

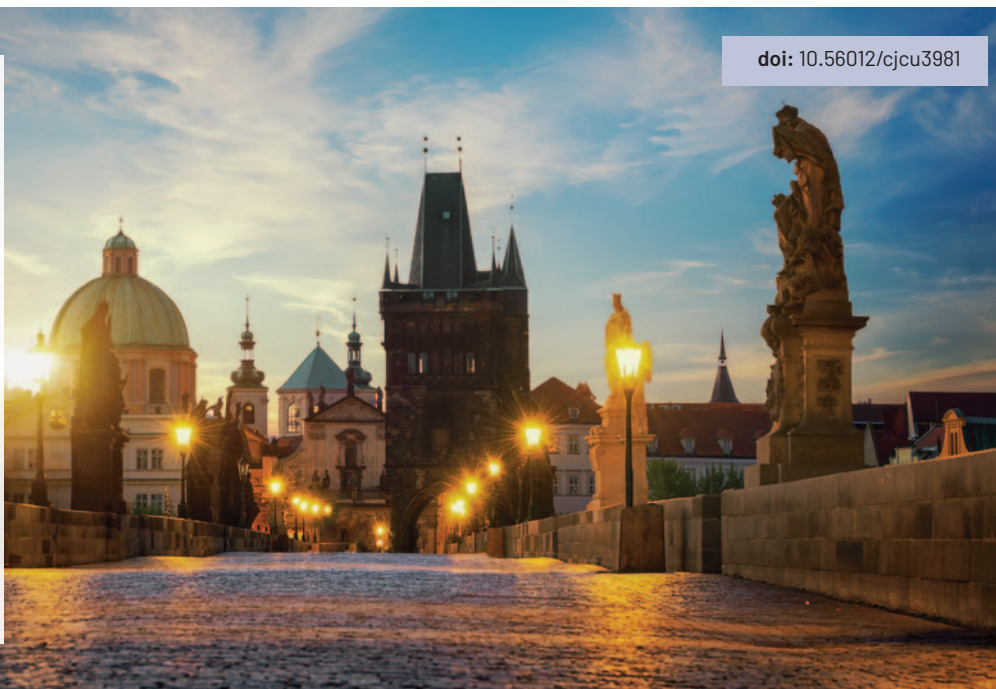
Abstracts from the EMWA Spring Conference Poster Session

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At the 2023 EMWA Spring Conference in Prague, Czech Republic, EMWA hosted a poster session.

There were posters related to many aspects of medical writing or of relevance to medical writers. The poster session presented an excellent way for EMWA members to see a snapshot of the latest thinking and research in their field. Please see the abstracts below.



P1 What is career satisfaction to a regulatory medical writer? Medical writing field awareness and the way forward: An online survey

Sara Fernandes, Mauro Meloni, Robert Panek, Gregory Morehouse, Rona Grunspan
Medical Writing, Quality & Editing and Clinical Trial Transparency, ICON plc

Introduction

People entering the medical writing field come from diverse backgrounds and many may not have considered the diversity of growth opportunities that existed when they began their careers. As the value of good medical writing has increased, we sought to understand the aspects of the job that medical writers (MWs) found rewarding and helped them shape the future of their writing profession.

Methods

An online survey was targeted to regulatory writers at different career levels to characterise job satisfaction. The survey aimed to understand if MWs had what they needed to be contented in their job, and which aspects were

important for professional development. Main areas of focus were: the relevance of technical versus non-technical skills, related training opportunities in career development, management efforts to keep MWs engaged, and satisfaction in being an important part of a team.

Results

Whether a MW sought to grow into a subject matter expert, or wished to evolve into a management role, the results show the key drivers for progression and momentum. MWs surveyed expressed that opportunities to collaborate, being part of a solid team, and company culture were key motivators for career progression. A stimulating work/team environment, management support, development/

training opportunities, and salary and other benefits were of highest importance for job satisfaction. Training areas considered most valuable to a MWs career included interpreting and reporting data, clinical document writing, and technical writing.

Conclusions

The surveyed MWs showed a balance of needs and interests that include communication, collaboration, time management, critical thinking, conflict resolution, and leadership skills. Further work could examine the relationship between career phase and needs for satisfying career development, because job satisfaction may be perceived differently depending on the level of experience of the MW.

