Completing Patient-Reported Outcome Measures Electronically: A Review of the Literature on Subject Burden in Clinical Trials

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ePRO CONSORTIUM

- The ePRO Consortium was established within the Critical Path Institute (C-Path) in 2011 to advance the quality, practicality, and acceptability of electronic data capture methods used in clinical trials for endpoint assessment.
- The ePRO Consortium's members are firms that provide electronic data collection technologies and services to the medical products industry for capturing clinical outcome assessment (COA)-based endpoints in clinical trials.
- Current members of the ePRO Consortium include: .assistek, Bracket, CRF Health, ERT, ICON, MedAvante, Medidata and YPrime.

OBJECTIVE

- In order to characterize important aspects of the clinical trial subject's experience, this review sought to identify published reports of the subject-perceived burden when completing patient-reported outcome (PRO) measures electronically as part of a clinical trial protocol.

METHODS

- This literature search was conducted in PubMed/MEDLINE, Embase, CINAHL, and PsycINFO databases. (See Table 1.)
- A secondary search was conducted on supplementary sources including reference lists of key articles and conference abstracts.
- Abstract and full-text reviews were completed and study data collated.

Inclusion Criteria:

- Study measured patient-reported outcomes and/or study addressed barriers to clinical trial participation
- Study measured patient burden in terms of device use, length of tool/measure, or time
- English language
- Full-text available
- Limited to humans

Exclusion Criteria:

- Not peer-reviewed literature (e.g., letter to editor, opinion/editorial)

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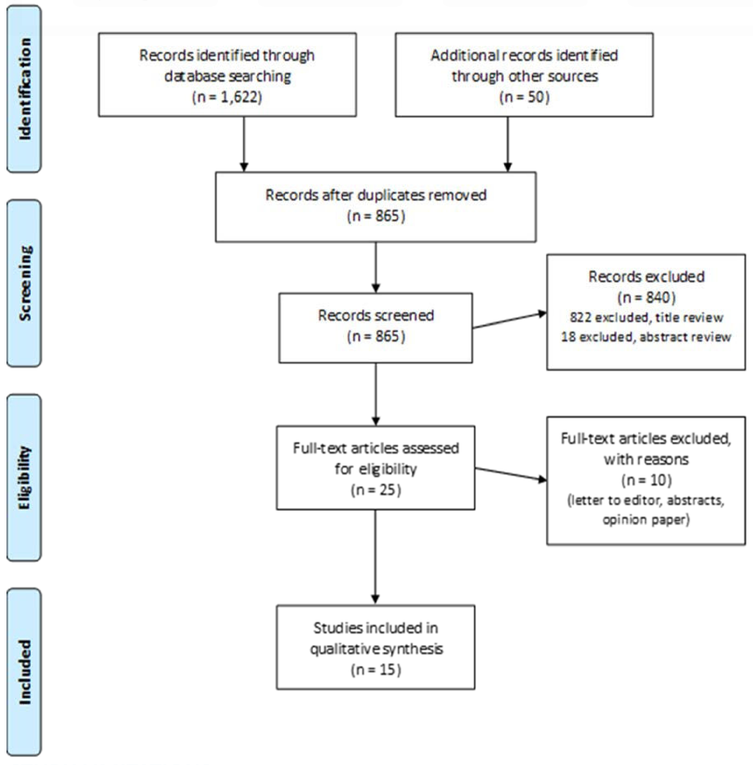
METHODS

Table 1: Search terms

Step	Search Terms
1	Patient Reported Outcome Measures[MeSH] OR Psychometrics[MeSH] OR Patient Outcome Assessment[MeSH] OR Surveys and Questionnaires[MeSH]
2	Burden[ALL]
3	(1) AND (2)
4	Patient Preference[MeSH] OR Patient Participation[MeSH] OR Patient Compliance[MeSH]
5	(3) AND (4)
6	(5) duplicates removed
7	(6) limited to English language
8	(7) limited to human(s)

RESULTS

Figure 1: Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram



STUDY LIMITATIONS

- No stand-alone qualitative studies which focused on the question of gaining a patient's perspective on using electronic devices.
- Small number of studies were returned from the literature database searches and further citation searches may yield a qualitative study designed to assess the patient perspective on the use of electronic devices.
- Two-thirds of the studies included in this review were conducted in the US. There may be limited generalizability to other populations regarding the burdens of reporting outcomes on subjects in clinical trials.

DISCLOSURES

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation:

- Shannon Vaffis, MPH: Nothing to disclose
- Mabel Crescioni, DrPH, JD, Critical Path Institute, Tucson, AZ, USA: Nothing to disclose

RESULTS

- Qualitative synthesis included 12 studies, rather than the originally projected 15, as several studies included results from overlapping projects.
- Categories were not mutually exclusive and studies could be counted in more than one category.

Table 2: Study characteristics

Study Characteristic	Studies (n=12)	Percent (%)
Method of Data Collection		
Electronic	10	83
Paper	4	33
Electronic, paper, and face-to-face interview	1	8
Mode of Administration		
Personal computer/laptop	4	33
Tablet	3	25
Smartphone/handheld	1	8
Interactive voice response	1	8
Paper	3	25
Combination of modes	1	8
Type of Measure		
Survey/questionnaire (one-time measure)	10	83
Diary (daily, repeated questionnaire)	3	25
Type of Study		
Clinical trial	5	41
Randomized	4	33
Non-randomized	0	0
Prevention trial	2	17
Behavioral health intervention	0	0
Qualitative	4	33
Quantitative	5	41
Therapeutic/Disease Area		
Cancer	6	50
Other	6	50
Subject Burden Description		
Time	9	75
Device use	10	83
Length of measure	4	33

CONCLUSIONS

- This review demonstrated an existing gap in the literature on how to define and measure the subject's burden of completing PRO measures electronically within clinical trials.
- To date, few studies have attempted to directly measure this concept. Some studies sought to understand subject preference for ePRO mode of data collection or commented on researchers' perceptions of what the burden to the subject might have been.
- However, to date there is no universally accepted measure of subject burden when completing PRO measures electronically.
- Further research can aid in identifying methods to measure the degree of burden placed on subjects when PRO data is captured electronically in clinical trials.

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