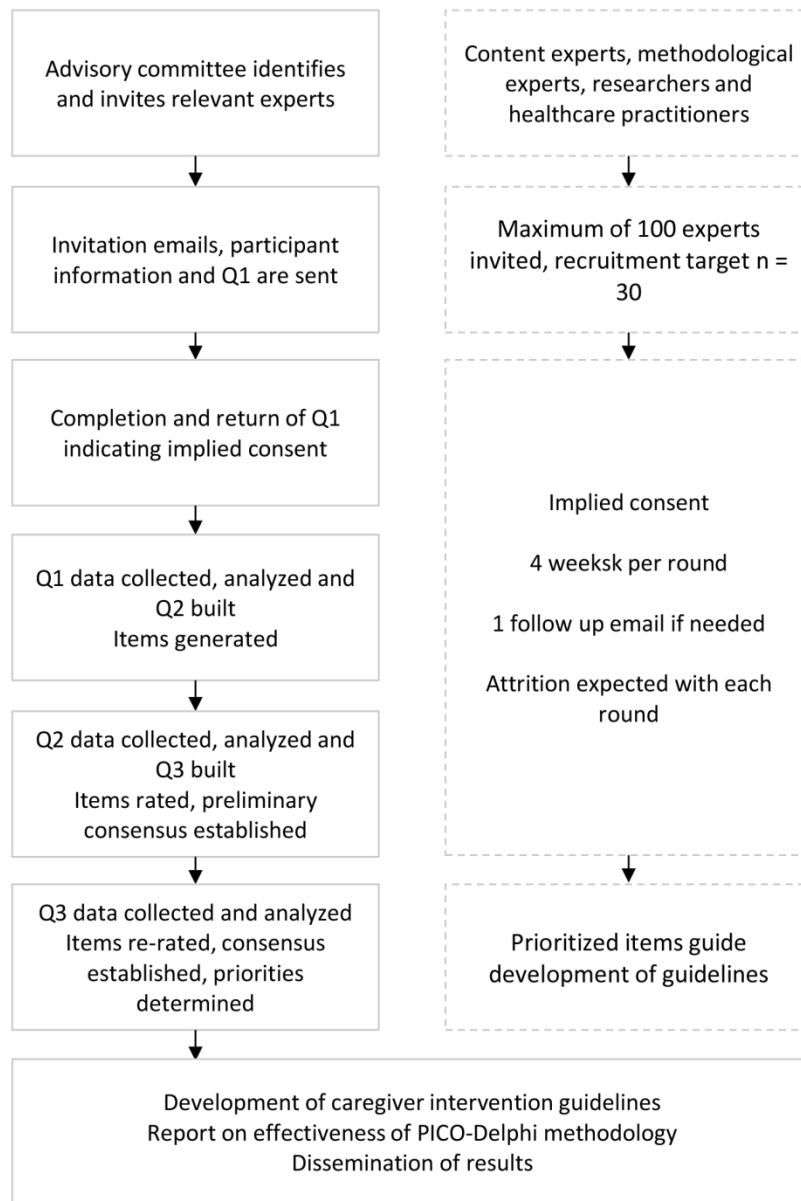


Figure 1

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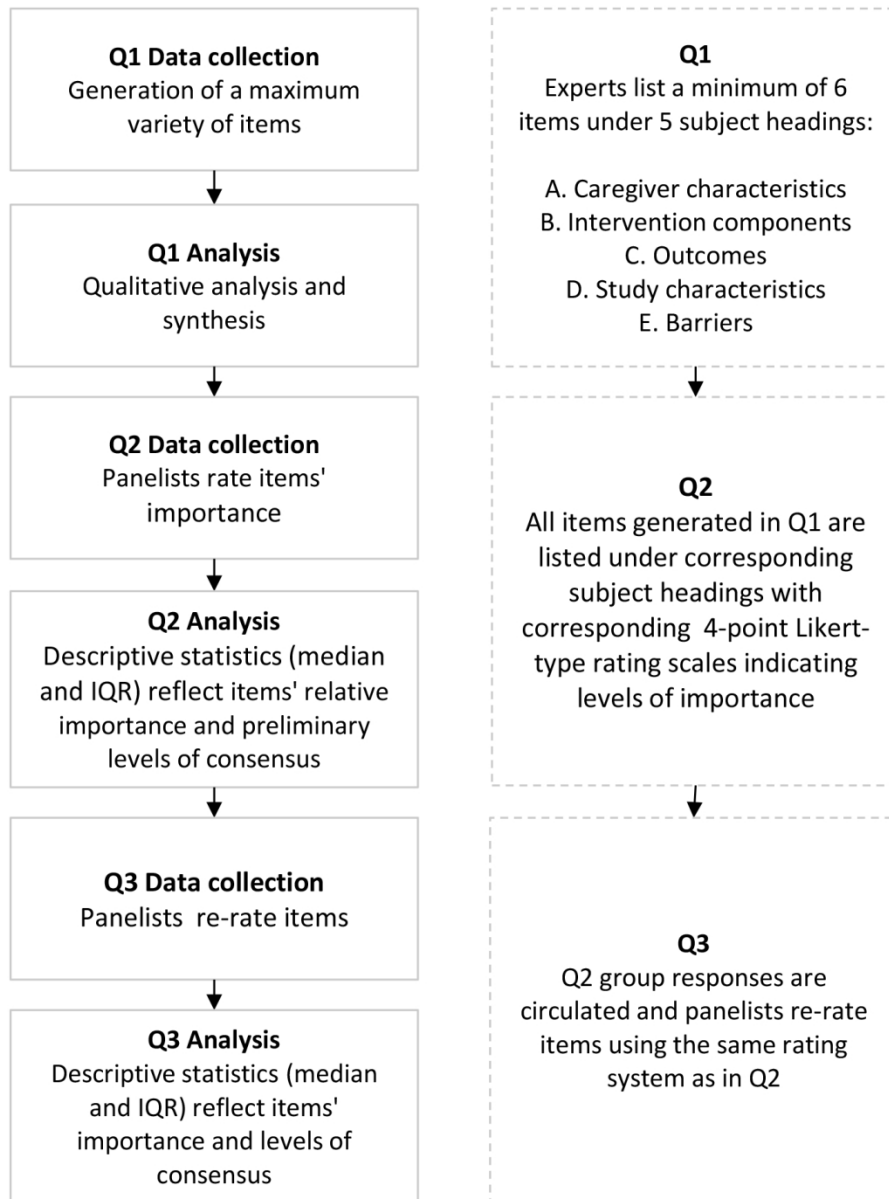


Figure 2

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Identifying priorities for cancer caregiver interventions: Protocol for a three round modified Delphi study

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Keywords:	Delphi, Caregiver, Cancer, Intervention

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5 **Identifying priorities for cancer caregiver interventions: Protocol for a three round**
6 **modified Delphi study**
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Abstract

Introduction Cancer is often considered a chronic disease, and most people with cancer have a caregiver, often a family member or friend who provides a significant amount of care during the illness trajectory. Caregivers are frequently in need of support, and a range of interventions have been trialed to improve outcomes. Consensus for optimal ways to support caregivers is not known. The aim of this protocol paper is to describe procedures for a modified Delphi study to explore expert consensus about important factors when developing caregiver interventions.

Methods and analysis Online modified Delphi methodology will be used to establish consensus for important caregiver intervention factors incorporating the PICO framework. Round 1 will comprise a free-text questionnaire and invite the panel to contribute factors they deem important in the development and evaluation of caregiver interventions. Round 2 is designed to determine preliminary consensus of the importance of factors generated in Round 1. The panel will be asked to rate each factor using a 4-point Likert-type scale. The option to state panelists reasoning for their rating will be provided. Descriptive statistics (median scores and IQR) will be calculated to determine each item's relative importance. Levels of consensus will be assessed based on a predefined consensus rating matrix. In Round 3, factors will be re-circulated including aggregate group responses (statistics and comment summaries) and panelist's own Round 2 scores. Panelists will be invited to reconsider their judgments and resubmit ratings using the same rating system as in Round 2. This will result in priority lists based on the panel's total rating scores.

Ethics and dissemination Ethics for this study has been gained from Deakin University Human Ethics Advisory Group. It is anticipated that the results will be published in peer-reviewed journals and presented in a variety of forums.

Strengths and limitations of the study

We adopted the PICO framework for the retrieval of relevant information with which to address the research question and Delphi methodology to explore levels of consensus and assess expert opinion.

Our Delphi study methodology represents a rigorous synthesis of expert opinion, can be replicated by other intervention researchers seeking to investigate and design appropriate interventions for varied clinical populations.

