



# Characterizing Medication Use Patterns Among Pregnant and Non-Pregnant Patients with COVID-19 in the Sentinel System

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# Disclosures

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- The views expressed in this presentation represent those of the presenters and do not necessarily represent the official views of the U.S. FDA.

# Study Overview

CONSIGN (COVID-19 Infection and Medicines in Pregnancy), a European Medicines Agency (EMA)-funded, international collaboration across various countries

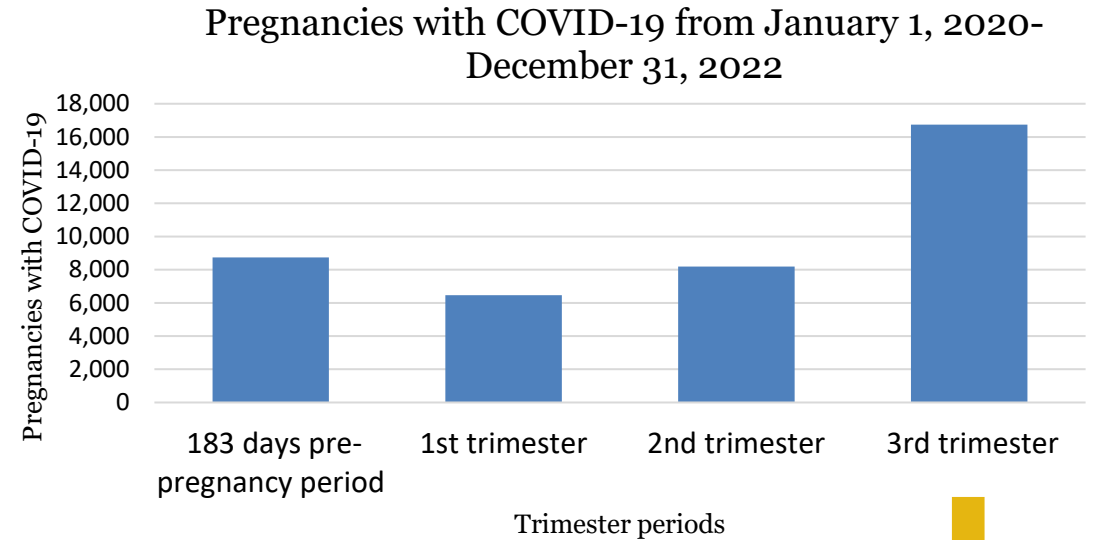
**Objectives:** To characterize COVID-19 severity and assess outpatient medication use patterns 30 days prior to and after COVID-19 diagnosis

## Study Population

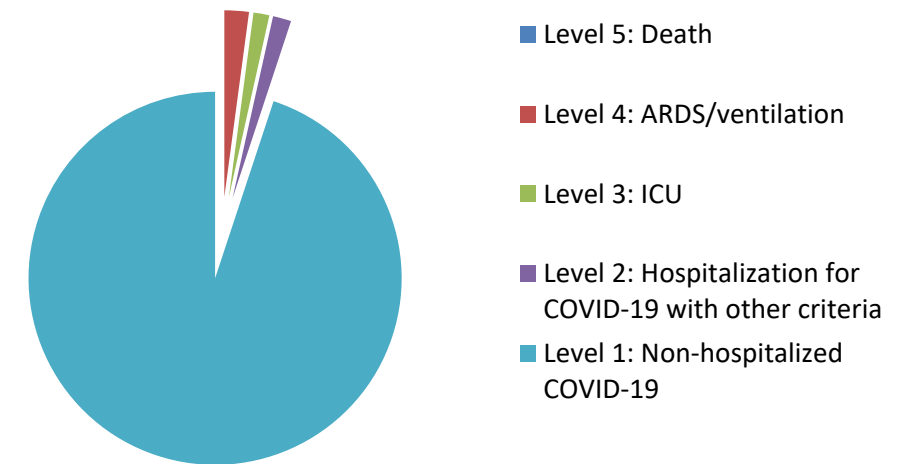
U.S. FDA's Sentinel System from January 2020-December 2022

Pregnant patients with COVID-19 by trimester, 6 months pre-pregnancy, and anytime during pregnancy

Non-pregnant patients with COVID-19 COVID-19 diagnosis date within +/-14 days of COVID-19 in matched pregnant patient

