MAPS
FOR Medical Affairs Professionals
BY Medical Affairs Professionals
Medical™ Affairs Professional Society

Welcome!

Complexities Beneath Plain Language Summaries: Challenges and Future Implications

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- The speakers have no financial conflicts of interest to report

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- This presentation is for informational purposes only and is not intended as legal or regulatory advice.

Agenda

- Brief introduction of the speakers
- Perspectives and experiences sharing on plain language summaries
- Q&A

Presenters

Speakers

Lisa M. DeTora

Associate Professor
Hofstra University, USA

Avishek Pal

Global Medical Director, Cell & Gene Therapies,
Novartis, Switzerland

Laura Dormer

Co-Founder and Editorial Director
Becaris Publishing Ltd, UK

Moderator

Raghuraj Puthige

Senior Scientific Writing Lead
Enago Life Sciences, India

Educational Objectives

This session will provide a learning opportunity for our audience by understanding:

1: Why plain language summaries (PLS) are complex

2 : Current challenges in harmonizing and developing global guidelines

3 : Future implications

Why is it challenging

Plain Language Summary

- In depth subject matter knowledge
- Engaging to hold reader's attention
- Strong communication skills – simplify technical concepts
- Clarity and brevity

Why no harmonized guidance

- **Lack of consensus on best practices: different approaches and recommendations**
- **Variation in audience needs and preferences: one-size-fits-all guidance for plain language summaries**
- **Complexity of scientific research: difficult to develop guidance that is applicable to all types of scientific research**
- **Limited resources: availability of significant time and resources at organization level or individuals**

Griffiths et al. Medical Writing, 2022;31(4)

PLS and GPP: Academic perspective

Lisa DeTora,
Associate Professor,
Hofstra University, USA

Good Publication Practice

- Originated at the turn of the 21st century to address key issues in company-sponsored research:
  - Transparency
  - Authorship
  - Publication process
- GPP 2022 is the fourth iteration
  - PLS recommended
- *FREE* to access

GPP 2022 Overview

GPP 2022 reflects the changing role of the publication professional & strengthens core values such as ethics, transparency, inclusivity, accountability and responsibility

- Updated guidance on the types of studies that should be published (e.g., HEOR, RWE, translational and biomarker studies)
- Information added on the role of patients as authors
- Improved and detailed guidance on author agreements, including the removal of the recommendation to limit author numbers
- Guidance on working with alliance partners
- Advice on the role of social media in publication planning
- **Guidance on enhanced content and PLSs for publications**
- Clarity of the timing of data sharing to improve transparency

A detailed supplement includes practical help on various topics

- Publication types
- Publication professional roles and professional development
- Steering committees
- Publication plans
- Publication working groups
- Authorship and contributorship determination
- Publication process
- Documentation

GPP, Good Publication Practice; HEOR, health economics and outcomes research; ISMPP, International Society for Medical Publication Professionals; PLS, plain language summary; RWE, real-world evidence. https://www.acpjournals.org/doi/full/10.7326/M22-1460

Please note: Slides adapted from materials courtesy of Nucleus Global, An Inizio Company prepared for ISMPP U

Major GPP principles

- Follow laws and guidelines
- Publish all biomedical research in a balanced, accurate, complete, and timely manner in a peer reviewed journal
- Avoid commercial interests
- **Promote transparency**
  - Support author accountability by sharing data
  - Plan before data are available; detail roles and responsibilities in writing
  - Disclose financial and other interests

- Include patient voices in planning and authoring as appropriate
- **Support communication to lay audiences**
- Support inclusivity and consider marginalized groups
- **Use enhanced content to reach lay and other audiences**
  - Use open and free to access options whenever possible
  - Reflect all regions in which research is conducted (authorship, planning, steering committees)
  - Exhibit leadership via training activities, policy development

GPP, Good Publication Practice; HEOR, health economics and outcomes research; ISMPP, International Society for Medical Publication Professionals; PLS, plain language summary; RWE, real-world evidence. https://www.acpjournals.org/doi/full/10.7326/M22-1460