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3 A research advisory committee is assembled to inform and guide the purposive sampling of
4 relevant stakeholders with high expertise in relevant fields, which ensures the input of high
5 quality information.
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7 Given the paucity of evidence with regard to cancer health care professionals' appreciation of
8 the needs of caregivers, this study focuses solely on participants in professional and academic
9 roles; however, data from this study will be used to inform future projects that focus
10 specifically on the views of caregivers.
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INTRODUCTION

The growing rate of people affected by cancer and advances in screening, early detection and treatment mean that more people are expected to live longer with the disease [1]. Many people with cancer have a caregiver, often a friend or family member, who undertakes complex and demanding caregiving tasks [2], often without training or resources [3]. Caregiver needs have shown to parallel or even exceed those of the person with cancer themselves [4, 5]. Negative impacts on caregivers have been reported and can include burden of care provision, depression, anxiety, reduced quality of life, loss of self-identity, loneliness, isolation, and a need for more information [6-11], although, some people also experience positives associated with care provision [7, 12]. Two thirds of caregivers, in a study of two hundred caregivers of people with advanced cancer, reported providing over 80% of the care [2]. Reported caregiving tasks included providing emotional support, administering medications, assisting with bathing, toileting and feeding and other daily living and domestic tasks [2].

Several systematic reviews have been conducted summarizing the cancer caregiver intervention literature [13-20]. Northouse and colleagues [21] presented a meta-analysis of the efficacy of caregiver intervention trials, categorising interventions as psychoeducational, skills training and therapeutic counselling. It was concluded that interventions had small to medium effects and were able to reduce burden, improve coping, self-efficacy and quality of life [21]. In a recent update of the Northouse review, Ferrell and Wittenberg [20] identified an increase in trials, noting that more interventions are being conducted in home settings or by telephone. They also found significant diversity in intervention studies for type, dose, format and content of interventions as well as measures and reported outcomes. Furthermore, the need to translate trials into practice was highlighted [20]. These reviews outline substantial variety in how caregiver interventions are delivered.

Given that interventions are costly, time consuming and challenging to conduct, it is essential that we understand those likely to benefit from intervention, what needs to target within an intervention, and when best to intervene. A recent international Delphi survey set out to identify priority topic areas for cancer caregiver research [22]. Topics achieving high consensus across expert panels included the financial impact of caregiving, routine screening of caregiver-reported outcomes and educating clinicians about caregiver needs. This research presents an important list of broad priorities, however

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3 there is opportunity to build on this work through understanding consensus about how caregiver
4 interventions can be delivered.
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8 The growing number of caregivers and associated burden requires careful consideration of multi-
9 stakeholder views in order to build a comprehensive understanding of the factors that matter most for
10 developing appropriate support interventions. The present study consists of multi-stakeholder enquiry
11 by using a sample of clinical and content experts to determine relevant factors for the practical and
12 clinical delivery of caregiver intervention.
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16 17 **Aim**

18 The aim is to solicit knowledge and consensus from relevant cancer-specific healthcare and academic
19 experts in order to develop guidelines for effective caregiver intervention design and evaluation. The
20 study will aim to elicit levels of expert consensus for five factors: 1) views on the caregivers who
21 should be the target of interventions; 2) the content and mode of delivery of the interventions; 3) the
22 potential outcomes and benefits; 4) the appropriate approaches and methodologies to evaluate
23 caregiver interventions and 5) the barriers to conducting caregiver research.
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30 **METHOD AND DESIGN**

31 **Study design**

32 Determining critical factors for the design and evaluation of caregiver interventions requires rigorous
33 enquiry into available evidence and relevant expert knowledge. To this end, a new Delphi
34 methodology was developed, which incorporates the PICO framework [23]. PICO refers to Patient
35 problem, Intervention, Comparison, and Outcome and is a framework used to answer a well-focused
36 clinical question by adopting an effective and evidence-based research approach [23]. The PICO
37 framework is used in this Delphi study to focus expert participation on systematically formulating
38 factors that are directly relevant to addressing the question at hand. Delphi research uses a multi-
39 stage, structured and iterative feedback process to elicit levels of opinion consensus on a given topic.
40 The present study uses the PICO framework in combination with Delphi methodology to
41 systematically generate new and translatable knowledge. Applying this method, items under each
42 subject heading will be generated and prioritized based on expert consensus and guidelines for future
43 caregiver intervention development formulated. The study flow is illustrated in Figure 1. The study
44 design follows the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT)
45 2013 Checklist [24].
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[INSERT FIGURE 1 HERE]

Figure 1 Design of modified Delphi using a series of three questionnaires (Q1 - 3).

Advisory committee

As recommended for priority setting research, an advisory committee has been established [25, 26] with topic and methodological experts, researchers and healthcare practitioners from a range of disciplines. The advisory committee will contribute to the selection of a sample of experts to be invited to the Delphi expert panel and develop guidelines based on the items that have achieved consensus.

