

THEME ARTICLE

Good Publication Practice (GPP) 2022 Update: An Interview with Dikran Toroser

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INTERVIEW


AMWA: Thanks Dikran for taking the time to speak to AMWA. First, I would like to recognize the time and effort by the steering committee and authors of the GPP 2022 update. This is a major update of the guidelines since GPP3,³ which was published in 2015. The work for the latest update started in April 2019, and the article was published in September 2022, so the entire process took more than 3 years from start to finish. *My first question is why there was a need for this major undertaking to update the GPP, and what are the main objectives of this update by the GPP steering committee and authors?*

Toroser: The publication field has been moving and changing at an extraordinarily fast pace in the last few years. For example, with the emergence of various enhanced content, publications are no longer just black-and-white pieces in a journal. The COVID pandemic was an incredible catalyst for many of the changes. Because people were not traveling to attend scientific conferences in person, there has been a huge need for digital enhancements, such as audio and video recordings, to be accessed virtually and on demand.

Another important factor is that the audience for scientific publications is evolving. The audience is no longer limited to a select few who are technically minded in the same field. Today’s audience includes those who are not experts in the same field, who are not experts at all, who are short of time, or who are from other parts of world. The changes in the audience and their needs are another force in shaping the changing publication field. These are among many reasons to update the GPP guidelines.

The latest GPP update builds on prior iterations of GPP guidelines and reflects the latest changes and advances in the publication field. It is worth mentioning that, as with all guidelines, GPP won’t be able to provide answers to all questions at work and requires day-to-day judgment calls by publication professionals to apply the principles in specific cases.

AMWA: The GPP 2022 update covers a wider scope of publications. For example, in the “Scope” section, the authors described research areas applicable to GPP guidelines:



Dikran Toroser was educated in the United Kingdom and has a PhD in biochemistry from Newcastle University in Newcastle upon Tyne. He did his postdoctoral research in the United Kingdom at the Cambridge laboratory on genetics and then moved to the United States to work as a biochemist and researcher for the US Department of Agriculture (USDA). He has an extensive background in scientific publications as well as medical writing. He has led scientific publication teams involved with preclinical, clinical, and mature product studies and publications. Dikran is one of the founding faculty for the University of California San Diego medical writing certificate and a consulting director for the program. Active in professional organizations such as the American Medical Writers Association (AMWA) and International Society for Medical Publication Professionals (ISMPP), Dikran most recently has been involved in compiling guidelines for publication professionals, including the AMWA-EMWA-ISMPP joint position statement on the role of professional medical writers¹ and GPP 2022, the latest 2022 update of Good Publication Practice (GPP) guidelines for company-sponsored biomedical research.²

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besides clinical research, the scope now includes translational and biomarker studies, nonclinical research, health economics, real-world evidence (RWE), and outcomes research.

Why should we include these additional types of research under GPP guidelines? Are there differences in planning and developing publications in these research areas other than traditional clinical research?

Toroser: A wider scope of publications reflects the increasingly complex nature of data and research in the health-

care space. For example, health economics and outcomes research became more important in terms of informing unmet medical needs as well as providing valuable information on health economics relevant to policy and decision-making from a payer's perspective. Research on real-world data (RWD) or real-world evidence (RWE) is another area of growing interest and importance because RWD and RWE are playing an increasing role in healthcare decisions by regulatory agencies such as the US Food and Drug Administration (FDA).⁴

Publication professionals today find themselves managing publications arising from expanding research disciplines besides the traditional clinical research; therefore, it is helpful that the updated GPP now covers the work that we do. Because of the differences in the research process and methodology, the cadence in publication activities for these additional types of research may be different from those for clinical research. For publications on complex data or analyses, there are added challenges in making the publications understandable and meaningful to the intended audience.

AMWA: GPP 2022 also calls out a few new publication types, notably enhanced content and plain language summaries. Definitions for these new publication types are provided in Supplement Section A. Guidelines on the planning and developing enhanced content and plain language summaries are also provided in various other sections in the supplement, from policies and procedures (Section B) to specific process steps such as publication plans (Section E) and publication development process (Section H).

Why are guidelines important for enhanced content and plain language summaries? For organizations that have not routinely worked on these new publication types, what are some key considerations?

Toroser: The need for these new types of publications reflects the fast-changing publication field and an evolving audience. The updated GPP guidelines support the use of enhanced content (such as video, audio, or infographics) and plain language summaries to augment the publication and increase its reach. For the teams who are new to these newer publication types, they would need to collaborate with stakeholders at their organizations to incorporate good practice in day-to-day work. GPP guidelines emphasized that enhanced content and plain language summaries should be developed following the same ethical and quality principles as the main publication. It is also important to consult the journals and congresses for their policies and requirements on enhanced content and plain language summaries.