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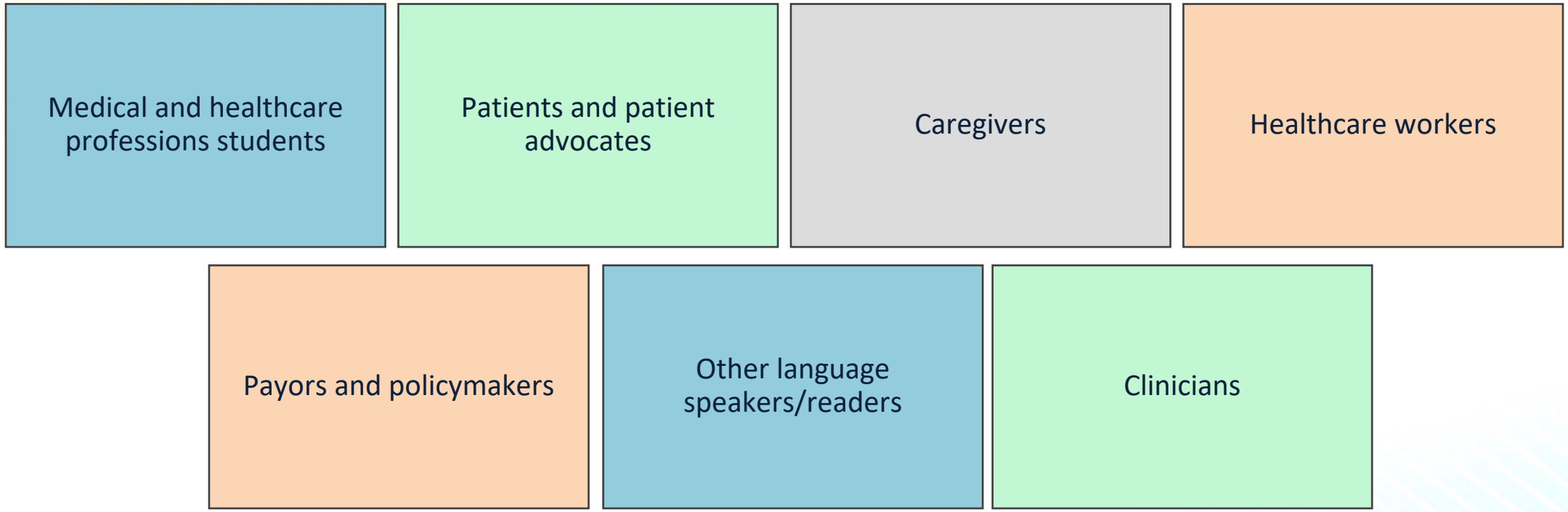
GPP 2022 Enhanced Content and PLS Recommendations

- Enhanced content and PLS are encouraged
  - At least abstract-length text PLS for all clinical trial data publications that follow CONSORT format (randomized, controlled trials)
    - Does not preclude additional enhanced content
  - Standalone PLS permissible for other data types
- Plan for PLS and enhanced content at all stages
  - Publication plan
  - Publication process
  - Include appropriate reviewers
  - Consider audiences

PLS audiences



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Where to find PLS information in GPP 2022

- Main Manuscript
  - Principles to Promote Transparency
- Supplement
  - Section A: Definitions
  - Section E: Publication Plans (Table 2)
  - Section F: Publication Working Groups
  - Section H: Publication Process (Table 6, Standalone Section)

PLS: Industry perspective

Avishek Pal

Global Medical Director, Cell & Gene Therapies, Novartis, Switzerland

PLS can be crucial in improving health literacy

Improving **health literacy** can improve **patient empowerment** leading to more effective **shared decision-making**

