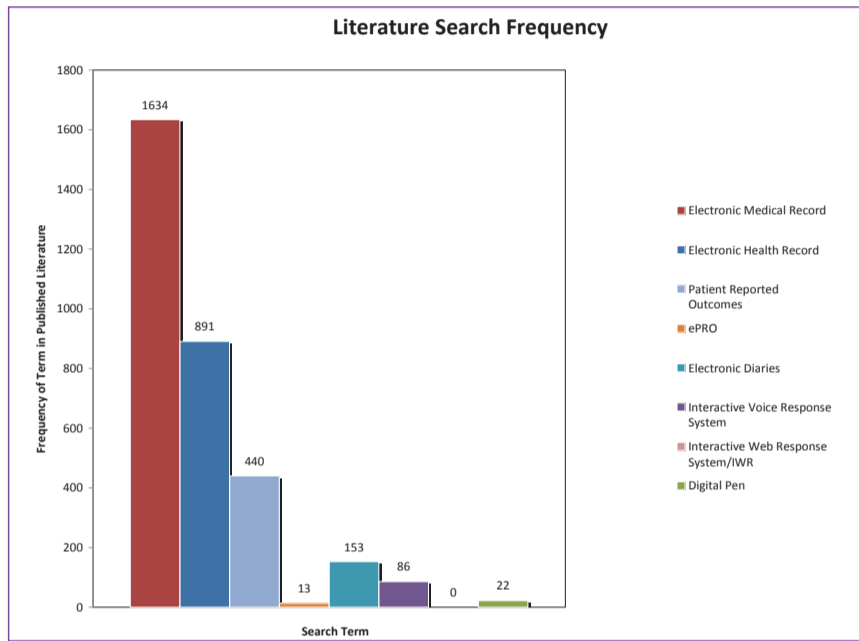


Updates and Innovations in Electronic Patient Reported Data Capture: A Review of the Evolution and Future Directions of ePRO

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OBJECTIVES

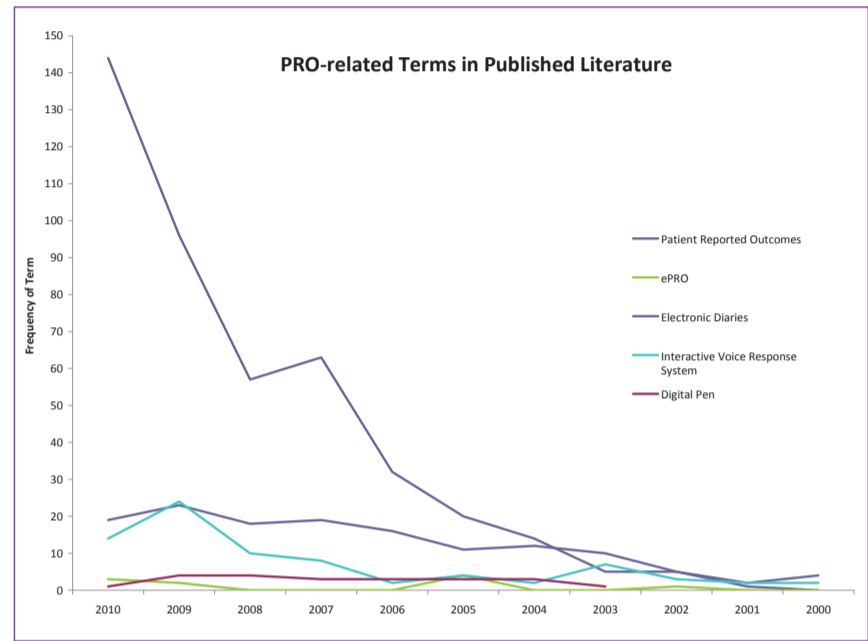
In clinical trials, the capture of patient-reported outcome (PRO) data has increased over the past decade. Regulatory guidelines, including the EMA's concern of Health-Related Quality of Life (HRQL) measurements and the FDA's emphasis on PRO data to support labeling claims, have led to a greater inclusion of PRO as clinical trial endpoints. As sponsors include more PRO measurements, many turn to electronic PRO (ePRO) data capture. This presentation summarizes literature from the last 9 years to report changes in the use of ePRO including projections for future applications in clinical trials, disease management and health policy.



