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• Call for abstracts now open for the 16th Annual Meeting of ISMPP. Submission deadline is Friday, January 10, 2020.
Mark Your Calendars

Mark your diaries!

2020 European Meeting of ISMPP
January 21-22, 2020
etcVenues - Bishopsgate
London, England, UK

Save the Date
16th Annual Meeting of ISMPP
Grand Hyatt - April 20-22, 2020
www.ismpp.org
We updated the Transparency Educational Series!

This is the **ONE STOP** Source on Data and Financial Transparency for Publication Professionals. **NOW UPDATED!**

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- To ensure anonymity and that all presenters receive your question, please choose the drop down box option: "Host & Presenters"
  Otherwise, all audience members will be able to see your submitted question
- We will make every effort to respond to all questions
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Objectives for this ISMPP U

At the end of this session, participants should be able to:

• Understand the role and value of plain language summaries in communicating data from medical publications

• Appreciate the issues facing medical affairs and publications teams in implementing a robust PLS development and review process in consideration of both compliance and emerging best practices

• Consider how best to integrate and implement PLS within the publication plan, also recognizing the diversity and rapid evolution of positions and perceptions among journal publishers and congresses.
• Tom Gegeny, MS, ELS, MWC, ISMPP CMPP™, joined Envision Pharma Group in 2006 and is currently a Senior Scientific Director and Team Lead. He has over 20 years of experience in medical communications, including previous roles as Executive Director and Senior Editor at The Center for AIDS Information and Advocacy in Houston and as Publications Specialist with the Houston Academy of Medicine–Texas Medical Center Library. He is a fellow of the American Medical Writers Association (AMWA) and served as AMWA President in 2009–2010. He also served as president of the Board of Editors in the Life Sciences (BELS) for 2015–2017. Tom has led workshops and given presentations at numerous meetings and conferences including ISMPP, AMWA, CSE, TIPPA, DIA, and others.
Kelly Soldavin

- Kelly Soldavin is a Medical Editor for the publisher Taylor & Francis Group and currently manages *Current Medical Research & Opinion* and the *Journal of Drug Assessment*, both PubMed/MEDLINE-indexed, peer-reviewed journals that publish original research focused on new and existing drugs and therapies across a range of therapeutic areas. Kelly has a special interest in open science and ethical and transparent publishing, and she has spoken on these topics at the International Publication Planning Meeting (TIPPA), as well as the Special Libraries Association (SLA) Annual Conference. She is also a member of the ISMPP Social Media and Web-based Metrics working group, leading the Patient Engagement in Social Media project. Prior to joining T&F in 2017, Kelly spent 14 years in the veterinary medicine publishing industry as an Editorial Director for peer-reviewed journals and resources focused on small animal clinical medicine.
A microbiologist by training, Avishek started off as a publication writer with GSK Vaccines nearly 13 years ago. Avishek’s work has included publication development, medical communications planning and strategy across varied disease areas spanning vaccines, oncology and pharma. He is currently Associate Director, Publications Excellence in Global Medical Affairs at Novartis Pharma. Avishek is a ISMPP Certified Medical Publication Professional™ (CMPP) and a member of the ISMPP U Committee.
Why Plain Language Summaries (PLS)?

The importance of the patient voice. . . .
Patient centricity and involvement in medicines development

- Benefits of patient involvement at early stages have been established
  - Clinical trial design
  - Data safety review and input
  - Patient surveys and advisory boards
  - Market research

- Virtually absent in publications and other communications of research studies/data
Patients are actively seeking and sharing scientific content

- Patients are actively seeking and sharing scientific content, including medical publications – but these are rarely clear, accessible, or relevant to patients\(^1\-^3\)

- Accessible scientific content has the potential to improve outcomes for patients by:
  - Helping interpret key findings
  - Helping discuss treatment options with HCPs
  - Highlighting relevance to patients
  - Empowering patients to participate in treatment decisions

---

Patients want to understand published research, but it isn’t that easy.

### IN A SURVEY OF PEOPLE WITH FRIEDRICH’S ATAXIA AND THEIR CARERS:

<table>
<thead>
<tr>
<th></th>
<th>Patients</th>
<th>Carers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most patients and carers were interested in scientific publications related to their condition</td>
<td>67.9%</td>
<td>78.8%</td>
</tr>
<tr>
<td>Few could understand scientific publications</td>
<td>12.0%</td>
<td>6.3%</td>
</tr>
<tr>
<td>Few considered the Internet (eg, Facebook, discussion forums) to be a useful source for better understanding</td>
<td>32.1%</td>
<td>5.7%</td>
</tr>
</tbody>
</table>

**PUBLICATION: TO MAKE CONTENT AVAILABLE TO THE PUBLIC**

**The Lancet, which?**

November 29, 2017 at 3:21 pm

Hi everyone,

Just wondering what publications publish the latest medical research and trials?

