



Characterizing Medication Use Among Pregnancies 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.

Background

Background

- Pregnant/breastfeeding patients are excluded from most clinical trials, importantly from initial COVID-19 vaccine and treatment trials
- Medication and vaccine safety is routinely assessed through post-marketing observational studies and pregnancy registries
- Several retrospective observational studies have characterized pregnant patients with COVID-19 but data on real-world utilization of medications is limited

CONSIGN

Covid-19 infectiOn aNd medicineS In preGNancy

- European Medicines Agency (EMA)-funded, international collaboration across various countries to understand the natural history of COVID-19 in pregnant people
 - Goal: to provide adequate data on the impact of COVID-19 in pregnancy to guide decision-making about vaccine indications, vaccination policies, and treatment options for COVID-19 disease and associated complications
- U.S. FDA's Sentinel System is one of several international collaborators, including the United Kingdom, Norway, Denmark, Germany, Spain, Italy, France, and Sweden

Study Objectives

CONSIGN Objectives

Objective 1:
Medication use

By trimester
at time of
diagnosis

Objective 2:
COVID-19 severity and
clinical outcomes

By
trimester at
time of
diagnosis

1a: Pregnant patients with COVID-19

2a: Pregnant patients with COVID-19

1b: Pregnant patients without COVID-19

2b: Non-pregnant patients with COVID-
19

1c: Non-pregnant patients with COVID-
19

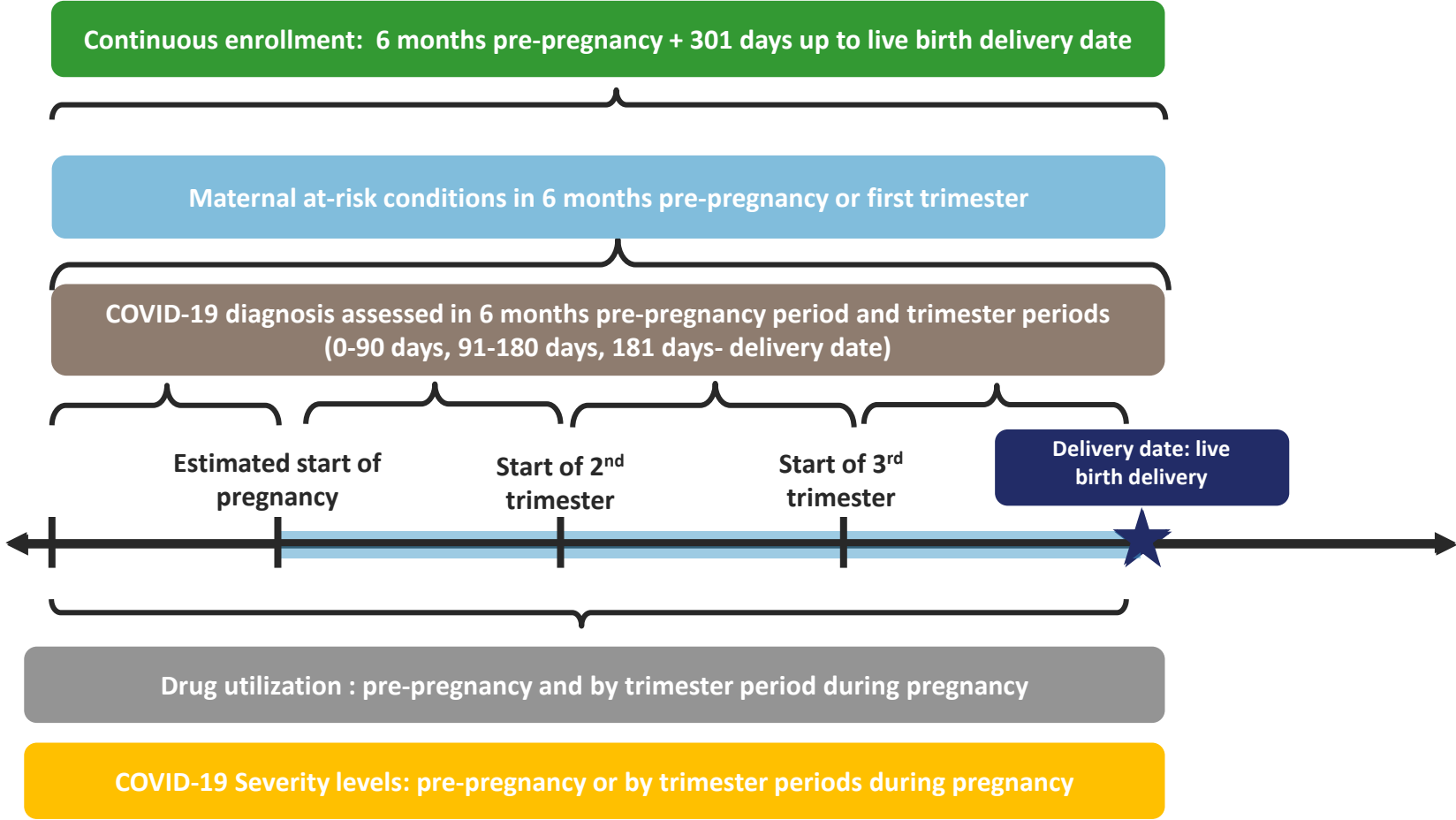
Study Cohort Identification

COVID-19 Identification

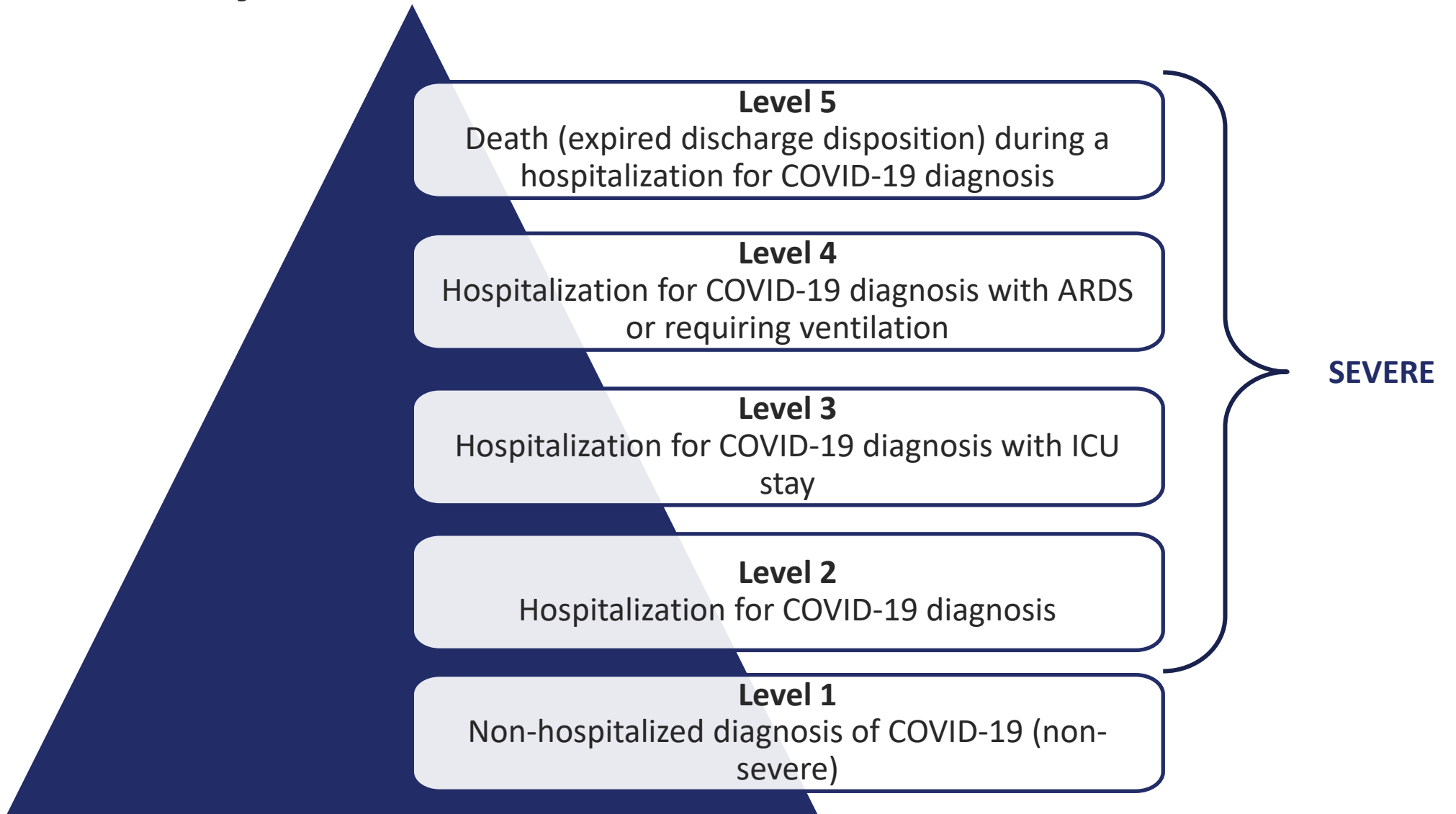
- COVID-19 related International Classification of Diseases (ICD)-10-Clinical Modification (CM) diagnosis codes,
OR
- Positive result of reverse transcription polymerase chain reaction (RT-PCR) or other Nucleic Acid Amplification Test (NAAT) for severe acute respiratory syndrome (SARS)-CoV-2