AMWA: The supplement of GPP 2022 was significantly expanded and reorganized. There seems an emphasis of making this updated GPP more usable to provide guidance on day-to-day work. For example, Section B describes the roles of publication professionals in developing publication policies and procedures as well as sharing best practices and continued professional development. Sections D through H detail various process steps in publication planning and development of individual publications, covering topics from publication steering committees to publication working groups, from publication plans to the process of individual publications.

Can you elaborate a bit more on the rationale behind the expansion and reorganization of the supplement? Is the expanded supplement in GPP 2022 intended as a tool for team training?

Toroser: Thanks for asking about the aspect of training, which had been brought up many times during this current GPP update. An important goal of the GPP document is to facilitate training of publication teams on best practices, both on principles and on day-to-day work processes.

Yes, the supplement of the GPP 2022 update was reorganized and reformatted to increase the clarity of various topics and to make the document easier to read. The supplement is a comprehensive document with a large amount of information; it will be helpful for publication teams to be familiar with the structure of the document so they can consult relevant sections to find guidance on certain topics.

AMWA: Publication professionals need to interact with a wide range of people—eg, company teams, authors, journal editors, and patients—in these various publication process steps and activities. *Can you speak to the role of publication professionals, perhaps an underappreciated leadership role, in educating others and implementing the GPP?*

What challenges may be faced by publication professionals in adopting GPP 2022? Any insights on how to overcome these challenges?

Toroser: The roles of publication professionals are evolving along with the evolving field. We are the gatekeepers of best publication practices in a complex and changing landscape, often faced with complex questions and ethical dilemmas. We shoulder important responsibilities of ensuring that authors meet their authorship criteria, of working with statisticians and other teams to provide data and study materials to authors, and of meeting requirements from the journals and congresses.

The important roles by publication professionals are also supported by the AMWA-EMWA-ISMPP joint position

statement,¹ which calls out the responsibility of professional medical writers in achieving quality publications in an ethical, accurate, and timely manner. Publication quality suffers when these responsibilities are not met to the full stringency. From my perspective, there has been more and more appreciation of the leadership role played by publication professionals.

In terms of challenges, the global nature of publications nowadays can be a challenge to navigate cultural differences. For example, authorship practice in another culture may require more nuanced considerations, including how we ask for feedback and approval from authors. This may require a good understanding of the culture and practice in a specific region to anticipate problems and come up with solutions.

AMWA: Many AMWA members are freelance writers, some of whom provide medical writing assistance to company-sponsored biomedical research publications. *For freelance writers who are new to GPP guidelines, are there specific sections or aspects in GPP 2022 that they may focus on?*

Toroser: I very much appreciate the opportunity to reach out to professional medical writers in the AMWA audience, who are an extremely important part of the publication professional community. My recommendation is that freelance writers should be closely familiar with the entire GPP document, especially ethical and quality principles. I hope that the GPP guidelines become an essential reference document for all medical writers.

AMWA: Besides publication professionals and teams, it seems that the other audiences for the updated GPP 2022 include journal editors, conference organizers, academic institutions, and the wider research community and public. *Have the authors received feedback from the wider audience on the GPP 2022 update? Is there anything we can do to promote dissemination of GPP 2022?*

Toroser: The GPP author group includes representation from the pharmaceutical industry, academic researchers, journal editors, and conference organizers. Also, the latest GPP update underwent review by volunteers from the public before it was finalized for submission. So, feedback from a wide range of perspectives was received during both the writing phase and the review phase.

GPP guidelines have already become a cornerstone for publication processes and procedures in the industry, especially at large companies. I anticipate that GPP guidelines will be more and more widely accepted by journals, congresses, and the academic research community. For example, we already built links with organizations such as the Asian Council of Science Editors in the Asia-Pacific region. ISMPP is also collaborating with various professional organizations such as the Medical Affairs Professional Society (MAPS) and Drug Information Association (DIA) to discuss and disseminate the latest GPP update.

AMWA membership is a crucial audience for GPP. I encourage AMWA members who are involved in scientific publications to get closely familiar with the GPP 2022 update. It takes continued effort to disseminate the latest GPP guidelines; we all can do our part through discussions with colleagues and stakeholders at professional development activities and in our day-to-day work.

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