Utilization of hormonal contraceptives during the postpartum period in the FDA Sentinel System

Keewan Kim[1], Bahareh Rasouli[2,3], Anandi Kotak[1], Rebecca Hawrusik[3], Megan Wiley[3], Nora P McElroy[3], Audrey Gassman[1], José J Hernández-Muñoz[1], Jummai Apata[1], Natasha Pratt[1], Adebola Ajao[1], Mayura Shinde[2,3]

[1] US Food and Drug Administration, Center for Drug Evaluation and Research, Silver Spring, MD, USA; [2] Harvard Medical School, Boston, Massachusetts; [3] Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, Massachusetts, USA.

Disclosures

- The authors have no conflicts of interest to disclose.
- This project was supported by Task Order 75F40123F19009 under Master Agreement 75F40119D10037 from the U.S. FDA.
- The contents are those of the authors and do not necessarily represent the official views of, nor an endorsement by, FDA/HHS or the U.S. Government.
- Some authors are employees of Harvard Pilgrim Health Care Institute, a non-profit organization that conducts work for government and private organizations, including pharmaceutical companies.
- Many thanks are due to the Sentinel Data Partners who provided data used in the analysis.

Background

Risk of venous thromboembolism (VTE) is high in the immediate postpartum period. Use of hormonal contraceptive (HC), either a combined hormonal contraceptive (CHC) or a progestin-only contraceptive (POC), is associated with an increased risk of VTE. Thus, postpartum women are generally advised not to start CHC earlier than 4 weeks postpartum if not breastfeeding. Recommendations for timing of initiating POC postpartum vary by products. Few studies have explored the timing of HC initiation in the postpartum period.

Objective

To describe the utilization patterns of HC initiation in the postpartum period among women in the U.S. FDA Sentinel System

Methods

Study design: Descriptive study

Data source: Administrative claims from 6 national health insurers in the U.S. (4 commercial health plans, Medicaid, and Medicare) contributing to the FDA's Sentinel Distributed Database

Study population: Women with a livebirth or stillbirth delivery who initiated at least one HC within the 12-month (52-week) postpartum period and with no history of previous deliveries within the past 12 months

Study period: January 2012 – January 2024

Study drugs

- CHCs: oral pills, transdermal system, and vaginal ring
- POCs: oral pills, intrauterine system (IUS), depot-medroxyprogesterone acetate (DMPA), and subcutaneous implant

Index date: The date of delivery (livebirth or stillbirth)

Methods: Describing the timing and type of HCs initiation within 12-month postpartum period

Results

- We identified 344,929 women who initiated CHC and 819,703 women who initiated POC in the 12-month postpartum period.
- The most initiated type of CHC was oral pills (83.8%), followed by vaginal ring (8.6%) and transdermal system (7.6%) [**Figure 1**].
  - Less then 2.5% of women started CHCs within 4 weeks postpartum.
  - CHC start peaked in week 7 (18.9%).
- The most initiated type of POC was oral pills (46.8%), followed by IUS (29.5%), implant (12.0%), and DMPA (11.7%) [**Figure 2**].
  - Approximately 6% of total POC users started during the first postpartum week, most commonly oral pills (79.0%) or an implant (10.7%). Thereafter, initiation fell below 3% through week 4. POC start peaked in week 7 (20.7%).
  - Initiation of IUS was less than 1% through week 4 and peaked in week 7 (17.4%).

Figure 1. Time to postpartum initiation of **CHC** among patients with livebirth or stillbirth delivery from 1/1/2012 to 1/31/2024