Rounds and timeline

In research areas where little is known, it is recommended to plan up to four Delphi rounds to ensure rigor in the development of items and consensus building [27]. However, where research builds on existing knowledge, a trend is evident toward adopting fewer rounds with successful outcomes. Delphi designs with fewer than four rounds have elicited expert agreement on topics such as the supportive care needs of adult cancer survivors [28], the needs of adolescents and young adult survivors [29] and standardized criteria for automatic referral to palliative care services [30]. The present study requires collection of focused expert knowledge to generate pertinent items and understanding of expert consensus in regards to the importance of items in order to set priorities. A 3-round Delphi is proposed to generate pertinent items (Round 1), explore preliminary consensus (Round 2), and finally rate the short-listed items to determine priorities based on levels of consensus achieved (Round 3). The feedback process will be conducted online in four week intervals [31] accounting for sufficient time to gather input, aggregate and re-circulate group responses, and to stepwise build questionnaires as data are collected and analyzed.

Questionnaires

Delphi is an iterative research methodology that builds upon ongoing data collection. Its primary research procedure is the systematic sequencing of questionnaires. Questionnaire 1 (Q1) will be available for distribution at the start of recruitment and Questionnaire 2 (Q2) and Questionnaire 3 (Q3) will be built based on participants' input. Q1, Section A to E representing five factors are

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2
3 outlined in the Data Collection section below. Q1 (item generation) will take approximately 15
4 minutes to complete and Q2 and Q3 (rating) are anticipated to take no more than 10 minutes to
5 complete.
6
7

8 9 **PARTICIPANTS**

10 **Selection of experts**

11 Expertise is defined as having both knowledge and experience in a given field and an expert is a
12 person with the capacity to articulate informed opinion and provide relevant input about their area of
13 expertise [32]. This study will purposely sample national and international experts in professional
14 and academic roles from relevant backgrounds able to provide salient information about caregiver
15 intervention priorities. The advisory committee will use its own professional networks and seek
16 further referrals for eligible study participants (snowballing). The following list of inclusion criteria
17 was developed to ensure recruitment of experts with strong understanding of cancer caregiver issues:
18 (1) healthcare or allied health practitioner with extensive clinical practice experience in oncology; or
19 (2) have published in the area of cancer caregiver research in the last 10 years, (3) sufficient written
20 English skills to communicate ideas effectively and capable of contributing relevant input; and (4)
21 willingness and availability to complete all three rounds.
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31 **Patient and Public Involvement**

32 In this study, experts are referred to as professionals and academics with expertise in intervention
33 design and delivery, rather than caregivers or others involved in administration or management of
34 support resources in the oncology setting. Previous Delphi studies include consumers as experts (e.g.
35 [29]), whereas others do not include the target group (e.g. [28]). It was expected that caregivers
36 would have unique views and perspectives [22] that would benefit from being fully explored with a
37 separate, dedicated and purposefully designed study, incorporating a diverse and representative range
38 of caregivers. This is considered an important avenue for future work. Patients and public are not
39 involved in this Delphi study.
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47 **Sample size**

48 Delphi panel membership is determined by the study purpose and its constraints [33] and can range
49 from single digits to low hundreds [34]. A panel of ten to eighteen experts is recommended to ensure
50 sufficient contributions [27, 34]. However, quality of data and levels of expert census are considered
51 of greater importance than the statistical power of response [35, 36], which distinguishes Delphi
52 research from a quantitative survey [34]. Taking account of the commonly high dropout rate in
53 Delphi studies, the recruitment target for this study is a maximum of 30 experts to allow for the input
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3 of a diversity of views while accounting for expected attrition. A maximum of 100 experts will be
4 invited to achieve the minimum target.
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7 8 **Recruitment**

9 Recruitment will use email invitations containing a short description of the study purpose and
10 participation requirements and access to Q1. Completion of Q1 will be considered implied consent.
11 Participation is voluntary and can be withdrawn at any stage. Participants can request their
12 demographic information and where possible other contributions to be withdrawn; however, due to
13 the study's iterative process not all contributions can be withdrawn once included in previous rounds.
14 If provided, reasons for declining or later withdrawal from the study will be recorded.
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20 **DATA COLLECTION AND ANALYSIS**

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22 The data collection and analysis sequence is illustrated in Figure 2 and the procedures for each round
23 (questionnaire) are detailed below.
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28 *[INSERT FIGURE 2]*

29 **Figure 2** Delphi data collection and analysis sequence.
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33 **Q1 Generation of items**

