Poster #50

Harmonizing Original Articles and Plain Language Publications to Maximize Audience Diversity While Ensuring Scientific Accuracy: Do Plain Language Summary of Publications Follow CONSORT Criteria?

Joseph Kruempel, PhD, ISMPP CMPP™
Heather Caballes, PhD
Tania R Iqbal, PhD, ISMPP CMPP™
Krystina M Neuman, PhD, ISMPP CMPP™

Citrus Scientific, Citrus Health Group, Inc., Chicago, Illinois, USA

Conclusions

- CONSORT scores were high for both clinical trial reports and PLSPs but significantly lower for PLSPs than the corresponding original articles
- Few PLSPs report statistical significance, address effect size or variance within a population, or discuss trial limitations
- Further effort is needed to establish consensus regarding items that should be reported in PLSPs and how to address reporting gaps using accessible language

Disclosures
Joseph Kruempel, Heather Caballes, Tania R Iqbal, and Krystina M Neuman are employees of Citrus Health Group, Inc.

Scan the QR code for a virtual version of this poster

21st Annual Meeting of the International Society for Medical Publication Professionals
May 11–14, 2025 | Washington, DC

Background

- Plain language summaries explain complex medical topics, including clinical trials, in a way that is clear and understandable to a broad readership, which may include nonspecialist healthcare professionals, patients, and caregivers
- Plain language summary of publications (PLSPs) are published as full-length standalone journal articles with their own digital object identifier and citation that summarize ≥1 original research or review article published separately in a peer-reviewed journal
- The EQUATOR Network publishes guidelines for the reporting of health research to promote transparency and accurate reporting; however, no EQUATOR guidelines exist for reporting clinical trials in PLSPs
- Data are limited pertaining to how well the information reported in PLSPs adheres to the original article and to quality standards for reporting clinical trials (eg, Consolidated Standards of Reporting Trials [CONSORT] 2010 guidelines and 2025 update)

Objective

To determine how closely PLSPs reporting clinical trials adhere to CONSORT reporting guidelines and assess similarity between PLSPs and the original research articles

Methods

- PubMed was searched for full-text, open-access articles published before December 13, 2024, that contained the words "plain language summary" in the title
- A single reviewer (JK) assessed articles for inclusion; articles were excluded if they were not PLSPs or covered topics outside of biomedicine (eg, food safety)
- 4 reviewers (JK, HC, TRI, KMN) assessed PLSPs by article type (eg, clinical trial, review, survey) and audience
- For PLSPs that reported clinical trials—including primary trial reports, subanalyses, and retrospective analyses—the original publication being summarized was identified, and reviewers used a modified CONSORT checklist (2010 guidelines) to evaluate reporting quality of PLSPs and the original article (**Table 1**)
  - Each of the 26 items were scored as 1 (fully reported), 0 (not reported), or N/A (not applicable)
  - A CONSORT score was calculated as the number of items identified as 1 (fully reported) divided by the total number of applicable items
- Mean and median CONSORT scores were calculated for both article types, and mean scores were compared between original articles and PLSPs using an unpaired, 2-tailed t-test

Table 1. Modified CONSORT Items[a]

Identification as randomized in the title
Abstract: summary of design, methods, results
Scientific background and explanation of rationale
Specific objectives or hypotheses
Description of trial design including allocation ratio
Important changes to protocol after trial commencement, with reasons
Eligibility criteria for participants
Settings/locations where data were collected
Interventions for each group and how/when they were administered
Defined primary and secondary outcome measures and how/when they were assessed
How sample size was determined
Explanation of interim analyses and stopping guidelines
Details of randomization and blinding, similarity of interventions
Statistical methods used to compare groups
Disposition, flow diagram
Dates of recruitment
Why trial was stopped
Demographic characteristics
Number of participants
Results
Effect size and measure of variance
Safety
Discussion of results
Limitations and generalizability
Registration and protocol
Funding and support

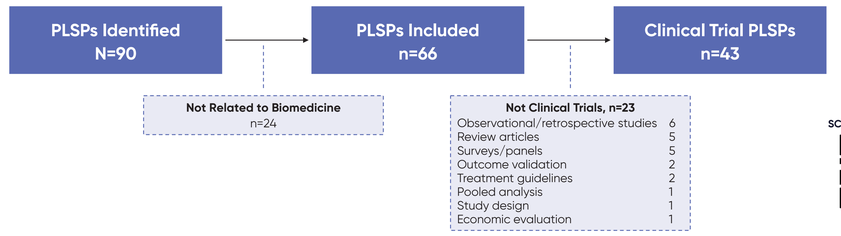
[a]Items were scored as 1 (reported in any form), 0 (not reported), or N/A (not applicable). Examples of items scored as N/A included "explanation of interim analyses and stopping guidelines" when the primary article did not report interim analyses, early stopping criteria, or if the trial was fully completed and details of disposition, recruitment, or safety in secondary analyses of published trials.

