

# Pharmacoepidemiology and Drug Safety’s Core Concepts in Pharmacoepidemiology Section at One Year: Where Do We Go from Here?

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## *Pharmacoepidemiology and Drug Safety’s* **Core Concepts in Pharmacoepidemiology Section at One Year: Where Do We Go from Here?**

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**Running title:** Core Concepts in Pharmacoepidemiology – Year 2

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## **Introduction**

In 2022, *Pharmacoepidemiology and Drug Safety (PDS)* launched a new section titled “Core Concepts in Pharmacoepidemiology.” The purpose of this section was to publish articles highlighting some of the key concepts in pharmacoepidemiologic study design and analysis. The need for this section was motivated by the desire for *PDS* to be recognized as a prominent source of educational information on foundational pharmacoepidemiologic topics. In addition, the collection of these articles could be cited as methodological references in future original research articles and grant proposals to provide strong justification for important research design and analytic decisions. The target audience for this collection of review papers includes individuals currently enrolled in pharmacoepidemiology training programs and related fields, researchers and practitioners who may not have a focused background in pharmacoepidemiology, as well as established pharmacoepidemiologists seeking to review key pharmacoepidemiologic methods. To ensure the educational

content would be accessible and interpretable by the target audience, the journal’s editors requested that each author team include a trainee, preferably as first author.

### ***PDS* Core Concepts in Pharmacoepidemiology – Year 1**

We began this initiative for *PDS* by developing an initial list of topics for inclusion in Year 1 of the Core Concepts in Pharmacoepidemiology section. Comments on this list and potential additional topics were solicited from the *PDS* Editor-in-Chief, *PDS* Regional Editors, and members of the International Society for Pharmacoepidemiology (ISPE) Publications and Communications Committee. After feedback and input was obtained, we prioritized the final topic list and selected seven for inclusion in Year 1 of the new section. Our initial invitation to writing groups focused on academic institutions with pharmacoepidemiology training programs, primarily as a means of ensuring inclusion of pharmacoepidemiology trainees. A full listing of the published papers and their topics (one is currently under review) is shown in Table 1.

### ***PDS* Core Concepts in Pharmacoepidemiology – Year 2 and Beyond**

In preparing for Year 2 of the Core Concepts in Pharmacoepidemiology section, we have made some modifications to our initial processes. We solicited further input from the *PDS* Regional Editors, their broader group of Associate Editors, and the ISPE Publications and Communication Committee to identify new topics for the section. After prioritization by the *PDS* Editor in Chief and Regional Editors, a list of nine topics for Year 2 of the Core Concepts in Pharmacoepidemiology section is included in the Box.

The ISPE Publications and Communications Committee provided valuable recommendations for broadening the writing groups beyond the academic sector and the need to communicate an inclusive and clear definition of ‘trainee,’ which are applicable to researchers in the industry/service provider and government/regulatory sectors. The new definition of a trainee for purposes of the *PDS* Core Concepts in Pharmacoepidemiology section is “*an individual enrolled in a pharmacoepidemiology training program or a recent graduate from a pharmacoepidemiology training program (within 3 years of completion of degree)*”. This change will broaden the potential writing groups for future articles authored by pharmacoepidemiology researchers within industry/service provider, governmental/regulatory, or academic sectors.

### **Call for Writing Groups**

If you are interested in contributing to one of the prioritized topics for Year 2 included above, or have suggestions for other topics, please contact the Section Editor (Jennifer.Lund@unc.edu) and include a letter of intent describing: 1) the topic of interest, 2) your proposed writing group (adhering to the specifications above), and 3) justification of your qualifications and expertise in the topic area. If multiple groups are interested, final writing group selections will be made by the *PDS* Editor-In-Chief, Regional Editors, and the Section Editor.

*PDS* and ISPE are leaders in the field and experts in the design and analysis of studies using real-world data and generating real-world evidence. As such, *PDS* and ISPE should lead efforts to develop articles to educate researchers, clinicians, and practitioners about the core principles in using these data and their promise to generate valid evidence. Our sincere hope is that this *PDS* Core Concepts in Pharmacoepidemiology section will serve as a repository for fundamental content for the field of pharmacoepidemiology that will promote the development and success of the field’s current and future leaders.

**Table 1. Summary of Topics for the Core Concepts in Pharmacoepidemiology Manuscripts – Year 1.**

<b>Author</b>	<b>Year</b>	<b>Institution</b>	<b>Title</b>
Acton EK et al	2022	University of Pennsylvania	Core concepts in pharmacoepidemiology: Key bi
Rasmussen L et al	2022	Odense University	Core concepts in pharmacoepidemiology: Measu
Weinstein E et al	2022	University of Pennsylvania	Core concepts in pharmacoepidemiology: Validat
Pottgård A et al	2022	Odense University	Core concepts in pharmacoepidemiology: Funda
Sendor R et al	2022	University of North Carolina at Chapel Hill	Core concepts in pharmacoepidemiology: Confo

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<b>Author</b>	<b>Year</b>	<b>Institution</b>	<b>Title</b>
Zhu Y et al	2021	University of Pennsylvania	Core concepts in pharmacoepidemiology: Violat

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**Box. Prioritized Topics for Core Concepts in Pharmacoepidemiology Section - Year 2.**

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Self-controlled designs in pharmacoepidemiology  
Quantitative bias analysis in pharmacoepidemiology  
Considerations and methods to address missing data in electronic healthcare data  
New versus prevalent user designs in pharmacoepidemiologic studies  
Methods for conducting multi-database studies  
Evaluation of drug-drug interactions in pharmacoepidemiologic research  
Methods to identify polypharmacy in claims data  
Principled use of artificial intelligence in pharmacoepidemiology research  
Time-to-event approaches in pharmacoepidemiology

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