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LETTER TO THE EDITOR

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Where to begin? Thirty must-read papers for newcomers to pharmacoepidemiology

Pharmacoepidemiology, the study of use and effects of medications, devices, diagnostics, and other medical interventions in large populations, is a science under constant development. New study designs are added to the armamentarium, new data sources are being leveraged, and new approaches are developed. All are changing the conduct of pharmacoepidemiological studies. In addition, the growing availability of electronic healthcare data, and the openness of regulators to review real-world evidence (RWE), is attracting a variety of disciplines who are new to epidemiologic methods in general and to pharmacoepidemiologic applications and causal inference work on drug effects in particular. For newcomers to the field of pharmacoepidemiology, this provides a challenge in assessing "where to begin" when diving into the ever-growing literature.

To establish a curated curriculum for newcomers covering the most important aspects for persons new to the field of pharmacoepidemiology, a group of senior pharmacoepidemiologists from five different countries, developed and solicited input to such a reading curriculum via social media

TABLE 1 Selected top 30 must-read papers

Category	First author (year)	Title	Reference
Basic methods	Greenland (2016)	Statistical tests, *p* values, confidence intervals, and power: A guide to misinterpretations	1
	Rothman (2013)	Why representativeness should be avoided	2
	Hernán (2018)	The C-word: Scientific euphemisms do not improve causal inference from observational data	3
	Stürmer (2020)	Methodological considerations when analyzing and interpreting real-world data	4
	Hill (1965)	The environment and disease: Association or causation?	5
	Ioannidis (2005)	Why most published research findings are false	6
	Hernán (2010)	The hazards of hazard ratios	7
Biases	Suissa (2020)	Time-related biases in pharmacoepidemiology	8
	Schisterman (2009)	Overadjustment bias and unnecessary adjustment in epidemiologic studies	9
	Platt (2009)	Time-modified confounding	10
	Gerhard (2008)	Bias: Considerations for research practice	11
	Renoux (2017)	Bias from depletion of susceptibles: The example of hormone replacement therapy and the risk of venous thromboembolism	12
	Funk (2014)	Misclassification in administrative claims data: Quantifying the impact on treatment effect estimates	13
	Hernán (2004)	A structural approach to selection bias	14
Reporting	Langan (2018)	The reporting of studies conducted using observational routinely collected health data statement for pharmacoepidemiology (RECORD-PE)	15
	Schneeweiss (2018)	Graphical depiction of longitudinal study designs in health care databases	16
	Wang (2021)	STaRT-RWE: Structured template for planning and reporting on the implementation of real-world evidence studies	17

(Continues)

TABLE 1 (Continued)

Category	First author (year)	Title	Reference
Methods and design	Hallas (2014)	Use of self-controlled designs in pharmacoepidemiology	18
	Lund (2015)	The active comparator, new user study design in pharmacoepidemiology: Historical foundations and contemporary application	19
	Perkins (2018)	Principled approaches to missing data in epidemiologic studies	20
	Hernán (2016)	Using big data to emulate a target trial when a randomized trial is not available	21
	Lipsitch (2010)	Negative controls: A tool for detecting confounding and bias in observational studies	22
	Schneeweiss (2007)	Increasing levels of restriction in pharmacoepidemiologic database studies of elderly and comparison with randomized trial results	23
	Stürmer (2006)	Insights into different results from different causal contrasts in the presence of effect-measure modification	24
	Pazzagli (2018)	Methods for time-varying exposure related problems in pharmacoepidemiology: An overview	25
	Vrijens (2012)	A new taxonomy for describing and defining adherence to medications	26
Statistical analysis	Stürmer (2014)	Propensity scores for confounder adjustment when assessing the effects of medical interventions using nonexperimental study designs	27
	Desai (2019)	Alternative approaches for confounding adjustment in observational studies using weighting based on the propensity score: A primer for practitioners	28
	Schneeweiss (2006)	Sensitivity analysis and external adjustment for unmeasured confounders in epidemiologic database studies of therapeutics	29
	Arbogast (2011)	Performance of disease risk scores, propensity scores, and traditional multivariable outcome regression in the presence of multiple confounders	30

(Twitter and LinkedIn) in March 2021. Our call received considerable attention from pharmacoepidemiologists all over the World. After removal of duplicates or papers covering the same topic as well as purely applied studies (i.e., with no specific methodological contribution), we grouped the remaining suggestions ($n = 64$) into (i) basic methods; (ii) biases; (iii) reporting/guidelines; (iv) methods and designs; and (v) statistical analyses. Across all papers, the remaining papers, each of the assessors, the authors of the present letter, was asked to vote for between 20 and 30 of the papers. We then selected, the papers with three or more votes ($n = 33$), followed by two rounds of adjustments to prioritize between partially overlapping papers, resulting in a final selection of 30 papers, or 1 month of daily readings in pharmacoepidemiology (Table 1).

The final list of papers covers a wide range of topics. Some of these articles are not specifically about the use and effects of drugs, but all touch upon core principles that we think should be part of the basic curriculum for newcomers to the field of pharmacoepidemiology and RWE, including researchers from other disciplines who are planning to use big data for causal inference work. We hope that it can prove to be useful as an introductory tool in pharmacoepidemiology, in addition to textbooks and other available materials.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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