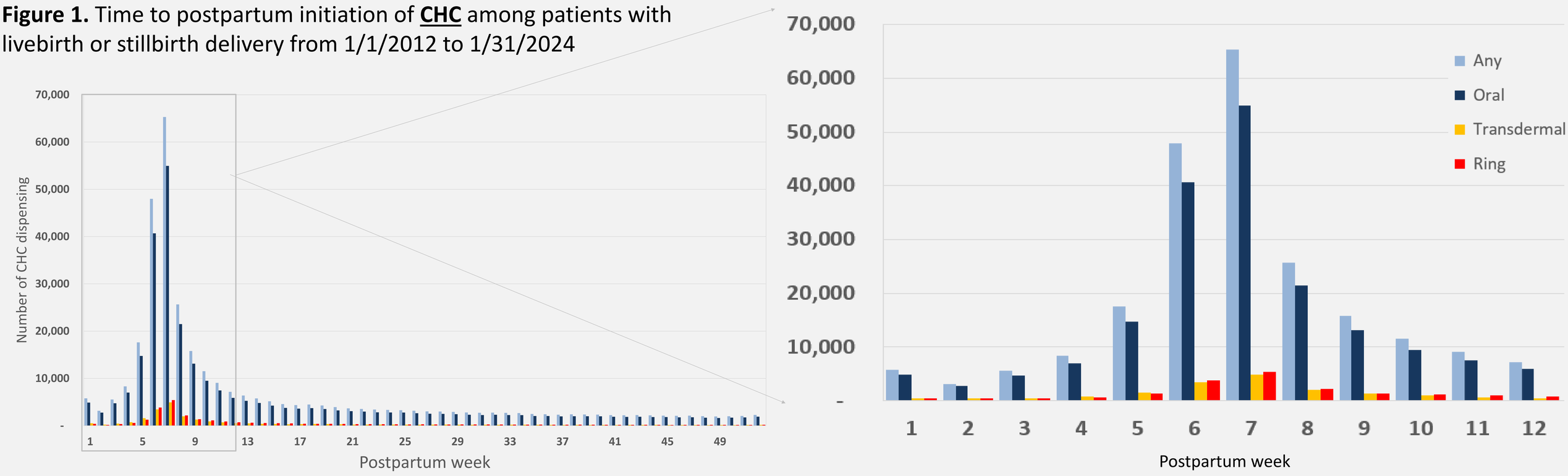
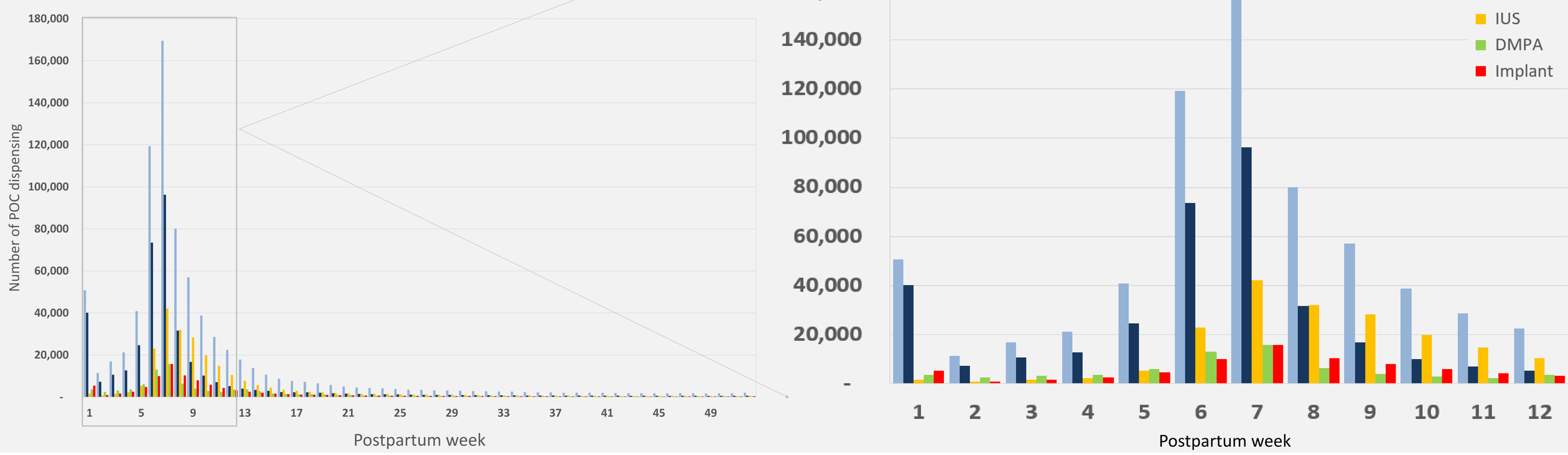


Figure 2. Time to postpartum initiation of **POC** among patients with livebirth or stillbirth delivery from 1/1/2012 to 1/31/2024



Conclusions

In this descriptive study, we observed the frequency of HC initiation within the first 4 weeks postpartum is generally low. However, by week 7, approximately 44% of women who used HC during 12-months postpartum period had started CHC and 53% had initiated POC. Further study is needed to characterize the risk of VTE in the immediate postpartum period (0-4 weeks) for specific type of HCs after birth in the U.S. population.