PCORnet COVID-19 Common Data Model Design and Results

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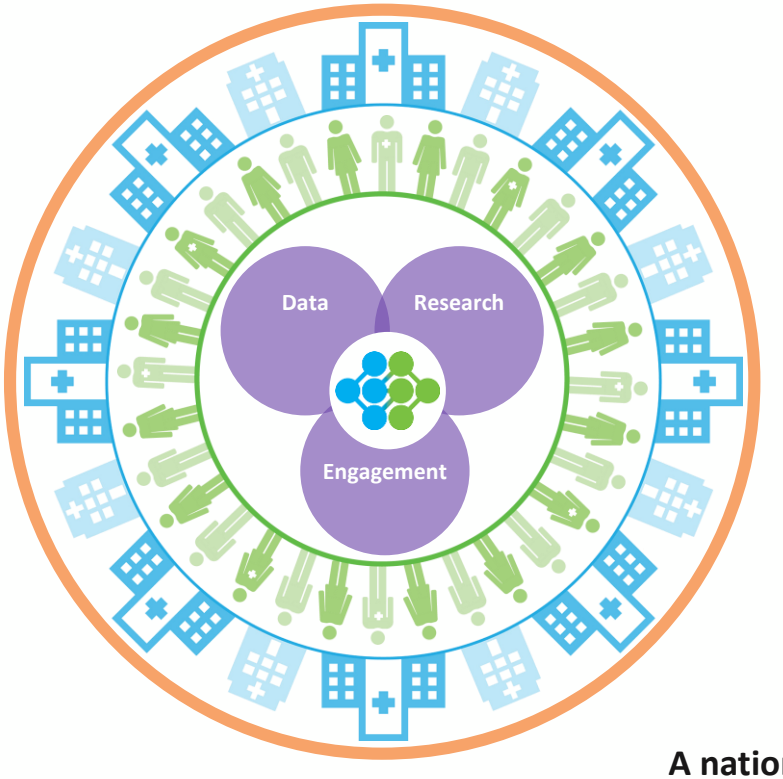
Agenda

Topic
PCORnet overview
PCORnet COVID-19 response: Subset Common Data Model
PCORnet COVID-19 response: Query development
Q/A

PCORnet is a "network of networks" that harnesses the power of partnerships



Clinical Research Networks (CRNs) + Health Plan Research Networks (HPRNs) + Patient Partners + Coordinating Center = A national infrastructure for people-centered clinical research

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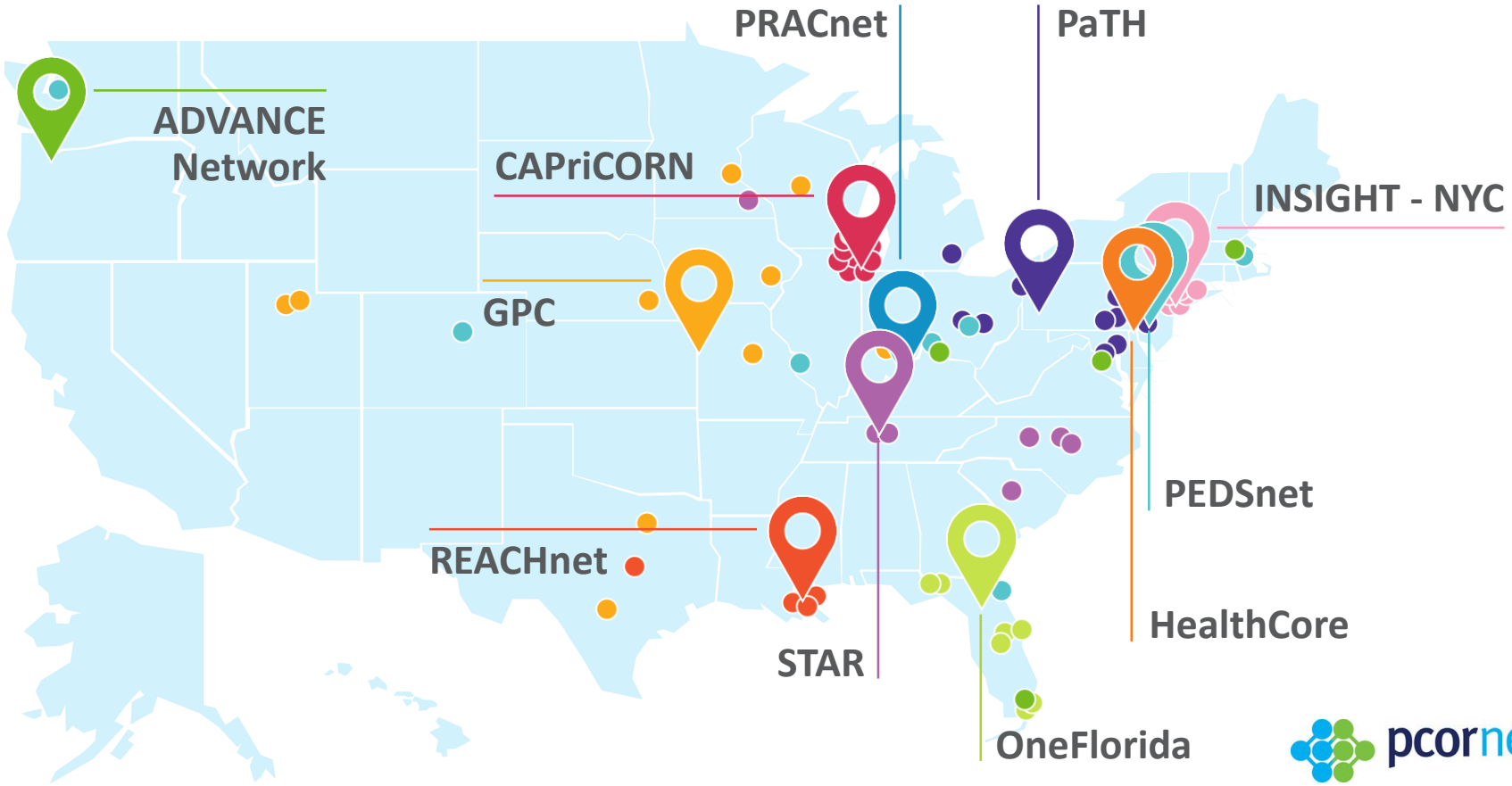
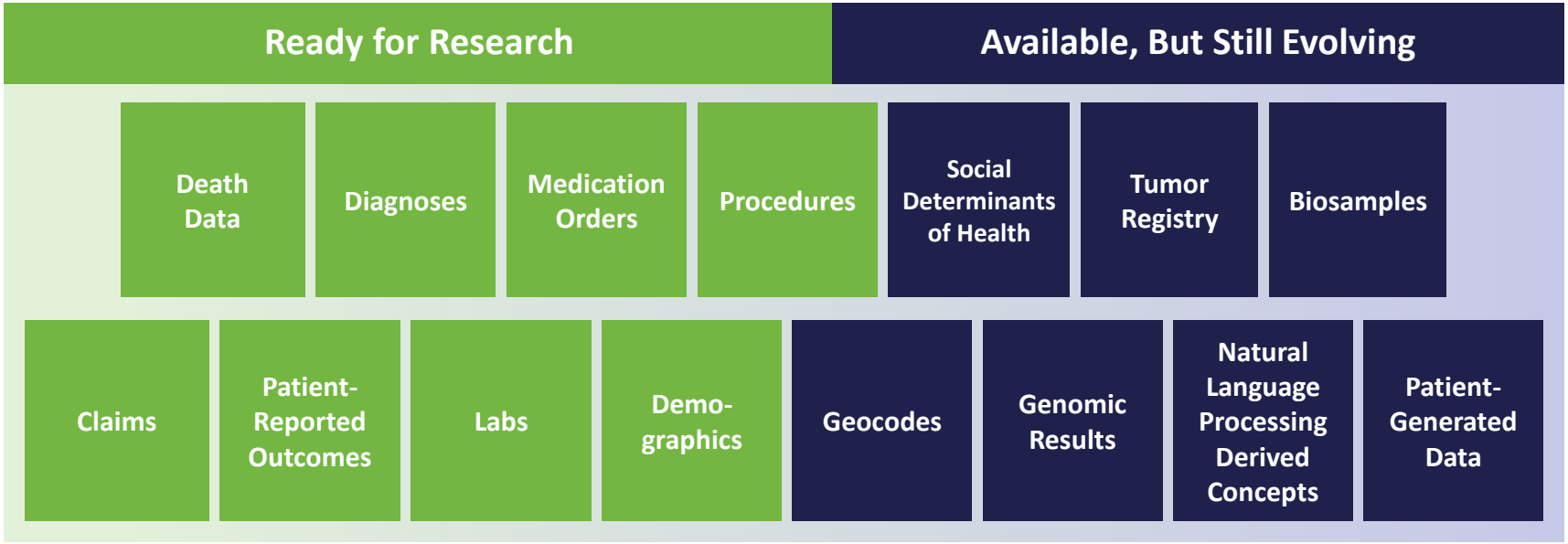
It starts with data