Exposure	Code	Code type	Care setting	Description
Diagnosis	B34.2	ICD-10-CM	Inpatient	Coronavirus infection, unspecified site
Diagnosis	B97.21	ICD-10-CM	Inpatient	SARS-associated coronavirus as the cause of diseases classified elsewhere
Diagnosis	B97.29	ICD-10-CM	Inpatient	Other coronavirus as the cause of diseases classified elsewhere
Diagnosis	J12.81	ICD-10-CM	Inpatient	Pneumonia due to SARS-associated coronavirus
Diagnosis	U07.1	ICD-10-CM	Any	COVID-19, virus identified

Study Design



COVID-19 Severity



Results

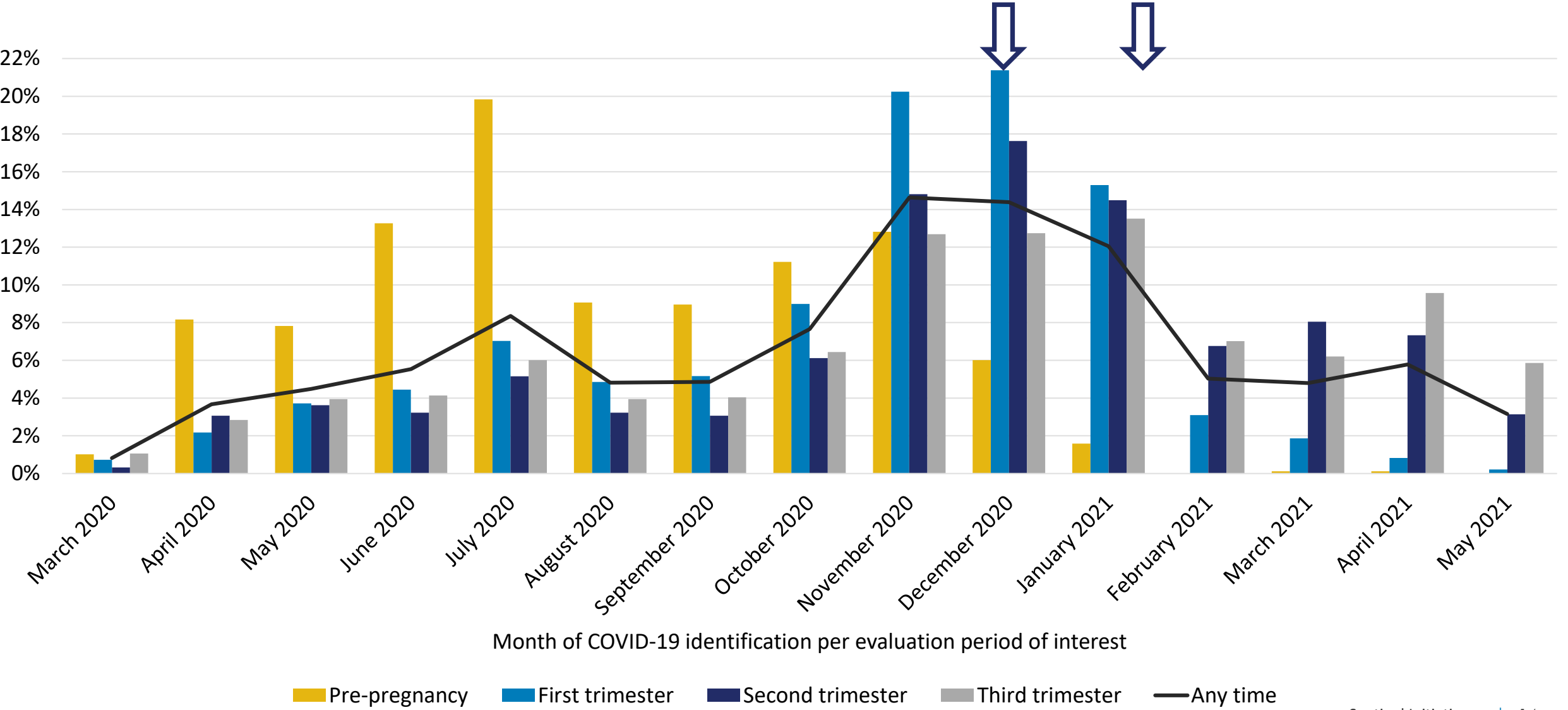
Study Cohorts in Sentinel between January 1, 2020 and May 31, 2021

