Session Report

Plain Language Double Feature (Pulling It All Together and Lost in Translation)

Speakers
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On May 3rd, at the 2024 AMWA Carolinas Conference, Chantelle Rein-Smith, PhD, CMPP and Lee Holland, PharmD, MPH presented an integrated session highlighting the significance of Plain Language Summaries of Publications (PLSPs) and Regulatory Plain Language Summaries (PLSs) in enhancing health literacy and accessibility of health information. Dr. Rein-Smith is Principal Writer and Consultant at Whitsell Innovations, Inc. and Dr. Holland is Associate Director of Plain Language Summaries at Certara.

Dr. Rein-Smith 's talk on Plain Language Summaries of Publications (PLSPs) covered the following topics.

Health Literacy:

- Personal health literacy is the ability to find, understand, and use health information for decision-making.
- Organizational health literacy enables equitable access to health information.
- Healthy People 2030 is a government initiative to improve the health of Americans over the next decade.
- Barriers to improved health literacy are complicated medical terminology, serious diagnoses, and complex self-care requirements.

Health Literacy in the U.S.:

- High health literacy among individuals aged 25-29 with high income, and advanced degrees.
- Low health literacy among individuals aged 65+ with low income, and less education.

Making Scientific Information Accessible:

- Challenges are complex language, lack of knowledge about sources like PubMed, and paywalls.
- One part of the solution is to “translate the science” by simplifying language and using plain language summaries.

Plain Language Summaries (PLSs) and Plain Language Summary of Publications (PLSPs):

- PLSs are short summaries accompanying scientific publications that are accessible and are usually published alongside the scientific article, free of paywalls.
- PLSPs are standalone citable manuscripts summarizing previously published scientific articles.
- Benefits are broader reach to patients, caregivers, policymakers, and healthcare providers, increased public trust, and informing policy decisions.
- Follow the journal guidelines while writing, identify the target audience, use an online readability tool to target a 6th-8th grade reading level, and use active voice and short sentences.

Dr. Holland's talk on Regulatory Plain Language Summaries (PLSs) included the following topics:

Regulatory Lay/Plain Language Summaries:

- Different from research summaries, focusing on clinical trial results at a 6th-8th grade reading level.
- Required by various international regulations, including the EU, UK, and Republic of Turkiye.

EU Regulations and Good Lay Summary Practice (GLSP):

- EU mandates PLS posting to the Clinical Trials Information System (CTIS) within a year post-trial and within 6 months for trials with pediatric participants.
- GLSP provides guidance on creating, writing, translating, and disseminating PLSs.
- Annex V contains the ten required elements that a regulatory PLS must contain.

Creating Effective Regulatory PLSs:

- Authors must navigate complex source documents such as Clinical Study Reports, Protocols, Informed Consent Forms, Statistical Analysis Plans to create accurate and patient-friendly summaries.
- Alignment with regulatory postings on ClinicalTrials.gov in the US and CTIS in the EU is essential.

Health Literacy and Clinical Trials:

- High health literacy is associated with increased willingness to participate in clinical trials.

Conclusion:

- Regulatory PLS writers require a comprehensive skill set, including regulatory knowledge, clinical trial document navigation, understanding of health literacy best practices, and ability to develop effective PLSs.
- Effective PLSs can be used to inform policy decisions and as educational tools to decrease disparities in enrollment in clinical trials, ultimately supporting better health outcomes.

Thank you, Dr. Rein-Smith and Dr. Holland, for an insightful and interactive session, which included a Q&A discussing the approach of finding and creating PLSs, as well as the evolving role of AI in this field with considerations for data privacy and confidentiality.

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