The PCORnet solution starts with real-world data. PCORnet-partnered CRNs and HPRNs can help users conduct research more efficiently. Users can access data from everyday medical encounters from more than 66 million people across the United States.



Next, the data must be usable

Lots of data is great, but for it to be useful it has to be standardized across systems. The PCORnet Common Data Model standardizes data into a single language, enabling fast insights, including:



Data available from several Clinical Research Networks, in the PCORnet Common Data Model and ready for use in research.

Data available at some Clinical Research Networks, may or may not be in the PCORnet Common Data Model and require additional work for use in research.

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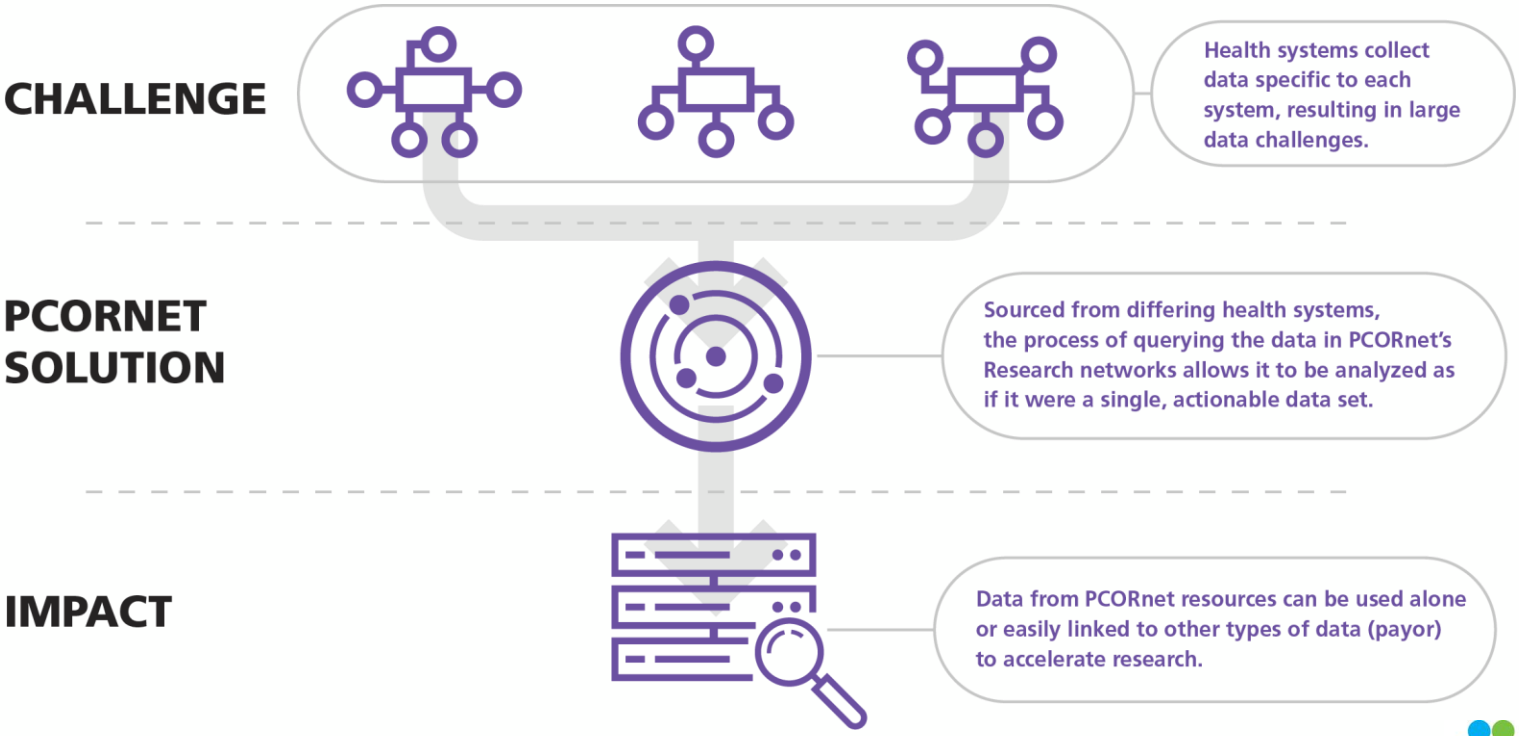
The Common Data Model

