PCR50

The Development of a Valid Qualitative Standardized Interview Manual

Kongsoe JH[1], Mubekapi-Musadaidzwa C[2], Casper R[2], Spiegelhalter K[3]

[1]CLINIGMA®, Copenhagen, Denmark, [2]CLINIGMA®, Cape Town, South Africa, [3]CLINIGMA®, Brighton, UK

CLINIGMA®

Objectives

The authors developed a qualitative standardized interview manual (SIM) that can be readily used for capturing and analyzing patient-experience data, tailoring for various conditions and phases of drug development.

The SIM seeks to build upon current methods for instrument development to address gaps in systematic qualitative methodologies in a way that efficiently meets the needs of drug development.

Introduction

There has been increasing regulatory expectation to include qualitative interviews in clinical trials to support the reporting and interpretation of clinical and patient-reported outcomes (PROs). CLINIGMA® is actively forging partnerships with pharmaceutical companies and academia who are pursuing innovative ways of Investigational New Drug (IND) approval, implementing patient-centered clinical studies, and launching in the market.

To support this effort with rigorous analytic approaches and efficient systematic methodologies, CLINIGMA® has created a Standardized Interview Manual (SIM) following the methodology in the FDA's PFDD series; the SIM creation included an iterative process with a systematic literature review, consultation with PRO experts, and an ongoing series of targeted cognitive interviews (Figure 1).

Figure 1: Iterative Process for Developing the SIM

Literature Review

Data Sources

A medical librarian, two senior researchers in patient-focused research, and four data analysts conducted a systematic literature review following PRISMA guidelines. Key terms were used to search PubMed Medline, Cumulative Index to Nursing & Allied Health Literature (CINAHL) EMBASE, and Cochrane Library bibliographic databases. In addition, an internet search was conducted via Google and Google Scholar.

Studies were assessed for methodological quality using the CASP qualitative critical appraisal checklist (CASP, 2020). Studies published in English and using qualitative research methods in combination with a clinical trial were then screened using specific inclusion/exclusion criteria.

Article Selection

The literature search generated 1703 journal articles. Article duplicates, abstracts, study protocols, reviews, theoretical commentaries, and those unrelated to clinical trials were excluded. Full published articles focused on the effect of investigational drugs/ treatment concerning patients' experiences of a particular disease and treatment, patients' satisfaction, and patient experience of the trial were included.

A total number of 23 papers remained. Qualitative data analysis software was then used to code the methods, results, and discussion sections separately. Analysts organized codes into themes which then informed the design of the interview manual modules and questions.

Synthesis

Research findings were extracted and summarised using an inductive approach. This approach entailed coding for emergent themes. Considerations of general categories of patient perspectives, experiences, and perceptions of clinical trials enabled the construction of higher-order themes. The intent was to compile data and summarize every finding defining patients' experiences.

The effort resulted in evidence-based interview questions on key topics considered in clinical trials with an adaptable structure for exploring patients' experiences. Each specific module provides context and a set of key topic areas followed by open exploratory questions and more direct probes. An overview document describes each module, identifies objectives, and details the purpose.

Expert Consultation

Data Sources

With the version developed from the literature review, consultation with 15 relevant subject matter experts sought to further the scope, applicability, and adaptability of the modules. Experts were selected from a variety of distinct and overlapping areas, including HTAs, HEOR, regulatory consultants, academia, PV, patient perspective, and COA administration.

The network was established through snowball methodologies using recruitment outreach on LinkedIn, at relevant academic conferences, and based on recent relevant publications.

Consultation Method

Experts received the updated version of the SIM prior to consultation. Then, two methodologies of consultation were used in conjunction based on expert preference and range of expertise.

For experts with more limited time or scope of expertise, a PowerPoint presentation with a discussion of relevant sections sought insight into areas of expertise.

For experts with a greater time commitment and broader expertise, semi-structured interviews gained in-depth perspectives across the interview manual, and then a sub-set of this selection of experts subsequently was used to review consolidated feedback to plan modifications for a refined version of the SIM.

