Plain Language Summaries: An Overview

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What are Plain Language Summaries?

Plain language summaries (PLS) are the simplest way to summarize the contents of scientific research and related outcomes in a more understandable way.[1] It involves the use of simple language that help readers to understand the complex concepts and information in the form of images or graphics. PLS can be an effective form of expanding the reach of any research work to a broader audience that could be non-specialists, scientists from different disciplines, patients, health care providers, caregivers etc.[2]

What is the need of PLS?

Scientific publications are the traditional way to present the research. However, this restricts audience accessibility because only scientists and researchers can interpret such core technical data, leaving the general public in the dark about what the researchers have done, what the results signify, and what applications might be made of them.[3] Their curiosity about the most recent advancements being made in science and technology gets stifled. Considering this concern, in the past, multiple publishing environments were established, in particular for the COVID-19 pandemic, to spread research material to a wider audience with a focus on the content being clear and accessible.[4] Therefore, the concept of developing PLS document is introduced to communicate research in an understandable way to a nonexpert audience that includes readers from different disciplines or not having awareness about the topic.[1] The simplified language used helps them to avoid re-reading the lines and makes the article much easier to understand at the first read.[5,6] In addition, these are focused on how to involve patients in developing PLS, as they are often an important audience for these summaries. Also, PLS of peer-reviewed articles can also be hosted elsewhere.[7]

What are the key features of PLS[7]

Language: should have non-technical language and jargon-free language that is understandable to non-specialist audiences.
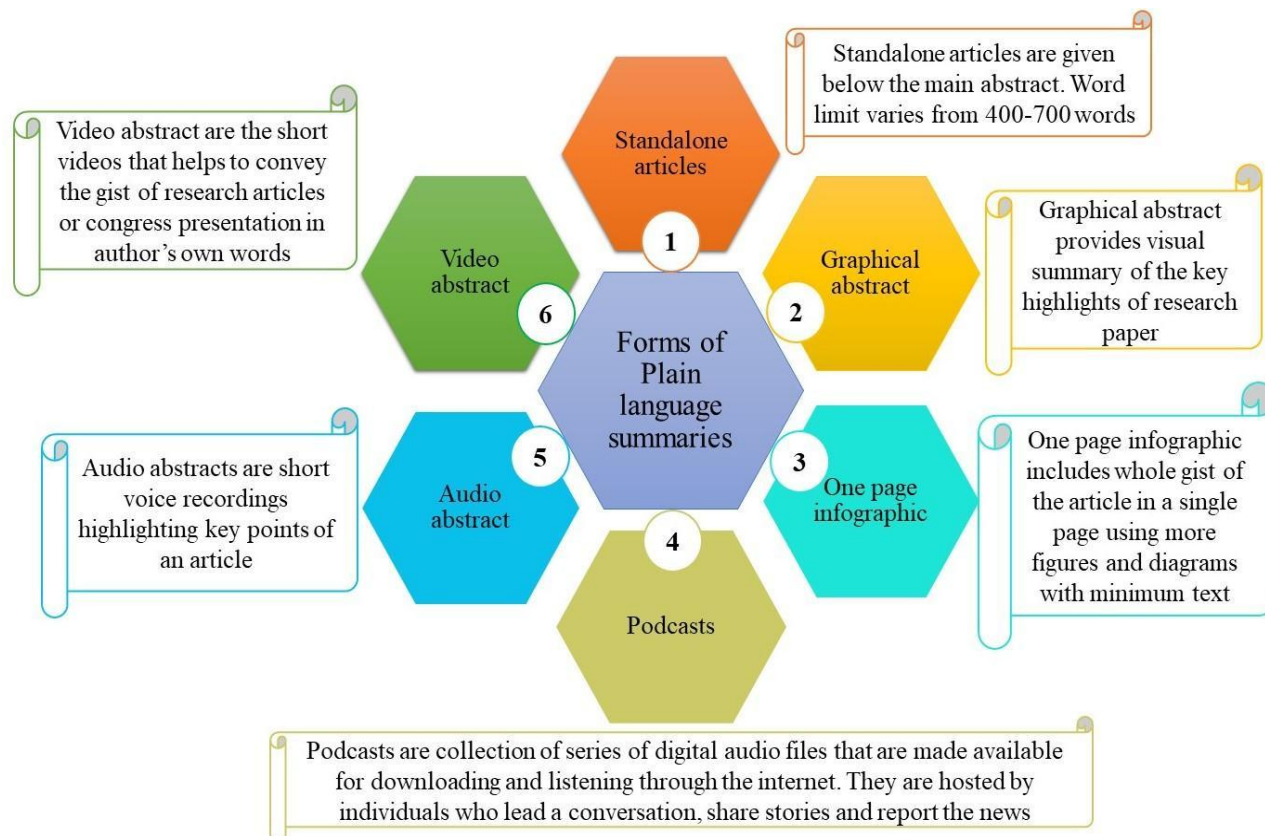
Audience: It includes patients, patient advocates, the general public, non-specialist clinicians, research scientists, decision-makers and a range of professionals in the healthcare community.