34 Q1 aims to elicit relevant issues for consideration (items), before quantitatively rating their levels of
35 importance in future rounds as judged by the expert panel.
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38 Sections A to F represent six different questions, and these sections will invite experts to list at least
39 items they deem of critical importance to the subject headings introduced. Additional space is
40 provided for detailed descriptions should participants wish to elaborate on their responses.
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42

43 A. Caregiver characteristics

44
45 *Are there specific groups of cancer caregivers that should be prioritised for intervention*
46 *research? Consider relevant demographic, medical, personal or clinical factors, to identify*
47 *high priority groups.*
48

49 B. Intervention components

50
51 *What intervention components are important in cancer caregiver intervention research?*
52 *Consider intervention content, and delivery method, setting and doses, for delivery of*
53 *optimal interventions.*
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55 C. Outcomes

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3 *Cancer caregiver interventions can target various outcomes, including caregiver, patient or*
4 *health service factors. Consider important outcomes for cancer caregiver intervention,*
5 *including who may benefit from interventions and for which outcomes.*
6

7 D. Study characteristics

8 *Cancer caregiver intervention outcomes can be investigated using a variety of approaches.*
9 *Consider which methodologies are important in understanding and evaluating the benefits of*
10 *caregiver interventions.*
11

12
13 E. Barriers

14 *What are the most significant barriers to the conduct of caregiver intervention research?*
15

16
17 F. Do you have any further comments about priorities for cancer caregiver interventions?
18
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21 Q1 Analysis

22 All data (items and explanations) will be entered and managed in qualitative data analysis software
23 NVivo [37]. The analysis will involve removing identical responses before subjecting the list of items
24 to interpretive content analysis as is consistent with the exploratory aim of the first questionnaire.
25 Each item will be examined and a broad summarizing label (code) will be assigned. These codes will
26 arise from the data itself rather than be pre-defined. As the analysis progresses and multiple similar
27 and connected codes arise, the analyst will begin grouping them into summarizing categories. Once
28 all items are coded and sorted into categories, the analyst will re-read all data and refine the
29 terminology to ensure all contributions are captured. An inter-rater process will assist interpretative
30 congruity as recommended for qualitative analysis [38]. In this step, a second member of the project
31 team will read all raw data and analytic work and any disagreement about interpretation or category
32 development will be discussed with the analyst until agreement is reached. This generates a list of
33 statements pertaining to each category.
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44 **Q2 Rating items**

45 Q2 will list all generated items according to subject headings they were submitted under and panelists
46 will be asked to rate each item's importance in order to establish preliminary levels of consensus.
47 Each item will be presented with a corresponding 4-point Likert-type scale (1 = Very unimportant, 2
48 = Unimportant, 3 = Important, 4 = Very important) and an option to indicate "No judgment" will be
49 provided including space for panelists to state their reasoning. To minimize response bias, Q2 will
50 list the items generated in Q1 without response statistics (number of experts who contributed to each
51 items).
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Q2 Analysis

Statistical analyses will be performed using IBM SPSS Statistics [39]. Descriptive statistics (median scores and IQR) will be calculated to indicate each item's relative importance based on the full response sample. Delphi studies use variable definitions and thresholds for determining opinion consensus [27]. For purposes of assessing levels of consensus, this study will use a predefined rating matrix, adapted from Meskell and colleagues [40], which is illustrated in Table 1.

Q3 Prioritizing items

Q3 will be designed to provide panelists the opportunity to reconsider their responses in light of preliminary levels of consensus achieved about the importance of each item. Additionally, the panel will be presented with summary comments about the reasoning for judgments made by other panelists. To assist clarity and consistency, Q3 will follow the same layout as the previous one. All items will be relisted under their respective subject headings with corresponding 4-point Likert-type rating scales. Additionally, this questionnaire will include aggregated statistical group responses generated for each items including: the level of importance of each factor based on group consensus thus far, a summary of group comments and reasoning for ratings of each item, and individual panelist's own Q2 response.

Q3 Analysis

Analysis for data collected in Q3 will use the same strategy as in the preceding round. The study aims to explore and quantify levels of agreement rather than achieve consensus, therefore this Delphi has been designed to progress through a pre-defined number of three rounds rather than continue until consensus is reached. Statistics will be calculated (median scores and IQR) to describe each item's importance and group consensus will be determined based on the consensus rating matrix. A final priority list of items will be generated.

Table 1 Consensus rating matrix.

