EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Network of Centres for Pharmacoepidemiology and Pharmacovigilance

ENCePP Working Group 1: Standards and Guidances

ENCePP WG1 & Plenary meeting
29-30 November 2022

Alejandro Arana

Mandate and objectives of WG1

Overall mandate:

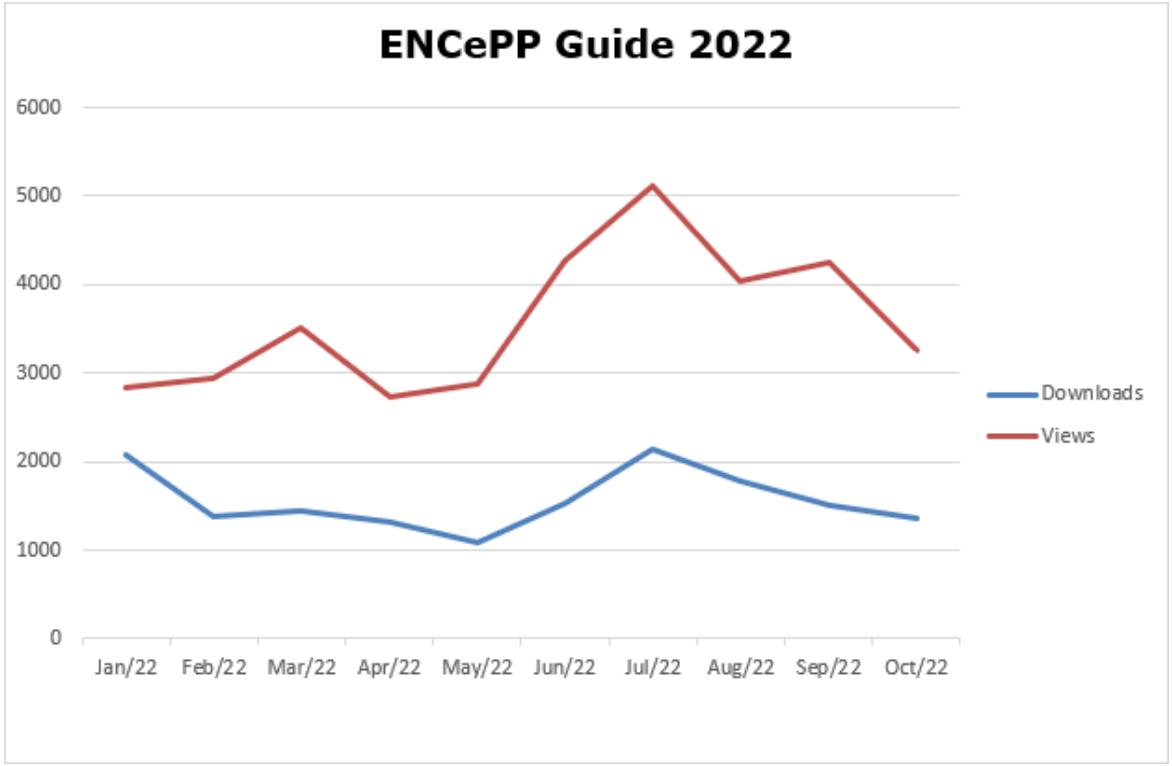
To address methodological aspects of the generation of evidence-based information supporting the needs of regulatory and HTA decision-making.

