

Off-label Prescribing Practices

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What does “Off-label” Mean?

Off-label prescribing means using an FDA-approved medication in a way that is not specified in its official labeling.

Off-label prescribing does not mean experimental or inappropriate.

- Different condition
- Different dose
- Different route of administration
- Different patient group

25%

of all pediatric prescriptions are off-label

Pediatric hypertension treatment is affected because many recommended medications lack pediatric labeling.

FDA Pediatric Labeling Reality

When guideline recommendations and labeling often diverge

Pediatric HTN Guideline Recommendations

When to start medication

Persistent HTN despite lifestyle changes

Symptomatic HTN

Stage 2 HTN

HTN with CKD or Diabetes

Preferred Drug Classes

Thiazide diuretics

ACE inhibitors

ARBs

CCB - dihydropyridine

Pediatric HTN Guideline Medications

CCB

- Amlodipine 
- Felodipine
- Isradipine 
- Nifedipine ER/XL

ACE

- Benazepril 
- Captopril 
- Enalapril 
- Fosinopril
- Lisinopril 
- Quinapril 
- Ramipril

ARB

- Candesartan 
- Irbesartan 
- Losartan 
- Olmesartan 
- Valsartan 

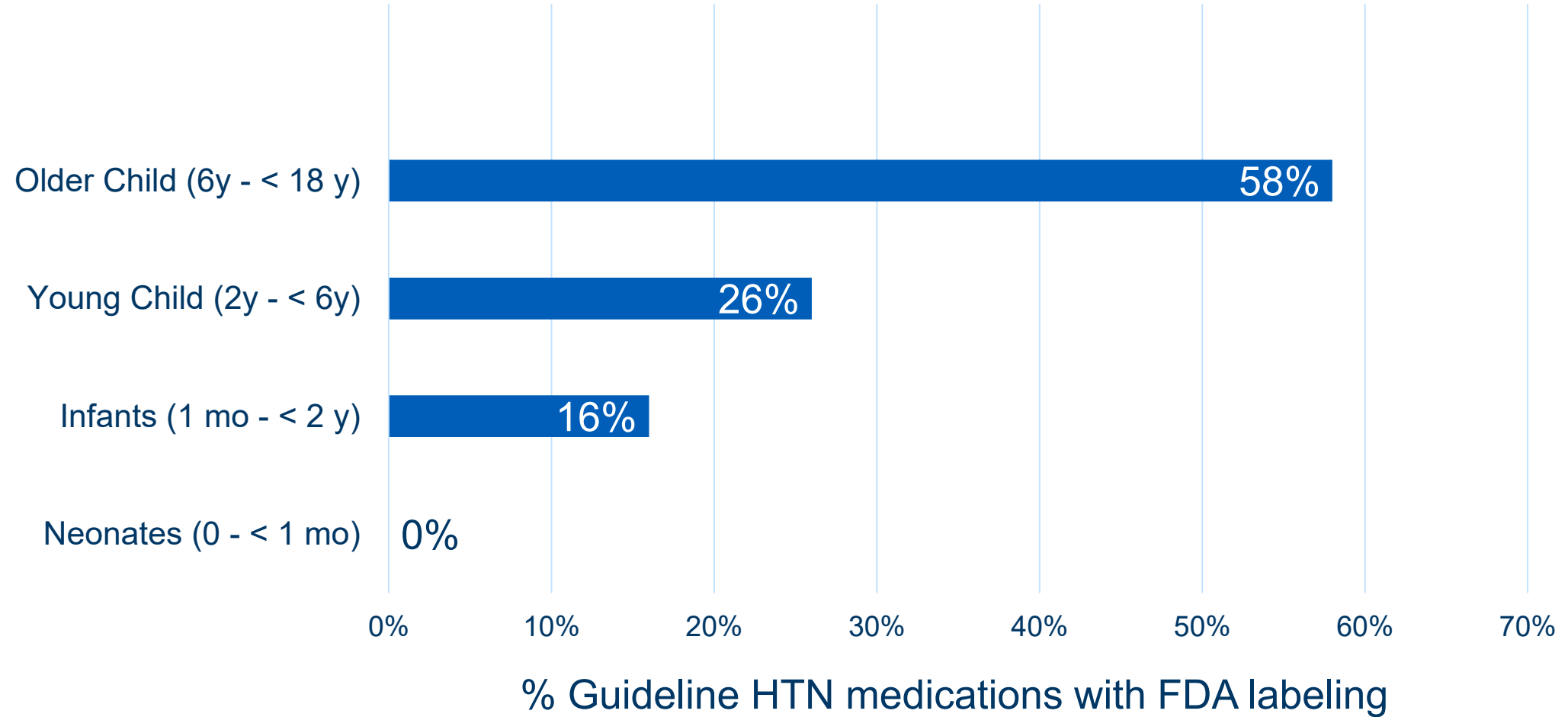
Thiazide

- Chlorothiazide 
- Chlorthalidone
- HCTZ 

 Commercially available oral suspension

 Pharmacy compound liquid

FDA Labeling Increases with Age, but Gaps Remain



Real-World Prescribing

How clinicians manage HTN despite labeling gaps

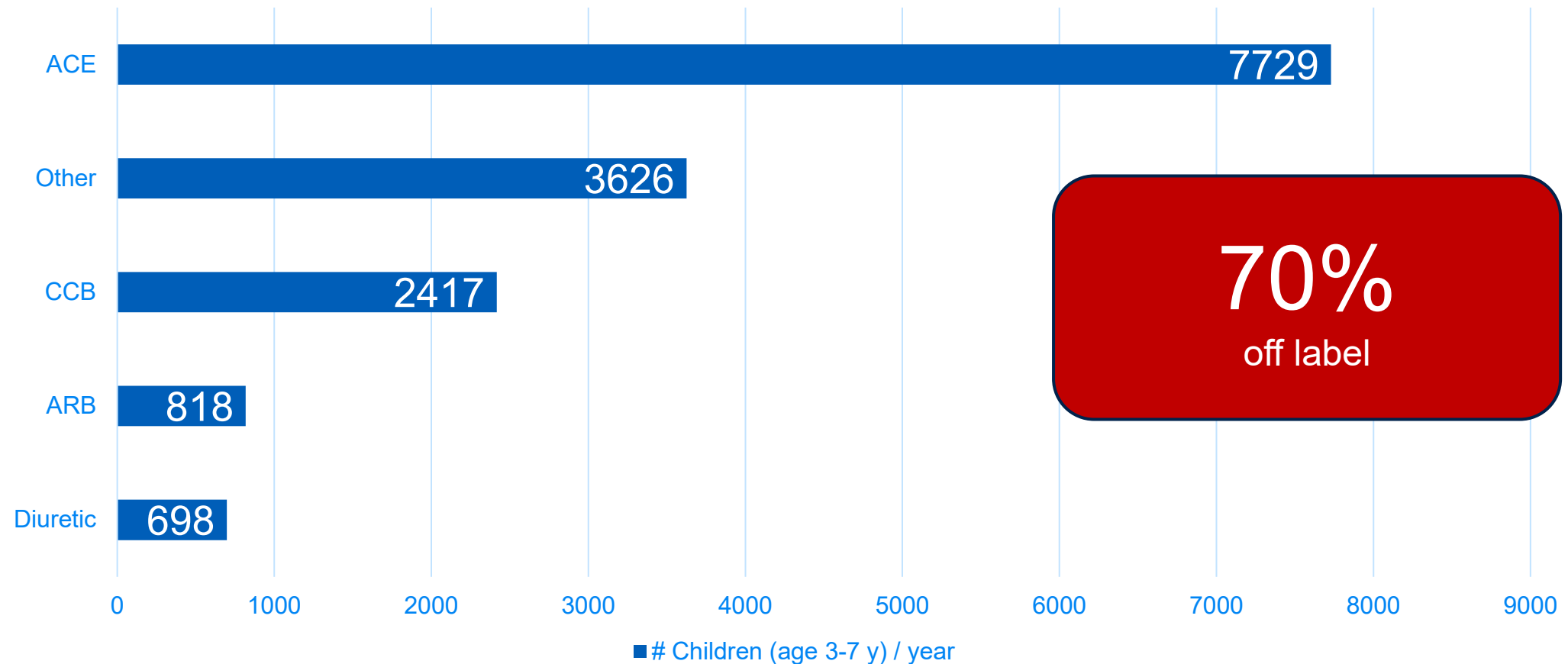
Pediatric HTN Rx Trends



- IQVIA Total Patient Tracker dataset
- U.S. outpatient retail prescription fills
- Captures ~ 94% of outpatient prescriptions
- HTN medication prescriptions for children
- Study period: 2017-2023

Trends in Pediatric Blood Pressure-lowering prescription fills during 2017-2023, AJPM Focus 2025;4(4):100356.)