Importance level	Numerical category of importance rating	High consensus	Moderate consensus	Low consensus	Direction of consensus
Very unimportant	One	70% or more in category one	60% or more in category one	50% or more in category one	Low importance
Unimportant	Two	70% or more in category two	60% or more in category two	50% or more in category two	
Important	Three	70% or more in category three	60% or more in category three	50% or more in category three	High importance

Very important	Four	70% or more in category four	60% or more in category four	50% or more in category four	
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ETHICS

The study was approved by the Deakin University Human Ethics Advisory Group. All consented participants will be assigned a unique identification code. Collected demographic information and contact details will include: name, contact phone number, e-mail address, description of professional role, years served in field of expertise, country of professional residence/affiliation. Participants' identifiable information will be matched with their unique identification code in one digital masterfile only. All data collected will be stored safely and securely in locked filing cabinets and in password protected folders on a secure drive (electronic data) that can be accessed only by the study investigators. Data will be kept for 5 years as per local ethics guidelines.

DISCUSSION

Combining the PICO framework and Delphi methodology

It is recommended that evidence-based medicine include a rigorous process for the formulation of clinical questions to find precise answers [41, 42]. Research shows that clinicians cross numerous questions in their practice and that up to two thirds remain unanswered [43, 44]. It is held that better question formulation and search process can lead to better solving unanswered questions [42, 45]. To this end, the PICO framework was developed to facilitate focused formulation of answerable clinical queries [23]. PICO is designed to elicit and precisely articulate the elements contained in clinicians' queries, which is considered key to efficiently retrieving relevant evidence for making evidence-based clinical decisions [46, 47] and for guiding searches and content for systematic literature reviews [48, 49]. The PICO framework lends itself to addressing questions such as caregiver intervention priorities, which require collection of items relating to caregivers themselves (P), the types and content of effective interventions (I) and the expected outcomes (O). While the study's information needs does not include a Comparison/Control (C) component, we are additionally interested in discerning the appropriate methodologies for evaluating and researching intervention outcomes. Huang and Demner-Fushman's [42] investigation of the PICO's suitability for clinical queries found that not all questions necessarily utilize all PICO components; in their study of 59 real-world clinical questions only two contained all four PICO elements. While the findings affirm the usefulness of PICO overall, it was noted that complex, real-world questions not always fit its formula squarely and may require modifications [42]. Our research question is focused on the need for healthcare response to the detected lack of appropriate caregiver support.

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3 The present study aims to not only collect high quality evidence and expert knowledge but
4 also prioritize areas of intervention and elicit levels of consensus amongst experts. The findings will
5 be placed into context with current research priorities and a growing body of work aiming to improve
6 cancer caregiver outcomes [22]. The Delphi method is well suited to solicit knowledge from varied
7 expertise and delineate degrees of (dis)agreement [34, 50] and alignment with other work. Delphi
8 studies are particularly effective in investigating areas where little prior knowledge exists [51], where
9 empirical data is lacking [52] and, where priority setting is desired [34]. The specific advantages of
10 the Delphi method adopted in our research include: the ability to collect expert opinion from diverse
11 disciplines [27], rapid communication processes [53]; overcoming peer-pressure and power struggles
12 through providing an anonymous forum [54], and the ability to coordinate multi-disciplinary
13 participants across countries [33]. The present paper aims to illustrate our study design clearly in
14 order for other intervention researchers to replicate the approach for answering similar questions for
15 different clinical populations or healthcare contexts. The combination of PICO and Delphi
16 methodology presents a novel and promising approach to rigorously and rapidly generating
17 instructive answers to complex healthcare problems.
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29 **What is an “expert”**

30 The success of a Delphi study is contingent on participants who are able to provide relevant input on
31 the research topic. The absence of specific guidelines for identifying experts challenge Delphi
32 researchers to seek suitable participants with appropriate expertise [34, 55]. “Informed advocates”
33 [34] and “specialist in their field” [33] are terms used by Delphi researchers, but there is little about
34 the specific qualities needed. In the absence of clear guidelines, the current study will follow the
35 definition adopted by Blaschke and colleagues [32], which describes the prerequisite qualities of
36 merited Delphi panelists, “individuals who possess both knowledge and experience representative of
37 the capacity to articulate informed opinion and provide relevant input about a given topic” (p. 2 – 4).
38 Consumers are not included in this research with the aim to conduct further work dedicated to
39 exploring their views. Additionally, exploring the views of administrators in future work would also
40 generate important data.
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50 **The Delphi expert panel**