Is the lancet a good publication and are any of you signed up to it in order to view the articles?

Just had a look and it won’t let me fully read the articles. Thanks

Rachael xx
PLS can enhance potential communication pathways between scientists and the public\(^1\)

- PLS can expand the potential audience of scientific content beyond scientific communities
- For example, the traditional abstract can reach other scientists but not the public
- Accurate, relevant PLS can help enhance communication pathways and reduce risk of information being misinterpreted or misrepresented

Patients and the public can amplify content sharing

The public tweets more than HCPs do about JAMA Patient Pages AND about related scientific articles.

Public outperforms HCPs

The public tweets more than HCPs do about JAMA Patient Pages AND about related scientific articles.

Patient-to-patient exchange over Twitter and other social media is the fastest and most direct route to disseminate latest evidence and best practice.

Kawaldip Sehmi
CEO, International Alliance of Patients’ Organizations

Three types of plain language summaries can broaden data dissemination


- The European Union (EU) Clinical Trials Regulation of 2014 requires sponsors to provide summary results of clinical trials in a format understandable to laypeople.¹, ²
- The FDA recognizes their importance but does not mandate them.³
- Not currently mandated
- Increasingly being explored by journals and industry
- For example, ADIS journals will accept a PLS submitted by the authors
Why develop and disseminate PLS?

Build trust
Facilitate shared decision-making
Reduce risk of misinformation
Raise awareness of study findings

SHARE REAL-WORLD RESEARCH ACROSS THE WORLD

PLS of publications
- Clinical trial results
- Real-world evidence
- Systematic reviews
- Narrative reviews
- Epidemiology studies
- HEOR studies
- Case studies etc...
& non-EU studies

Lay summary of clinical trial results
Overcoming compliance concerns – Communication of results 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.
How to consider PLS for publications?

Finding your place on the learning-growth curve. . . .
Access to PLS is rapidly evolving

- Some congresses are encouraging patient attendees and are supporting the experience of patient delegates
- The EU Clinical Trials Regulation requires trial sponsors to provide PLS of clinical trial results, expected to go into effect from 2020
- Some publishers/journals are beginning to encourage and allow PLS of peer-reviewed publications; trends indicate greater interest and sharing on social media

Summary results of clinical trials will be available in EU database

ASCO specifically encourages patients, survivors, caregivers, and advocates to attend

Late Breaking Abstracts

Patient advocates may register to attend the 2019 Annual Meeting at a reduced rate. There is no separate approval for the patient advocate role. Each individual must be approved by ASCO staff in order to register at this reduced rate. Those that are approved will receive a registration code and instructions. Registration rules, deadlines, criteria, and instructions are available on the Patient Advocate section of the ASCO Annual Meeting website, under "Special Rates Categories."

Patient advocate registration includes:
- Access to all Educational Sessions and Scientific Sessions
- Access to Poster Sessions
- Access to 2019 ASCO Annual Meeting Videos and Slides
- Access to the Patient Advocate Lounge: Room 1492
- Ability to purchase a Ticketed Session Pass

Adis and other journal publishers offer a PLS that can be published with the manuscript

Plain language summaries (PLS) are intended for readers requiring a succinct, simplified overview of a manuscript (such as informed patients and caregivers), and scientists outside of the field who may not have an in-depth knowledge of the topic. The aim of PLS is to assist in understanding the scientific content and overall implications of the manuscript. While some prior understanding of the topic may be assumed, shorter sentences without ambiguous or unnecessarily complex terms are recommended, as well as use of the active voice. PLS should be up to 290 words in length, and be placed after the Abstract of the article under the heading: Plain Language Summary. PLSs should be submitted to the relevant journal alongside the respective article in order for PLS to be published after the main abstract – but if submitted retrospectively, will be published as an accompanying to the article via a Retrospect positioned underneath the abstract. All PLSs are peer-reviewed, either at the same time as the submitted article or later if submitted separately.
Case study: PLS of congress abstracts (APLS) Accessed via QR codes at ASCO 2018

THE CHALLENGE
- Patients are demanding access to the latest scientific information and becoming more involved in major scientific congresses (eg, ASCO, ESMO)
- Pharma client wanted to address this unmet need and demonstrate a compliant, tangible commitment to patient involvement

