Editor's note

The year 2020 marks the 25th anniversary of the *Journal of Managed Care + Specialty Pharmacy*. To commemorate this milestone, we are publishing a series of articles that document the changes to the journal and profession over the past 2 and a half decades. Each month we reprint an original article from a previous year, dating back to 1995. The reprinted articles feature topics of significance in our industry. Each reprinted article is accompanied by a contemporary reflection that will consider the historical significance of the topic, as well as the current and future state.

Laura E. Happe, PharmD, MPH
Editor-in-Chief

Real-world evidence enhances decision making

Daniel C Malone, RPh, PhD

The widespread availability of administrative claims and, now electronic medical records has enabled the ability to use this information to provide further insights into what and how care is being delivered and its associated cost. Before engaging in a discussion of the benefits of real-world evidence (RWE), it is necessary to state that not all real-world data (RWD) are RWE. In a seminal paper, Sherman et al. (2016) from the U.S. Food and Drug Administration (FDA) delineated between RWD and RWE. RWD is the collection of health-related information, and when stored electronically, these data can be used for analyses to answer a wide variety of research questions.¹ On the other hand, RWE is the transformation of RWD into evidence that can aid health care decision making at the patient, provider, and payer levels.

In 2017, my colleagues and I (Hurwitz et al.) published a study in *JMCP* that evaluated pharmacy and

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therapeutics (P&T) monographs for use as RWE.²

It was disappointing, but not surprising, that we found only 4% of the cited references of P&T monographs to be RWE analyses. However, our analysis identified 12 high-quality comparative

RWD effectiveness studies that were included in therapeutic class reviews.

We also interviewed managed care pharmacists and physicians and learned that there was keen interest in RWE for other decision processes besides the P&T process, especially those concerning safety and management of complex conditions.³ At that time, the momentum for RWE was building and as apparent by the number of RWE studies published in *JMCP*. Over the course of 2019, an average of 6 (range: 3-13) studies that used RWD was published per issue. In the March 2020 issue of *JMCP*, Happe et al. published recommendations for the visual presentation of RWE study

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J Manag Care Spec Pharm.
2020;26(12):1612-14

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designs and also reported that in 2018 this journal published 84 RWE studies, three quarters of all original research articles in the journal.⁴ Happe et al. also indicated that managed care pharmacy uses RWE for “utilization, contracting, quality measurement, and safety programs.”

Over the past decade, other applications of RWE have expanded greatly, including serving as historical controls for single arm trials,^{5,6} confirming findings from randomized controlled trials (RCTs),⁷ evaluating subpopulations not well studied in