51 Depending on the research objectives, Delphi panels may comprise of experts from a single
52 discipline or represent a broad mix. A heterogeneous pool of experts may serve innovation and
53 creative, combinatorial insights into unexplored questions through crosspollination of expertise.
54 When a research question is already well-focused, a homogeneous panel of experts may serve
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3 addressing an identified research need. The present study requires focus on the singular task of
4 determining priority items for developing future caregiver support intervention. It is necessary to
5 engage those who contribute to healthcare decision-making, policy development and provision.
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8 9 **Issues of anonymity in Delphi research**

10 Providing participant anonymity distinguishes online Delphi studies from other research
11 methodologies that involve expert participation, for example, in focus groups. Ensuring experts'
12 anonymity can mitigate the potentially negative impacts relating to different power relationships and
13 expert status [34], and individuals may feel more confident to submit their views openly and freely
14 without group pressure or judgment [33]. There is no agreement upon level of anonymity or de-
15 identification [34]. Advantages of not providing anonymity are noted to promote recruitment due to
16 association with other experts and introducing greater accountability for considered responses [34].
17 While balancing advantages and disadvantages and also recognizing challenges relating to a small
18 but well-established cancer caregiver research community, the present study will preserve participant
19 anonymity.
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28 29 **STUDY STATUS AND DISSEMINATION**

30 Round 1 data collection for this study began in August 2018. Data analysis is planned to be
31 completed by October 2018 and will be used to inform rounds 2 and 3, which are anticipated to be
32 completed by March 2019. The final result of this Delphi study is planned to be submitted for
33 publication by July 2019. At this stage a lay summary of results will be sent to participants on
34 completion of the study. Results will be presented as the total number of factors generated in Q1, a
35 summary of factors taken into Q2, and the final results from Q3. Expert recommendations will be
36 drafted for refinement and verification in ongoing research. It is anticipated that the results of this
37 research project will be published in peer-reviewed journals and presented in a variety of
38 organizational, conference and social media forums.
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46 **Contributors** SB, SDL, PL, SA, AU conceived the study and drafted the initial protocol manuscript.
47 SB, SDL, PL, SA, AB, PS, SC, MK, AU are responsible for the design of the study and SB, SDL,
48 PL, SA, AB, PS, SC, MK, AU critically revised the manuscript and related study materials. All
49 authors have read and approved the final manuscript.
50

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55 **Competing interests** None declared. All authors have completed the ICMJE uniform disclosure
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3 **Figure 1**

4 **Figure 2**
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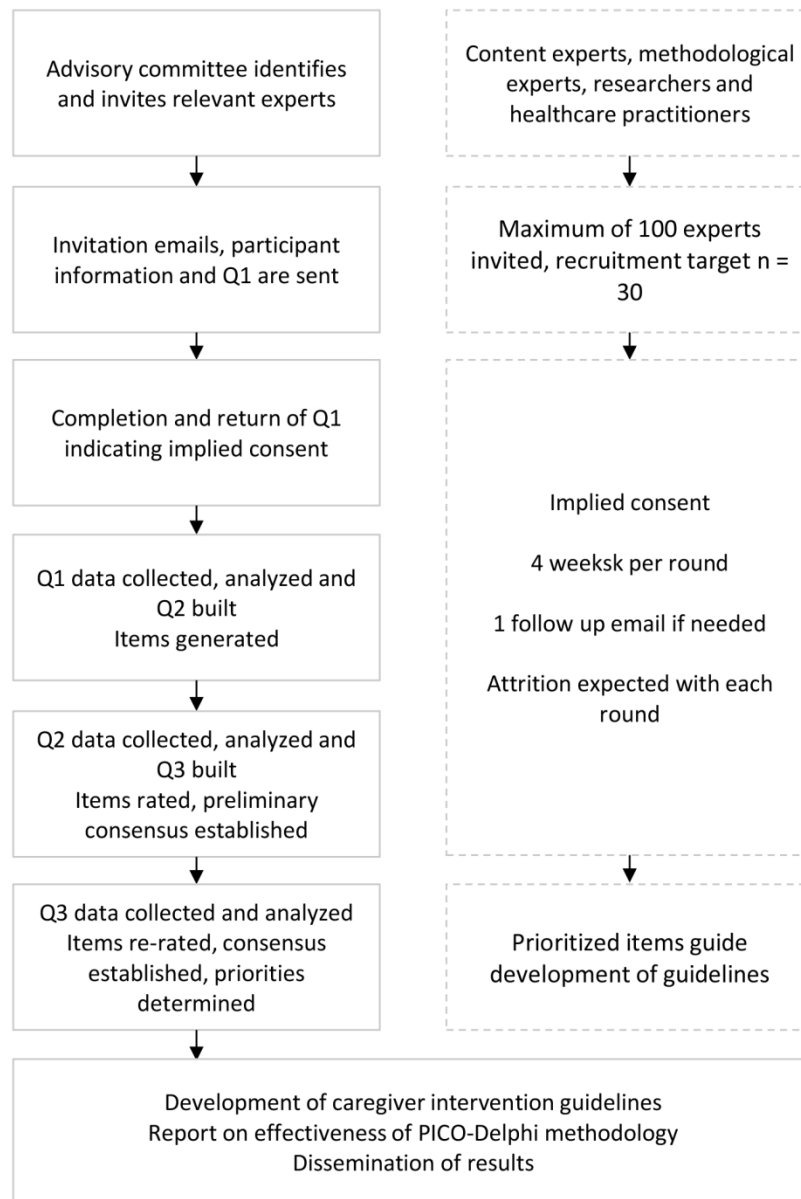