Office of Disease Prevention and Health Promotion

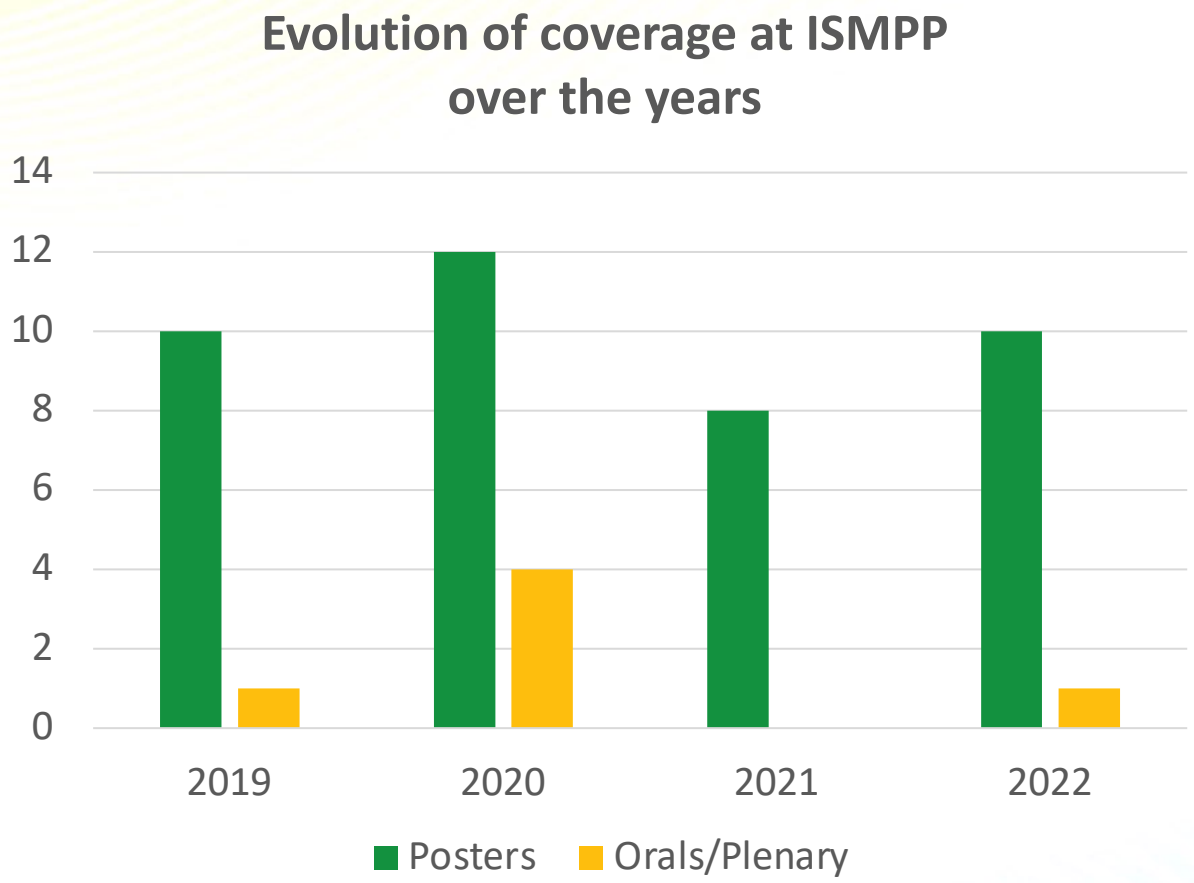
U.S. Department of Health and Human Services

PLAIN LANGUAGE: A PROMISING STRATEGY FOR CLEARLY COMMUNICATING HEALTH INFORMATION AND IMPROVING HEALTH LITERACY

Purpose statement

This issue brief describes why plain language is a promising strategy for clearly communicating health information and improving health literacy.

Interest in PLS is high in the medcomms community

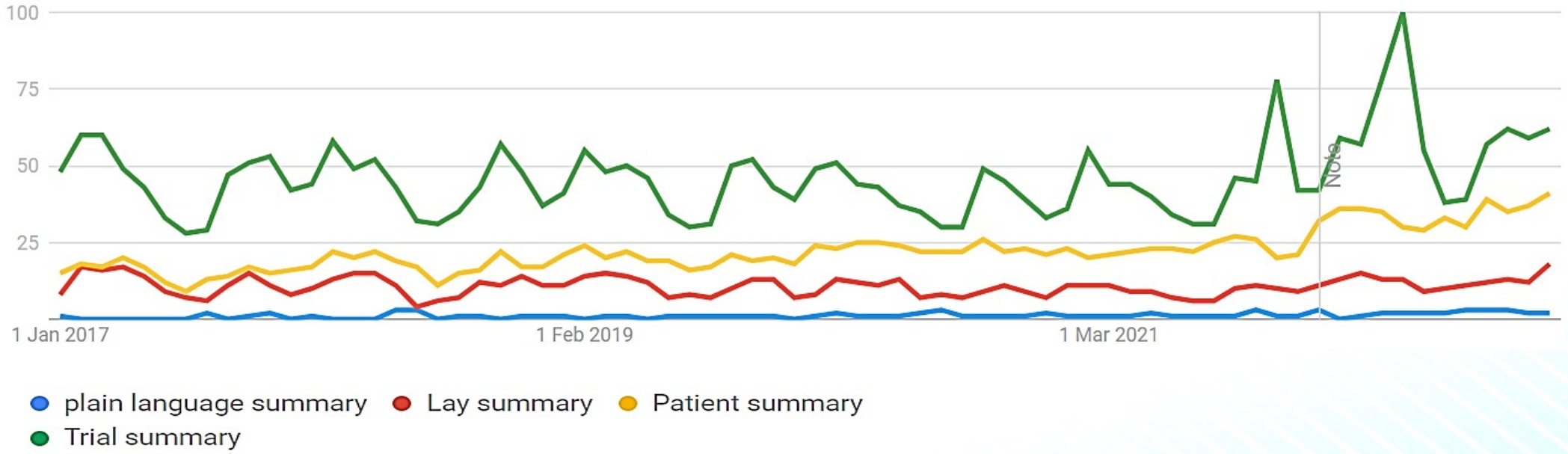


Evolution of themes since 2019

- Questions around feasibility, process optimization, compliance
- Experience sharing (Pharma, publishers)
- Practical recommendations (pt orgs), innovative formats

5-year Google trends however indicate otherwise!

