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Reporting formative qualitative research to support the development of quantitative preference study protocols and corresponding survey instruments: guidelines for authors and reviewers

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Abstract

Background: Formative qualitative research is foundational to the methodological development process of quantitative health preference research (HPR). Despite its ability to improve the validity of the quantitative evidence, formative qualitative research is underreported.

Objective: To improve the frequency and quality of reporting, we developed guidelines for reporting this type of research. The guidelines focus on formative qualitative research used to develop robust and acceptable quantitative study protocols and corresponding survey instruments in HPR.

Methods: In December 2018, a steering committee was formed as a means to accumulate the expertise of the HPR community on the reporting guidelines (21 members, seven countries, multiple settings, and disciplines). Using existing guidelines and examples, the committee constructed, revised, and refined the guidelines. The guidelines underwent beta-testing by three researchers and further revision to the guidelines were made based on their feedback as well as from comments from members of the International Academy of Health Preference Research (IAHPR) and the editorial board of *The Patient*.

Results: The guidelines have five components: introductory material (4 domains); methods (12); results/findings (2); discussion (2); and other (2). They are concordant with existing guidelines, published examples, beta testing results, and expert comments.

Conclusions: Publishing formative qualitative research is a necessary step towards strengthening the foundation of any quantitative study, enhancing the relevance of its preference evidence. The guidelines should aid researchers, reviewers and regulatory agencies as well as promote transparency within HPR more broadly.

Key Points for Decision Makers

- These are the first guidelines on reporting formative qualitative research on patient experience that support the development of quantitative preference study protocols and corresponding instruments.
- These guidelines focus on reporting techniques that enhance transparency and trustworthiness, thereby improving the likelihood that the scientific contributions of quantitative preference studies are well-founded, improving the validity of the quantitative evidence.

Author Contributions

ILH made substantial contributions to the conception and design of the work, drafted the manuscript, revised the manuscript critically for intellectual content, and provided final approval of the manuscript.
BMC made substantial contributions to the conception and design of the work, revised the manuscript critically, and provided final approval of the manuscript.
JC, KB, CV, RD, and HP made substantial contributions to the design of the work, revised the manuscript critically, and provided final approval of the manuscript.
All authors agree to be accountable for all aspects of the work.

Précis: We developed guidelines to improve the frequency and quality of reporting formative qualitative research used to develop robust and acceptable quantitative health preference research.

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Compliance with Ethical Standards

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1.0 Introduction

Patient preference information includes the experiences, perspectives, needs and priorities of patients and can be collected via qualitative or quantitative methods [1, 2]. Qualitative evidence is generally exploratory, actionable and hypothesis generating. Quantitative evidence typically tests hypotheses or informs predictions. Either approach, individually or in combination, can be used to support formative data collection, as primary research methods, or as an evaluative approach [3]. Here we explicate one specific use of qualitative research, which is to support development of a study protocol and corresponding survey instrument for subsequent quantitative research.

The expanding role for preference evidence in regulatory and policy decision-making has led to rapid growth in the development and use of quantitative preference studies [4]. Such studies often include a survey instrument that produces quantitative preference evidence on the relative desirability or acceptability of attributes that differ among alternative strategies [5]. Common examples include discrete choice experiments (DCE) or best-worst scaling (BWS). Quantitative preference studies may include other preference-elicitation tasks (e.g., preferences for alternatives tested in a cross-over study) or questions intended to personalize the patient experience (e.g., preferences for the use of advanced directives). Quantitative preference assessments emphasize relative value and provide quantitative evidence on the patient's perceptions or experiences, perspectives, needs and priorities with regards to a disease, condition, treatment, service (including diagnostics and preventive services) or system.

The following discussion pertains to preference study research designs, which includes protocols and survey instruments (Figure 1). The protocols typically include a survey instrument, as well as all other aspects of overall survey design and application (e.g., administration/delivery, additional instrument content, special considerations for the population of interest). Although this discussion is framed in terms of the patient experience, we use "patient" as shorthand to capture a number of groups for whom preference information may be collected to use in health care decision making. These groups include patients, of course, but also users of health care or social services, caregivers, recipients of public health interventions, providers, and general populations.

Qualitative research methods are commonly used to describe and analyze attitudes, behavior and motivations from the point of view of those being studied [7]. Contrary to their quantitative counterparts, qualitative researchers collect, analyze and interpret non-numeric data such as language, images, and other forms of expressing meaning [8]. Examples include, but are not limited to, in-depth and semi-structured interviews, focus groups, discussion groups (in-person or online), direct observation, documentary analysis, and secondary analysis of existing qualitative data [9]. It is increasingly accepted that qualitative evidence is central to the development of any quantitative preference study protocol or instrument [5, 10, 11]. First, qualitative studies take into account that people themselves are experts on their experience or living with a condition. This makes qualitative methods well-suited to help researchers understand preference-sensitive domains and how to best capture them. Second, qualitative evidence from an appropriate purposeful sample of individuals can be transformed into standardized questions for other individuals (e.g., preference instruments) as a means to assess the commonality of experiences or preferences within a particular population. This process of using formative qualitative research to support quantitative methods can be both efficient and scalable. Third, qualitative methods help establish content validity, or demonstrate appropriateness and comprehension relative to the concept intended to be measured in the specific context of the study. This can improve the likelihood that the scientific contributions of the preference study are well-founded, thereby improving the validity of the quantitative evidence.

Despite being foundational to the methodological development process, the use of qualitative research for this purpose tends to be underreported in the preference literature. While there has been an overall upward trend in the absolute number of health preference studies, including DCEs, the reported use of formative

qualitative research for improving face validity as a percentage of total number of studies remains low [4]. Moreover, the quality of the reporting of qualitative methods tends to be excessively brief, limited in the description of an analytic approach, and lacking information on the impact of qualitative methodologies on design [12-16]. Inadequate reporting makes it impossible to determine if there is sufficient rigor in the conduct of the qualitative research [12, 13, 17]. These trends are problematic because as demand for preference evidence continues to climb, consumers of the quantitative evidence should be able to ascertain the rigor of their qualitative foundation. Transparency, and resulting confidence in quantitative evidence, can be improved by publishing the qualitative research that supported the study design or instrument development. This qualitative evidence itself is a scientific contribution and should be disseminated in detail and separately from quantitative evidence [18, 19]. There are multiple examples of paired, sequential manuscripts [20-25].