Written by: PLS are usually written by the authors of the original publication; additional authors, such as patients not involved with the original publication, can also be included.

Accessibility: Each PLS has its own DOI i.e., it is fully citable, indexed on relevant databases and discoverable.

What are the different types of Plain Language Documents?

With the need for inclusivity, diversity, accessibility, and transparency, plain language documents become an integral mode of communicating and translating knowledge of scientific and medical research.[8] PLS are intended to be as original as the accompanying publication in delivering true scientific information or research findings and are part of a peer review process. The content must be consistent with that of the underlying publication and must not be promotional in language, tone, or style.[7,9] The published examples have included several formats for PLS such as graphical abstracts, podcasts, videos, single page infographics etc.[10] (Figure 1). Moreover, to translate complex scientific researches and expand their discoverability, different types of plain language documents have also been described based on purpose, scope, target audience and publishing criteria (Table 1).

Video abstract are the short videos that helps to convey the gist of research articles or congress presentation in author's own words

Standalone articles are given below the main abstract. Word limit varies from 400-700 words

Graphical abstract provides visual summary of the key highlights of research paper

Audio abstracts are short voice recordings highlighting key points of an article

One page infographic includes whole gist of the article in a single page using more figures and diagrams with minimum text

Podcasts are collection of series of digital audio files that are made available for downloading and listening through the internet. They are hosted by individuals who lead a conversation, share stories and report the news

[1] *Figure 1: Different forms of PLS*

- **Data sources:** Key references used in the main article
- **Funding sources:** Include the details of the sponsor that provided financial/administrative support for study
- **Keywords:** Play a vital role in finding your abstract. Use keywords while directly reflecting the key content of your manuscript (in case of abstract for journal) or your study (mainly for conference)
- **Clinical trial registration number,** wherever applicable

Table 1: Types of plain language documents[11]

	Publication associated PLS	**Standalone PLS of publication**	**Regulatory lay summaries**
Purpose	Brief jargon free summaries primarily of peer reviewed publications	Full-length standalone secondary manuscripts that translate primary published manuscript into plain language with visual formatting	Mandated summaries of clinical study reports
Audience	For non-specialist readers (typically target reading age of 14-18 years)	For patient audience (typically a variable reading age)	For study participants (typically a target reading age of 9-13 years)

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Scope	Covers the content of associated manuscripts	Covers one primary manuscript and may include patient voice for wider scope	Reports on one study only with a focus on primary endpoints and safety
Guidelines and criteria	Formats vary by author and journal preferences but best practice and convention encourage text based and concise plain language summaries that are peer reviewed alongside the manuscript	Author guidelines available from Future Science Group	Outline mandated in EU CTR no.546/2014
Publishing site	Text based and concise plain language summary can be indexed on PubMed. Hosted with the associated publication either embedded in the main manuscript or supplementary material	Published by Future Science Group Journals and Becaris Publishing Journals	Intended to be published in central CTIS portal, but are currently hosted in sponsor websites and other portal
Terminologies	Publication plain language summary, Publication lay summary	Plain language manuscript	Clinical trial summary, Patient summary, Lay summary

What are the regulatory guidelines updates on preparing PLS?

- Good Publication Practice 2022 (GPP 2022) guidelines encourages use of PLS following quality principles and same ethics as the main publication. The guideline specifies that a text based PLS should follow Consolidated Standards of Reporting Trials (CONSORT) guidance.[12]

- GPP 2022 states that every biomedical publication should include PLS to improve the understanding of information being presented. PLS should be indexed and fully accessible either as a part of a publication or can be available as open access.

- PLS based on clinical outcomes should include clinical trial identifier number and should cite the original publication from which the information is obtained.

- In addition, clinical trials (Phase 1-4) conducted under European Union Clinical Trial Regulation 536/2014 (EU CTR 536/2014) are required to prepare and submit PLS of clinical data results in six months for pediatric trials and twelve months after the conclusion of a trial.