Ambiguity still exists in nomenclature when general public search for info



https://trends.google.com/trends/explore?date=2017-01-01%202022-12-21&q=plain%20language%20summary,Lay%20summary,Patient%20summary,Trial%20summary

5-year Google trends however indicate otherwise!

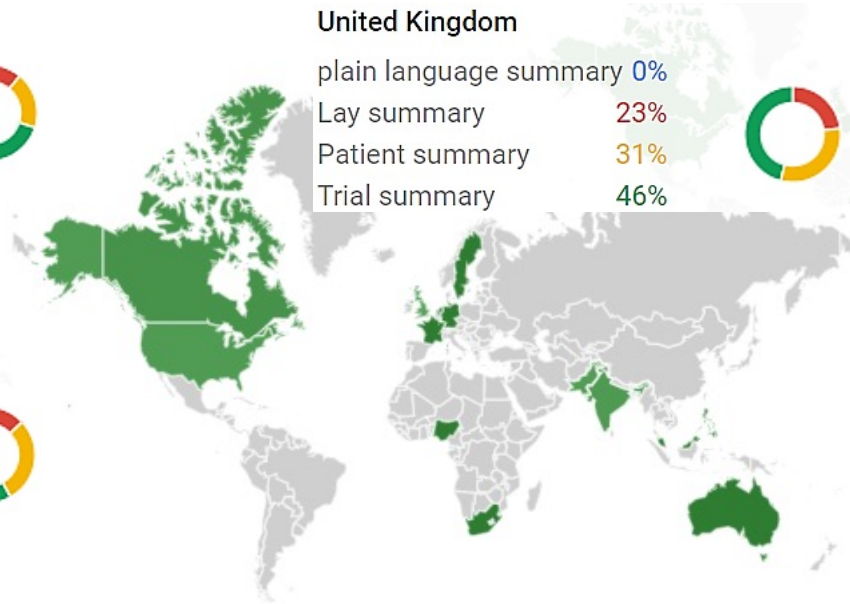
Search is still concentrated in specific regions which mirror medcomms presence

Canada

plain language summary	0%
Lay summary	11%
Patient summary	19%
Trial summary	70%

United States

plain language summary	1%
Lay summary	12%
Patient summary	29%
Trial summary	58%



United Kingdom

plain language summary	0%
Lay summary	23%
Patient summary	31%
Trial summary	46%

India

plain language summary	0%
Lay summary	9%
Patient summary	32%
Trial summary	59%

Australia

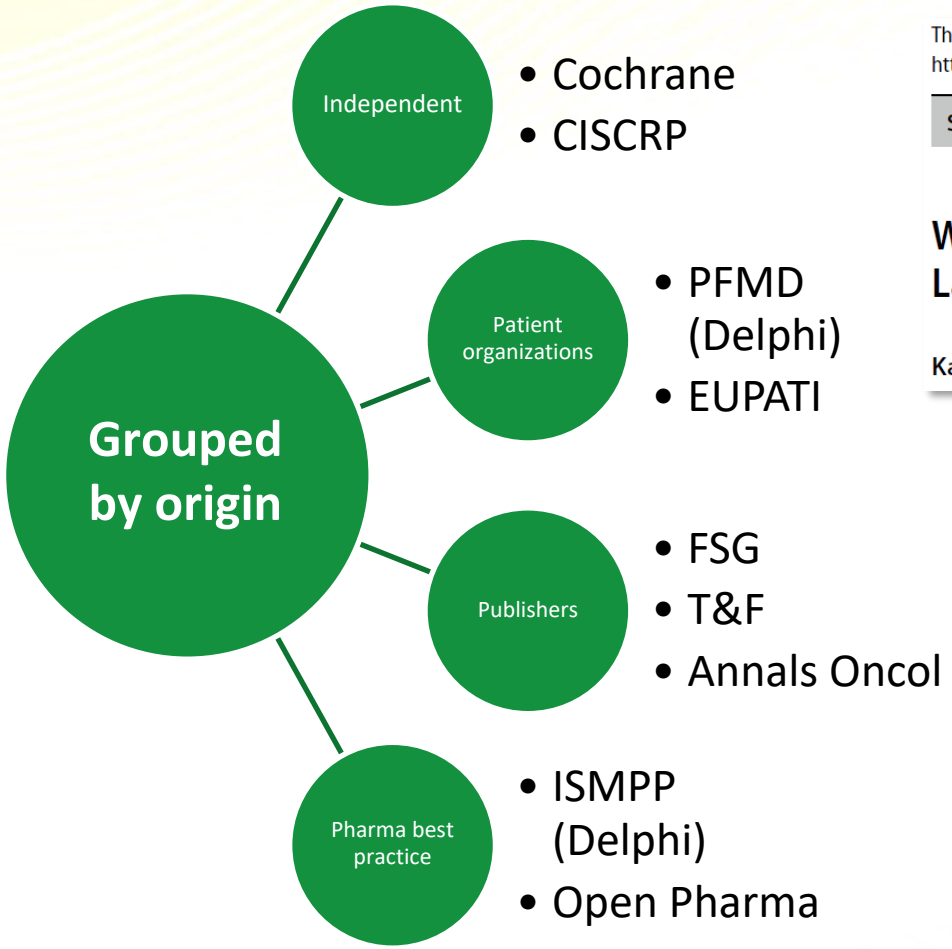
plain language summary	0%
Lay summary	0%
Patient summary	0%
Trial summary	100%