Multiple barriers impede publication of formative qualitative research for publication. These include quantitative audiences, including journal editors, who may not fully appreciate its necessity and contribution, a culture of not reporting the qualitative basis for such work, and journal space constraints making it difficult to publish evidence used in the formative process in the same paper as the quantitative evidence, especially given that qualitative results require space to be reported well. Finally, there is limited guidance on reporting formative qualitative research for preference study protocols and instruments. Compounding these submission barriers, editors and reviewers are often unsure how formative qualitative research should be evaluated in the peer-review process [13, 19]. Editors may not know which reviewers have knowledge of qualitative methods in health preference research. On one hand, reviewers from disciplines traditionally associated with qualitative work may not understand the nuances of preference research [26]. On the other hand, reviewers from disciplines not traditionally associated with qualitative work (e.g., economics) may undervalue qualitative evidence and may not be equipped to evaluate qualitative evidence due to a lack of formal training in these methods [26, 27].

The objective of this article is to provide guidelines for health preference researchers on the reporting of formative qualitative research that supports the development of quantitative preference study protocols and survey instruments. These guidelines should also help editors and reviewers evaluate such manuscripts. This paper starts with a discussion on the general use of qualitative research methods then focuses on reporting guidelines. Using examples taken from the literature, this paper highlights successful formative research and provides guidance on how qualitative methods and evidence should be reported in detail and published to complement quantitative manuscripts.

2.0 Methods

2.1 Steering Committee

The need for reporting guidelines was identified in publication and through professional society discourse (e.g., International Academy of Health Preference Research (IAHPR)) [18]. In December 2018, a steering committee was formed as a means to accumulate the expertise of the research community on the reporting guidelines (see Acknowledgements). Volunteers were sought from members of IAHPR and the editorial board of *The Patient* based on their expertise and leadership in the field. The steering committee (led by ILH) consists of 21 members spanning seven countries (United States, Canada, United Kingdom, Netherlands, Germany, Singapore, and Australia). Its membership represents researchers in academia, research/consulting, hospitals, and industry.

2.2 Constructing guidelines

One author (ILH) reviewed existing guidelines on reporting qualitative research, which were tailored specifically for informing quantitative study design and instrument development. (Figure 2). The steering committee was asked to nominate relevant published examples of qualitative evidence. These retrospective examples provided committee members with a common basis for discussion on methods and

evidence reporting. Using existing guidelines and the examples, the steering committee constructed, revised, and refined the primary domains of the guidelines. Committee members submitted comments to one author (ILH) for consolidation and reconciliation. Areas of conflicting opinions or items requiring further attention were resolved during a group conference call on March 25, 2019. The draft guidelines were updated based on that discussion. The draft guidelines were approved by the committee and then underwent beta-testing. Its first draft was provided to three preference researcher teams independent of the steering committee who had conducted formative qualitative work to inform their quantitative research. Beta testers prepared manuscripts according to the draft guidelines and submitted their manuscripts along with feedback on the draft guidelines to the committee. The study authors revised the draft guidelines based on testing results and the beta-testers revised their submissions to produce prospective examples. Beta-tester comments were relatively minor; they primarily suggested opportunities to clarify the guidance or items that were infeasible. In parallel to testing, members of *The Patient* editorial board and the IAHPR were invited to comment on draft guidelines.

2.3 The Role of Guidelines for Reporting Qualitative Evidence

The research team relied on existing reporting guidelines and evaluative criteria for independent qualitative research (Table 1) [26, 28-32]. The guidelines we developed rely most heavily on the Standards for Reporting Qualitative Research (SRQR) and the Consolidated Criteria for Reporting Qualitative Research (COREQ) [28, 29]. COREQ and SRQR were chosen because they are the qualitative research guidelines recommended by the Enhancing the Quality and Transparency of Health Research (EQUATOR) Network, a leading authority and trusted resource on health research reporting. EQUATOR is an international initiative to promote transparent, accurate reporting and wider use of guidelines to improve the reliability and value of health literature [33]. Furthermore, both COREQ and SRQR are based on prior published guidelines and expert review and therefore incorporate much of the previous guidelines work. The SRQR is a 21-item checklist intended for a wide range of qualitative approaches and therefore has broad relevance [28]. COREQ is a 32-item checklist for reporting on interviews and focus groups specific to healthcare [29]; these criteria are used by a number of journals, including *The Patient* [34].

Fit-for-purpose guidelines are warranted when broad guidelines fail to accommodate a specific use [26, 30, 32]. For formative qualitative research, the objective is focused on key deliverables to facilitate quantitative research, namely the creation of study protocols and instruments. For instance, formative research may be designed to provide actionable evidence on specific levels of an attribute in a preference-elicitation task. The purpose is also typically related to the theoretical underpinnings of the quantitative research. For instance, the focus of the qualitative inquiry may be to confirm that attributes are of interest and independent. From a practical perspective, fit-for-purpose guidelines can account for the disciplinary style of studies published in the field, resonate with the target audience and involve the use of terminology familiar to researchers in the field.

3. Results

3.1 Formative Qualitative Research Reporting Guidelines

The final guidelines below focus on reporting research, with an emphasis on justifying decisions based on underlying theory and context (summarized in Table 2). We note items for which the general criteria apply and highlight areas that require particular attention for the field or where the field's guidelines may deviate from traditional qualitative reporting guidelines. We present items in the order in which a study is typically conducted. Examples of qualitative research are provided for illustrative purposes only and not intended as directives for the design or conduct of health preference research (Table 3).

3.1.1 Introductory Material

Title and abstract. Identify the study as formative qualitative research for designing a quantitative preference study protocol or instrument in the title and abstract. The abstract should specify the nature of its deliverables, namely a study protocol or preference-elicitation instrument.