	COVID-19 in 183 days pre-pregnancy	COVID-19 in first trimester	COVID-19 in second trimester	COVID-19 in third trimester	Total patients (pre-pregnancy or during pregnancy)
Pregnancies with COVID-19	143	270	664	1,942	2,747
Non-pregnant matched episodes ¹ with COVID-19	143	270	663	1,936	2,744

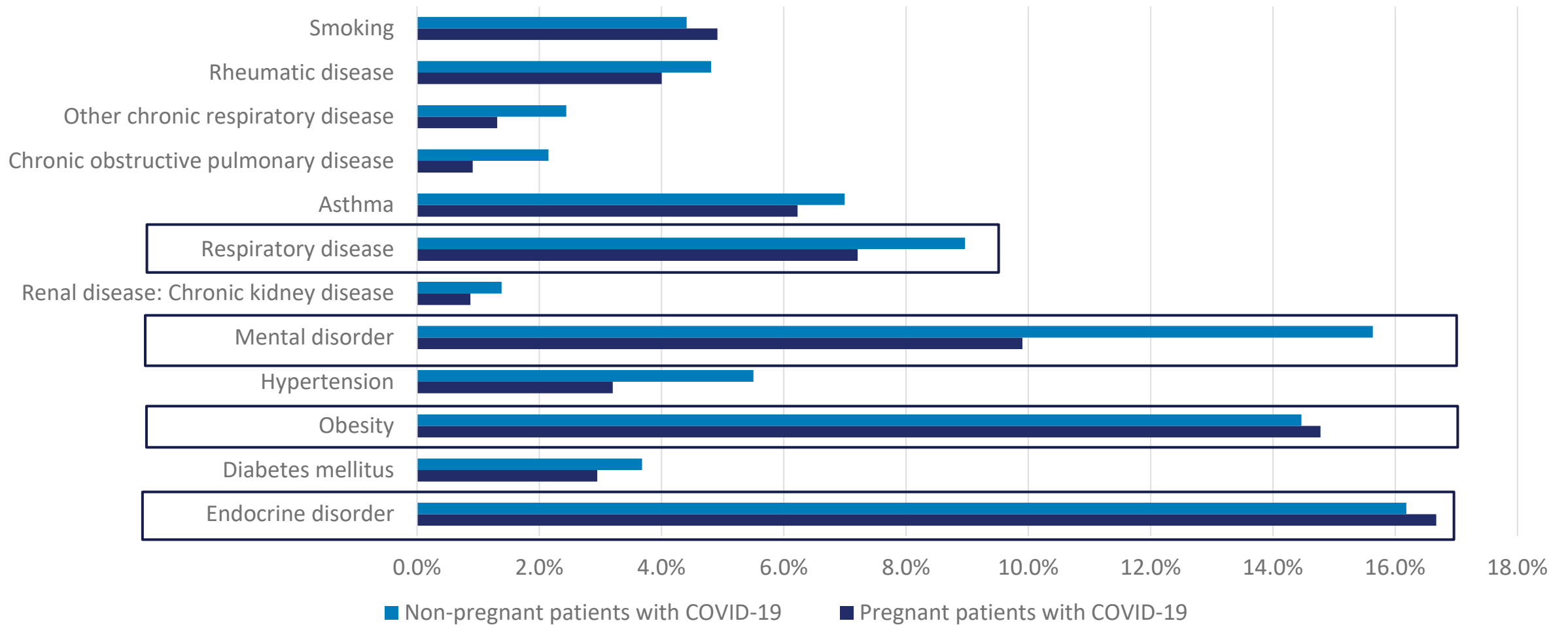
¹For each identified pregnancy, patients were matched within Data Partner who had first enrollment episodes without live birth delivery that met all inclusion criteria, were the same age (integer), and where the eligible enrollment spans overlapped the entire pregnancy duration and 183 days pre-pregnancy period. Patients and comparator episodes were allowed to be used multiple times as controls, and patients with a pregnancy episode were allowed to contribute a separate comparator episode.

