

Prevalence of Plain-Language Summaries (PLSs) in Open Access Patient-Reported Outcome (PRO) Publications

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Background

- As patients and their caregivers become more involved in their own care, easy-to-understand sources of information are increasingly important.^{1,2}
- While digital innovation has improved access to publications, technical language represents a barrier to understanding for the lay population.^{1,2}
 - Clinical trial publications are traditionally targeted to experts within the field of study and often contain medical jargon.
- The inclusion of plain language summaries (PLSs) in publications have made scientific data more digestible and accessible for a wider audience.^{1,2}
 - Patient-reported outcome (PRO) publications are of particular interest, as they describe the experience of patients, burden of illness, and potential improvements with disease interventions.

Objective

- To report the prevalence and characterization of PLSs in PRO publications.

Methods

- A targeted literature review of open access publications in the last 5 years (2018-2023) was performed in PubMed using the search term "patient-reported outcomes" and filter "clinical trials."
- PROs were defined as any report on the status of a subject's condition reported directly by the subject, without any external interpretation; PLSs were defined broadly as short, text-only summaries of articles using layman terms.
- The primary outcome was the number of publications that included PLSs, and the secondary outcome was characterization of the PLS, including Flesch-Kincaid (FK) grade level and PLS format.
- The reading level of each PLS was assessed using the FK grade level test via Microsoft Word, which accounts for the average sentence length, average number of syllables per word, and the number of words (Figure 1).³ Scores correlated to US grade-school levels; plain language is considered to be approximately an eighth-grade reading level.

Figure 1. Flesch-Kincaid grade level formula

$$FK = (0.39 \times ASL) + (11.8 \times [n_{sy} / n_w]) - 15.59$$

Key: ASL – average sentence length; n_{sy} – number of syllables; n_w – number of words.

Results

- A total of 3,594 publications were identified in the PubMed search. Of those, 2,615 reported PROs and were included for analysis. A total of 867 PRO publications included PLSs (Figure 2).

Publication characteristics

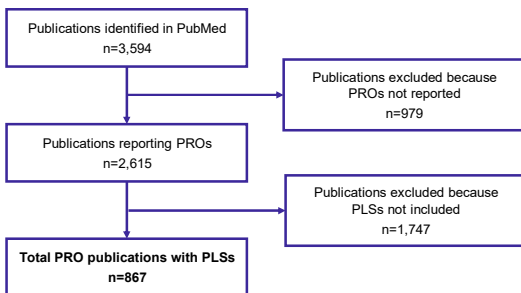
- The majority of publications were interventional trials (n=776/867).
- The most common disease states were oncology, psychiatry, cardiology, and gastroenterology (n≥75 publications each) (Table 1).

PLS characteristics

- PLS formats were widely varied, including titles such as "key points," "what is known about this topic," or "lay summary."
- Of the included 868 PLSs, the mean (interquartile range [IQR]) FK grade level was 17.8 (15.5-20.2), and the median (standard deviation [SD]) was 17.9 (3.8).

Results (cont.)

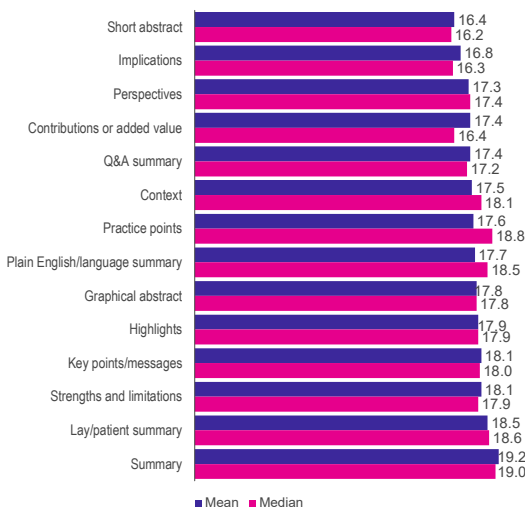
Figure 2. Literature screening process



Key: PLS – plain language summary; PRO – patient-reported outcome.

- When considering the FK grade level by category of PLS, short abstract PLSs had the lowest mean FK grade level at 16.4 (IQR: 14.5-18.2), and summary PLSs had the highest at 19.2 (IQR: 16.3-20.6) (Figure 3).
- Even in publications where the PLS category was labeled "lay or patient summary" (n=20) or "plain English/language summary" (n=55), the mean FK grade levels were 18.5 (IQR: 15.9-20.1) and 17.7 (14.5, 20.1), respectively.

Figure 3. Flesch-Kincaid grade level by PLS category



Key: PLS – plain language summary; Q&A – question and answer.