Problem formulation. Description and significance of the problem should pertain to the qualitative work, the goals of the quantitative study it informs, and the context in which it will be used. Motivation should include relevant theory based on existing empirical work and published literature.

Purpose. Explicitly state that the objective of the qualitative research includes the collection of actionable evidence for decisions regarding the design of a study protocol or the development of an instrument. Apart from a named protocol or instrument, the authors should specify the aspect(s) of the formative process to be delivered. For one example of a well-articulated purpose that includes attribute/level selection as well as special requirements of their patient population for protocol design, see Danner et al. (2016) [35]. Multiple deliverables are appropriate if they each relate to essential components of the quantitative research. For instance, formative qualitative research of this nature most frequently informs the identification and description of attributes and levels [4, 15, 36, 37]. Qualitative evidence may facilitate the development of meaningful and culturally competent language or assess the understandability of instructions (i.e. comprehension) or layout (e.g. length, complexity, overall experience) [13, 38]. Other potential contributions include insights into variables driving market segmentation and identification of potential interactions between attributes [17].

3.1.2 Methods

Qualitative approach. Methods are a means to achieve deliverables. Every article should justify why qualitative research methods and the specific research paradigm (e.g., thematic analysis or grounded theory) were the best approach to produce actionable evidence, linking methods to deliverables [30]. Reliance on convention or precedence alone is not usually acceptable. For instance, attribute generation is likely to require different methods (e.g., focus groups) than enhancing the understandability of instructional text for a study or instrument (e.g., cognitive debriefing interviews) [10, 38].

Theoretical framework. The relevant theoretical framework that informs both the qualitative and quantitative study and how the work fits within the relevant field should be described. For instance, preference studies are often based on economic theory; therefore, the qualitative and quantitative methods may incorporate its tenets (e.g., recognizing tradeoffs) [39].

Researcher characteristics and reflexivity. Authors should acknowledge their own influence on the research process (reflexivity), as well as the influence of community members who may shape the understanding of the patient experience. For instance, the research team may include physicians who understand the breadth of patient experiences and patients who understand the depth of their own experience. Each circumstance influences the research process differently. If the instrument is developed using a community-engaged approach, the influence of the community on the qualitative work should be described. Incorporating the community's input—through the use of stakeholder advisors or community committees—can play an important role, either as an element of the qualitative research, or as a separate complementary exercise [40, 41]. For example, DosReis et al. (2016) describe how stakeholders acted as coinvestigators in their study by providing advice on how to identify and recruit an appropriate sample for a preliminary qualitative exercise to identify attributes and levels [42]. The stakeholder advisors also informed the analysis of the qualitative data and reviewed the final themes to ensure the attributes and levels informed by qualitative research were appropriate.

Sampling strategy and process. All sampling within qualitative research is expected to be purposeful in some way, but the particular nature of the sampling strategy should be detailed, including both what the strategy aims to achieve (e.g., maximum variation across a number of named characteristics for which the

sample varies), and the process of how and where participants were approached (e.g., key informants or snowball) [43]. Witter et al. (2011) provide an example of a particularly thorough sampling strategy [22]. The rationale likely depends on participant availability and the direction the data take the investigator. In instrument development, researchers often employ multiple strategies within the same study involving multiple data collection methods and/or multiple stakeholders (e.g., patients or caregivers), in which case all should be described fully.

Sampling adequacy. Sampling should not focus on the number of units, but should be strategically focused to collect actionable input for the development process [44, 45]. Frequently in this context, those needs are a diversity of perspectives. Often in qualitative work sampling adequacy is determined by saturation achievement, when no new key concepts are being identified with each successive unit of data collection. If this is the case, the basis for recognizing and achieving saturation should be described and set apriori. However, it should be noted that not all qualitative approaches rely on saturation as a basis for sample size [46]. Furthermore, sampling adequacy with respect to instrument development may differ from general qualitative work because smaller samples may be adequate because of the more limited study purpose.

With respect to attribute identification, attaining sampling adequacy may need to be addressed in non-traditional ways. Preference studies typically aim to understand perceptions of attributes that differentiate alternative treatments, services, or outcomes, many of which are hypothetical. Whilst in some cases participants may raise key differentiating attributes spontaneously through describing their experiences during data collection, in other cases potential options may need to be described to participants to explore their views of them, though taking care not to 'lead' the respondents toward a particular outcome. Sampling adequacy may be assessed when researchers have collected a pre-specified range of responses regarding potential attributes.

Sample. Researchers should report the number (i.e. sample size) and relevant characteristics of participants, documents or events included in the formative research. This should be reported separately for each distinct sample or event. Researchers should be explicit about how the sample is expected to be reflective of, or different from, the quantitative sample. Response rates should be reported if applicable given the sampling strategy (e.g. not relevant for snowball sampling).

Ethical review. Authors should report having ethics approval for formative research, apart from their quantitative research, although the specifics vary by country. Some ethics committees determine formative qualitative research not to be human subjects research or exempt (in the United States under the new Common Rule exempt is the expected determination), however, the authority of that judgement should not be granted to researchers. Researchers should document ethics committee decisions in the reporting of both qualitative and quantitative evidence [47].

Data collection methods and sources. Researchers should clearly report why particular method(s) were chosen for particular purposes, populations and contexts. Common examples include individual interviews and focus groups, in which case the qualifications and training of interviewers and facilitators, and their relationship to participants (if any), should also be reported [28]. Formative qualitative studies informing instrument development may involve a combination of methods and/or populations (e.g. patients and providers) either because there are multiple purposes or as a way to triangulate information. For example, Al-Janabi et al. (2008) use meta-ethnography with interview follow-up [48]. A study to inform conceptual attribute development and questionnaire testing may incorporate cognitive debriefing interviews with think aloud and retrospective probing techniques for language refinement. The setting and salient contextual factors should be reported, such as if non-participants were present during a focus group. If recording devices were used or field notes were taken, those should be described. Duration of events (e.g. interview length) should be reported if applicable.