*Query period end dates were selected based on inpatient (IP) data availability per DP. Please refer to final report for a list of dates of available data for each DP.

COVID-19 Identification in Pregnant Patients During the Pandemic

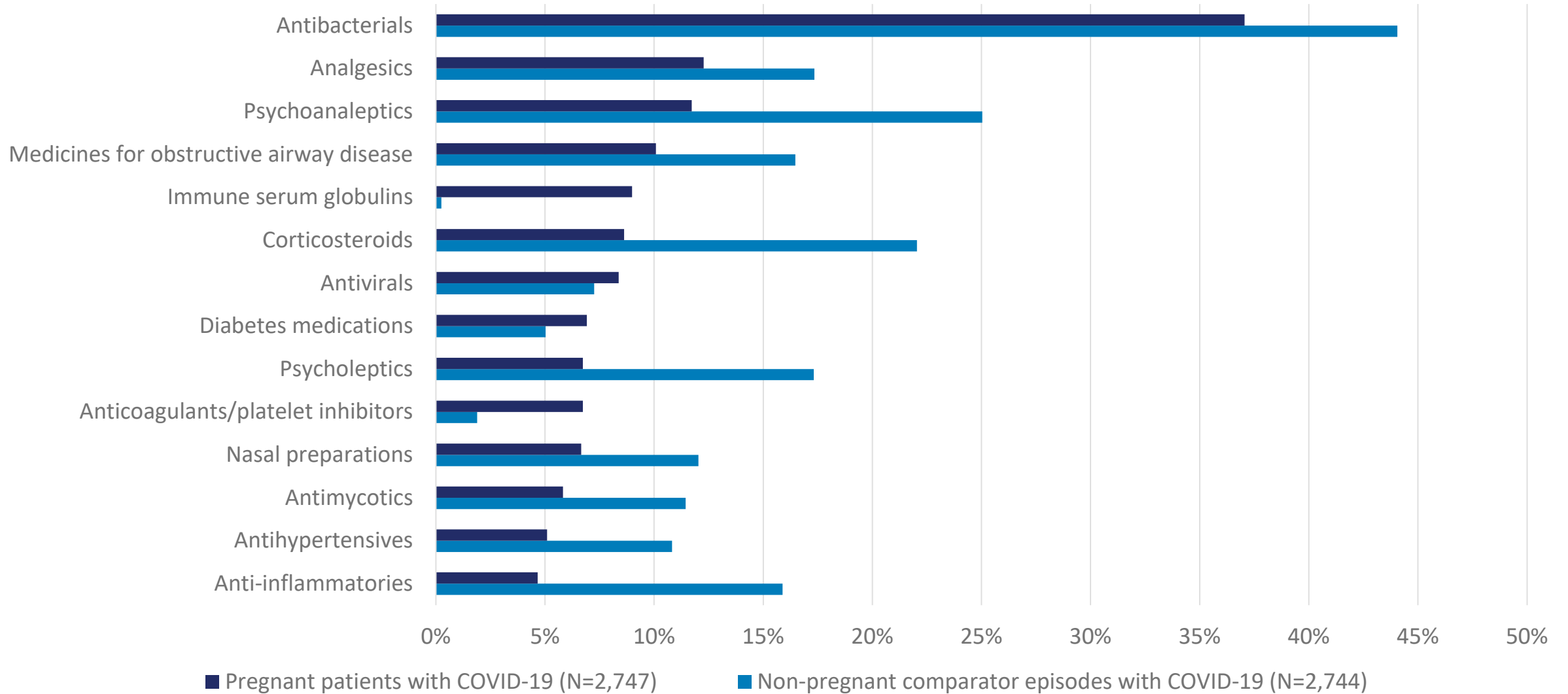


