The agency perspective-
Patient authorship and plain
language summaries

Phil Matthews, PhD, CMPP
Portfolio Director & Team Lead,
Envision Pharma Group

December 10, 2019
Objectives

• To gain an overview of where patients can be involved in the publications lifecycle
• To explore best practices and real-world examples of patient involvement in 2 key areas:
  - Patient authorship of publications
  - Plain language summaries (PLS)
    • Practical considerations
Many patients want to understand published research: but it isn’t always that easy.

How do we do it?

“Stakeholders agree that more effective patient involvement is needed to ensure that patient needs and priorities are identified and met.

Despite the increasing number and scope of patient involvement initiatives, there is no accepted master framework for systematic patient involvement”

First steps to involving patients in the publications lifecycle

What evidence do we need?  How can we get this evidence?  Who needs this evidence?  Was the evidence useful?

Publication planning  Publication generation  Publication sharing  Publication use & assessment

Publications Steering Committee guest  Patient contributor or author  Plain language summaries  Quantitative & qualitative PAOs, Pts, HCPs, Company

Publication needs

What evidence is still missing?
Overcoming compliance concerns

Discuss the Code (early) – communication is not promotion

FDA: “It has long been FDA policy not to consider a firm’s presentation of truthful and non-misleading scientific information about unapproved uses at medical or scientific conferences to be evidence of intended use when the presentation is made in non-promotional settings and not accompanied by promotional materials…”

FDA Memorandum – Public Health Interests and First Amendment Considerations…January 2017; p 21.
FDA perspective on involving patients in our publications

FDA speaker encouraged industry and publication professionals to continue to involve patients in drafting and publishing articles.

Chinyelum (Chi-Chi) Olele, PharmD, CDR, USPHS
Patient Engagement Advisory Committee (PEAC) Manager
FDA’s Center for Devices and Radiological Health (CDRH).
First steps to involving patients in the publications lifecycle

What evidence do we need?

How can we get this evidence?

Who needs this evidence?

Was the evidence useful?

Publication planning

Publication generation

Publication sharing

Publication use & assessment

Publication Steering Committee guest

Patient contributor or author

Plain language summaries

Quantitative & qualitative PAOs, Pts, HCPs, Company

Publication needs

What evidence is still missing?
Patients are already authoring peer-reviewed publications. They are meeting authorship criteria set by:

- General Medical Journals
- Specialist Journals
- Industry-focused Journals
- Patient-focused Journals

Industry co-authors included Pfizer, Novartis, UCB Pharma, GSK, Merck (passed ‘compliance concern’ barrier)
Evidence
World-first systematic review... with patient authors

Selected by industry peers (via blinded peer review) for an oral presentation at the 15th Annual Meeting of ISMPP
21 Evidence-based recommendation, before during and after manuscript preparation
First steps to involving patients in the publications lifecycle

What evidence do we need?

Publication planning

Publication Steering Committee guest

How can we get this evidence?

Publication generation

Patient contributor or author

Who needs this evidence?

Publication sharing

Plain language summaries

Was the evidence useful?

Publication use & assessment

Quantitative & qualitative PAOs, Pts, HCPs, Company

Publication needs

What evidence is still missing?
First steps to involving patients in the publications lifecycle

- **What evidence do we need?**
  - Publication planning

- **How can we get this evidence?**
  - Publication generation
  - Publication Steering Committee guest
  - Patient contributor or author

- **Who needs this evidence?**
  - Publication sharing
  - Plain language summaries
  - Quantitative & qualitative PAOs, Pts, HCPs, Company

- **Was the evidence useful?**
  - Publication use & assessment

**Publication needs**

**What evidence is still missing?**
Plain language summaries can empower patients in their discussions with HCPs

• Access to PLS can give patients a sense of empowerment

• In a survey of patients and caregivers, 81% felt that PLS would help them to discuss treatment options with HCPs


VALUE TO PATIENTS

The more informed a patient is, the better the conversation they can have with their doctors.