France, Germany, Sweden, Nigeria, South Africa searched only for trial summaries

plain language summary Lay summary Patient summary Trial summary

https://trends.google.com/trends/explore?date=2017-01-01%202022-12-21&q=plain%20language%20summary,Lay%20summary,Patient%20summary,Trial%20summary

Diversity in guidelines could be challenging



The Patient - Patient-Centered Outcomes Research
https://doi.org/10.1007/s40271-022-00606-7

SCOPING REVIEW

What Author Instructions Do Health Journals Provide for Writing Plain Language Summaries? A Scoping Review

Karen M. Gainey[1] · Jenna Smith[1] · Kirsten J. McCaffery[1] · Sharon Clifford[2] · Danielle M. Muscat[1]

We found variation between journals in the content and detail of instructions provided, for example the word count/PLS length, content, structure and recommendations regarding the use of jargon in the author instructions for PLS.

PLS could be improved with consistent instructions developed with the assistance of consumers.

Reminder: LESS IS MORE!

Gainey et al, 2022. Journal instructions variability https://link.springer.com/article/10.1007/s40271-022-00606-7

Industry experience-sharing definitely helps

Pfizer experience[1]

1 We approach the **key stakeholders** involved at each stage:
- Internal company colleagues: medical, clinical, corporate affairs, compliance, legal.
- Patient partners.
- Plain language experts: medical writers, editors, and graphic designers.
- Congress organizers.

2 We consider the **target audience** for APLS at congresses

Patients and carers are key
- Patient delegates are powerful drivers of information.[4,7]

All congress attendees
- Wider healthcare professional community.
- Non-specialist medical attendees.[1]

6 We engage all **relevant stakeholders**

Internal company colleagues
- Include asset-specific, subject-matter experts.

Lead authors of the scientific abstract
- Given the opportunity to review.

Medical writers
- A team trained in the use of plain language includes editors and graphic designers.

Patient partners
- Patients who review the initial drafts bring their experience of health conditions, and are able to user-test APLS.

7 **Key considerations**

We use a standard template
- Developed using approved company guidelines and available industry plain language principles.[4,9]

We use a standardized process
- To ensure consistency across APLS.

11 Reaching the **target audience**
- Each APLS can be accessed at conferences via QR codes on the scientific presentations.
- Information sheets, including APLS QR codes, are provided upon request.

PLANNING

3 We liaise with **lead authors**
- To secure agreement to develop APLS of the scientific abstracts.

4 We secure approval from **congress organizers**
- To include access to APLS via QR codes on presentations.
- To share APLS reactively via QR codes on information sheets.

5 We proactively share **timelines**
- To inform all stakeholders of the process.

DEVELOPMENT

8 We ensure that APLS reflect **original content** of the scientific abstract
- The abstract is used as the data source as it is the enduring, publicly available record.

9 We undertake **regular plain language training** sessions
- For internal and external stakeholders.

10 We use **plain language and numeracy principles** throughout

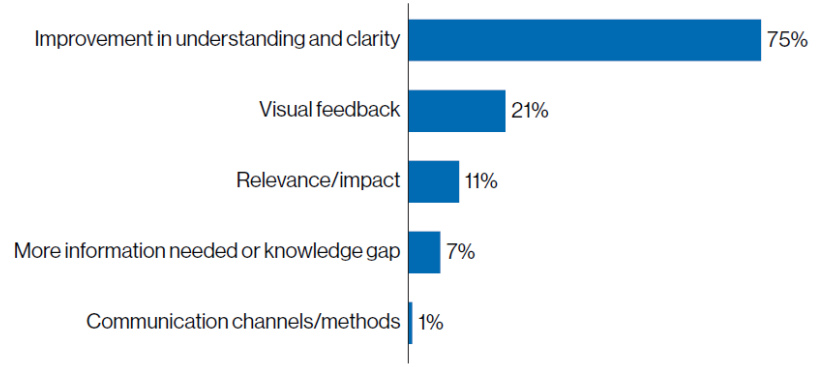
Simple visuals to enhance understanding
Avoid jargon
Use short, simple sentences
Active voice
Open-ended questions as headers
Bullets, not plain text
Use whole numbers
Use natural frequencies, such as "1 in 10 people" to represent 10%

DISSEMINATION
- APLS are posted on a microsite until 60 days after the congress, enabling broader audience access to the APLS.
- APLS have been mentioned in a company press release for one congress (ESMO) and posted on the company media page for four congresses in 2019 (ESMO, ESMO Asia, SABCS and ASH).

