Implications of Non-Medical Switching in Medicare Part D: An Updated Rapid Review of the Literature

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INTRODUCTION

The Inflation Reduction Act (IRA) gives the Centers for Medicare & Medicaid Services authority to set a maximum fair price (MFP) for selected drugs in Medicare. The law also redesigns the Part D benefit structure, with some improvements in patient affordability while also shifting more liability onto plans and other stakeholders. One anticipated consequence of the IRA is that price reductions of selected drugs may lead insurers to implement strategies (e.g., prior authorization, step-edits, formulary exclusions) to steer patients towards the drug with the lowest net price (i.e., MFP drug or competitor that offers higher discounts) and deter access to other treatment options used to treat the same clinical condition, leading to non-medical switching (NMS). A prior literature review of studies (2015-2018) demonstrated that NMS is commonly associated with negative or neutral endpoints (Weeda et al., 2019).

OBJECTIVE

To review more recent literature to assess the clinical, equity, economic, resource utilization, and behavioral impact of NMS, an issue that is expected to grow and be exacerbated under the IRA.

METHODS

We conducted a rapid literature review to update to a prior systematic review (Weeda et. al, 2019), on the impact of NMS on medication use and health outcomes. We defined non-medical switching, as "switching to a chemically distinct but clinically similar medication for reasons other than lack of clinical efficacy or response, adverse effects or poor adherence." We also excluded articles on nonmedical switch of a reference biologic to a biosimilar medicine. Articles were included in the qualitative synthesis, and findings were summarized (Figure 1).

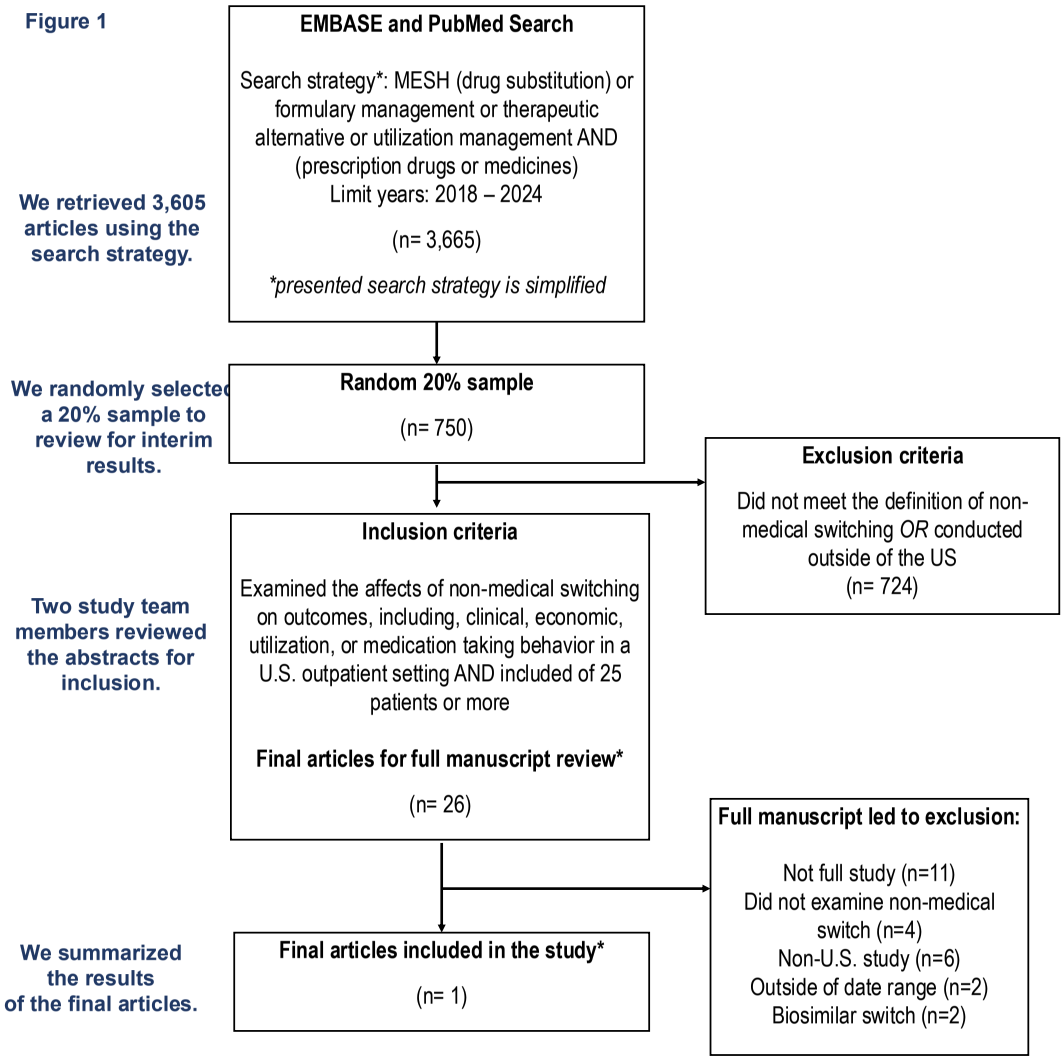
PRELIMINARY RESULTS

Based on the search strategy, 3,665 articles were identified. Based on a random 20% sample (n=750) of these articles, 1 article met inclusion criteria. The negative association between health outcomes and NMS observed in the Gilbert I., 2021 study serves to corroborate prior evidence of the potential negative effects of NMS.

POLICY IMPLICATIONS

The IRA has the potential to increase use of plan strategies that lead to NMS which may prevent older adults from accessing treatments that may be the best fit for an individual patient. Adequate access to treatment options in the disease areas implicated by IRA's MFP process (e.g., heart failure, chronic kidney disease, stroke prevention, diabetes, and psoriasis) is essential to improving quality of care and reducing health disparities. In order to reduce risk of NMS and drive patient-centered equitable care, it will be essential to carefully monitor plan strategies in the years after the IRA is implemented, as well as monitoring the impact on access to therapeutic alternatives and patient centered outcomes.

Figure 1



* Preliminary results

Non-medical switching is associated with clinical gaps in care and exacerbations.

Title	First Author, Year	Population	Non-Medical Switch	Follow-Up Period	Analysis	Outcomes
Association of Nonmedical Switches in Inhaled Respiratory Medications with Disruptions in Care: A Retrospective Prescription Claims Database Analysis	Gilbert I., 2021	Medicare Part D patients with asthma or COPD	Patients taking a corticosteroid/ long-acting beta-2 agonist experienced a formulary block	1 Year	Retrospective claims analysis	**Clinical:** On average, patients with a non-medical switch experienced an average gap in care without an inhaler of 4 months, and 23% of patients did not fill any inhaler within 1 year of the NMS. **Medication Use:** Among patients with a gap in care, 47% of patients filled a medicine indicative of an exacerbation.

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