THE SOLUTION
- Accessible, understandable, usable PLS of 12 scientific abstracts
- Scan the QR code to access the PLS
- View the PLS on a device
- Menu options to:
  - Download the PLS
  - Print the PLS, or
  - Access the original scientific abstract (redirected to the ASCO website)

THE IMPACT
- Every APLS was accessed
- APLS access peaks aligned with the corresponding research presentation day
- The most viewed APLS corresponded with the cancer types with the highest profiles at ASCO

Every APLS was accessed

AUTHOR: ‘There has been strong interest in the PLS from non-MD attendees, specifically RNs, and Patient Advocacy Group attendees who believe this is an important step’

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

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

Rheumatoid arthritis (RA), psoriatic arthritis (PsA), and axial spondyloarthritis (axSpA) are three common inflammatory rheumatic diseases that can lead to deformities and joint destruction. Few studies have compared disease burden across patients with these diseases. The objective of this study was to compare disease burden in patients with RA, PsA, or axSpA in routine US clinical practice.

Methods

This study included adults with RA, PsA, or axSpA enrolled in the Corrona RA and PsA/SpA registries between March 2013 and March 2018. Patient and clinical characteristics at enrollment were compared between patients with RA vs. PsA and RA vs. axSpA using t tests or Wilcoxon rank-sum tests for continuous variables and χ² or Fisher’s exact tests for categorical variables.

Results

A total of 11,350 patients with RA, 2003 with PsA, and 495 with axSpA were included. Patients with RA had shorter mean symptom and disease duration (9.4 and 7.6 years, respectively) than those with PsA (11.2 and 8.4 years) or axSpA (16.7 and 9.8 years). Patients with PsA had lower mean physician global assessment (18.6 vs. 27.3), higher patient global assessment (43.2 vs. 36.9), comparable pain (58.9 vs. 59.5), and lower fatigue (41.1 vs. 43.4) scores than those with RA. Patients with axSpA had comparable mean physician global assessment (25.5 vs. 27.3) and higher patient global assessment (50.2 vs. 36.9), pain (46.1 vs. 39.5), and fatigue (48.3 vs. 43.4) scores than those with RA.

Conclusions

Disease burden in patients with PsA or axSpA was comparable to or greater than in patients with RA on the basis of common patient-reported outcome measures but appeared lower when assessed using RA disease activity measures, suggesting that disease-specific approaches to care are needed to optimize disease management.
Different format options for PLS

**Text-only PLS:**
Impactful layout to optimize the reader experience

- Different weights and styles of text help show reader which information is important
- Call-outs using contrasting colors to draw attention to key messages
- Clear sections using color block sand divider lines
- Use of bullets and spacing

**Text and visuals PLS:**
Visuals can enhance communication of key data points

- Including visuals to help communicate key points; this is especially beneficial when it comes to comparing data

**Full infographic PLS:**
Fully engages the reader; digital options
Increase in resources available

Mobilisation of the #PatientEngagement community interested to share their work in a non-competitive & anonymised space is crucial. Discover inspiring initiatives engaging #patients in ‘The Book of Good Practices’ launched by Patient Focused Medicines Development (PFMD).

https://www.envisionthepatient.com/plstoolkit/
Addressing the need for PLS in publications

WHY?

- Information that is easy to access and understand can prevent misinformation
- People have a right to information that is about them: transparency builds trust
- PLS can increase the reach of data to different audiences and are often shared on Social Media
- By empowering patients, PLS can facilitate shared decision making

HOW?
Addressing the need for PLS in publications

**WHY?**

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**HOW?**

- Work with legal teams from the outset to ensure a compliant plan that avoids ‘cherry picking’ of data for PLS
- Consider the optimal format and communication channels for PLS including open access journals and congresses
- Combine scientific understanding, plain language expertise, graphical communications skills, and patient partner insights
Audience Poll (1)

Have any clients or associates inquired about developing a PLS for a journal publication or congress presentation?

A. Yes
B. No
C. I’m not sure
Have you worked on developing a PLS for a clinical trial or publication/presentation of data?

A. Yes, directly (writing, editing, or reviewing)
B. Yes, indirectly (as part of team planning/implementation)
C. No, not at all
Plain
Language
Summaries

The Five Ws
Answering key questions about PLS

The Challenges
Assessing struggles to develop & disseminate

Tips & Best Practices
Proposing solutions for the challenges
Disclosure Statement

• I am an employee of Taylor & Francis Group, an Informa business. I have no other relevant financial relationships or interests to disclose.