Novartis experience[3]

Global Oncology Patient Insights Panel (GOPIP)

Figure 1. Total Comments Received (N=102) for All PL Pieces (n=10)[a]



[a]Some comments were counted in multiple categories, so the total amounts exceed 100%.

Ipsen pledge[2]

JANUARY 25, 2022

Our pledge: summaries in plain language for all journal publications

By Will Gattrell

Today, we are broadening our commitment to providing everyone with the opportunity to read and understand our research. From July 2022, we will publish, as a minimum, a 250-word plain language summary alongside all company-sponsored journal publications from human studies.

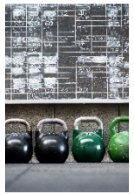
1. Chari et al, ISMPP AM 2020; 2. https://www.ipsen.com/our-pledge-summaries-in-plain-language-for-all-journal-publications; 3. Patel et al, ISMPP AM 2021.

Questions that still need answers

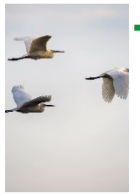
Questions from 2021

PLS guidelines	How do we ensure a consistent, optimal, and compliant approach to PLS across different sponsors and regions?	8
Transparency	How do we know which publications to do a PLS for?	6
Non-promotional	How can we ensure that PLS are accurate, balanced, and neutral?	5
Trust	If we **don't** do PLS, do we risk undermining trust between patients and industry?	4
Patient and public involvement in PLS	How do we best involve key stakeholders in co-creation?	3
Access to PLS	How can we ensure that PLS are easily accessible for all target audiences?	3
Global considerations	How do we ensure PLS are appropriate for different regions and cultures?	3

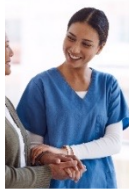
Arnstein et al, ISMPP AM 2021.



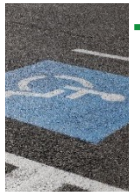
Nomenclature



Guidelines



Patient involvement



Accessibility

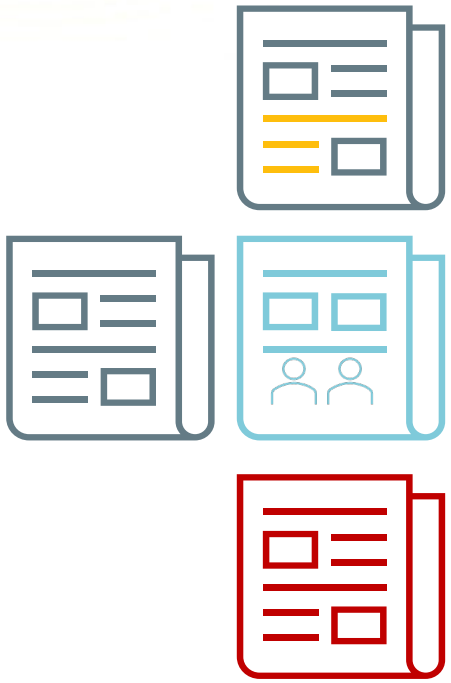
PLS and article features: a publisher's perspective

Laura Dormer

Co-founder, Becaris Publishing Ltd, UK

How can we publish PLS?

Three methods have emerged for the publication of PLS:



