

Shannon Vaffis, MPH and Mabel Crescioni, DrPH, JD on behalf of the ePRO Consortium

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- Not peer-reviewed literature (e.g., letter to editor, opinion/editorial)

## REFERENCES

- Ashley, A., et al. (2013). Integrating Patient Reported Outcomes With Clinical Cancer Registry Data: A Feasibility Study of the Electronic Patient-Reported Outcomes from Cancer Survivors (ePOCS) System. *Journal of Medical Internet Research*, 15(10), e230.
- Carter, G., et al. (2008). Computerized Assessment of Quality of Life in Oncology Patients and Carers. *Psycho-Oncology*, 17, 26-33.
- Glanz, K., et al. (2006). Improving Dietary Self-monitoring and Adherence With Hand-held Computers: A Pilot Study. *American Journal of Health Promotion*, 20(3), 165-170.
- Grady, D., et al. (2009). Is a Shorter Hot Flash Diary Just as Good as a 7-day Diary? *Menopause: The Journal of the North American Menopause Society*, 16(5), 932-936.
- Grant, M. and Booth, A. (2009). A typology of reviews: an analysis of 14 review types and associated methodologies. *Health and Information Libraries Journal*, 26, 91-108.
- Gurvich, E., et al. (2013). Use of Novel Technology-Based Techniques to Improve Alcohol-related Outcomes in Clinical Trials. *Alcohol and Alcoholism*, 48(6), 712-719.
- Hahn, E., et al. (2007). The Impact of Literacy on Health-Related Quality of Life Measurement and Outcomes in Cancer Patients. *Quality of Life Research*, 16(3), 495-507.
- Hahn, E., et al. (2004). The Talking Touchscreen: A New Approach to Outcomes Assessment in Low Literacy. *Psycho-Oncology*, 13, 86-95.
- Hallum-Montes, R., et al. (2013). Improving Completion Rates for Client Intake Forms Through Audio Computer-Assisted Self-Interview (ACASI): Results from a Pilot Study with the Avon Breast Health Outreach Program. *Journal for Healthcare Quality*, 36(6), 47-53.
- Hjermstad, M., et al. (2012). Computer-based Symptom Assessment is Feasible in Patients with Advanced Cancer: Results From an International Study, the EPCRC-CSA. *Journal of Pain and Symptom Management*, 44(5), 639-654.
- Khurana, L., et al. (2016). Patient preference for using computers, smartphones, and internet to participate in COPD clinical trials. *European Respiratory Journal*, 48.
- Khurana, L., et al. (2016). Patient Preference for Display of Electronic Patient-Reported Outcomes in COPD Clinical Trials: Wording, Question Format, and Navigation Button Placement. *European Respiratory Journal*, 48.
- Khurana, L., et al. (2016). Patient Preference for Display of Electronic Patient-Reported Outcomes: Wording Emphasis, Question Format, and Navigation Button Placement. *Value in Health*, 19(3), A178.
- Khurana, L., et al. (2016). Patient Preference for Display of Electronic Patient-Reported Outcomes in Osteoarthritis Clinical Trials: Wording Emphasis, Question Format, and Navigation Button Placement. *Arthritis and Rheumatology*, 68, 3095-3096.
- Ku, J., et al. (2004). Voiding Diary for the Evaluation of Urinary Incontinence and Lower Urinary Tract Symptoms: Prospective Assessment of Patient Compliance and Burden. *Neurology and Urodynamics*, 23, 331-335.
- Pallet, E., et al. (2009). The Brief Fatigue Inventory: Comparison of Data Collection Using a Novel Audio Device with Conventional Paper Questionnaire. *Journal of Pain and Symptom Management*, 38(3), 390-400.

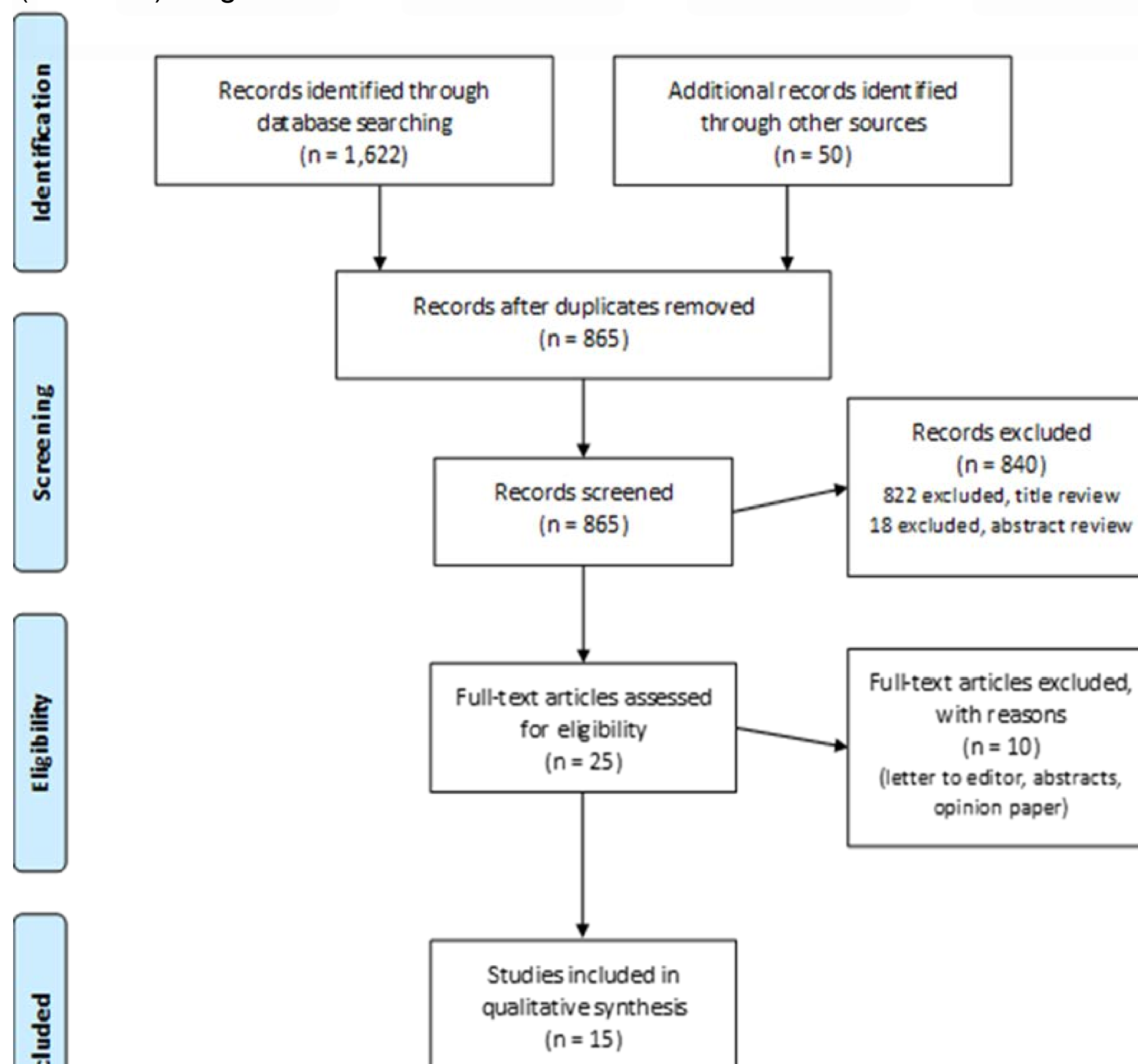
## METHODS

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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