P2 Blinded assessment of key publication content produced by ChatGPT from a sample poster

John Plant¹, Jacqueline Janowich Wasserott², Athanasia Benekou³, Phillip Leventhal⁴, Jonathan Pitt¹

1 Evidera, Paris, France

2 Evidera, Brussels, Belgium

3 Evidera, Athens, Greece

4 Evidera, Lyon, France

Introduction

Written content produced by artificial intelligence (AI) could revolutionise the medical writing industry. ChatGPT, a chatbot for a new large language model AI, was publicly released for free beta testing in November 2022. This study examined ChatGPT's ability to generate key publication content from a poster.

Methods

ChatGPT generated the following content from a sample poster: target journal recommendation, manuscript title, abstract, keywords, and lay summary. Three blinded reviewers, all working in a publications team of

a contract research organisation, were asked to rate the results with the instructions that they were assessing a job candidate. A 5-point scale from 1 (worst) to 5 (best) was used to rate the content generated as well as compliance with instructions, language accuracy, and language style. Reviewers also provided comments as free text and made an overall assessment (positive, neutral, negative).

Results

Median scores were 2.5 for target journal selection, 3.5 for title choice, 2 for the abstract, 4 for keyword selection, 3.75 for the lay summary, 4.5 for following instructions, 4 for

language accuracy, and 4 for language style. Reviewer comments highlighted flaws like awkward wording, questionable journal selection, and poor content and language in the lay summary and abstract, especially poor reporting of results. Overall ratings were neutral for one reviewer and negative for two.

Conclusions

ChatGPT performed poorly at producing most of the key publication content requested, although it performed well at following instructions and completing limited linguistic tasks that did not require an understanding of the content.

P3 Does publishing on MedRxiv affect a manuscript's outreach?

Pedro Caldas Custodio de Campos Silva^{*†}, Christian Matheou[†], Alex Marshall, Shilpa Khobragade

* Corresponding author,

† Joint first authors

Lumanity Communications, Surrey, UK

Introduction

The free online archive for medical and health research preprint manuscripts, medRxiv, allows authors to deposit unpublished research articles. Here, we explore whether depositing preprints on medRxiv impacts citations and alternative metric measures post-publication.

Methods

PubMed API was used to download article details from BMJ Open, which exclusively publishes medical research, from June 2018–September 2022. Downloaded articles were matched by their DOI to preprints from the medRxiv archive that were self-reported as published (n=308). A selection of BMJ Open

articles (n=1000) that did not match the medRxiv records were randomly selected to act as a control. Citations and Twitter shares were collected for both groups and compared by years since publication. Due to the non-normal distribution of the datasets, a Mann-Whitney U analysis was performed to test for significance between groups each year (p<0.05 taken as significant).

Results

One, two, and three years post-publication, articles with preprints had significantly higher citation counts than articles without preprints (p<0.00001, p<0.00001 and p<0.0001, respectively). In addition, Twitter shares were

significantly higher for articles with preprints one, two, and three years post-publication versus articles without preprints. A similar trend was seen when COVID-19 articles were removed, with the exception of year 3 for Twitter shares.

Conclusions

Articles posted as preprints on medRxiv are associated with significantly more citations and Twitter shares one, two, and three years after publication in BMJ Open than articles without medRxiv preprints. This preliminary analysis suggests there may be a benefit, in increased citation counts and Twitter shares, to pre-publishing clinical research.

P4 Challenges of mass balance studies (including absorption, distribution, metabolism, and elimination [ADME] and absolute bioavailability studies) in medical writing

Irene Lako, Jeroen Kolnaar, Noëlle Zweers, Thea van den Bosch, Yavé Lozano-Navarro, Judith Hettinga, Alida Weeke-Klump

Department of Medical Writing, Quality & Editing and Clinical

Trial Transparency, ICON plc, Groningen, The Netherlands

Introduction

Mass balance studies with (radio) labelled drugs are part of the clinical development programme of almost any new small molecule drug, to obtain information on the absorption, distribution, metabolism, and elimination (ADME) and absolute bioavailability of drugs in the human body. The aim of this review is to provide an overview of new developments and identify challenges of mass balance studies in medical writing (MW).

Methods

Standard and new designs for mass balance studies are collected from literature and combined experience available at ICON plc.