Results

Included Studies

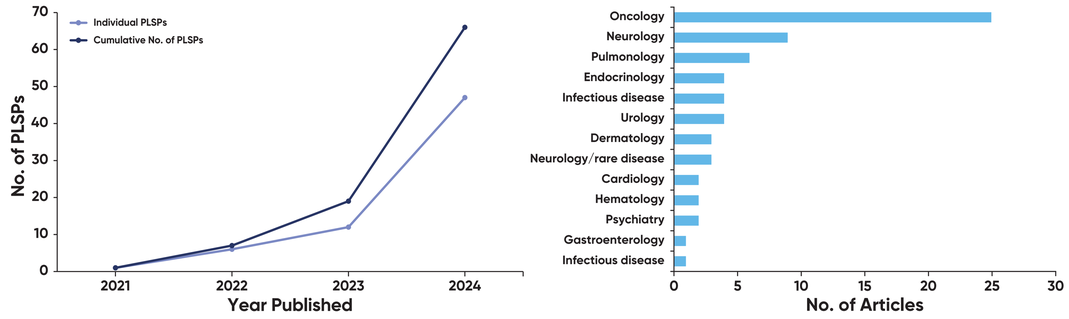
- A total of 66 PLSPs met inclusion criteria, 43 of which reported clinical trial results (**Figure 1**)
  - 43 clinical trial PLSPs and 42 open-access original articles (of 47 identified) were assessed for CONSORT reporting
  - Scan QR code for a full list of included articles

Figure 1. Article Attrition



- All PLSPs were published in or after 2021, and a range of study types and audiences were included (**Figure 2**)
- Overall, 64 of 66 PLSPs (97%) were funded by industry, and 64 (97%) acknowledged a medical writer

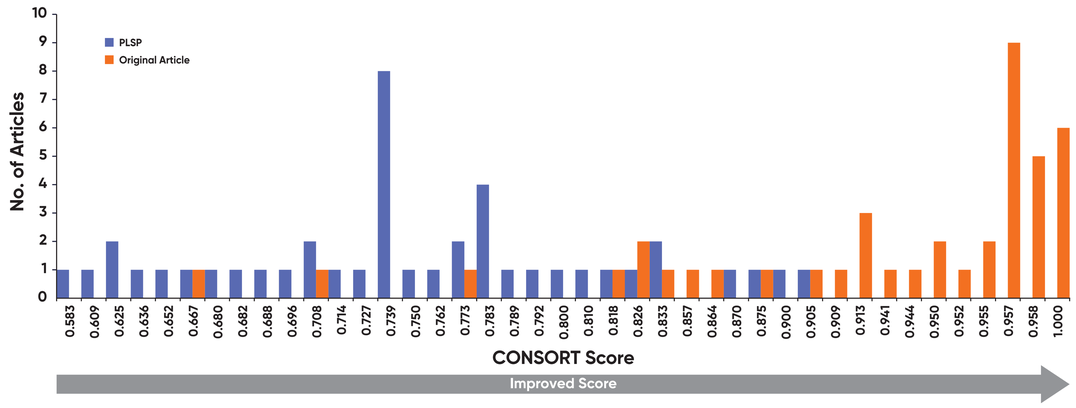
Figure 2. PLSP Publication Year and Therapeutic Area



CONSORT Reporting

- Mean (SD) CONSORT scores were 0.748 (0.076) for PLSPs and 0.920 (0.076) for original articles; median (range) CONSORT scores were 0.739 (0.583–0.905) and 0.955 (0.667–1.000), respectively
- CONSORT scores for original articles were generally higher than for PLSPs (**Figure 3**)
- Overall mean scores for original articles were significantly higher vs PLSPs (P<0.001)

Figure 3. CONSORT Scores of PLSPs and Original Articles



- 15 of 26 (58%) CONSORT items were well reported (≥80% of articles reporting item) in PLSPs, and 18 of 26 (69%) were well reported in the original articles
- Lower CONSORT scores in PLSPs were drive n by lower reporting of CONSORT items related to statistics (including sample size determination and effect size or variance) and study limitations (**Figure 4**)

Figure 4. CONSORT Items Reported in Original Articles and PLSPs