- Other national regulatory agencies including US Food and Drug Administration (USFDA) and Health Canada also recommend use of PLS for the clinical data findings.[13]

- The Patients Focused Medicine Development (section 3) provides set of instructions on how to create PLS of conference presentations and journal articles **(Figure2)**.[7]
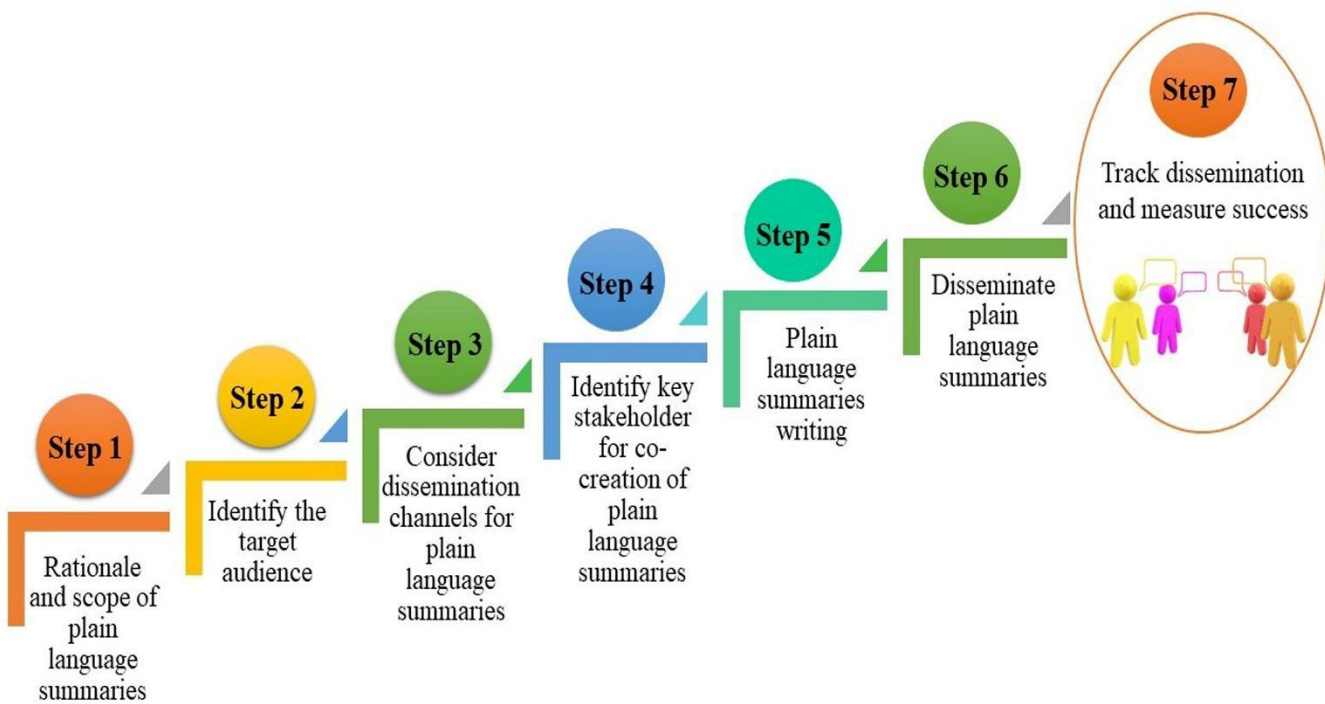
Figure2: Step-wise approach to develop PLS

What are the challenges and their solutions in developing PLS?

Despite substantial value and utmost need for PLS, several challenges are still there particularly related to a need for improved awareness and education among the society (Table 2).

Table 2: Possible solutions to the challenges related with PLS

Challenges	Examples	Solutions
Different set of Terminologies[11,14]	Lay language summaries are defined as patient lay summaries, clinical trials summary, regulatory summary and trial result summaries	Professional associations and regulatory bodies involved in PLS discussions should collaborate to further establish consensus for growing awareness on PLS related terminologies
Low uptake of PLS[14,15]	PLS indexed on PubMed has relatively low uptake i.e., the yearly prevalence of PLS indexed on PubMed was 929.1 per million articles in 2021	Identification of the target audience seeking to access research outcomes is important to expand the uptake of PLS by creating awareness and providing education thus encouraging publishing journals to initiate and generate mandate guidelines to adapt these publishing landscapes

PLS quality[16]	Ensuring quality of PLS that follow health literacy best practices and meet end user needs	Readability metrics which assign a numerical reading age or level helps to quantify PLS quality. However, readability metrics can be easily skewed such as by the inclusion of long disease or drug name and should not be relied upon a definitive goal. Hence, user-testing with target audience representatives is a better way to assure PLS quality
Discoverability of publication associated PLS and standalone PLS[10]	PLS are tagged on PubMed to expand the discoverability of scientific research but it is not necessary that all the stakeholders are aware of PubMed and use it for the reading purpose	Developing easily accessible, discoverable and cross-publishers of PLS according to end user needs to ensure its discoverability by the target audiences

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