Baseline At-Risk Conditions



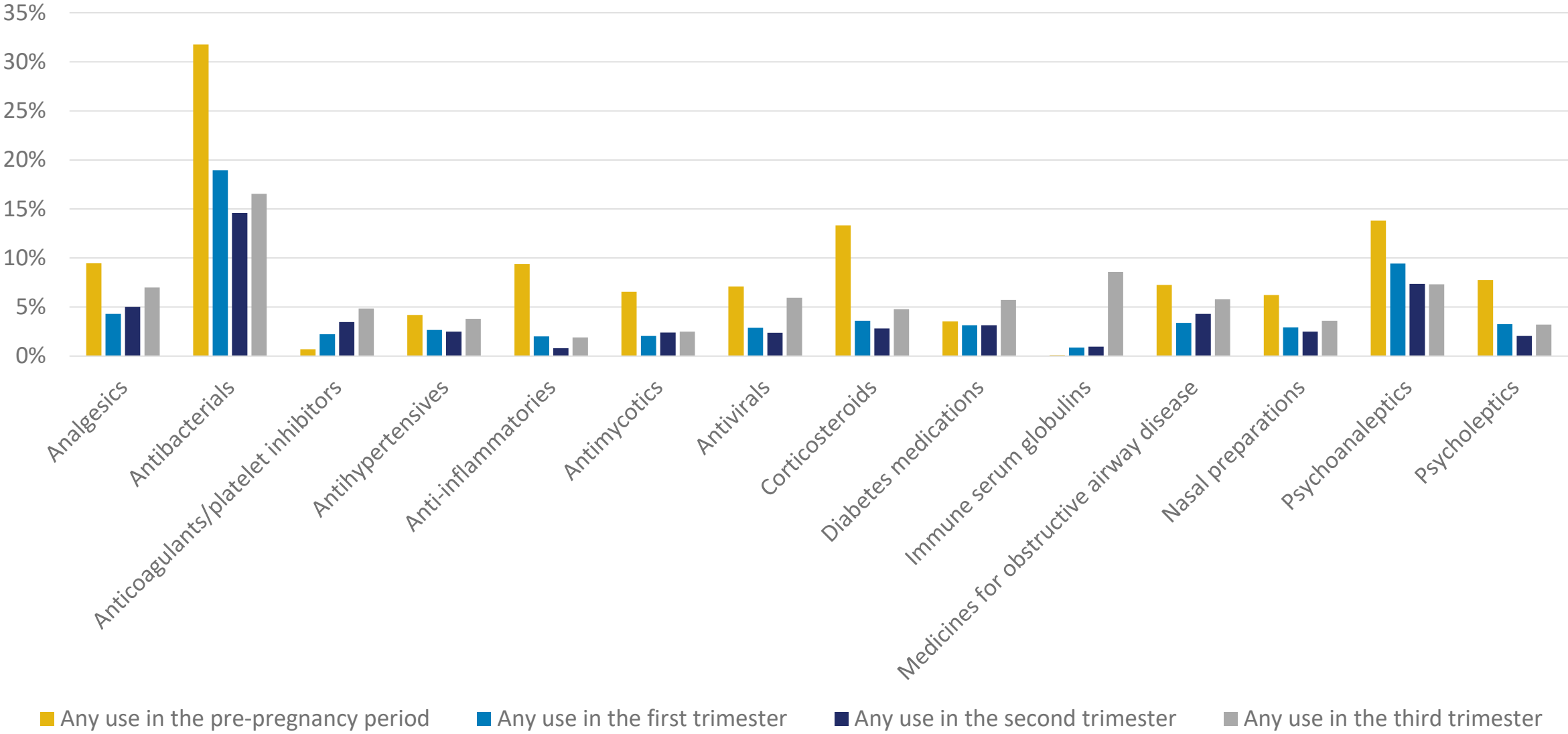
*At-risk conditions assessed in 6 months pre-pregnancy and first trimester of pregnancy in pregnant patients with COVID-19 and corresponding time periods in non-pregnant patients