The Common Data Model, developed by PCORnet, is a key component of the Network's infrastructure and central to its work. PCORnet's Common Data Model standardizes millions of data points from a variety of clinical information systems into an innovative common format that can be used for specified research projects.



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Using the PCORnet & the CDM to support infectious disease surveillance & research

- All the **core data elements** needed to support COVID-19 research and surveillance have a home in the PCORnet CDM (partners may need to prioritize loading them, however)
- Current expectations within PCORnet are that partners **refresh their CDM every quarter** and run a comprehensive data quality assessment
  - Refresh dates – January, April, July, October
  - Once refresh and quality assessments are complete, data are ~1-3 months old
- Question: Can PCORnet partners stand up a version of the CDM with more up-to-date information to allow for a **more rapid characterization** of the PCORnet COVID-19 population?

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PCORnet COVID-19 response

- **Goal**: To characterize the cohort of COVID-19 patients and provide detailed information on demographics and pre-existing conditions.
  - Short-term: Quickly initiate a COVID-19 tracking system to report on basic information.
  - Medium-to-long-term: Track COVID-19 patients across the disease course.
- Create a **rapidly refreshed stand-alone version of the CDM** that includes coronavirus patients plus other patients with respiratory illnesses since January 2020.
- Create a **query that will be reissued weekly**, so sites will have an opportunity to join effort once they are ready ("wave" approach).
- Establish a network-wide **COVID-19 Workgroup** to advise on CDM and query development, research use, and dissemination

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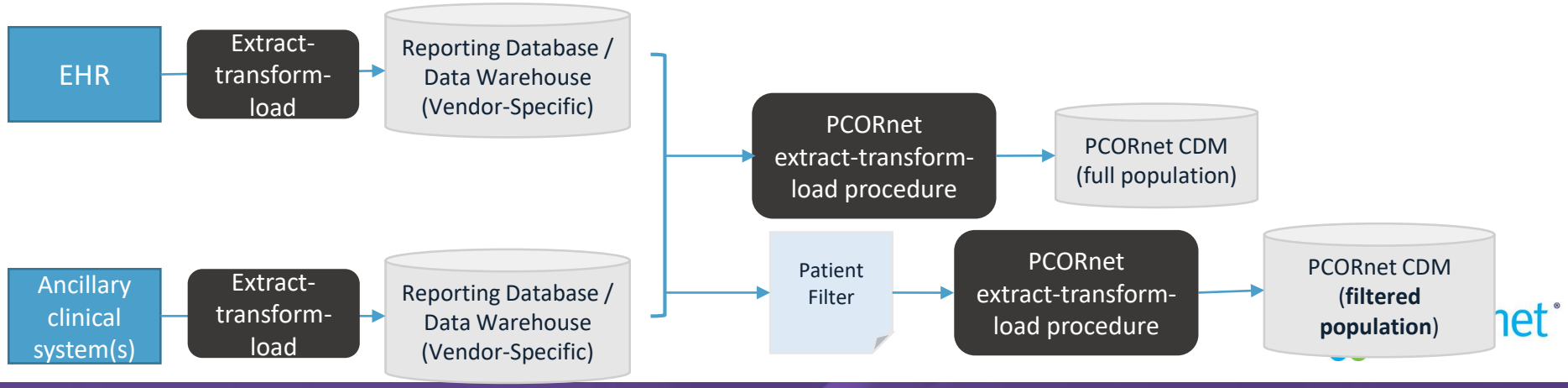
Strategy: subset-CDM for more up-to-date results

- Volume of data at some partners prevents a rapid refresh of the full CDM population, so the network was presented with several options on how to filter (if needed):
  - All patients with a visit in 2020
  - Patients with diagnoses for COVID-19, influenza and related complications (e.g., pneumonia, respiratory distress, etc.)
- Structure of the PCORnet CDM remains the same to allow the use of the analytical tools & quality assessment packages



Data elements to include in the CDM (grouped by priority)

- COVID-19+ indicator (Y/N flag)
- SARS-CoV-2 test results (antigen & antibody)
- Remdesivir use (order / administration)
- Admission to ICU (Y/N flag)
- Use of mechanical ventilation (Y/N flag)
- Other less-common labs relevant for COVID-19-related research (e.g., D-dimer, procalcitonin, ferritin, high sensitivity C-reactive protein)

- Selected inpatient vitals (respiratory rate, heart rate, temperature, O2 saturation, fraction of inspired oxygen)
- Peripheral oxygen saturation (SpO2)/fraction of inspired oxygen (FiO2) [ratio]
- Chief complaint (from Emergency Department visits)

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Guidance to facilitate loading of new data elements

COVID-19 CDM Data Elements

Document change history:

Date	Description
5/4/2020	For COVID-19-affected flag Implementation Guidance, changed CONDITION_CODE to CONDITION.
5/8/2020	Fixed copy-paste error in mechanical ventilation guidance.
5/11/2020	Updated general guidance on populating derived fields; Added remdesivir as a data element.
5/27/2020	Updated guidance for the COVID-19 flag. Updated guidance for remdesivir. Added link to codes for mechanical ventilation. Added color coding for most recent changes.

