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Application and Implementation of the Prevalent New-User Design in Pharmacoepidemiologic Cohort Studies: A Scoping Review

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Abstract

Background and Aims: The prevalent new-user design (PNUD) is a novel pharmacoepidemiologic approach that enables inclusion of all initiators of a new medicine, including those switching from a comparator treatment. The PNUD requires treatment switchers to be compared to those continuing prior therapy. To avoid bias, appropriate adjustment for treatment history is required.

This study aims to review the use and implementation of the PNUD in pharmacoepidemiology, focusing on the uptake of the method in practice, the clinical setting and specific design decisions and their potential for mitigating bias.

Design and Methods: We searched for relevant articles published between 2017 and 2025. Studies were included if they used observational data to apply the PNUD in evaluating medicine safety or effectiveness. We extracted information on the clinical use case, study entry criteria, and how prior treatment was accounted for when selecting matched comparators.

The protocol has been registered with the Open Science Framework (OSF).

Results: 266 articles were retrieved, and 51 eligible studies were identified. Use of the PNUD has increased since 2017, with more than half (n = 26) published since 2023. The three most common

diseases studied were type 2 diabetes (n = 22), schizophrenia and psychosis (n = 7), and rheumatoid arthritis (n = 5), accounting for 67% of all studies. Studies in other disease areas increased from 20% (2017-2022) to 46% (2023-2025). Extraction is ongoing, and results will be presented at the symposium.

Conclusions: The PNUD is increasingly used in pharmacoepi and is being applied across a broader range of disease areas.

Impact: There are currently no best practice guidelines for conducting studies using the PNUD. This review will examine how the design is being applied in practice and inform detailed recommendations to guide its implementation and reporting. These recommendations will ensure that PNUD studies generate reliable evidence of medicine safety.