Medication Use

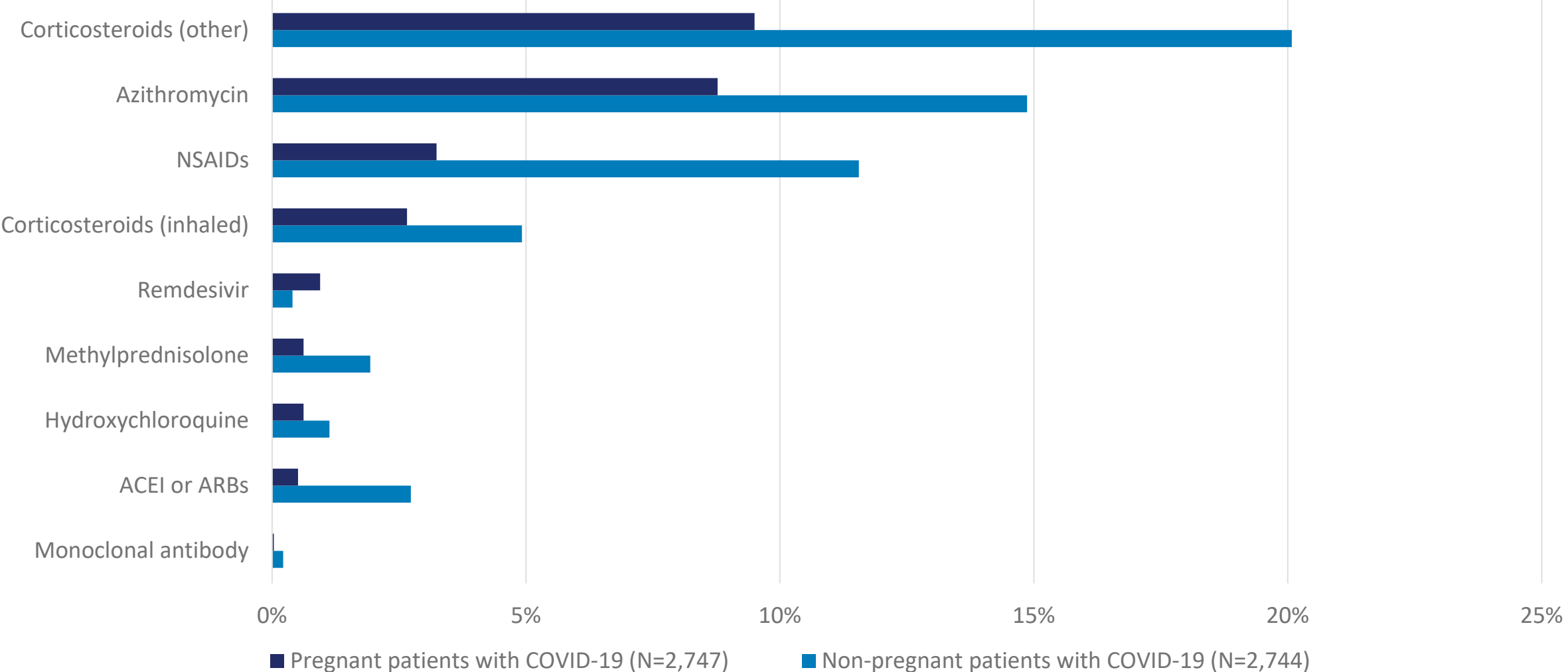


*Assessed pre-pregnancy or during pregnancy among pregnant patients with COVID-19 and corresponding time periods in non-pregnant patients with COVID-19