Note: The following data elements are listed in priority order. If it is not possible to add all elements by the initial curation cycle, please use this ranking to guide your efforts. However, if you are stalled waiting for data to become available, it is permissible to skip and element and move on one further down the list. Load these elements into the COVID-19 CDM first, with a plan to add to the full population CDM in time for the July and October 2020 Data Curation cycles.

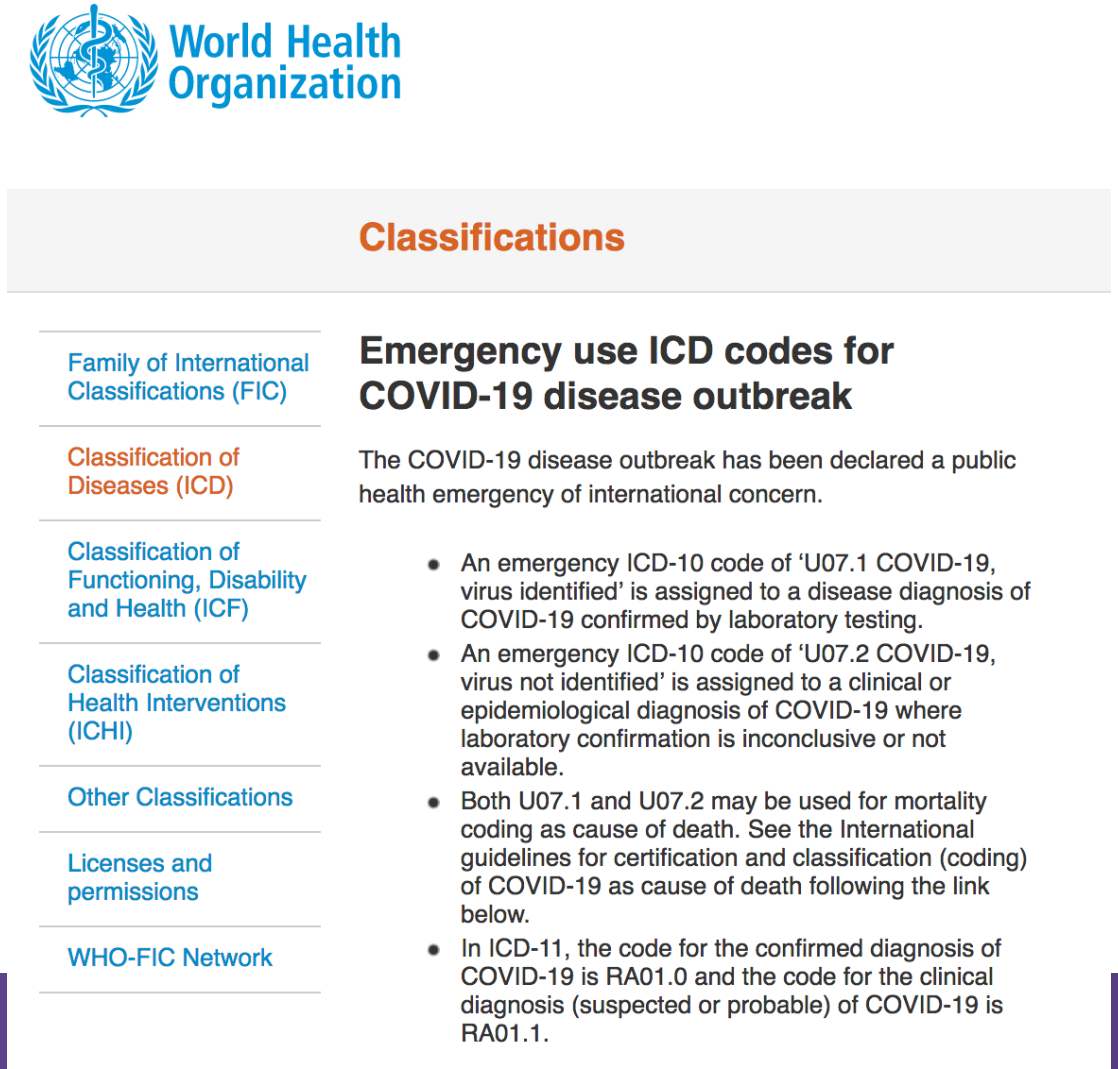
For the elements that require derivation based on multiple fields in the EHR (e.g., ICU admission, mechanical ventilation), the preference is to have more elements at "good enough" coverage than a single element at 100%. Sites are encouraged to consider an iterative approach to populating these data (e.g., 1st version of ventilator usage relies on procedure codes only; future versions leverage inpatient flowsheets)

Data element	CDM Table	Implementation Guidance
Flag to indicate patient is COVID-19-affected (e.g., positive, resolved disease)	CONDITION	• If institution has a dashboard of COVID-19-affected patients (e.g., patients with active and/or resolved disease), a flag record should be created for each one. • Expected to include all patients with a positive SARS-CoV-2 antigen test. May not necessarily include all patients who have a recorded COVID-19 diagnosis code at a given institution (e.g., U07.1) if that code is also used for patients under investigation. Do not include patients who only have a positive SARS-CoV-2 antibody test result. Additional guidance is forthcoming on how to handle those patients. • Use CONDITION_TYPE="AG" and CONDITION = "COVID" • Set CONDITION_SOURCE="PC"

Data standards in a pandemic – It's not exactly like this…

https://xkcd.com/2029/

…but it's been close



World Health Organization

Classifications

- Family of International Classifications (FIC)
- Classification of Diseases (ICD)
- Classification of Functioning, Disability and Health (ICF)
- Classification of Health Interventions (ICHI)
- Other Classifications
- Licenses and permissions
- WHO-FIC Network

Emergency use ICD codes for COVID-19 disease outbreak

The COVID-19 disease outbreak has been declared a public health emergency of international concern.