Figure 1

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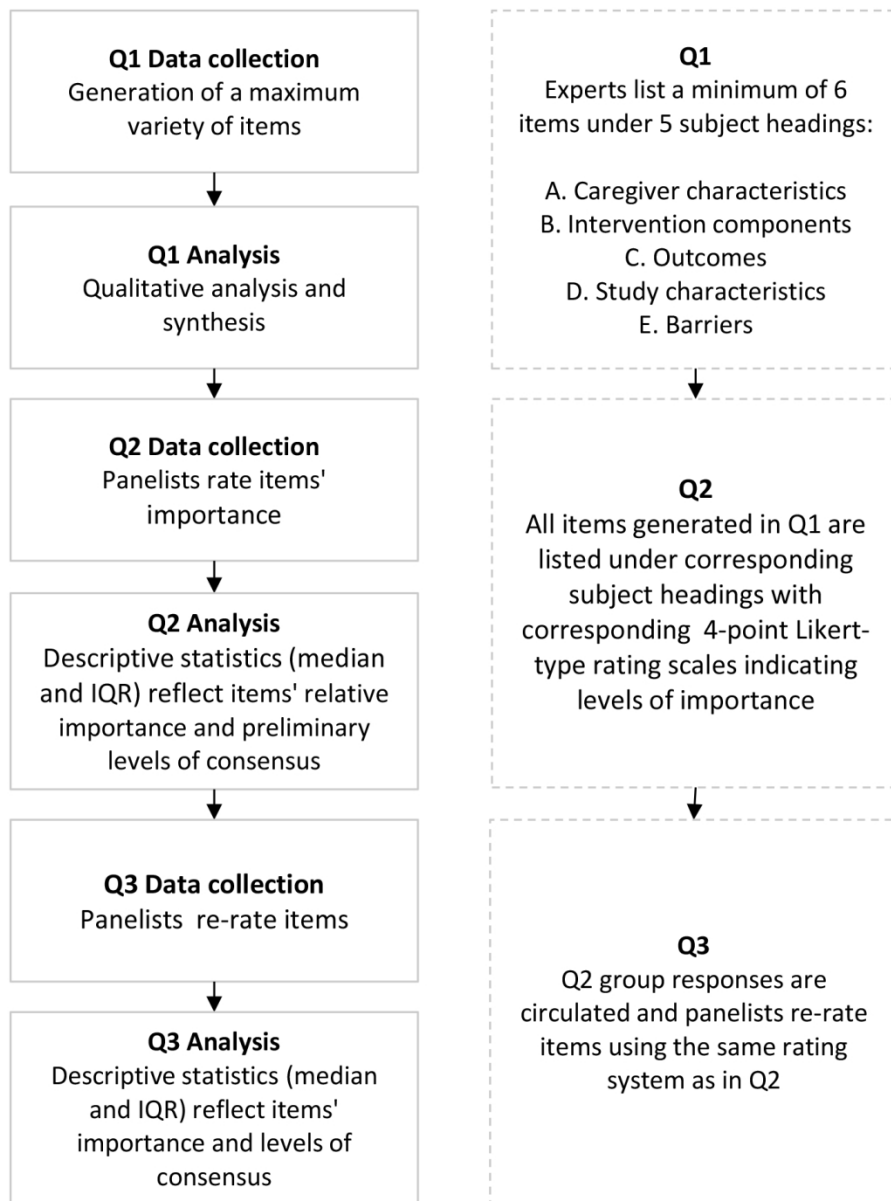


Figure 2

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