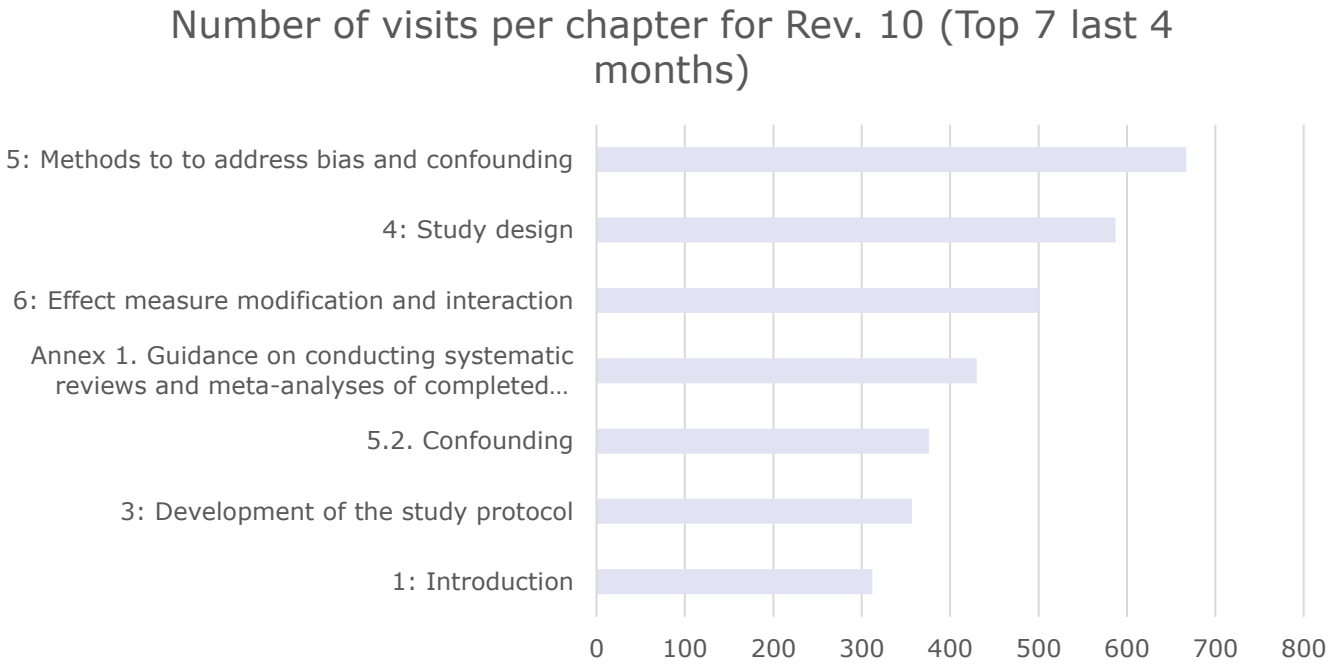
ENCePP research standards and guidances	
Chair:	Alejandro Arana
• Identify areas in which research standards and guidances relevant for ENCePP activities are needed and identify or develop such guidance.	
• Periodically review the ENCePP Checklist for Study Protocols.	
• Periodically review the Guide on Methodological Standards in Pharmacoepidemiology.	
• Monitor the development of accreditation systems and their methodologies.	
• Support training relevant to the ENCePP standards.	
• Support the implementation of new and existing standards.	

10th revision of the ENCePP Guide; Released July 2022

- 2 New Chapters
  - Use of artificial intelligence in pharmacoepidemiology (Chapter 15.5)
  - Real-world evidence and pharmacoepidemiology (15.6)
- 1 new Annex on Methods for the evaluation of medicines in pregnancy and breastfeeding
- Foreword highlighting the continued involvement of ENCePP in sound pharmacoepidemiological research including COVID-19 topics
- Update of each chapter by the corresponding authors
  - Extensive revision of **chapter 15.1 and 15.2** Comparative effectiveness research and Vaccine research
  - Extensive revision of **chapter 14.3**. Design and analysis of pharmacogenetic
  - Recommendations on the use of statistical significance for the interpretation of evidence have been added in the Overview of study designs (4.1)
- https://www.encepp.eu/standards_and_guidances/index.shtml

ENCePP Guide





Lessons learned from Rev. 10

- EMA large amount of work to identify topics to be updated, and what can be improved
- Continue to draw lessons to apply in routine pharmacoepi and public health emergencies
- Continue to address emerging topics/challenges
- More structured process for contacting and involving new authors.
- (re)engagement of the entire ENCePP community to contribute could be fostered at the plenary
- It was also noted that the notion of RWE should be more emphasised – not only in Chapter 15.6. (Discuss adjusting the title of the Guide)

Possible new topics or changes for 11th rev. of ENCePP Methods Guide

- use of the estimand framework for observational studies: relevance, influence on study design and analysis.
- clone-censor-weight approach to prevent immortal-time bias
- Target trial emulation
- Use of external comparators
- more structured presentation of study designs (including graphs)

Activities for 2022-23

Update the ENCePP Checklist for Study protocols based on recent methodological developments

ENCePP description of the ISPE-ISPOR Harper study protocol template

Thank you for your attention!

www.encepp.eu

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