VALUE TO DOCTORS

[Use of a plain-language summary] could help generate dialogue, increase efficiency and streamline communication between HCPs and patients.
Three types of summaries broaden data dissemination: two relate to publications


- Mandated by the EU Clinical Trials Regulation No. 536/2014 – will be housed in the EU database (2020 onwards)¹,²
- The FDA recognises their importance but does not mandate them³

- Not currently mandated
- Increasingly being explored by journals and industry
- Cover a much broader range of evidence types than clinical trial results lay summaries
In a review of ~7630 journals, <1% published PLS alongside the main abstract.

Many journals currently publishing are newly established and have always included PLS in their formats.

Submitting a PLS as supplementary information can provide more layout options that may improve readability.

---

Journal variation in *what, who, when, where*

Assessment of 10 journals from different publishers identified as having PLS using eLIFE

**Terminology**
- 9 different terms for PLS were found

**Requirements**
- Are PLS developed by authors?
- When are PLS required?
- Are PLS required for all research articles?

**Location**
- The sharing mechanism/location of PLS varies:
  - 8/11 within articles or supplemental material
  - 6/11 in a separate area of the journal website
  - 3/11 via social media
  - 1/11 and/or archived on a separate website

**Accessibility**
- All PLS are freely accessible, with the exception of ACS Infectious Diseases – email follow-up determined that these PLS are only for the press, and are not publicly available.

**PubMed visibility**
- Are PLS noted on PubMed?

Fitzgibbon et al, ISMPP EU 2019.
The PLS of Publications Toolkit

Launch of the world’s first PLS of Publications Toolkit
Supported by Envision’s partner, Patient Focused Medicines Development, and co-created with patients, publishers, editors, industry

Winner, ‘Best Practice’ Award, at ISMPP Annual Meeting 2019 and selected for Guided Poster Tour

Plain Language Summaries (PLS) of Publications Toolkit

A best-practice resource for PLS of peer-reviewed publications and congress abstracts

https://www.envisionthepatient.com/plstoolkit/
Three types of summaries broaden data dissemination: two relate to publications

- **Clinical study report**
- **Peer-reviewed publication**
- **Congress abstract**

**Lay summaries**
- Mandated by the EU Clinical Trials Regulation No. 536/2014 – will be housed in the EU database (2020 onwards)\(^1\)\(^2\)
- The FDA recognises their importance but does not mandate them\(^3\)

**PLS of publications**
- Not currently mandated
- Increasingly being explored by journals and industry
- Cover a much broader range of evidence types than clinical trial results lay summaries

---

PLS of congress abstracts (APLS)

THE CHALLENGE

- Patients are demanding access to the latest scientific information
  - Becoming more involved at congresses (e.g., ASCO, ESMO)
- Pharma client wanted to address this unmet need
  - Demonstrate a compliant, tangible commitment to patient involvement

THE SOLUTION

- Accessible, understandable, usable APLS
- Scan QR code to access PLS
- View PLS on a device
  - Menu options to:
    - Download PLS
    - Print PLS, or
    - Access original scientific abstract (redirected to the congress website)
- An information sheet listing the titles and hyperlinks to the full APLS are made available to patient advocates if permitted by congress
- Press release and news article on company website

IMPACT: Every APLS was accessed

185 APLS have been co-developed with patients and authors

- Over 4600 page views
- Over 1600 additional actions
PLS of congress abstracts (APLS)

APLS development by trained team of writers, designers, and editors

APLS review by medical/clinical/legal teams and lead authors

APLS review by patient partners

APLS finalization and upload to website
APLS practical considerations

Source
- Abstract vs poster
- Which abstracts?

Appropriate language, discordant comments
- Plain language vs scientific
- Widely understandable vs accuracy
- Consistency: across abstracts, across meetings
- Glossary

Training
- Agency, different type of writing for MWs
- Pharma company
- Authors
- Patients

Timeline
- Draft text
- Graphics
- Data QC
- Reviews
- Layout

Final adjudication
Patients are authoring peer-reviewed publications.
- Evidence-based recommendations can help us to minimise risks and maximise benefits

Interest from publishers, pharma and patients is increasing

Plain language summaries are an ‘easy’ first step to involving patients in publications

Key considerations include
- Keeping to plain language
- Consistency across outputs
- Timelines

Practical tools and guidance are available to support you