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Are external grants or funds being used to support this research?: No external grants or funds are being used to support this research.
How did you learn about the YODA Project?: Internet Search

Conflict of Interest

https://yoda.yale.edu/system/files/coi_form_3.pdf
https://yoda.yale.edu/system/files/coi_form_sb_0.pdf
https://yoda.yale.edu/system/files/coi_form_mr.pdf
https://yoda.yale.edu/system/files/coi_form_pg.pdf
https://yoda.yale.edu/system/files/coi_form_ro.pdf
https://yoda.yale.edu/system/files/coi_form_pk.pdf

Certification

Certification: All information is complete; I (PI) am responsible for the research; data will not be used to support litigious/commercial aims.
Data Use Agreement Training: As the Principal Investigator of this study, I certify that I have completed the YODA Project Data Use Agreement Training

1. NCT00887198 - COU-AA-302 - A Phase 3, Randomized, Double-blind, Placebo-Controlled Study of Abiraterone Acetate (CB7630) Plus Prednisone in Asymptomatic or Mildly Symptomatic Patients With Metastatic Castration-Resistant Prostate Cancer

What type of data are you looking for?: Individual Participant-Level Data, which includes Full CSR and all supporting documentation

Research Proposal

Project Title

Co-designing a resource sheet to aid Prostate Cancer patient's interpretation of PRO data from a clinical trial: Asynchronous online patient study

Narrative Summary:

Clinical trial data has long been reserved for scientific experts, trialists and regulators. The inclusion of patient-reported outcomes (PROs) in clinical trial designs engages patients as research partners and brings new opportunities to improve the efficiency of clinical trial data communications. This observational study aims to develop a resource sheet which summarizes PRO data from the perspectives of patients with prostate cancer. Descriptive statistics, measures of central tendency and dispersion and qualitative research methods will be used analyze online survey and patient interview data to achieve PRO data visualizations and scripts that are useful and easy to interpret.

Scientific Abstract:

Background: There is a paucity of research on optimal presentation formats to communicate clinical trial data to patients
Objective: Use patient-centric methods to co-develop of a patient-friendly resource sheet displaying clinical trial PRO results.
Study Design: A 3-part mixed design will include: 1) an ePRO online survey; 2) qualitative interviews; and 3) a final resource sheet tested for its usefulness in communicating PRO clinical trial data.
Participants: 30 patients with prostate cancer will complete an online survey and 15 patients will participate in

cognitive debriefing interviews. Final resource sheet distribution will involve approximately 20 patients.
Outcome Measures: The study will include 6 PRO results from the COU-AA-302 trial. Each PRO result will be displayed in 6 different visual formats that patients will evaluate for their level of relevance, clarity, and interpretability.
Statistical Analysis: Descriptive data from the screening and demographic form will be tabulated to characterize the participant sample. Participant responses to questions about survey data will be analyzed descriptively with a score of 1-3 (1: Participant's response demonstrated clear understanding of the data presentation and aligns with the intended interpretation; 2: Participants correctly interpreted the overall message of the data presentation, but the response highlighted some confusion with how this was interpreted from the data; 3: Participants showed no understanding of the data presentation and the interpretation was incorrect). Measures of central tendency and dispersion will be used to summarize the results. Day 7 survey data will be analyzed using categorical frequency counts to ascertain preferences. This analysis will help develop a draft resource sheet summarizing the PRO data which will be evaluated by participants in one-on-one interviews and further refined after receiving feedback from members of PCR's patient community.

Brief Project Background and Statement of Project Significance:

Patient involvement in clinical trials is increasing, both as drug makers and governmental and regulatory entities recognize the vital contributions of measures such as Patient Reported Outcome (PRO) measures in drug development. Already, the US Federal Drug Administration (FDA) is committed to making clinical trial endpoint terms more understandable to patients and has engaged patients in multiple venues to garner input on patient-friendly definitions for clinical trial endpoint terms (Kim, 2019).
As patient involvement in clinical trial research increases, so too does the need for appropriate methods to present thorough and meaningful data to the patients involved in the trial through organizations such as Patient Advocacy Groups (PAGs). Research has already shown that when presented with outcome data, while patients and clinicians tend to rate similar graphical formats highly in terms of ease-of-use and interpretability, they differ in terms of the amount of statistical data that is useful to them (Brundage et al, 2015). To that end, there is a growing need for materials that can display PRO and clinical outcome data for patients in a format that works for that population. This is particularly pertinent in conditions where the patient perspective gathered in clinical trials can directly inform decisions about treatment in clinical practice (Mercieca-Bebber et al., 2018). Cancer care is routinely informed by patient priorities and preferences (Basch et al., 2018). Prostate cancer is the second most common cancer diagnosis in men, worldwide, and is estimated to account for 174,650 new cancer cases and 31,620 deaths in the United States during 2019 (American Cancer Society, 2019). Similar prostate cancer mortality rates are reported for Western Europe (Bray et al 2018, Ferlay et al 2018).
The study described in this proposal seeks to enhance the communication of PRO data from the COU-AA-302 to an audience of patients with prostate cancer. The 3-part methodology suggested in this study serves to capture the patient perspective about what is relevant, useful, and easy to understand about prostate cancer PRO data measured during the trial. It provides an example of how to best communicate PRO data using relevant, useful, and easy to understand graphical displays. We hope to apply this methodology to other disease areas and benefit from the perspectives of other patient communities in the future.