Rules and regulations that apply to studies with radiolabelled drugs, limitations in study design, and their impact on the MW processes are described. Challenges for MW are identified based on an informal survey on experiences and challenges with mass balance studies among ICON's early phase MWs.

Results

A variety of study designs is currently used for mass balance studies. Variation is found in labels used, amount of radioactivity administered, excreta collected, duration of studies, dosing sequences, and populations used. A clear description of the procedures followed, the objectives of the study design, and

the results obtained is challenging for clinical documents including subject-facing documents.

Conclusions

Mass balance studies are an exciting type of studies with specific challenges for MW. New developments give rise to more opportunities to collect data in wider populations and with lower exposure to radioactive materials. Due to the increasing complexity of these studies, explaining the followed approach in a protocol, clinical study report, or subject-facing document requires more guidance for MW.

P5 Evaluating the publication of randomised controlled trials in inflammatory bowel disease by trial outcome and journal attributes

Slavka Baronikova¹, Kim Wager², Frances Thompson³, Iain Haslam⁴, Helen Woodroof⁴, John Gonzalez¹

¹ Galapagos NV, Mechelen, Belgium

² Oxford PharmaGenesis, Oxford, UK

³ PharmaGenesis London, UK

⁴ Aspire Scientific, Macclesfield, UK

Introduction

Journal attributes by trial outcome were explored for published randomized controlled trials (RCTs) in inflammatory bowel disease (IBD) using machine learning (ML).

Methods

PubMed literature searches were conducted between 1/06/2015 and 24/08/2022 for RCTs that included the terms "Crohn disease", "ulcerative colitis" or "inflammatory bowel disease". Publications were screened using artificial intelligence to include primary analyses of phase 2–4 pharmaceutical interventional RCTs only. RCT interventions and outcomes were assessed using the ML

model Generative Pre-trained Transformer 3. Journal affiliation, impact factor (IF) and RCT phase were assessed manually.

Results

The search returned 1038 publications, of which 138 were RCTs for pharmaceutical interventions (in 35 unique journals). The majority of RCTs (83/138 [60.1%]) were published by society-affiliated journals (n=19). Overall, 30 RCTs reported negative results, of which most (22/30 [73.3%]) were published by society-affiliated journals, and nearly half (13/30 [43.3%]) by two journals (IF, 10.0 [n=7]; IF, 22.7 [n=6]). Most RCTs published in non-society-affiliated journals reported

positive results (45/55 [81.8%]; 13 journals); all except for one non-society-affiliated journal published a single negative RCT. Of the 30 negative RCT articles, 63.3% were open access; 14, 10 and 6 publications reported phase 2, 3 and 4 RCTs, respectively.

Conclusions

The results of this exploratory analysis suggest that society-affiliated IBD journals publish more RCTs, including negative RCTs, than non-society-affiliated/general medicine journals. This may have implications for choice of target journal for such data. As only IBD RCTs were assessed, the significance of these findings for other therapy areas is unknown.

P6 The prevalence and incidence of sickle cell disorders in Germany

Angela Anastasia Asante AAA, University of Bremen, MnB Health Lab GmbH
Potsdam, Germany

Introduction

Due to globalisation and migration, sickle cell disease (SCD) and Sickle Cell Trait (SCT) is spreading to demographic regions where it does not originate, for example; Europe, the Americas and others. This study sought to estimate the trend of sickle cell disorders in Germany, from year 2006 to 2016.

Methods

Analyses were made using claims data of statutory health insurance providers from the German Pharmacoepidemiological Research Database (GePaRD), which covers about 20% of Germany's general population. Statistical Analysis System (SAS) was the primary tool for data analysis.

Results

The year 2016 had the highest incidence rate and prevalence proportion of 3.60 and 27.17 per 100,000 persons respectively. The age cohort 30–39 almost consistently had the highest prevalence proportions annually, especially year 2016, which was 3.67 per 10,000 persons. This was significantly higher among males belonging to this age cohort, compared to their female counterparts.

Conclusions

About 20% to 40% of the population of some sickle cell endemic regions in West and Central Africa have Sickle Cell Trait. Until now, there are some modest increases in the prevalence of sickle cell in Germany, compared to the very

high prevalence in West and Central Africa. Recently, universal newborn screening for SCD has been introduced, which will help to identify SCD/SCT early on and increase awareness of the disease in the light of ongoing migration movements from endemic regions. This is one of the first studies on sickle cell in Germany using claims data. Results reveal dynamic epidemiologic developments, especially after year 2015.