Data collection instruments. Targeted data collection instruments are required to achieve qualitative study aims. Qualitative instruments may be highly structured, semi-structured, or relatively unstructured and participant led. Instruments should be described and provided for each qualitative research method as supplementary documents. For example, Abiiro et al. (2014) include a focus group discussion guide as an Additional File [49]. Where copyright issues are of concern, the instruments need not be published, but should be made available for peer-review. The use of questions, prompts, guides and pre-testing should be documented.

Data processing and data analysis. A detailed description of analytic methods should be provided, usually naming a specific approach (e.g., content analysis, constant comparison) and the analytic procedures. Dancet et. al. (2011) provide a detailed description of staged, data analysis using content analysis with constant comparison [24]. Data processing tools such as data management software (e.g., NVivo or MaxQDA are popular examples) or services (including transcription or translating services) should be reported.

Techniques to enhance trustworthiness. Be transparent, explicit and robust in procedural descriptions and explanations and justification. By definition, qualitative research is exploratory, not hypothesis driven, which allows greater flexibility in the analysis of qualitative evidence. Nevertheless, the final analytic approach, who conducted the analysis, how was it done, and triangulation and quality control processes should be explicit. A reviewer should be able to follow the progression of events, decisions and logic which produced the findings. For example, if text is coded according to themes as part of the analysis, descriptions of the number and qualifications of coders, development and refinement of a code book, process for assessing coder agreement and adjudication, and derivation of themes would enhance transparency and demonstrate rigor.

3.1.3 Results/findings

Synthesis/interpretation. The main findings will depend on the purpose of the qualitative research; however, in the context described in this article it will invariably inform the development of the quantitative study protocol or instrument. For instance, formative research intended to develop and refine attributes and levels should include a complete list of finalized attributes and levels (i.e., descriptive framework). While the qualitative research article will report the final scaffolding of the instrument, it is also expected that the final product also be presented as an input in an article reporting the quantitative evidence. Reports should include relevant concepts not included as attributes and why (e.g., methodological reasons may prevent a concept that cannot be manipulated from being included). A description of how the researcher interprets the qualitative evidence and translates it to deliverables must be included. When qualitative researchers report results as themes, they must also clearly articulate how they converted themes to attributes. Applying quantitative statistical analyses to qualitative data is not always meaningful, particularly in small samples.

In contrast to quantitative research where the results are presented with little interpretation, in qualitative work analysis, synthesis and interpretation may occur simultaneously. Depending on analysis methods, they may be presented together in the results section, separately in the results section, or the interpretation may be presented in the discussion section. Most importantly, the presentation of the results should tell a cohesive story.

One possible way to present information is to demonstrate the value of the formative process by explicitly showing components that change based on the qualitative evidence [38]. If there are many components, iterations exemplifying major changes should be described [39]. For instance, the discussion may represent an expansion of the diversity of themes by describing potential attributes that were not encountered during the initial literature review. For studies in which multiple methods or phases are used,

results should be reported for each method or phase, so the reader can understand the individual impact of each approach. Kløjgaard et al. (2012) provide detailed results and conclusions for each phase (i.e., method) of qualitative research conducted and include three sets of proposed attributes and levels to illustrate incremental refinement [38]. Formative qualitative research for development of other types of instruments provide excellent examples of this type of reporting. Al-Janabi et al. (2008) illustrate how two methodologies each uniquely shape the final attribute list [48]. Sutton and Coast (2014) and Canaway et al. (2017) demonstrate how each phase of a two-phase process contributed actionable evidence to develop and refine the attribute list [50, 51]. Stevens et al. (2009, 2010) used a two-phased approach to develop a full descriptive system and published the results of each phase [52, 53].

In addition to expanding the diversity of themes, the value of the formative process can also be used to show how qualitative evidence is used to reduce a list of many themes to a manageable number of items (e.g. domains or attributes). Abiiro et al. (2014) illustrate the derivation of a final attribute/level list from a conceptual list of potential attributes/levels obtained from the literature; they also detail how expert opinion was used to reduce the list [49]. Reporting of the iterative process is not limited to studies that use multiple methods or phases. Ke et al. (2013) describe the process of clarifying and confirming attributes while using one qualitative method [54].

Beyond identifying and refining attributes and levels, qualitative methods can provide actionable evidence, for example to select a choice format and experimental design. Michaels-Igbokwe et al. (2014) demonstrate how qualitative research led to the use of both an unlabeled and labeled DCE (and the labels used in the latter), an unforced choice format, and the framing of the choice task [55].

Formative qualitative research for preference-elicitation instruments may verify that the context presented (i.e., vignettes) are sufficient for respondents' to respond in a meaningful way. For example, physicians may need information about a hypothetical patient age and patients may need information on what motivates the decision to consider proposed alternatives. Like themes, these modifiers may increase or simplify during the formative process to enhance response quality.

Evidence. Reporting of qualitative evidence to substantiate analytic findings may require forms of data displays that are new to quantitative researchers. Creative use of exhibits and appendices can make up for the limitations on word counts, especially for quotes, which are important evidence of the veracity of the findings. For example, the use of quotes in a table to support attribute selection has been reported for numerous studies [35, 42, 49, 56, 57]. Quotes may be followed by demographic tags (e.g., age, sex, or condition) if their inclusion enhances the interpretation [50].

Major themes should be reflected, and minor themes should be identified along with justification for inclusion or exclusion in final inputs. For instance, variation in experience may be of particular relevance to understanding the patient experience and ensuring there are no inadvertently omitted variables in quantitative work to follow. Negative cases, or examples in which the patient experience differs from the majority of evidence, should be highlighted [30, 45]. Care should be taken to differentiate spontaneous versus prompted identification of important findings that influence study protocol design and instrument development. For formative qualitative research, the goal is to generate actionable information regarding the topic based on previously identifiable possibilities and new information provided by participants [19].