- When considering the FK grade level by study design, literature reviews had the lowest mean FK grade level at 15.2 (IQR unavailable due to small sample size, n=2), and interventional trials had the highest FK grade level at 17.9 (IQR: 15.5-20.2) (Figure 4).
- When considering the FK grade level by most commonly identified disease states, gastroenterology publications had the lowest mean FK grade level at 17.7 (IQR: 14.9-20.2), and cardiovascular publications had the highest FK grade level at 18.6 (IQR: 16.5-20.5) (Figure 5).

Table 1. Publication characteristics

Characteristics, n	Total PRO publications with PLSs (n=867)	Characteristics, n	Total PRO publications with PLSs (n=867)	Characteristics, n	Total PRO publications with PLSs (n=867)
Study design type		Disease state			
Economic model	2	Anesthesiology	3	Ophthalmology	8
Interventional trial	776	Audiology	4	Orthopedics	45
Interview or survey	34	Bariatrics	4	Otolaryngology	8
Literature review	2	Cardiology	84	Pain	6
Noninterventional trial	50	Dentistry	5	Palliative care	7
Protocol	3	Dermatology	34	Pediatrics	5
PLS label		Emergency medicine	2	Pharmacogenomics	1
Context	29	Endocrinology	25	Physical medicine and rehabilitation	6
Contributions or added value	11	Gastroenterology	75	Podiatry	1
Graphical abstract	1	Geriatrics	8	Psychiatry	92
Highlights	34	Hematology	10	Pulmonology	39
Implications	55	Infectious disease	23	Rheumatology	52
Key points/messages	477	Internal medicine	26	Sleep	7
Lay/patient summary	20	Nephrology	1	Speech therapy	1
Perspectives	18	Neurology	74	Surgical care	35
Plain English/language summary	55	Obstetrics and gynecology	23	Urology	11
Practice points	5	Oncology	142		
Q&A summary	70				
Short abstract	10				
Strengths and limitations	54				
Summary	28				

Key: PLSs – plain language summaries; PRO – patient-reported outcome; Q&A – question and answer.

Figure 4. Flesch-Kincaid grade level by study design

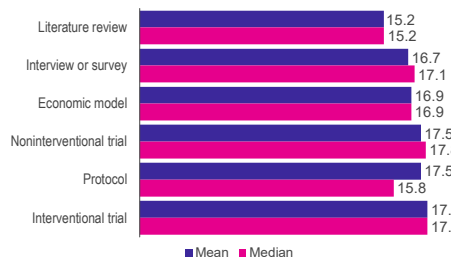
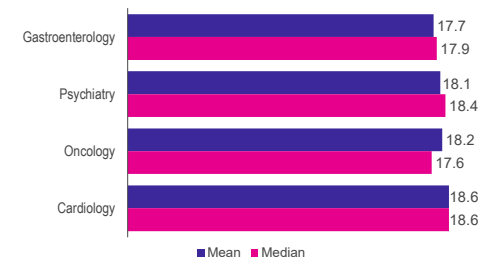


Figure 5. Flesch-Kincaid grade level by disease state



Limitations

- Only open access publications were included, so the results may not be generalizable to paywalled publications. However, this was intentionally done to ensure the lay population would also have access to the included publications.
- We assessed readability based on the FK grade level; readability can be assessed using a variety of tests and may vary depending on the tool used. Additionally, the FK grade level is affected by the publication layout, which may have biased our results to be higher compared to a readability assessment that does not consider layout.
- As PLS does not have a standard definition, we included several formats of PLSs, such as "key points." Journals may not have categorized these as PLSs or instructed authors to aim for a specific reading level, which may have biased our results to be higher (eg, greater than eighth grade) reading level.

Conclusions

- Most PLSs included in PRO publications in scientific journals are above the generally accepted readability recommendation for lay materials of lower than an eighth-grade reading level.
- There is an unmet need for the incorporation of PLSs into scientific publications to diversify readership, reduce information inequality, and meet the growing demand for easily digestible information, particularly in publications that would be of most interest to patients, such as PRO publications.
- Standards and guidance for PLSs need to be established to support authors upon submission to scientific journals.

References: 1. Dormer L, Schindler T, Arnstein Williams L, et al. A practical 'how-to' guide to plain language summaries (PLS) of peer-reviewed scientific publications: results of a multi-stakeholder initiative utilizing co-creation methodology. *Res Invol Engagem.* 2022;8(1):23. 2. Maurer M, Siegel JE, Firminger KB, et al. Lessons learned from developing plain language summaries of research studies. *Health Lit Res Pract.* 2021;5(2):e155-161. 3. Flesch R. A new readability yardstick. *J Appl Psychol.* 1948;32(3):221-233.