- An emergency ICD-10 code of 'U07.1 COVID-19, virus identified' is assigned to a disease diagnosis of COVID-19 confirmed by laboratory testing.
- An emergency ICD-10 code of 'U07.2 COVID-19, virus not identified' is assigned to a clinical or epidemiological diagnosis of COVID-19 where laboratory confirmation is inconclusive or not available.
- Both U07.1 and U07.2 may be used for mortality coding as cause of death. See the International guidelines for certification and classification (coding) of COVID-19 as cause of death following the link below.
- In ICD-11, the code for the confirmed diagnosis of COVID-19 is RA01.0 and the code for the clinical diagnosis (suspected or probable) of COVID-19 is RA01.1.

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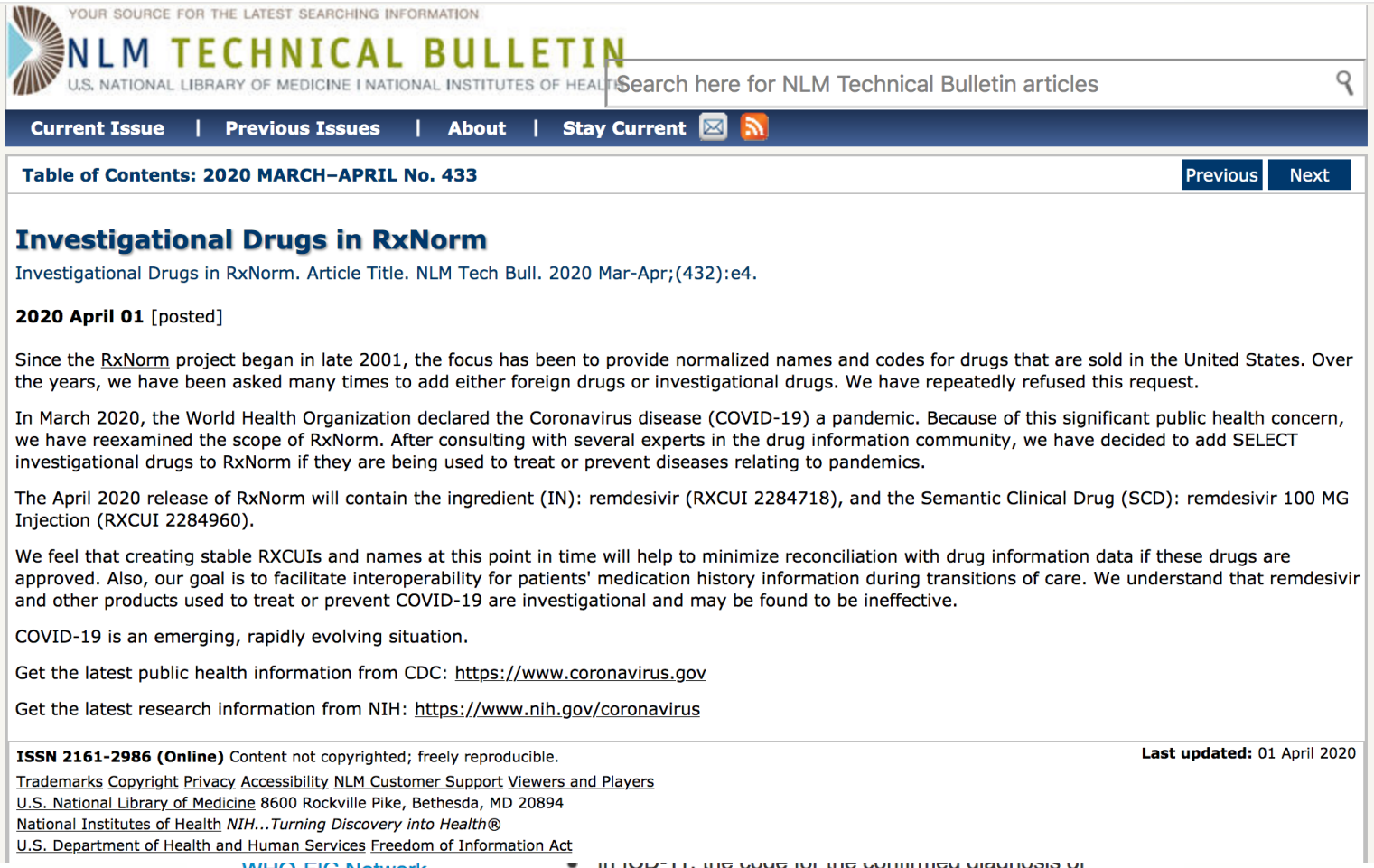

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Investigational Drugs in RxNorm

Investigational Drugs in RxNorm. Article Title. NLM Tech Bull. 2020 Mar-Apr;(432):e4.

2020 April 01 [posted]

Since the RxNorm project began in late 2001, the focus has been to provide normalized names and codes for drugs that are sold in the United States. Over the years, we have been asked many times to add either foreign drugs or investigational drugs. We have repeatedly refused this request.

In March 2020, the World Health Organization declared the Coronavirus disease (COVID-19) a pandemic. Because of this significant public health concern, we have reexamined the scope of RxNorm. After consulting with several experts in the drug information community, we have decided to add SELECT investigational drugs to RxNorm if they are being used to treat or prevent diseases relating to pandemics.

The April 2020 release of RxNorm will contain the ingredient (IN): remdesivir (RXCUI 2284718), and the Semantic Clinical Drug (SCD): remdesivir 100 MG Injection (RXCUI 2284960).

We feel that creating stable RXCUIs and names at this point in time will help to minimize reconciliation with drug information data if these drugs are approved. Also, our goal is to facilitate interoperability for patients' medication history information during transitions of care. We understand that remdesivir and other products used to treat or prevent COVID-19 are investigational and may be found to be ineffective.