Reporting qualitative evidence that informs the formative process and adheres to these guidelines will usually require the space of a full-length original research article, especially when manuscripts make a methodologic contribution, include a broad array of evidence, are combined with other methods such as a systematic review of the literature, or fulfil other research objectives alongside. In some cases, the draft study protocol or instrument may also be included as an appendix document or as a reference (e.g., clinicaltrials.gov). Likewise, subsequent manuscripts, particularly those which build from the results, will

cite the qualitative evidence and its reference material providing its readers with a more transparent understanding of the formative process. A short-form version (1500-2000 words) with use of an appendix for supporting materials may be well-suited to formative qualitative research nested within quantitative or mixed methods articles.

Discussion. Discussion points generally include interpretations, implications, transferability, contribution(s) to the field, strengths and limitations. To this end, authors can report specific findings that will accelerate future research and highlight any relationships of the formative research to prior qualitative and quantitative research and the larger body of knowledge on patient experience. This may include differences relative to prior research (context, items, attributes, definitions, decisions about ranges, etc.). Ke et al. (2013) compare their results with literature on attributes, other qualitive development studies, and discuss implications for future DCE development [54]. Multi-country studies may report on cultural adaptation and the merits of pooling or separating countries with regard to study or instrument design, depending upon the extent to which elicited concepts align across countries. Ryden et al. (2017) highlight the challenges in conducting formative qualitative research across cultures and languages from five countries [58]. Gilbert et al. (2018) elucidate similarities and differences across English- and non-English-speaking participants in Australia [59].

Given the more open-ended or conversational nature of qualitative research, there may be findings outside the primary purpose (e.g., evidence of preference heterogeneity or differential attribute functioning). Such evidence may be reported separately and noted in the discussion under potential future research. For example, qualitative research may lead to further quantitative research within a targeted subpopulation relevant to the full quantitative study (e.g., non-native English speakers). However, findings outside the original scope and purpose should be reported with appropriate limitations about the research context whereby the findings were ascertained.

4.0 Discussion

This article proposes best practices for reporting formative qualitative research for a specific purpose: to inform the design of study protocols and instrument development for quantitative preference research. The goal is to facilitate transparent reporting of the development process as informed by formative qualitative research. Transparency allows for the demonstration of and assessment of rigor. We drew upon the expertise from researchers from a range of disciplines, organizations and countries with experience with qualitative methods, and published guidelines for a broad array of qualitative work [28, 29]. We tested the reporting guidelines against manuscripts in development and revised them based on the feedback.

A limitation is that this study did not conduct a systematic review of all qualitative reporting guidelines available, particularly those outside of health and health care. However, we heavily relied on previous work that has summarized and codified existing guidelines, and guidelines directly applicable to instrument development, which provided sufficient synthesis to tailor guidelines for our purpose [12, 13, 28, 29]. Nor did we conduct a systematic review of qualitative formative research on patient preference information and therefore may have overlooked good examples. Third, our steering committee was representative of a broad range of preference researchers, but practicalities prevented us from being able to leverage the expertise of all researchers. Fourth, we did not use a consensus process. The committee was engaged throughout the entire process and feedback was solicited and incorporated at every stage. Fifth, the guidelines underwent limited testing and further testing might be required. Like other publication guidelines, we anticipate updating the guidelines as our experience with it matures [60, 61]. A final limitation is that adherence to these reporting guidelines may not be sufficient to ensure methodological rigor; it should however facilitate the reporting of formative qualitative research in a way that can demonstrate rigor and increase transparency.

Some argue that it is difficult to apply guidelines for qualitative research because the field is broad and diverse and cannot be evaluated by one set of criteria [26, 62, 63]. Rigor transcends methodology and its components include transparency, quality processes, and appropriate methods. Furthermore, the benefits of imperfect guidelines outweigh the risks associated with potentially constricting guidelines or no guidelines. Not having guidelines presents a disservice to the health preference research community, because without them, formative qualitative research may be viewed as lacking rigor, nonscientific, or remain unpublished due to the lack of clarity around how they should be written or the inability to effectively conduct peer-review. To account for the risk of potentially constricting guidelines, the guidelines are flexible enough to accommodate a variety of aims and methods that are appropriate for protocol design and instrument development. Moreover, the specific nature of formative research allows for a narrower field, even if diverse in application.

We recommend these guidelines be used by *The Patient* and other journals interested in patient experience. This will facilitate connecting these studies with the right audience, which is consumers and conductors of quantitative preference studies. Authors are encouraged to pursue publishing such qualitative data in the same journals as their quantitative studies and not rely solely on journals more typically associated with qualitative research.

When findings are sufficiently compelling (i.e., not solely results of instrument pilot testing and/or cognitive debriefing), authors should pursue publishing formative qualitative evidence as a stand-alone publication. As a field, we should consider the merits of formative qualitative research being published separately to change the cultural acceptability, establish rigor for quantitative studies, get research to the right audience, and demonstrate that qualitative research is not just complementary to our work, but a necessary foundation [39]. However, when independent publication is not feasible or warranted, then authors are encouraged to submit a report alongside a quantitative manuscript as an appendix using these reporting guidelines.

Reviewers are encouraged to use these guidelines to gauge integrity of qualitative work. Reviewers should be particularly focused on transparency and appropriate justifications for decisions made throughout the process. Over time, we expect reviewers will become more experienced in evaluating these articles. If these guidelines are ever updated, we will most certainly recruit reviewers to provide insights on how they can be improved.

Future work may wish to expand these guidelines beyond protocol and instrument development, to include other uses of qualitative studies directly related to quantitative studies of health preferences. For instance, future guidelines may address reporting the use of debriefing as a way to provide an in-depth understanding of quantitative data or the use of mixed-method designs to more fully capture patient experience [57]. Future iterations may expand these reporting guidelines to emerging types of patient experience data.

5.0 Conclusions

Similar to quantitative studies in health preference research, formative qualitative research should be held to comparable standards and published in order to provide evidence of rigor, demonstrate face and content validity, and avoid faulty conclusions based on preference evidence. Publishing formative qualitative research is a necessary step towards strengthening the foundation of any quantitative study, enhancing relevance of its preference evidence.