• The views expressed during this presentation are my own and do not necessarily reflect those of Taylor & Francis Group.
The Five Ws of Plain Language Summaries

Answering key questions about PLS
WHAT are PLS?

“Plain language descriptions of the design and aggregate results of individual clinical studies.”¹

PLS can also describe or be used in²⁻⁵:

• Original research beyond clinical trials
• Narrative and systematic reviews
• Case reports
• Congress abstracts
• Research proposals
• Grant or faculty applications

Can e-cigs help me to quit smoking?

Quitting smoking is one of the best things we can do for our health. By quitting, we lower our chances for heart problems, lung problems, cancer, and many other issues. But it isn’t easy. Your doctor can provide advice and tools to help you as you try to quit. Recently, some companies have claimed that using electronic cigarettes, or e-cigs, can help you quit smoking. Here’s what we know about e-cigs so far.

What is an electronic cigarette (e-cig)?

There isn’t a perfect answer because e-cigs come in a lot of different forms. They can look like cigarettes, pipes, metal tubes, or even like USB sticks. In general, they are handheld devices that have a battery and a space for liquid. The liquid is usually nicotine with some flavoring and other additives. The battery heats up the liquid into a vapor, and the user inhales the vapor. This is why e-cigs are sometimes also called “vapes” or “vaporizers.”

Are they safe?

E-cigs haven’t been around long enough for us to say whether they are safe or not, in the long term. Many experts believe that they are less harmful than smoking normal cigarettes but more harmful than not smoking at all. They are not safe for people who are pregnant. In most states, they are illegal to have for people under the legal smoking age.

Can e-cigs help me quit smoking?

Scientists and doctors have done several studies to see if people who use e-cigs are able to quit. These studies show that when you check on people after 6 months, they are more likely to quit if they are using nicotine e-cigs than if they tried quitting “cold turkey”. However, most studies have not shown e-cigs to be better than other quitting tools, like nicotine gum or patches. You should try the other tools before e-cigs because they have more research supporting them and are FDA approved.

Reprinted from:
https://conservancy.umn.edu/handle/11299/114743
WHO reads PLS?

Patients and clinical study participants, plus:

- General public
- Patient advocates
- Researchers
- Students and faculty
- General clinicians
- Therapy area specialists
- Healthcare professionals
- Publishing professionals
WHY create PLS?

“The goal of a lay summary is to aid study participants [patients] and the general public in understanding clinical study results.”¹

“Enhance communication pathways between scientists and the public.”⁷

“Make scientific advances understandable and accessible to all.”⁸

“Provide something that is simple and actionable.”⁹
WHERE can you find PLS?

- Alongside published, peer-reviewed articles
- Congress poster presentations/abstracts
- Government agency online repositories
- Pharmaceutical company/healthcare industry websites
- Medical school archives, such as UMN’s https://conservancy.umn.edu/handle/11299/114743
- Social media, as additional route or only route
<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1975</td>
<td>Flesch-Kincaid readability test</td>
<td>created; produces grade level scores that predict level of education required to read selected text</td>
</tr>
<tr>
<td>1998</td>
<td>Plain Language Action Network</td>
<td>begins providing plain language training to US government agencies</td>
</tr>
<tr>
<td>2010</td>
<td>Plain Writing Act (US)</td>
<td>requires use of plain language for information disseminated to general public</td>
</tr>
<tr>
<td>2014</td>
<td>EU Clinical Trial Regulation 536/2014</td>
<td>requires a summary—in a “format understandable to laypersons”—be posted to EU portal within 1 year of clinical trial end; goes live in 2020</td>
</tr>
<tr>
<td>2015</td>
<td>Medical Research Involving Human Subjects Act (Netherlands)</td>
<td>states that a scientific summary, including lay summary, be submitted within 1 year of study completion</td>
</tr>
<tr>
<td>Current</td>
<td>National Institutes of Health (US)</td>
<td>requests that dissemination of information on NIH-funded clinical trials be “broad, transparent, timely, and responsible”</td>
</tr>
</tbody>
</table>
The Challenges of Plain Language Summaries

Assessing struggles to develop & disseminate
Challenges in Development

1. **NOMENCLATURE.** PLS are identified by a wide variety of names that are used interchangeably or depending on context, such as intended audience or specific format\(^1,14,15\)

2. **GUIDELINES.** There is no standard approach to writing and formatting PLS, including guidance on language and quality, nor agreement on who should be authors.

3. **COMPLIANCE.** Are PLS considered promotional materials? Is a company’s legal team going to prevent development and publication of PLS?