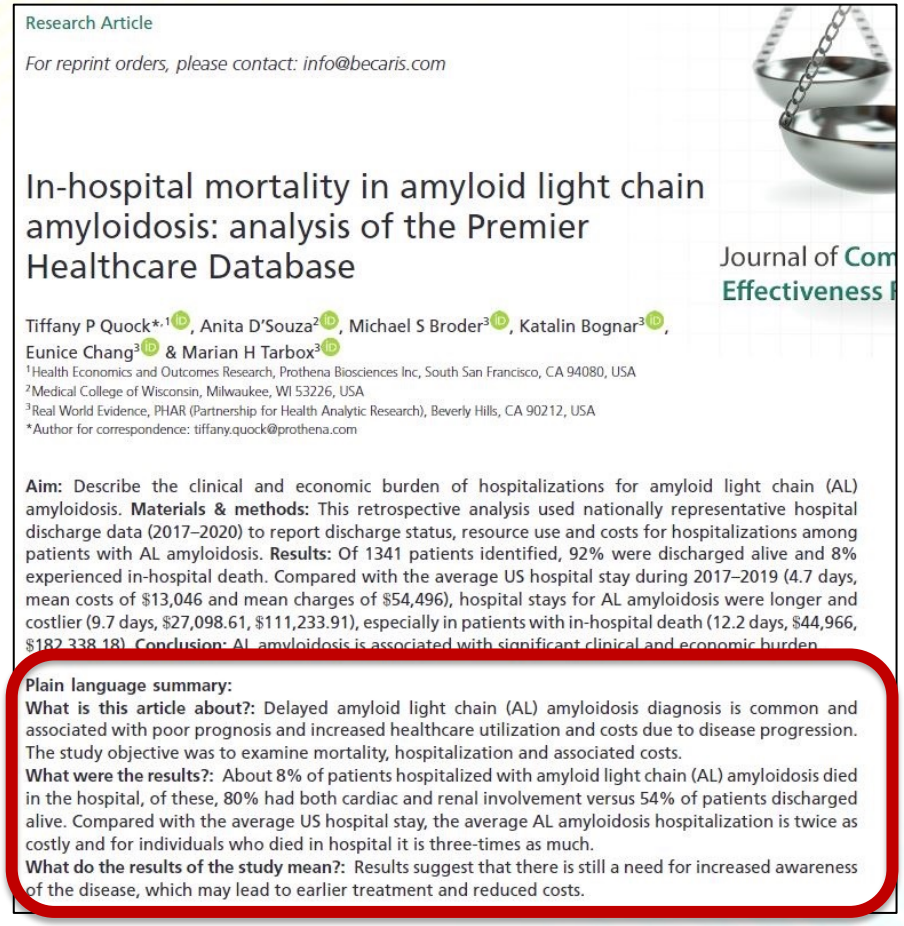
Plain Language Summary **within** a journal article

Plain Language Summary **alongside** a journal article (supplementary materials)

Plain Language Summary of Publication as a **standalone** journal article

PLS within a journal article

- Similar in length to a regular abstract
- Featured within an article alongside the main abstract
- Peer reviewed as part of the article content as usual
- Appear on PubMed



Research Article

For reprint orders, please contact: info@becaris.com

In-hospital mortality in amyloid light chain amyloidosis: analysis of the Premier Healthcare Database

Journal of Com
Effectiveness

Tiffany P Quock*,[1], Anita D'Souza[2], Michael S Broder[3], Katalin Bognar[3], Eunice Chang[3] & Marian H Tarbox[3]

[1]Health Economics and Outcomes Research, Prothena Biosciences Inc, South San Francisco, CA 94080, USA
[2]Medical College of Wisconsin, Milwaukee, WI 53226, USA
[3]Real World Evidence, PHAR (Partnership for Health Analytic Research), Beverly Hills, CA 90212, USA
*Author for correspondence: tiffany.quock@prothena.com

Aim: Describe the clinical and economic burden of hospitalizations for amyloid light chain (AL) amyloidosis. **Materials & methods:** This retrospective analysis used nationally representative hospital discharge data (2017–2020) to report discharge status, resource use and costs for hospitalizations among patients with AL amyloidosis. **Results:** Of 1341 patients identified, 92% were discharged alive and 8% experienced in-hospital death. Compared with the average US hospital stay during 2017–2019 (4.7 days, mean costs of $13,046 and mean charges of $54,496), hospital stays for AL amyloidosis were longer and costlier (9.7 days, $27,098.61, $111,233.91), especially in patients with in-hospital death (12.2 days, $44,966, $182,338.18). **Conclusion:** AL amyloidosis is associated with significant clinical and economic burden.

Plain language summary:

What is this article about?: Delayed amyloid light chain (AL) amyloidosis diagnosis is common and associated with poor prognosis and increased healthcare utilization and costs due to disease progression. The study objective was to examine mortality, hospitalization and associated costs.

What were the results?: About 8% of patients hospitalized with amyloid light chain (AL) amyloidosis died in the hospital, of these, 80% had both cardiac and renal involvement versus 54% of patients discharged alive. Compared with the average US hospital stay, the average AL amyloidosis hospitalization is twice as costly and for individuals who died in hospital it is three-times as much.

What do the results of the study mean?: Results suggest that there is still a need for increased awareness of the disease, which may lead to earlier treatment and reduced costs.

J Comp Eff Res. 2022 Dec 7. doi: 10.2217/cer-2022-0185. Online ahead of print.