P7 Knowledge, awareness and practice in using digital enhancements in scientific publications: Survey from academicians, healthcare and industry professionals, and medical writers

Namrata Singh, Turacoz B.V, The Netherlands
Shruti Shah, Turacoz Healthcare Solutions Pvt Ltd, India

Introduction

Digital enhancements (DEs) attract more views, have strong social media presence and increase geographic reach of scientific publication. The current survey-based study assessed knowledge, awareness, and practice in incorporating DEs in scientific publications (DESPs).

Methods

A 20-question survey was circulated via e-mail and social media (LinkedIn and Whatsapp) to academicians, healthcare and industry professionals, and medical writers. Responses received from August 6, 2022, to September 16, 2022, were assessed using univariate analyses.

Results

In total, 256 responses were received (68 academicians, 73 clinicians, 41 industry professionals, 66 medical writers, 3 pharmacists, 5 did not specify). About 49% had >5 years of work experience. Most respondents (74%) agreed that DEs can help in better visualisation of presentation, improve publication reach and enhance reader engagement. While 59% of respondents were aware of different DESPs, only 40% of respondents used these; most used DE was infographics (51%). While 84% of respondents were interested in DESPs, 66.4% respondents considered inadequate budgets as a major constraint for developing DEs, followed by lack of knowledge in selecting the right DE (51.5%) and inadequate access to relevant tools and

platforms (36%). Most respondents suggested having discrete publication guidelines (74%) and clear company policies (85%) for using DESPs. The majority of respondents suggested having more awareness programmes (91%) and relevant trainings (90%). About 79% of respondents suggested involvement of publications-specific organisations (ISMPP, EMWA, AMWA, MAPS) in increasing DESPs usage.

Conclusions

Results suggest that while DESPs are slowly gaining popularity, increased awareness by publication-specific associations and training opportunities will encourage more authors to engage DESPs.

P8 Good Publication Practice 2022: What is new from the medical writer's perspective?

Surayya Taranum, Phillip Leventhal, Jonathan Pitt
Evidera-PPD, France

Introduction

The 2022 Good Publication Practice (GPP 2022) guidelines were published in September 2022. Here, we identified updates relevant to medical writers (MWs) producing publications.

Methods

GPP 2022 guidelines were compared to GPP3. Search terms including “medical writer”, “writer”, and “writing”, were used to extract changes relevant to MWs.

Results

GPP 2022 has expanded the term “publications” to include plain language

summaries and enhanced content such as videos, audios, and infographics. Key updates relevant to MWs producing publications include: (a) a statement that MWs enhance the quality of publications; (b) authors must agree to work with a MW before the start of the project, provide direction and initial outline to the MW, and perform the final data check to ensure the quality and accuracy of the publication; (c) a MW may be listed as an author if they fulfil all the ICMJE criteria and is not disqualified from authorship by paid employment as a MW; (d) publications should include the MW's name, professional qualifications, affiliation, and funding source;

(e) MWs should not use their personal social media accounts to share information on company-sponsored research publications; (f) MWs should engage in formal training offered by relevant organisations (e.g., EMWA, AMWA, and ISMPP).

Conclusions

GPP 2022 provides important clarifications on the transparency, recognition, roles, and responsibilities of MWs. MWs should be aware of these updates and communicate them to their clients and collaborators.

P9 Language validation for patient documentation: Automated tools or layperson readability tests?

Laura Martínez-Campesino, Beatriz Rodríguez-Grande, Ariadna Navarro-Aragall, Mohamed Koched, Séverine Oudine-Fantin, Stewart Richmond
NAMSA

Introduction

Within the MedTech industry, information written for patients was often developed without language validation. Introduction of the EU Medical Device Regulations (2017/745) emphasised a need for greater transparency. This requires manufacturers to provide clear and comprehensible documentation for users, the acceptability of which may be demonstrated through readability tests (RTs). Automated RT tools exist which use formulas that consider sentence length, word simplicity, etc. This validation study considers the performance of three different automated RTs, when compared against an assessment of readability and comprehension involving real lay people.