Data Availability Statement

Data sharing not applicable to this article as no datasets were generated or analyzed during the current study.

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Figure 1. Conceptual overview of reporting formative qualitative research for design of preference study protocols and corresponding instruments

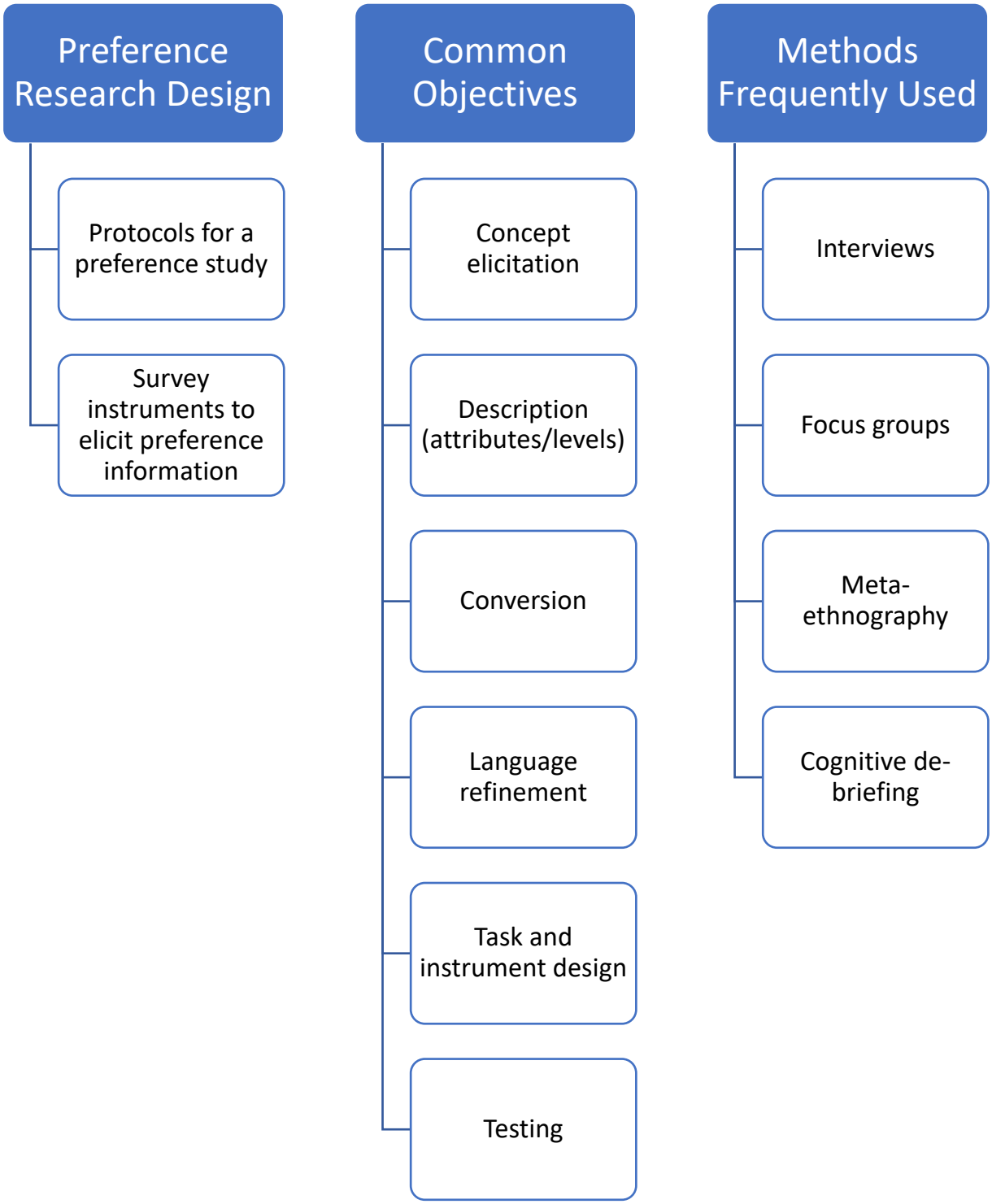

Figure 2. Guidelines development process used by the Steering Committee

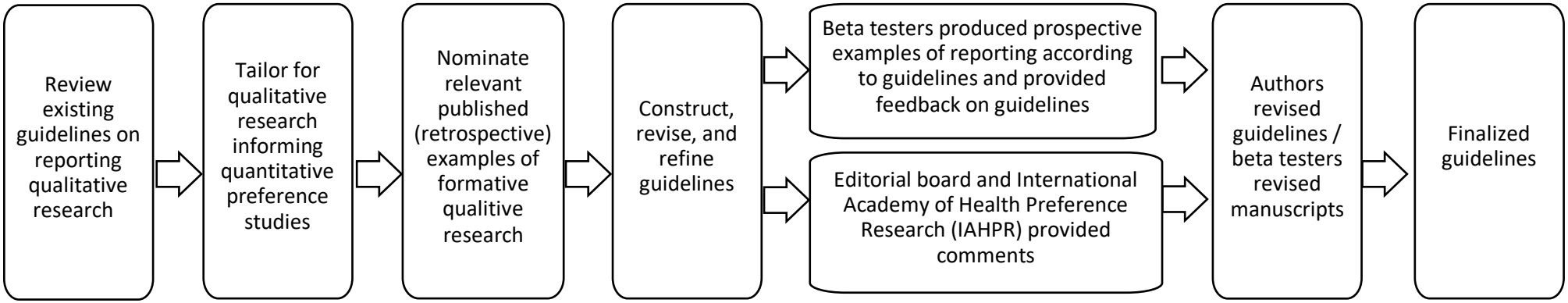

Table 1. Existing guidelines on reporting qualitative research

Author/Year	Goals	Reference
O'Brien et al. (2014)	Standards for Reporting Qualitative Research (SRQR) are based on a synthesis of recommendations. Intended to be broad and flexible to accommodate many contexts.	[28]
Tong et al. (2007)	The Consolidated Criteria for Reporting Qualitative Research (COREQ) focuses on 3 domains: 1) Research team and reflexivity; 2) Study design; and 3) Analysis and findings. Focuses on interviews and focus groups only.	[29]
Coast et al. (2012)	Coast and colleagues focus on qualitative methods for attribute development for discrete choice experiments, a popular methodology for preference elicitation. Identifies 9 reporting requirements that represent a minimum but suggest their inclusion within the main study in circumstances where studies are more ad hoc or conducted to a specific issue.	[13]
Cohen & Crabtree (2008)	Presents 7 evaluative criteria for assessing qualitative research articles in health care.	[26]
Kitto et al.(2008)	Present criteria for authors and reviewers for assessing qualitative research intended for publication in a medical journal	[30]
Côté & Turgeon (2005)	Presents checklist for critical appraisal of qualitative research in medicine and medical education	[32]
Daly et al. (2007)	Presents a hierarchy of evidence for assessing health research, emphasizing the capacity of reported research to provide evidence-for-practice or policy ranging from single case studies (level 4) to generalizable studies (level 1).	[44]

Table 2. Guidelines for reporting qualitative research informing the design of quantitative health preference study protocols and preference-elicitation instruments

Item	Traditional Qualitative Research Guidelines	Additional guidelines for informing patient experience	SRQR Item	COREQ Item
Introductory Material				
Title	· Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach or data collection methods.	· Concise description of the nature and topic of the study identifying the study as qualitative research to inform quantitative preference study design or instrument development.	1	--
Abstract	· Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions.	· Includes identifying the study as qualitative research to inform study design or instrument development. · Specify the nature of the quantitative research the work informs and deliverables (e.g., study protocol or survey instrument).	2	--
Problem formulation	· Description of the problem/phenomenon studied. · Review of relevant theory, empirical work. · Problem statement.	· Additional description of the problem/phenomenon to be studied in the quantitative preference study that will follow. · Review of relevant theory, empirical work, and published literature related to patient experience data. · Description of why patient experience information is required to inform the design of the sequential study.	3	--
Purpose	· Purpose of the study and specific objectives or questions.	· Should explicitly state the intention to develop a preference instrument to collect preference evidence. · Specify what aspect of instrument development the study informs (e.g. attribute development). · Purpose of the study and specific objectives or questions for the for the quantitative study the qualitative work informs.	4	--

Methods				
Qualitative approach	· Qualitative approach (e.g. ethnography, grounded theory, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g. postpositivist, constructivist/interpretivist) is also recommended. · Rationale	· Rationale for why qualitative research methods and research paradigm are appropriate for instrument development-related research question. · Rationale for the choice should be explicitly stated and should be rooted in gaining information about experience of those being studies.	5	9
Theoretical framework	--	· Relevant theoretical framework that informs the qualitative and quantitative study. · Description of how research fits within the relevant field.	--	--