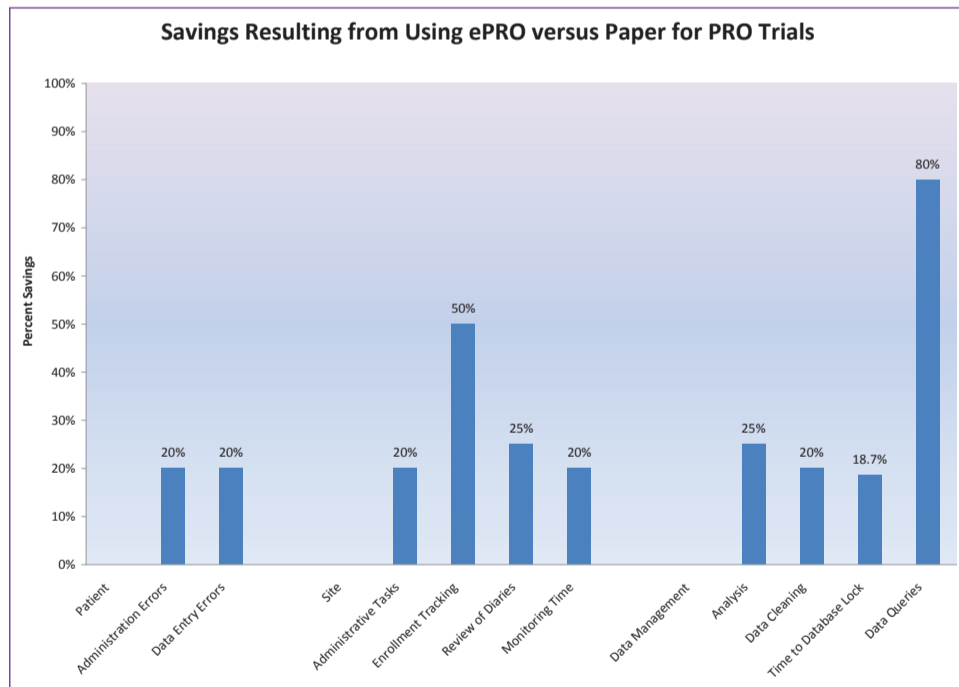
Graph 1: Frequency of terms related to electronic healthcare found in PubMed.

METHODS

This presentation is a synthesis of literature in peer reviewed journals regarding ePRO from 2000 to 2010. Key search terms include "patient reported outcomes", "electronic patient reported outcomes", "electronic diaries", "interactive voice response system", "interactive web response system" and "digital pen". The literature review made use of meta-databases such as PubMed.



Graph 2: Increase in use of the term "PRO" in publications since 2000. Terms show a general increase in frequency over time of use in literature found in PubMed.



Graph 3: Savings resulting from using an electronic solution for a trial collecting PRO data, as compared to a paper data collection method.

RESULTS

The use of ePRO has increased since a decade ago, due to greater movement in healthcare towards electronic solutions and to regulatory emphasis on PRO collection in clinical trials. The use of PRO questionnaires is steadily increasing, while terminology for electronic PRO solutions varies. The literature shows no results for Interactive Web Response Systems and few findings for ePRO. Electronic diaries continue to increase in popularity across therapeutic areas and age ranges. Interactive Voice Response Systems and Digital Pen terms had a peak number of occurrences in the literature in 2009. Researchers use ePRO in various population settings, whereas the application of IVRS is not limited to outcomes trials but also for behavioral intervention studies and drug randomization protocols. Data show that electronic solutions benefit sites, subjects, and sponsors by reducing administrative responsibilities, errors during data collection, and need for data clarifications.

CONCLUSIONS

The poster characterizes the scope of experience with PRO and related fields as reported in scientific literature. Analysis demonstrates savings when using ePRO compared to paper and improved data quality with ePRO compared to data captured using paper collection methods. Due to literature emphasis, the poster will focus on clinical trials but will also examine other healthcare fields such as disease management and health policy. Attendees will learn about the evolution of ePRO.

REFERENCES

PAREXEL's Bio/Pharmaceutical R&D Statistics Sourcebook 2009/2010, Waltham, MA: PAREXEL International Corporation; 2009.