COVID-19 is an emerging, rapidly evolving situation.

Get the latest public health information from CDC: https://www.coronavirus.gov

Get the latest research information from NIH: https://www.nih.gov/coronavirus

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WHO-FIC Network

COVID-19 is RA01.0 and the code for the clinical diagnosis (suspected or probable) of COVID-19 is RA01.1.

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…but it's been close

LOINC Prerelease Terms

DISCLAIMER

These codes are currently under development by the LOINC team, and are subject to change prior to inclusion in a public release. It is possible that they may not be published in the next, or any, public release. They are provided here for *informational purposes only*.

1,073
NEW LOINC CODES
LAST UPDATED
2020-05-22

SPECIAL USE

Special Use codes are developed in response to an urgent or emergent situation. These codes are based on the most up to date information available at the time of their creation. They have undergone the normal QA terminology process. LOINC supports their use in the unique situation that resulted in their rapid creation. However, be aware that downstream users may not be ready to handle prerelease codes until they are published in an official release.

Guidance for mapping to SARS-CoV-2 LOINC terms

Full list of LOINCs related to SARS-CoV-2/COVID-19
The page linked above includes an option to export terms in CSV format.

Receive email notices of new Special Use LOINC terms

scroll/swipe to view more columns →

Created On	LOINC	Long Common Name	Special Use	Component	Prop	Time	System	Scale
2020-05-21	95354-7	Transfuse convalescent plasma [Volume]	⚠	Transfuse convalescent plasma	Vol	Pt	^Patient	Qn
2020-05-21	95355-4	Convalescent plasma given [Volume]	⚠	Convalescent plasma given	Vol	Pt	^Patient	Qn
2020-05-20	95209-3	SARS coronavirus+SARS coronavirus 2 Ag [Presence] in Respiratory specimen by Rapid immunoassay	⚠	SARS coronavirus+SARS coronavirus 2 Ag	PrThr	Pt	Respiratory	Ord

Identifying COVID-19 patients

- Diagnosis codes (ICD-10):
  - **B34.2** – Coronavirus, unspecified site
  - **B97.29** – Other coronavirus as the cause of diseases classified elsewhere
  - **U07.1** – 2019-nCoV acute respiratory disease – emergency ICD-10 effective April 1, 2020
- Laboratory result (LOINC) – FAQ: https://loinc.org/sars-coronavirus-2/
  - Informed by feedback from sites and site mapping when only internal codes

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Query History

- March 27/April 15 – testing and initial queries, **up to 28 sites**
- April 22/29 – Diagnostic codes only for case definition, COVID labs assessed – **12,419 COVID patients, 36 sites**
- May 7 – Lab-test based case definition added – **29,268 COVID Dx, 21,085 COVID + PCR, 38 sites**
- May 13 – Lab-based cohort separated by care setting, Kawasaki's/toxic shock – **24,516 COVID Dx, 26,774 COVID + PCR, 37 sites**
- May 20 – Separation of children and adults, added ethnicity
- June 10 – Refinement of care setting; separate ED from inpatient

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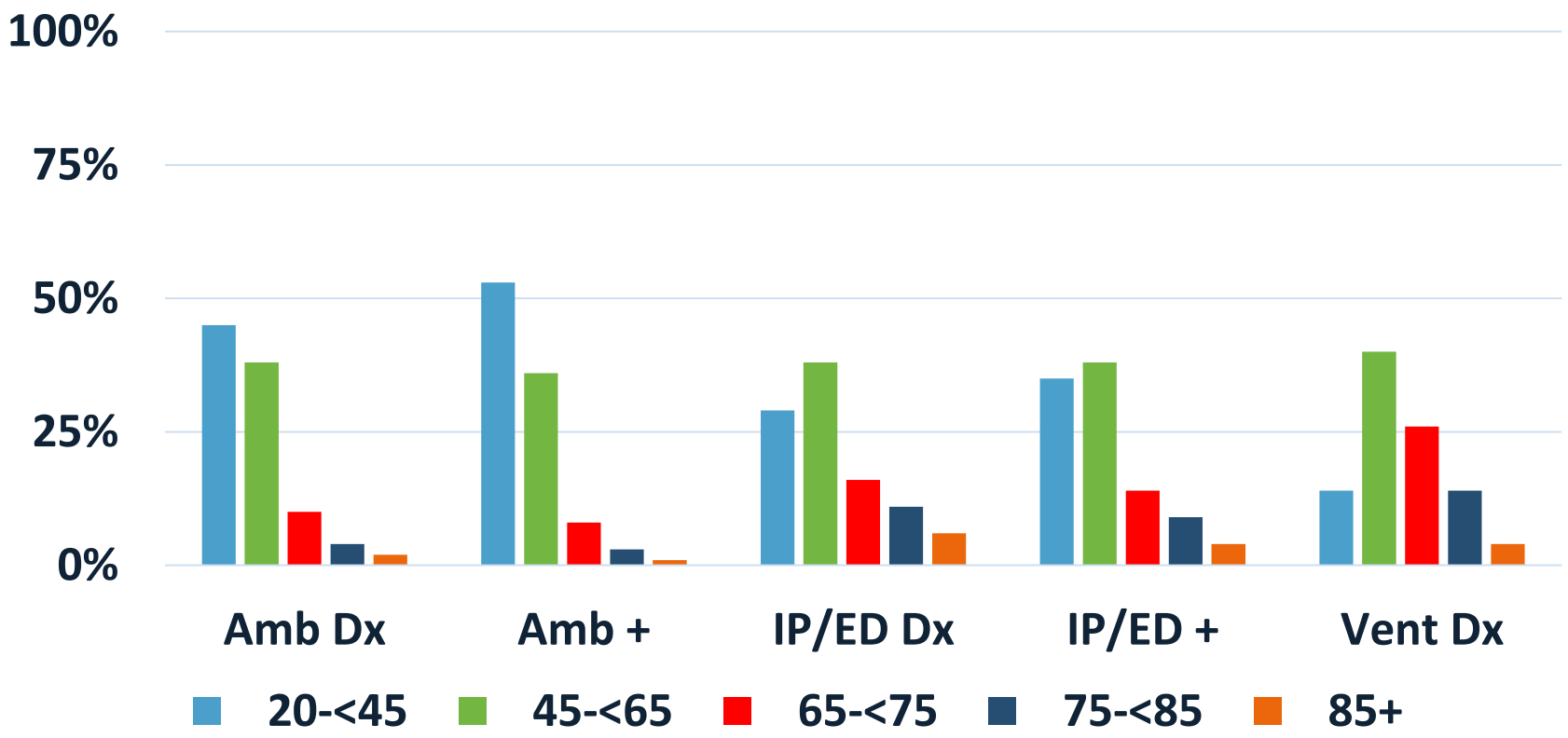
Issues that we worked through