Methods

A RT was developed including success criteria: at least 90% of the questions should be correctly answered by 80% of lay people (with no prior knowledge of medical terminology). Three groups of laypersons (n=24; 24; 12) performed RTs on documents/sections that were also evaluated using automated tools (Readable; Grammarly; Microsoft Word). The results of each method were compared.

Results

While all automated RTs suggested “unacceptable” readability levels, results obtained directly with participants demonstrated that the documentation used was readable (success criteria met).

Additionally, participants' feedback suggested that, although some documents were too long, the level of detail, information, and organization were appropriate.

Conclusions

Medical writers' training and language validation enhance documents' readability. Although automated tools are a cheap and quick alternative to layperson RTs, over-reliance on automated tools may provide misleading results. RTs performed on participants provide more relevant results to confirm the adequacy of the information provided. The effectiveness of combining automated and layperson RTs still requires further investigation.

P10 A case study of whether ChatGPT can produce abstracts that meet CONSORT for Abstracts requirements

Athanasia Benekou¹, John Plant², Michael Franklin³, Jonathan Pitt², Phillip Leventhal²

1 Evidera-PPD, Greece

2 Evidera-PPD, France

3 Evidera-PPD, USA

Introduction

Artificial intelligence tools, such as ChatGPT, have the potential to create documents that resemble human writing. However, whether ChatGPT can simulate high-quality scientific writing consistent with standard reporting guidelines is unknown. We thus assessed whether ChatGPT-produced abstracts could meet CONSORT for Abstracts reporting requirements.

Methods

A randomised controlled trial publication (N Engl J Med. 2020;383:2603–15) was selected based on its relatively short text, limited number of tables and figures, and widely understood topic (COVID-19). To fit within

the size limitation of its data entry field, ChatGPT was used to shorten each section of the text by two-thirds. These shortened sections were then combined and enriched with any CONSORT-related missing information and entered back into ChatGPT with the instructions to generate a CONSORT-compliant (a) structured abstract under 250 words and (b) title. The CONSORT for Abstracts checklist was used to assess the quality of the outputs. A qualitative evaluation was also conducted.

Results

The ChatGPT-generated abstract contained 277 words. Of the 17 items in the CONSORT for Abstracts checklist, 10 items (59%) were

reported, and 5 (35%) were not reported: participants, blinding, numbers randomised, numbers analysed, and trial registration. Two items were considered not applicable (12%). The abstract text did not always match the sections; it was repetitive and at times hard to comprehend.

Conclusions

ChatGPT did not comply with the CONSORT for Abstracts checklist and generated a poorly written abstract. Therefore, it cannot be considered effective at producing scientific abstracts of sufficient quality.

P11 A method of selecting appropriate Quality of Life Patient Reported Outcomes Measures in clinical trials

Valia Maria Barbosa, Onthatile Serehete, Sian Lucking, Gillian DunnGalvin, Irene Cisma Diaz, Atlantia Food Clinical Trials Ltd.

Introduction

Quality of Life (QoL) Patient Reported Outcomes Measures (PROMs) has become popular to assess participants' perception of their own health and wellbeing. Selecting an appropriate measure is important for the reliability and validity of the overall self-perception and definition of participant and patient QoL.

Methods

The review was completed on peer-reviewed studies conducted between 2012 and 2023 using PRISMA methodology. An electronic search was completed on the following

databases: PubMed, Cochrane, and ClinicalTrials.gov. The questionnaires design and applicability were compared to best practice as per DeVellis and Thorpe (2021).

Results

The review identified five generic, validated QoL questionnaires: World Health Organization Quality of Life Assessment Instrument (WHOQOL), 36-item Short-Form Health Survey (SF-36), 12-item Short-Form Health Survey (SF-12) Nottingham Health Profile (NHP), and Euro-Quality of Life Questionnaire (EuroQoL, EQ-5D). SF-12 was found to be the most suitable, due to ease of

use, low participant burden, and ability to identify difference between quality of life domains.

Conclusions

Choosing an appropriate measure to assess QoL in clinical trials is complex. Factors that may affect the responses are complexity and timing of the questionnaire during the trial. Understanding how participants perceive their QoL may inform clinical "best" practices allowing them to be more patient-centric. A trial does not only consist of data collection in order to be published, it consists of processes to improve the participants' health.