Researcher characteristics and reflexivity	· Identify researcher characteristics that may influence the research, including personal attributes (e.g. occupation, gender), qualifications (i.e. experience and/or training), relationship with participants (e.g. new or existing), assumptions, and/or presuppositions. · Potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results and/or transferability.	· Consider describing depth vs. breadth of understanding of the patient experience. · When community engagement is used to facilitate developing study design, describe its role, either as an element of qualitative research or as a separate but complementary exercise. · Consider reporting the capacity to which the researcher will be involved in design and conduct of the future quantitative research.	6	1-8
Sampling strategy and process	· How and why research units (e.g. participants, documents or events) were selected, approached. · Rationale	· Sampling strategies should be articulated for each method and for each sample used, including what the strategy aims to achieve (e.g., maximum variation). · Rationale should be linked to both the qualitative work and the plans for the subsequent quantitative research.	8	10-11, 13, 16
Sampling adequacy	· Criteria for deciding when no further sampling was necessary.	· Focus should be on most appropriate data to meet the needs rather than on number of units. · Should be discussed in the context of the purpose of the formative work	8	22
Sample	· Number and relevant characteristics of participants, documents, or events included in the study; level of participation.	· Report for each distinctive sampling strategy/process identified. · Identify and justify how it is reflective of or different from the anticipated future sample for the quantitative study.	12	12

Ethical review	· Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues.	· Documentation of ethics committee decisions in reporting of both qualitative and quantitative evidence.	9	--
Data collection methods and sources	· Types of data collected. · Details of data collection procedures including (as appropriate) setting/site, salient contextual factors, presence of non-participants, start/stop date of data collection and analysis, whether events were recorded or field notes were taken. Report duration of events, if applicable. · Iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings. · Rationale	· Nothing additional · Nothing additional · Nothing additional · Rationale for choice should be directly related to how it serves the future quantitative study as well as the purpose of the qualitative work. A combination of approaches may be used for multi-purpose qualitative studies (where each method serves a different purpose) or for a single purpose study in which authors wish to triangulate information.	7,10	14,15,19, 20,21
Data collection instruments	· Description of instruments (e.g. interview guides, questionnaires, search strategies) and devices (e.g. audio recorders) used for data collection. · Note if instruments were pre-tested, pilot tested, and if applicable, how changed over the course of the study.	· Include any instruments as part of the peer-review process, if applicable. Does not necessarily need to be published. · Nothing additional	11	17
Data processing	· Methods for processing data prior to and during analysis, including transcription, data entry, data management, and security, verification of data integrity, data coding, and anonymization/deidentification of excerpt. · Include any data processing tools such as software or services (e.g. transcription or translation service).	· Transparent, explicit, robust procedural descriptions and explanations and justifications. Describe progression of events, decisions and logic. · Nothing additional	13	--
Data analysis	· Process by which inferences, themes, etc., were identified and developed including the researchers involved in data analysis. · Usually references a specific paradigm or approach · Rationale	· Nothing additional · Nothing additional · Nothing additional	14	27
Techniques to enhance trustworthiness	· Techniques used to enhance trustworthiness and credibility of data analysis (e.g. member checking, audit trail, triangulation, double-coding). · Rationale	· Nothing additional · Nothing additional	15	23, 24