- Evolution of case definition
- Lab data
  - Presence/absence of lab test data
  - Concordance of diagnosed/lab confirmed cases
- Adults/children
- Query logic on care setting

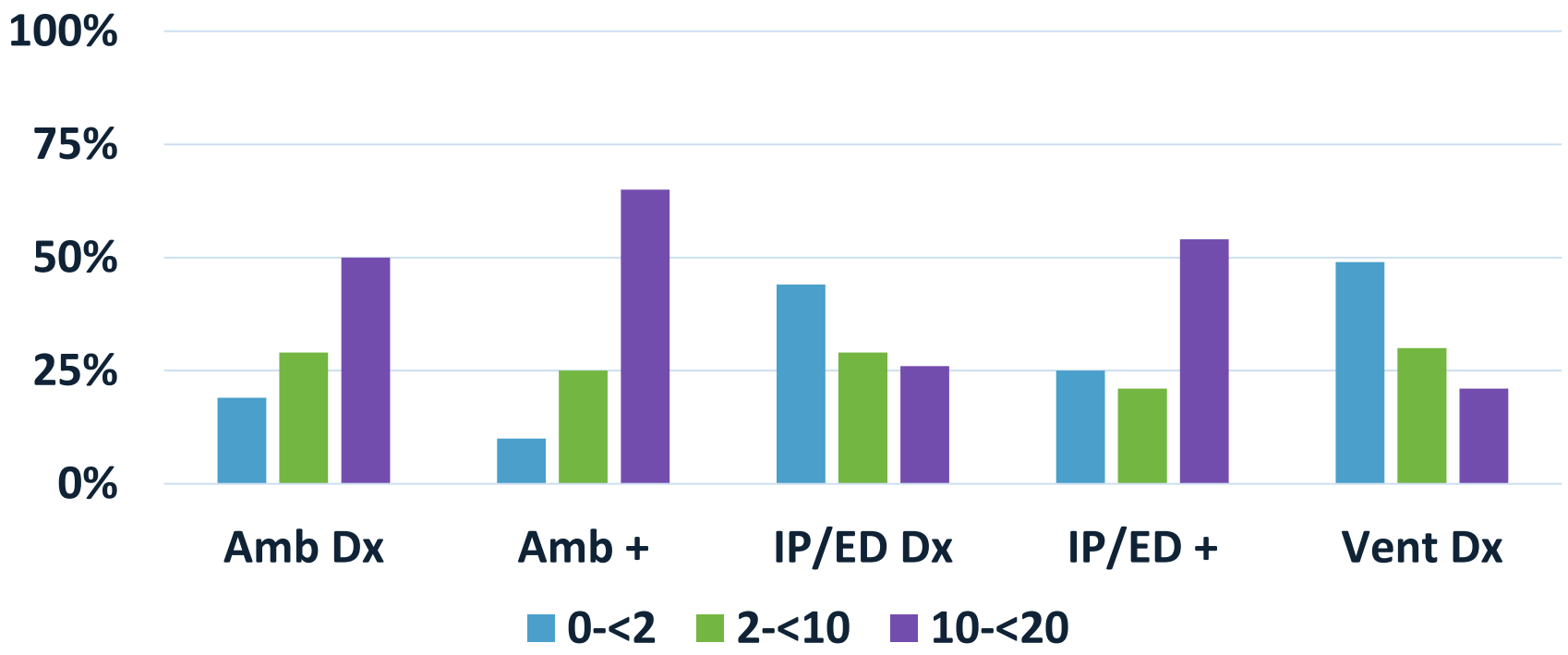
COVID CDM Queries – May 20-26th

- 42 data contributing sites responded
- 36,928 adults and 3,895 children with a coronavirus diagnostic code
- 32,789 adults and 2,949 children with COVID-19 + PCR test
- More than 100,000 with viral pneumonia and 200,000 with influenza