Medication Utilization by Trimester among Pregnant Patients with COVID-19

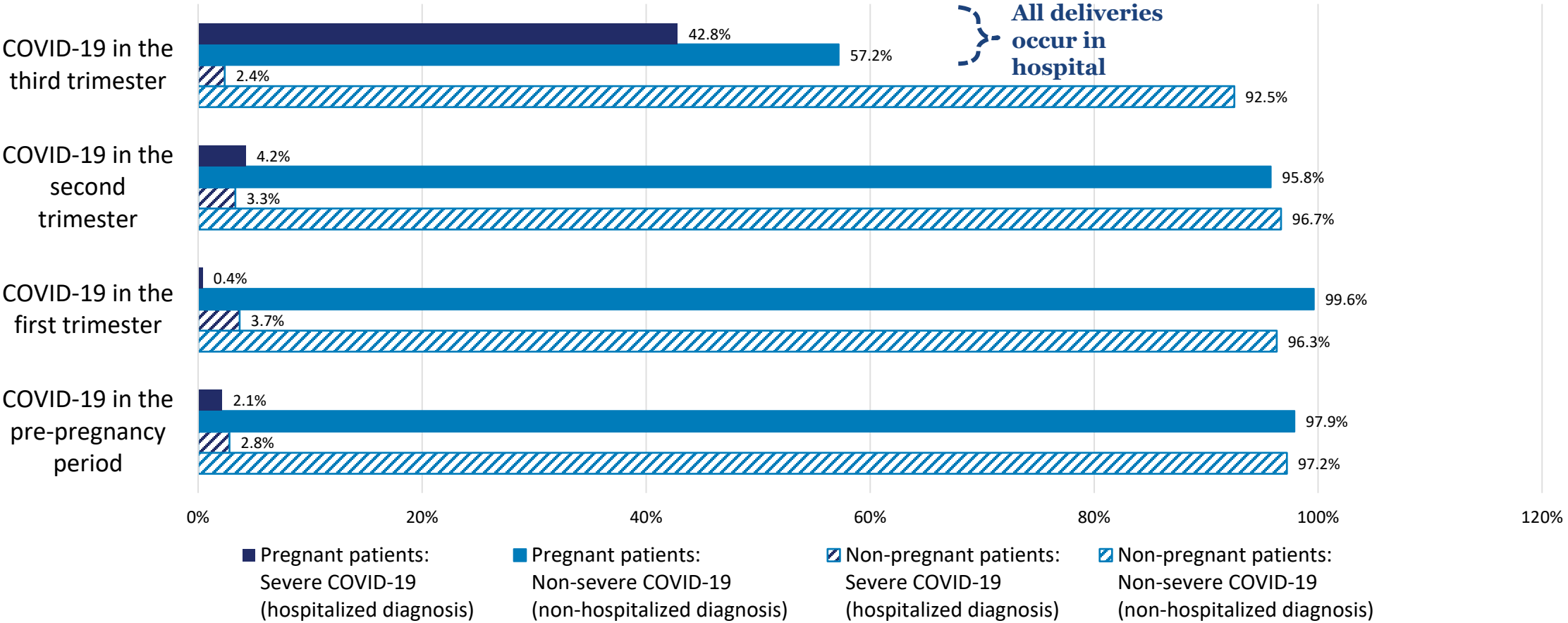


Potential COVID-19 Medications



*Assessed pre-pregnancy or during pregnancy among pregnant patients with COVID-19 and corresponding time periods in non-pregnant patients with COVID-19
 NSAID- Non-steroidal anti-inflammatory drug; ACEI- Angiotensin converting enzyme inhibitors; ARB- Angiotensin receptor blockers

COVID-19 Severity



Conclusions

Conclusions

- We characterized pregnant patients with COVID-19 and described patterns of outpatient medication use among pregnant and non-pregnant patients with COVID-19
 - Corticosteroids, azithromycin, and NSAIDs more commonly used in non-pregnant patients with COVID-19
- Findings from this analysis can be difficult to be interpret since:

Pregnancy

- Immune system changes over the course of pregnancy
- Tendency to stop medication use at beginning of pregnancy and restart after delivery

Pandemic

- Geographic differences in COVID-19 prevalence
- Temporal differences in COVID-19 prevalence

Treatment

- Changes in COVID-19 testing, treatment patterns, and best clinical practices
- Changes in healthcare-seeking behavior throughout the pandemic
- Vaccine uptake over time (could not assess)

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Questions

Supplemental Slides

Pregnancy Cohort Selection