Specific Aims of the Project:

The objective of this study is to develop a PRO data resource sheet that meets patient-focused standards of relevance, usefulness, and interpretability. To reach this objective, this study proposes to:
1. To elicit the perspectives of people with PC on the interpretability of PRO data and preferences for presentation of PRO data
2. To develop and test (iterate) a patient-informed resource sheet containing PRO data with people with PC

What is the purpose of the analysis being proposed? Please select all that apply.
Other

The work from Snyder and Brundage left some open questions, which we hope to be able to probe as part of our proposed research. These include but are not limited to how best to draw attention to important clinical findings when presenting individual data

Research Methods

Data Source and Inclusion/Exclusion Criteria to be used to define the patient sample for your study:

The study will use PRO data and develop presentation formats based on the Johnson and Johnson's COO-AA-302 trial. Stage 1 will recruit approximately 30 English-speaking males aged ? 18 years old with PC in the UK who are members of the PCR patient panel. Participants will have access to an internet browser, receive care for PC, and they will be fluent in English. Patients will be excluded if diagnosed with any other condition involving cognitive deficits or visual impairments, and currently participating in a clinical trial.
Stage 2 will recruit approximately 15 English-speaking adults with PC in the UK who are members of the PCR patient advisory board based on the same eligibility criteria as in Stage 1 and willing and able to complete a 45-60 min interview. It is best practice to conduct 7-10 cognitive interviews (Willis 2005), However, sample size requirements vary (Patrick et al, 2011).
In Stage 3, The resource sheet will be sent to all adults with PC in the UK who are members of the PCR patient community (approximately 20 people). No further inclusion or exclusion criteria required.

Primary and Secondary Outcome Measure(s) and how they will be categorized/defined for your study:

PRO data from the COO-AA-302 trial will be used to develop a series of presentations of 6 PRO results in 6 different presentation formats. Each participant will be sent a weblink to one piece of PRO data in one format each day for 6 consecutive days. Each day, participants will be asked to describe the data, and to rate the relevance, clarity and ease of understanding of the PRO results. On day 7, participants will view single PRO result appearing in all 6 presentation formats and asked to choose their preferred format. The objective of Stage 1 is to elicit the perspectives of people with PC on the interpretability of the PRO results presented to them, and to ascertain their preferences for the presentation format. This information will be used to draft a resource sheet containing PRO results from the COO-AA-302 trial. The main outcome of this study will be development of a resource sheet based on the qualitative analysis of patient views about the relevance, usefulness, and ease of understanding of the presentation formats.

Main Predictor/Independent Variable and how it will be categorized/defined for your study:

The main independent variable of the study is the graphical format that will be used to vary the presentation of the FACT-P total or subscale results.

Statistical Analysis Plan:

Descriptive data from the participant-reported screening and demographic form will be tabulated to characterize the participant sample.
Qualitative data from the day 1-6 survey (question 1) will be analyzed descriptively. For each presentation format, the researchers who designed the data visualizations will provide a summary of the intended interpretation. Participants response to what the data is showing will be assigned a score between 1 and 3 based on the extent to which the response clearly indicates understanding and aligns with the intended interpretation. A score will be assigned to the participants response independently by 2 researchers. Discrepancies will be discussed and a single score determined. Score data will be summarized at a both a PRO result and presentation format level (separately), using measures of central tendency and dispersion. Quantitative data from the day 1-6 survey (questions 2-4) will be presented descriptively in the total sample. Data on relevance (question 2) will be summarized at a PRO result level to ascertain which PRO results are most relevant to participants, using measures of central tendency and dispersion. Data on clarity (question 3) will be summarized at a presentation format level to ascertain which presentation format is most clear, using measures of central tendency and dispersion. Data on ease of understanding (question 4) will be summarized at a both a PRO result and presentation format level (separately) to ascertain which PRO data and which presentation formats are easiest to understand, using measures of central tendency and dispersion. Quantitative data from the day 7 survey (question 1) will be presented descriptively in the total sample, using categorical frequency counts to ascertain preferences. Qualitative data from the day 7 survey (question 2) will be analyzed descriptively, with verbatim quotes summarized by presentation format and PRO result.
Stage 2 Data Analysis
Descriptive data from the participant-reported screening and demographic form will be tabulated to characterize the participant sample.
High level analysis will be done in waves, after each wave of interviews. This allows the interview guide to be adjusted to reflect the findings of the interviews. Interviewers' notes will be used to consider enhancement of understandability and clarity.
Following completion of all interviews, the audio files will be transcribed verbatim. Any personally identifiable

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information in the transcripts will be removed and the transcripts will be loaded into the MAXQDA software program for coding. A coding framework will be developed to provide an organization for grouping information similar in content. Data analysis will focus on assessing the relevance of concepts and ease of understanding of visual displays and descriptive information presented to patients in the resource sheet. During the analysis of concepts that surface in the transcripts, the coding framework will be expanded and reorganized to offer the best way to group and present the qualitative data. All quantitative (categorical and continuous variables) from the screening, demographic and concept rating data will be analyzed to generate tables of descriptive statistics (count, percent, mean, median, SD).
Stage 3 Data Analysis
Descriptive data on age, gender and duration of PC will be tabulated to characterize the participant sample. Quantitative data from the questions will be presented descriptively, using categorical frequency counts to ascertain how useful the information was (question 1) and whether the recipients would like to receive similar in the future (question 2). Qualitative data from question 3 will be analyzed descriptively, with verbatim quotes summarized.
Software Used:
RStudio

Project Timeline:

Prepare study materials: Jan-Feb 2022
IRB review/approval: Feb 2022
Respondent recruitment: March - May 2022
Data collection: April - June 2022
Reporting: May - August 2022
Dissemination: September 2022

Dissemination Plan:

IQVIA PCS plans to share this research during an ISOQOL symposia in September 2022. HEOR journals of interest include Quality of Life Research or The Patient. However, we are also considering oncology journal. This will be discussed with PCR.

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Supplementary Material:

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