Results/findings				
Synthesis and interpretation	· Main findings (e.g. interpretations, inferences, and themes) might include development of a theory or model, or integration with prior research or theory.	· Main finding will inform development of quantitative study protocol, or instrument for quantitative assessment (e.g. final attribute and/or levels list). · Describe how qualitative data are interpreted and translated to highly specific instrument. · Demonstrate the value of the formative process by showing major iterations on the design that change with additional qualitative evidence collected. · Report results for each method used so readers can understand the impact of each approach. · Attributes that are important, as still part of the theory generated, but not selected because they are not able to be manipulated, should be reported.	13,16	
Evidence	· Links to empirical data. Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic findings. · Demonstrate consistency between data presented and findings.	· Negative cases and variation are of particular relevance to understanding the patient experience and ensuring no omitted variables in quantitative work to follow.	17	29-32
Discussion				
Integration with prior work, implications, transferability, and contributions to the field	· Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship discussion of scope of application/generalizability; identification of unique contributions to scholarship in a discipline or a field.	· Consider findings that have value for generalizable knowledge of patient experience, will hasten future preference work and contribute to the larger body of knowledge for a particular content area. · Highlight any differences relative to prior research (attributes, definitions, decisions about ranges, etc.).	18	
Limitations	· Trustworthiness and limitations of findings.	· Nothing additional	19	
Other				
Conflicts of interest	· Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed.	· Nothing additional		
Funding	· Sources of funding and other support; role of funders in data collection, interpretation and reporting.	· Nothing additional		

Table 3. Example publications of formative qualitative studies to inform preference-elicitation instrument development

Health context	Author/ year	Reference	Instrument type	Quantitative instrument proposed use	Qualitative data collection method	Analytic approach	Results	Reason noted
Patients with autoimmune conditions	Fargher et al. 2007 Payne et al. 2011	[20, 21]	DCE	Stated preference elicitation	Semi-structured interviews; focus groups	Constant comparison	Key themes	Provides a topic guide and example show cards used to stimulate discussion; sequential publications
Health labor market	Witter et al. 2011 Vujicic et al. 2011	[22, 23]	DCE	Stated preference elicitation	Key informant interviews, in-depth interviews; focus groups	Thematic analysis with inductive coding*	Key themes; Draft attributes	Purpose well-described; thorough discussion of sampling strategy; sequential publications
Patients that experienced infertility care	Dancet et al. 2011 van Empel et al. 2011	[24, 25]	DCE	Stated preference elicitation	Focus groups	Content analysis with constant comparison	Model; dimensions of the concept	Detailed description of analytic approach in stages; sequential publications
Age-related macular degeneration	Danner et al. 2016	[35]	AHP and DCE	Stated preference elicitation	Focus groups and ranking exercise	Deductive content analysis	Attributes and levels	Purpose well-described; Provide sample quotes to support identification of themes and attributes/levels
Patients with degenerative disc disease	Kløjgaard et al. 2012	[38]	DCE	Stated preference elicitation	Observational fieldwork, interviews, pilot test	Content analysis*	Attributes and levels	Report how each of multiple methods contributed to design; provides detailed results and conclusions for each phase of research

Patients with type 2 diabetes (focus on framework)	Janssen et al. 2016	[41]	DCE and BWS	Stated preference elicitation	[Expert consultation, stakeholder engagement,] Pre-test interviews and pilot testing	n/a	Attributes and levels	Describes engagement with a community advisory board
Caregivers of children with intellectual disability and a coexisting mental health condition	dosReis et al. 2016	[42]	DCE	Stated preference elicitation	In-depth interviews and focus groups	Grounded theory; constant comparison, Q methodology, concept mapping	Attributes and levels	Describe the use of stakeholder advisors to conduct qualitative work; detailed description of mixed methods (disparate qualitative and quantitative) for formative work including their rationale and analytic approach
Micro health insurance in low- and middle-income countries	Abiiro et al. 2014	[49]	DCE	Stated preference elicitation	Interviews; focus groups; expert opinion	Content analysis*	Final list of attribute and levels	Derivation of final attribute list from conceptual themes; include interview/discussion guide; key quotes in table; use of expert opinion to reduce attribute number

Parent perspectives on services for children with cleft lip/palate	Ke et al. 2013	[54]	DCE	Stated preference elicitation	Semi-structured interviews	Constant comparison	Final list of attributes and levels	Detailed description of two iterations using a single method
Sexual and reproductive health and HIV services in rural Malawi	Michaels-Igbokwe et al. 2014	[55]	DCE	Stated preference elicitation	Focus groups and interviews	Thematic analysis	Decision map, labels, attributes and levels	Use of qualitative work to inform identifying attributes/levels, selecting a choice format, and choosing an experimental design
Patients with recent onset schizophrenia	Beusterien et al. 2017	[56]	BWS	Stated preference elicitation	Interviews; cognitive debriefing	Not specified	Conceptual model of treatment outcomes; revised attributes	Provide sample quotes to support identification of concepts for conceptual model and attributes;
Liver cancer control	Bridges et al. 2011	[57]	DCE	Stated preference elicitation	Open-ended qualitative interviews conducted	Interpretive phenomological analysis (IPA)	Qualitative prioritization, attributes	Use of IPA; Summary table of quotes illustrates attribute choices; mixed methods article
Patients with type 2 diabetes - multinational	Ryden et al. 2017	[58]	DCE	Stated preference elicitation	Interviews with clinical experts and patients	Content and thematic analysis approach	Attributes and levels	Highlight the challenges in conducting formative qualitative research across cultures and languages
Cataract surgery services	Gilbert et al. 2018	[59]	DCE	Stated preference elicitation	Semi-structured interviews and review panel	Thematic analysis with inductive and deductive coding	Attributes and levels	Addresses differences in results between English speakers and non-English speakers participants

Notes: DCE = discrete choice experiment; AHP = Analytic hierarchy process; BWS= best-worst scaling; ObsRO = observer reported outcomes; n/a = not applicable
* Not explicitly stated but defined based on interpretation of the manuscript by the guideline authors