Modifications

Based on expert consultation, modules were better organized for pre-, during, and post-trial usage; selected items were directly connected to commonly used PROs, including the SF-36, EQ-5D, and the WHO-DAS 2.0 as composite indicators; and instructional content was augmented to clarify instrument adaptability.

1. Burden of Disease
2. Patient Preferences
3. Benefit-Risk Assessment
4. Trial Participation
5. Treatment Outcome
6. Meaningful Change
7. Patient Satisfaction

Figure 2: Resultant Modules for the SIM

Cognitive Interviews

Data Sources

Cognitive interviews with people experiencing a particular condition were conducted. While additional cognitive interviews are performed ad-hoc to assure the SIM is fit-for-purpose with rare conditions to meet client needs, initial cognitive interviews were performed with four people each who were experiencing five chronic diseases.

Interview Method

As with expert consultations, patient respondents were provided with a copy of the interview manual prior to the interview to support more in-depth responses.

Then, a semi-structured interview manual sought to verify that the SIM is meaningful regarding relevance, comprehension, and completeness along with exploring health literacy, recall periods, and response options.

Patients were permitted to guide the interview focus and depth in order to prevent interviewee burden and decreased data quality.

Refinements

Along with the prior steps in the iterative process, patient feedback was documented in an item-tracking matrix summarizing the creation, deletion, and modification of item content.

Because of the variety of disease trajectory, burden, and experience, patient feedback has been reserved for alignment as the SIM is fit-for-purpose with study objectives in relevant clinical trials.

Conclusions

With the expectations for improved content validity in interview manuals yet the need for more efficient solutions to integrate patient voices, the application of the FDA iterative developmental process proved constructive, even though labor-intensive, in developing a qualitative interview manual for use in drug development.

The seven modules of the SIM based on published literature along with alignment from expert consultation on PRO usage means the SIM is ready to be efficiently tailored to clinical trials to turn narratives into outcomes.

References

Carr, A. J., & Higginson, I. J. (2001). Are quality of life measures patient centred?. BMJ (Clinical research ed.), 322(7298), 1357–1360. https://doi.org/10.1136/bmj.322.7298.1357

Contesse, M. G., Valentine, J. E., Wall, T. E., & Leffler, M. G. (2019). The case for the use of patient and caregiver perception of change assessments in rare disease clinical trials: a methodologic overview. Advances in therapy, 36(5), 997-1010.

Crane, S., Backus, L., Stockman, B., Carpenter, J. S., Lin, L., & Haase, J. (2018). Understanding treatment burden and quality of life impact of participating in an early-phase pediatric oncology clinical trial: a pilot study. Journal of Pediatric Oncology Nursing, 35(1), 25-35.

Critical Appraisal Skills Programme (2018) Qualitative Checklist. Retrieved from: https://casp-uk.b-cdn.net/wp-content/uploads/2018/03/CASP-Qualitative-Checklist-2018_fillable_form.pdf

Erickson, P., & Patrick, D. (1993). Health status and health policy: quality of life in health care evaluation and resource allocation. New York: Oxford University Press.

Eton, D. T., Ramalho de Oliveira, D., Egginton, J. S., Ridgeway, J. L., Odell, L., May, C. R., & Montori, V. M. (2012). Building a measurement framework of burden of treatment in complex patients with chronic conditions: a qualitative study. Patient related outcome measures, 3, 39–49. https://doi.org/10.2147/PROM.S34681

Vodicka, E., Kim, K., Devine, E. B., Gnanasakthy, A., Scoggins, J. F., & Patrick, D. L. (2015). Inclusion of patient-reported outcome measures in registered clinical trials: evidence from ClinicalTrials. gov (2007–2013). Contemporary clinical trials, 43, 1-9.

Wolfe, F., Walitt, B. T., Katz, R. S., & Häuser, W. (2014). Symptoms, the nature of fibromyalgia, and diagnostic and statistical manual 5 (DSM-5) defined mental illness in patients with rheumatoid arthritis and fibromyalgia. PloS one, 9(2), e88740.

23 Reviewed Articles: clinigma.com/SIMLitReviewRefs