Most Antihypertensive Use in Young Children Is Off-label



Neonatal HTN Meds

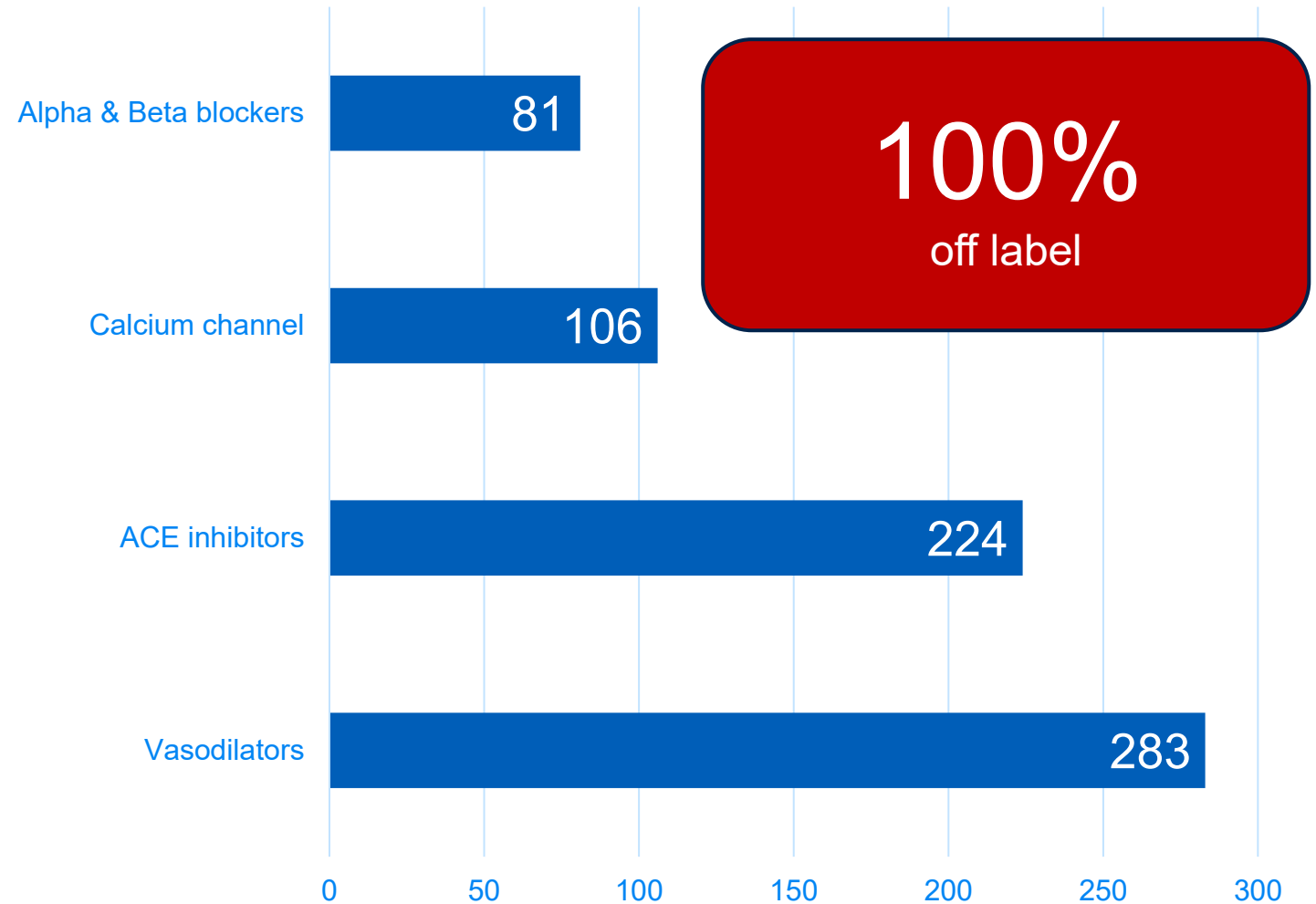


- Pediatric Health Information System (PHIS)
- Covers ~ 20% Children's hospitals
- HTN Drug Utilization NICU (2005-2009)

Incidence and Treatment of Hypertension in the Neonatal Care Unit. *Journal of the American Society of Hypertension* 5.6 (2011): 478-483.

NICU Hypertension Treatment Relies on Multiple Drug Classes

764 neonates
with a HTN diagnosis
(excludes congenital CVD)



Key Takeaways

- Off-label prescribing is common in pediatrics.
- Pediatric hypertension management is especially affected by labeling gaps.
- Guideline-recommended therapies often extend beyond FDA-approved age indications.
- Real-world prescribing shows broad clinical use despite limited labeling
- Off-label prescribing remains essential to pediatric hypertension care.