In-hospital mortality in amyloid light chain amyloidosis: analysis of the Premier Healthcare Database

Tiffany P Quock [1], Anita D'Souza [2], Michael S Broder [3], Katalin Bognar [3], Eunice Chang [3], Marian H Tarbox [3]

Affiliations + expand

PMID: 36476016 DOI: 10.2217/cer-2022-0185
Free article

Abstract

Aim: Describe the clinical and economic burden of hospitalizations for amyloid light chain (AL) amyloidosis. **Materials & methods:** This retrospective analysis used nationally representative hospital discharge data (2017-2020) to report discharge status, resource use and costs for hospitalizations among patients with AL amyloidosis. **Results:** Of 1341 patients identified, 92% were discharged alive and 8% experienced in-hospital death. Compared with the average US hospital stay during 2017-2019 (4.7 days, mean costs of $13,046 and mean charges of $54,496), hospital stays for AL amyloidosis were longer and costlier (9.7 days, $27,098.61, $111,233.91), especially in patients with in-hospital death (12.2 days, $44,966, $182,338.18). **Conclusion:** AL amyloidosis is associated with significant clinical and economic burden.

Keywords: AL amyloidosis; hospitalization; mortality

Plain language summary

What is this article about? Delayed amyloid light chain (AL) amyloidosis diagnosis is common and associated with poor prognosis and increased healthcare utilization and costs due to disease progression. The study objective was to examine mortality, hospitalization and associated costs. What were the results? About 8% of patients hospitalized with amyloid light chain (AL) amyloidosis died in the hospital, of these, 80% had both cardiac and renal involvement versus 54% of patients discharged alive. Compared with the average US hospital stay, the average AL amyloidosis hospitalization is twice as costly and for individuals who died in hospital it is three-times as much. What do the results of the study mean? Results suggest that there is still a need for increased awareness of the disease, which may lead to earlier treatment and reduced costs.

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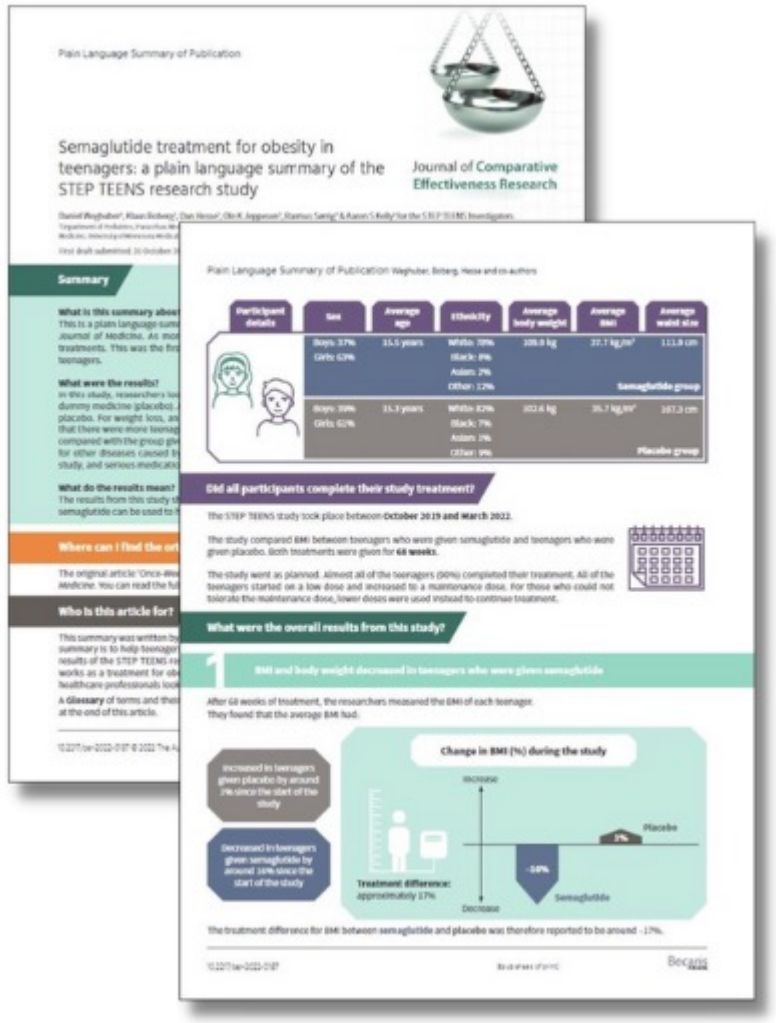
Supplementary PLS

- Published within an article's supplementary materials
- Peer reviewed as part of the article content as usual
- Infographic style
  - Mixture of formats: text, graphics, video, audio
- Can sometimes be added post-publication (separate peer review)

PLS as standalone articles

- Standalone PLS articles, known as Plain Language Summary of Publication articles (PLSPs)
- Infographic style
  - Mixture of formats: text, graphics, video, audio
- Peer reviewed
  - Readability and accuracy
- Indexed
- Citable (have their own DOI)



Other types of article feature

Graphical abstracts

Video abstracts

Podcasts

Infographics

Q & A

Thank you