4. **PATIENT ROLE.** There is also no consensus on the patient’s role in developing PLS. Should they be authors? Review the PLS prior to publication? Act as peer reviewers after submission to a journal?
Challenges in Dissemination

1. **SELECTION.** Should all studies, articles, and presentations have PLS? Or only selected ones? How do you select which ones need a PLS?

2. **JOURNALS.** Not only is it difficult to determine which journals publish PLS, there are also a wide variety of approaches in PLS policies.²

3. **ACCESSABILITY.** Most PLS are open access (freely available); however, 11% of journals do not make PLS available or place them behind a paywall.⁷

4. **VISIBILITY.** There are no easy ways to find PLS, whether searching a journal website, PubMed, social media, or through a search engine, such as Google.¹⁴
Tips & Best Practices for Plain Language Summaries

Proposing solutions for the challenges
Establishing Consensus

**Nomenclature.** Use the term “plain language summary” consistently across medical publishing and the industry.

**Guidelines.** Create a set of standard guidelines and best practices for development and dissemination of PLS.

**Patient Role.** Determine the ways in which patients can contribute to PLS as authors and reviewers.

**Journals.** Develop registry of journals that provide PLS, including their PLS policies.

**Accessibility.** Mandate that all PLS be published open access.

**Visibility.** Encourage publishers of PLS to host them together or develop search function on their website that allow PLS to be easily identified.
Tips on Getting Started

✓ Develop pilot program that identifies 2 to 3 opportunities for PLS or, during pub planning, identify which papers will have PLS

✓ Educate colleagues in order to create support and buy-in for PLS

✓ Determine type of PLS and select studies:
  • Clinical trial results, manuscript, or poster
  • Phase II/III studies are better than Phase 1 or HEOR

✓ Realize that the needs of patients with rare diseases are uniquely met by PLS

✓ Remember that the PLS process mirrors publication development—involve the same people in both processes

✓ Identify audience needs by involving patient reviewer and patient groups

✓ Consider choosing a medical writer as an author—they typically have the best skill set for writing PLS
Addressing Compliance Concerns

✓ Talk with your legal team and explain regulatory drivers (EU Clinical Trial Regulation and US Plain Writing Act)

✓ Set up appropriate firewalls—do not mix PLS with other promotional materials

✓ Include all study data in PLS to avoid any appearance of “cherry picking”

✓ Add legitimacy to PLS by:
  • Using EMA process/template
  • Publishing PLS in peer-reviewed journal

✓ Ask yourself: “Am I reporting data or advocating for a product?”

EMA = European Medical Agency
Advice on Writing & Format

✓ **Contact journal editor** for info on policies, format, and submission of PLS

✓ Have the PLS **written for the 8th grade level**; use Readable.com to help gauge academic level of writing

✓ **Refer to Universal Patient Language** ([www.upl.org](http://www.upl.org))

✓ The most effective PLS **include infographic elements**; best practice is fully infographic with digital options

✓ **Take a look** at these other resources:
  - PLS Tool: [https://ktdrr.org/resources/plst/](https://ktdrr.org/resources/plst/)
  - Summaries of Clinical Trial Results for Laypersons[^16]
Delivering the PLS

- Ensure the PLS is published Open Access or made freely available
- Determine how the PLS will be accessed. Best practice is stand alone publication with its own DOI, linked to full manuscript
- Discuss HTML tagging and search engine optimization (SEO) with editor/production team
- Send PLS to clinical trial participants and patients
- Distribute PLS through social media channels, but tailor its format for that audience
- Create patient portal where PLS of all clinical trials are hosted
- Consider additional outlets for PLS: medical info patient response letters, patient society communications, patient web portals
- Partner with patient advocacy organizations
- ASCO 2018: PLS were accessed by QR code on poster—all PLS were accessed; most on the day of presentation
• Plain language summaries make scientific information understandable to all.
• Patients are actively seeking and sharing current medical research. They should play a key role in the PLS conversation.
• Consensus on nomenclature, patient role, and best practices in PLS development and dissemination is needed.
• Involve the entire publication team, including journal editors, in PLS planning.
• Many options exist for PLS distribution—determine how best to reach your intended audience.
References

THANK YOU!
Questions

• To ask a question, please type your query into the Q&A box
• To ensure anonymity, before sending please choose the drop-down box option, "Hosts and Presenters." Otherwise, ALL audience members will be able to see your submitted question
Thank You for Attending!

• We hope you enjoyed today's presentation.
• Please check your email for a link to a survey that should take only a few minutes to complete.
• We depend on your feedback and take your comments into account as we develop future educational offerings. Thank you in advance for your participation!