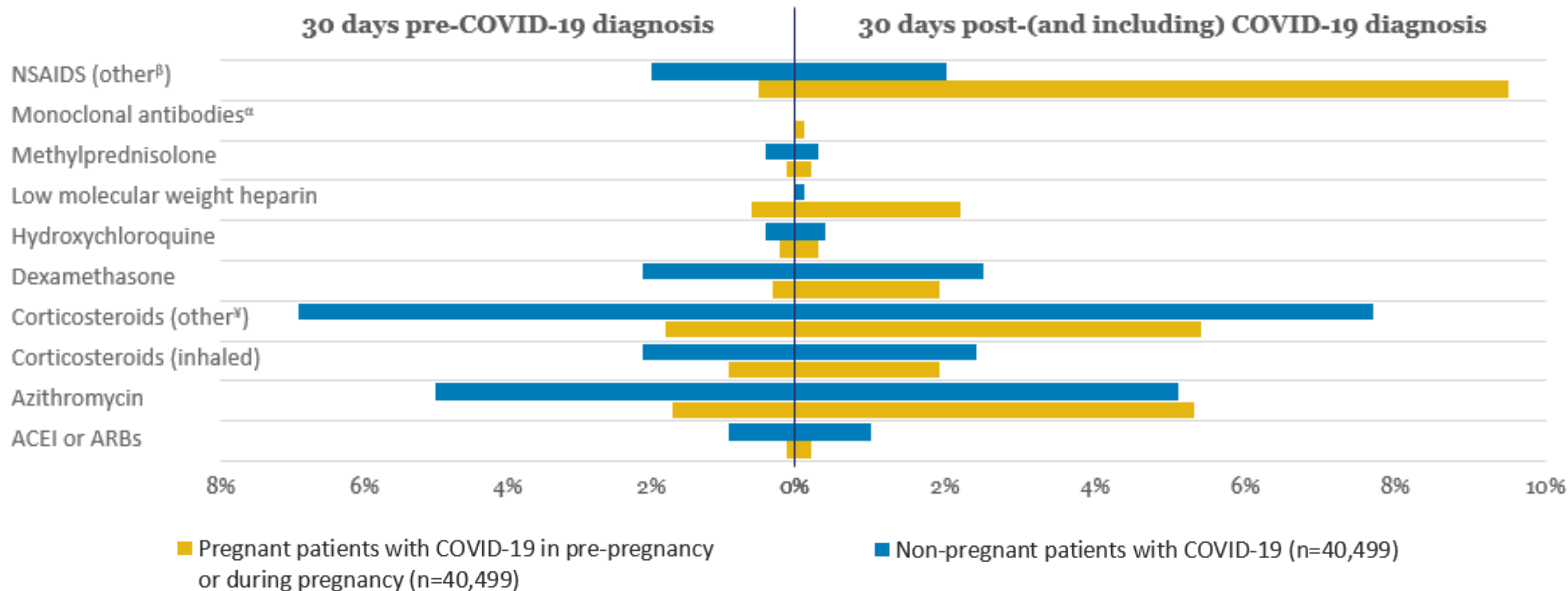


COVID-19 severity among pregnant patients with COVID-19 in 3rd trimester



# Study Results

Medication use patterns 30 days prior to and post COVID-19 among pregnant and non-pregnant\* patients with COVID-19



NSAID- Non-Steroidal Anti-inflammatory Drugs, ACEI- Angiotensin Converting Enzyme Inhibitors, ARB- Angiotensin Receptor Blockers

\*Non-pregnant patients included patients without live birth delivery that A) had COVID-19 within +/- 14 days of COVID-19 in the matched pregnant patient; B) had a birth date within +/- 365 days of the matched pregnant patient's birth date, and C) where pregnant duration overlapped the eligible enrollment spans.

<sup>γ</sup> Corticosteroid other included betamethasone, dexamethasone, beclomethasone, fludrocortisone, methylprednisolone, prednisolone, cortisone, hydrocortisone, and triamcinolone.

<sup>β</sup> NSAID other included diclofenac, etodolac, fenoprofen, flurbiprofen, ibuprofen, indomethacin, ketorolac, meclofenamante, mefenamic acid, nabumetone, naproxen sodium, oxaprozin, piroxicam, sulindac, and tolmetin

<sup>α</sup> Monoclonal antibodies assessed included bamlanivimab, casirivimab, etesevimab, imdevimab, sotrovimab, and bebtelovimab

Other COVID-19 medications including baricitinib, chloroquine, heparin, interferon-beta, interleukin 6 inhibitors, lopinavir/ritonavir, monoclonal antibody, prednisolone, and remdesivir were used in <1% of pregnant and non-pregnant patients with COVID-19