Second meeting of the CIOMS Working Group on Harnessing the Potential of Pharmacoepidemiology for Public Health (PEPH)

Virtual meeting, 26 February 2024

Participants

CIOMS: Hervé le Louet (HL) (President); Lembit Rägo (LR) (Secretary-General).

Academia: Bernard Bégaud (BB) (University of Bordeaux, France); Kate Gillespie (Institute for Health Metrics and Evaluation (IHME) at the University of Washington); Yola Moride (YM) (Rutgers University, USA).

Industry: Ana Sofia Afonso (Eli Lilly, The Netherlands); Alex Asiimwe (Gilead); Alicia Gayle (Chiesi, Italy); Selin Cooper (AbbVie, UK); Karin de Haart (IQVIA, The Netherlands); Véronique Kugener (VK) (Takeda, USA); Marie-Laure Kurzinger (MLK) (Sanofi, France); Innocent Ngwa (Roche, Switzerland); Patricia Saddier (MSD, USA); Muhamad Younus (Pfizer, USA).

Intergovernmental organization: Noha Iessa (NI) (WHO, Switzerland)

Regulatory: Craig Allen (MHRA, UK); Takashi Ando (Pharmaceuticals and Medical Devices Agency, Japan); Monique Falconer (Food and Drug Administration (FDA), USA); Miguel Ángel Maciá (Spanish Agency for Medicines and Medical Devices, Spain); Doris Oberle (Paul Ehrlich Institute, Germany); Hui-Lee Wong (HW) (FDA, USA).

Welcome and opening remarks

CIOMS president Hervé le Louet (HL) opened the meeting and thanked participants for their efforts to date and that the time has come to merge the two sub-groups.

HL mentioned that the possibility of overlap between CIOMS working groups (WGs) 15 and ICH WG M14 had been raised but that this is in fact not probable given the guidance provided by the relevant concept notes.

Lembit Rägo (LR) mentioned that following COVID, some analysis has been made of randomized controlled trials but that no analysis has been carried out that covers pharmacoepidemiology (PE) studies and their good and not-so-good contributions to public health.

LR welcomed new member Noha Iessa (NI) (WHO) to the group. She is also a member of the M14 WG of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). NI explained the group's remit which is to develop a harmonized guideline (based on the existing guidance available from regulatory agencies) on the planning, design and analysis of PE studies that use real-world data for safety assessment of medicines. A draft of the guidance is now circulating for comments. Timelines have slipped a little since extra time was needed to obtain initial consensus among the regulatory agencies who are part of the WG. (Comments were received previously from the European Medicines Agency and US FDA, as a result of which changes were made to the draft.) ICH anticipates that the next draft will be finalized before the end of this year. NI will share the next draft with this group.

Summary of Sub-group 1 discussions

Yola Moride (YM), who leads Sub-group 1, summarized the key points of the two sub-group discussions held so far (December 2023 and January 2024). The sub-group has worked on preparing a list of concepts and terms that would be relevant when seeking to optimize use of PE for public health. This has include reviewing and listing terms included in the Glossary of ICH terms on the CIOMS website.

In addition, Sub-group 1 has discussed the potential value of inviting a public health expert or experts – with expertise in the concepts and metrics used in public health – to join it. To date, one such expert – Kate Gillespie (KG) of the Institute for Health Metrics and Evaluation – has joined the sub-group.

It has agreed a working title for the report: *The role of PE for public health: rationale and scope of enquiry*.

YM met with Véronique Kugener (VK) who leads Sub-group 2 to verify that there is no overlap between the two groups in terms of the content under discussion.

YM indicated that Sub-group 1 will prepare an extended outline of its report section for the upcoming in-person meeting scheduled for May.

Summary of sub-group 2 discussions

Sub-group 2 has met three times and each group member has been assigned to a specific topic. The specific topics are:

- the intent of PE and current PE practice
- the relevant framework to apply to PE, in accordance with the setting (academe, industry, pharmacology)
- gaps with respect to PE and public health, specifically looking at communication.

VK underscored that Sub-group 2 considers it important that a public health expert participate in the WG to help reflect on the topic of communication and public health. Given the many different communication channels, the sub-group considers that, in addition, the participation of a media communications expert would be useful. It discussed the contact and impact of communication on individuals and on society. Those making decisions regarding health policy include not only pharma and regulators, but also health professionals, patients and their family members. Communication has to be crafted appropriately for each target group.

Discussion points

- There may be overlap between the sub-groups in their discussion of what is PE; the two sub-groups could be merged sooner rather than later for this specific topic. However, the most important activity at this stage remains that of pooling ideas; dealing with overlap and deciding what elements to take from each sub-group be carried out later.
- The report should be practical and should therefore include some examples and some tools.
- **If the sub-groups provide specific names of potential additional WG members (in particular of communications experts and public health experts), CIOMS will issue formal invitations to them. YM will forward the names that Sub-group 1**

has generated. YM indicated that three members of Sub-group 1 are involved in public health (Kate Gillespie, Masao Iwagami, and Ando Takashi). HL commented that existing WG members are all involved to some extent in public health. The need is for a communications expert who is sensitive to public health, rather than for a public health expert. VK will forward the name of a social media expert. HW proposed some specific names.[1]

- Public health experts from other geographic regions should be invited to join the group. **Hui-Lee Wong will seek to provide some names. NI will investigate whether anyone at WHO (headquarters) involved in presenting Science in 5, and any public health specialists (if any) working with a WHO disease programme, could be invited to join the WG. She will also investigate whether WHO has a methodology, framework or tools for use when communicating public health issues.** LR underscored that those invited to participate must be able to make a real contribution.
- In thinking about gaps in communication, we can consider what data are available and how they can be used. In Europe, a lot of data has been harmonized, but this is not the case in the USA. In low- and middle-income countries, lack of resources can mean that the focus is more on prevention than on treatment. In such circumstances, the data collected might not be particularly relevant to PE studies. The type of data collected can also influence how and what is communicated in the domain of public health. So if a communications expert joins the WG, this person should be able to understand PE data, and how to package it for more general consumption. The who, what and how of public health communication needs to be covered by the WG, but epidemiology specifically must be covered.
- Many interventions are financed by pharma or regulated by regulatory agencies and have their own specific objectives. Their focus is on getting the right product onto the marketplace and evidence is collected with this objective in mind, creating a certain asymmetry.

New working group members assigned to sub-groups

KG is already working with Sub-group 1.

Alex Asiimwe deals with real-world evidence and will join Sub-group 1.

NI will work with Sub-group 2.

Next steps

The next in-person meeting will be held in Paris, on 22 and 23 May 2024, hosted by Sanofi. **Both sub-group will meet in March. They will exchange any materials or drafts with each other ahead of the meeting;** YM underscored that identifying any gaps is as important as dealing with any duplication or overlap. **YM and VK will also meet ahead of the meeting to plan possible meeting topics and content.**

[1]Ed Yong, previously of *The Atlantic*, who received the Pulitzer Price for Explanatory Reporting for a series on the COVID-19 pandemic, the Victor Cohn Prize for Excellence in Medical Science Reporting and the John P. McGovern Award from the American Medical Writers Association; Amy Maxmen a senior reporter with Nature, including on Ebola and COVID-19 and who has received awards including the Victor Cohn Prize for Excellence in Medical Science and the AAAS Science Journalism Award for Ebola reporting.