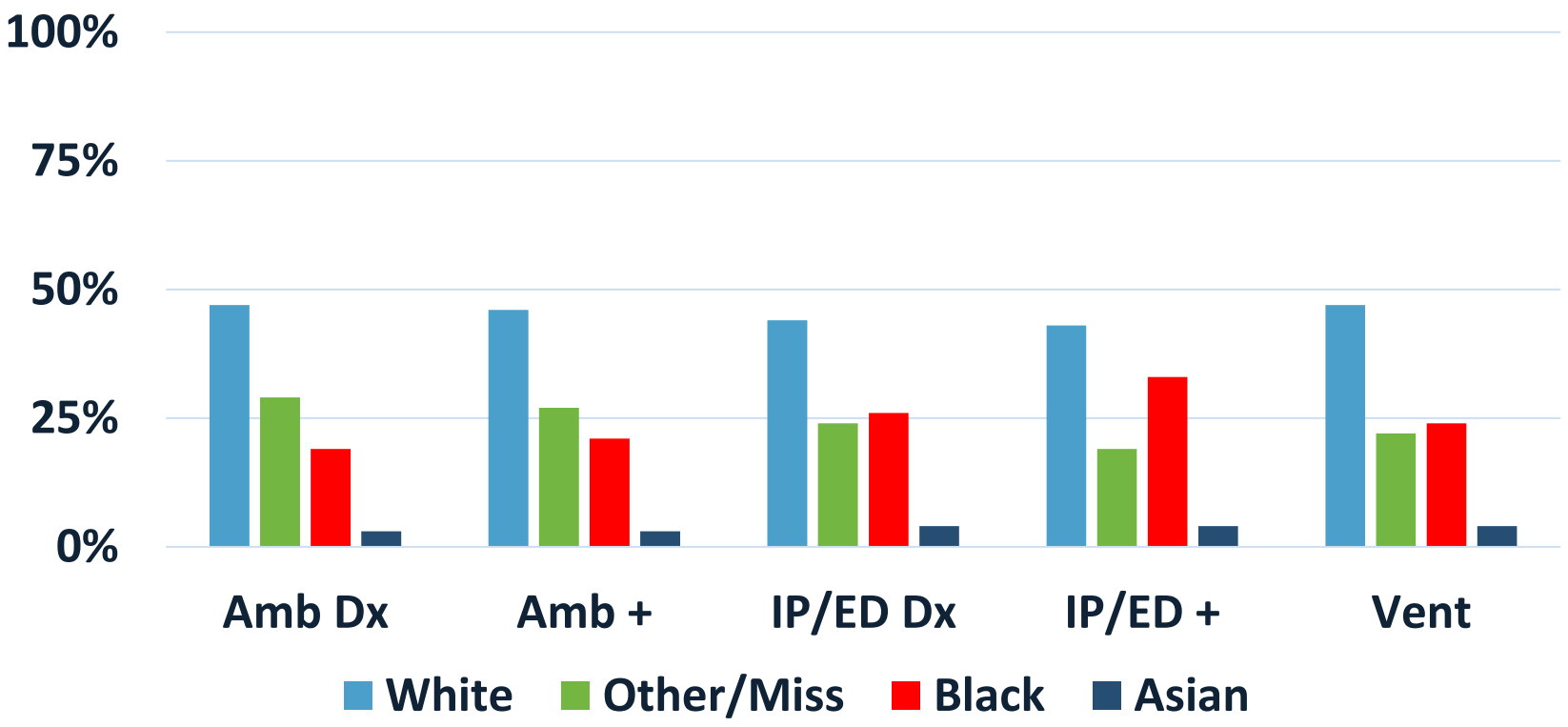
Age: COVID By Setting, Adults



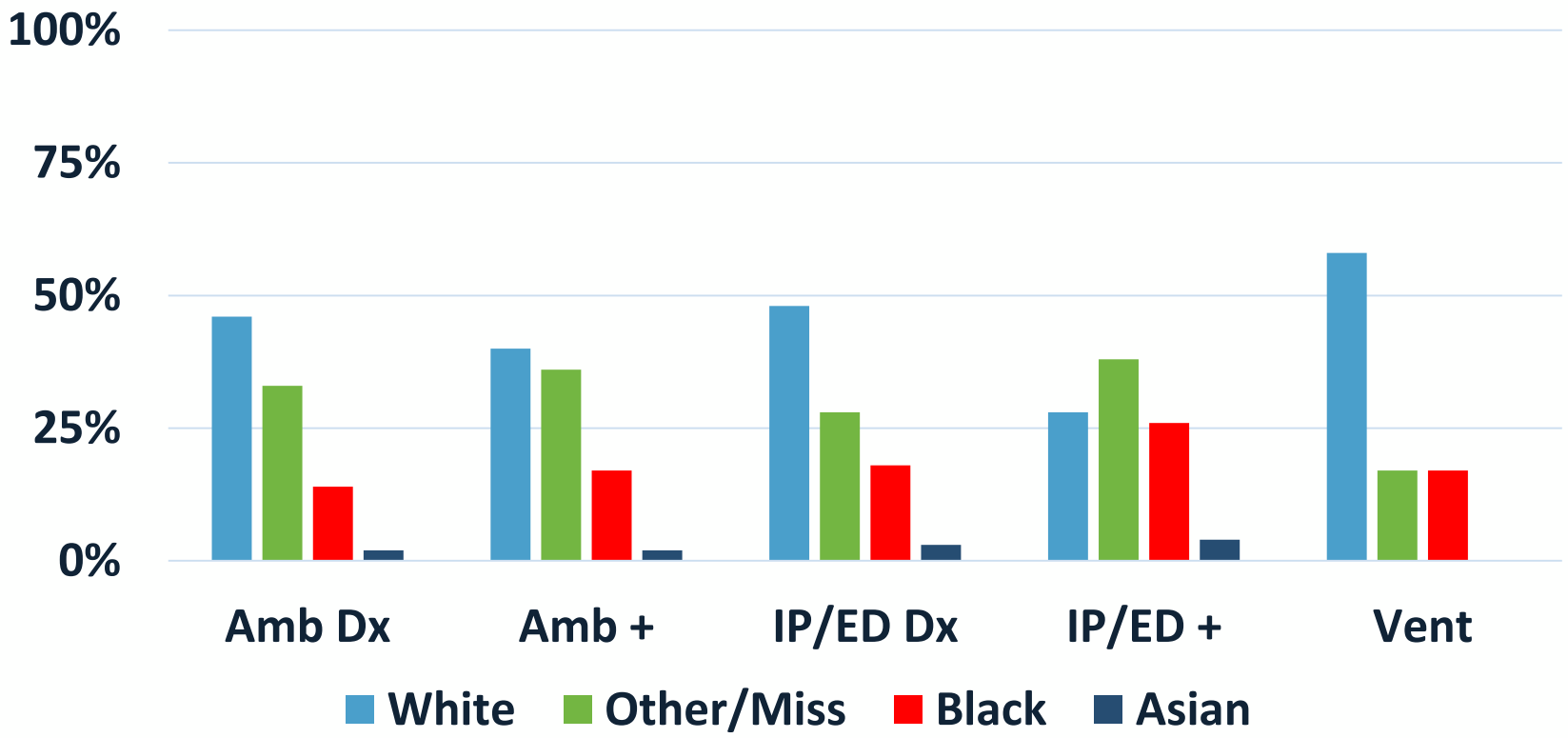
Age: COVID By Setting, Children



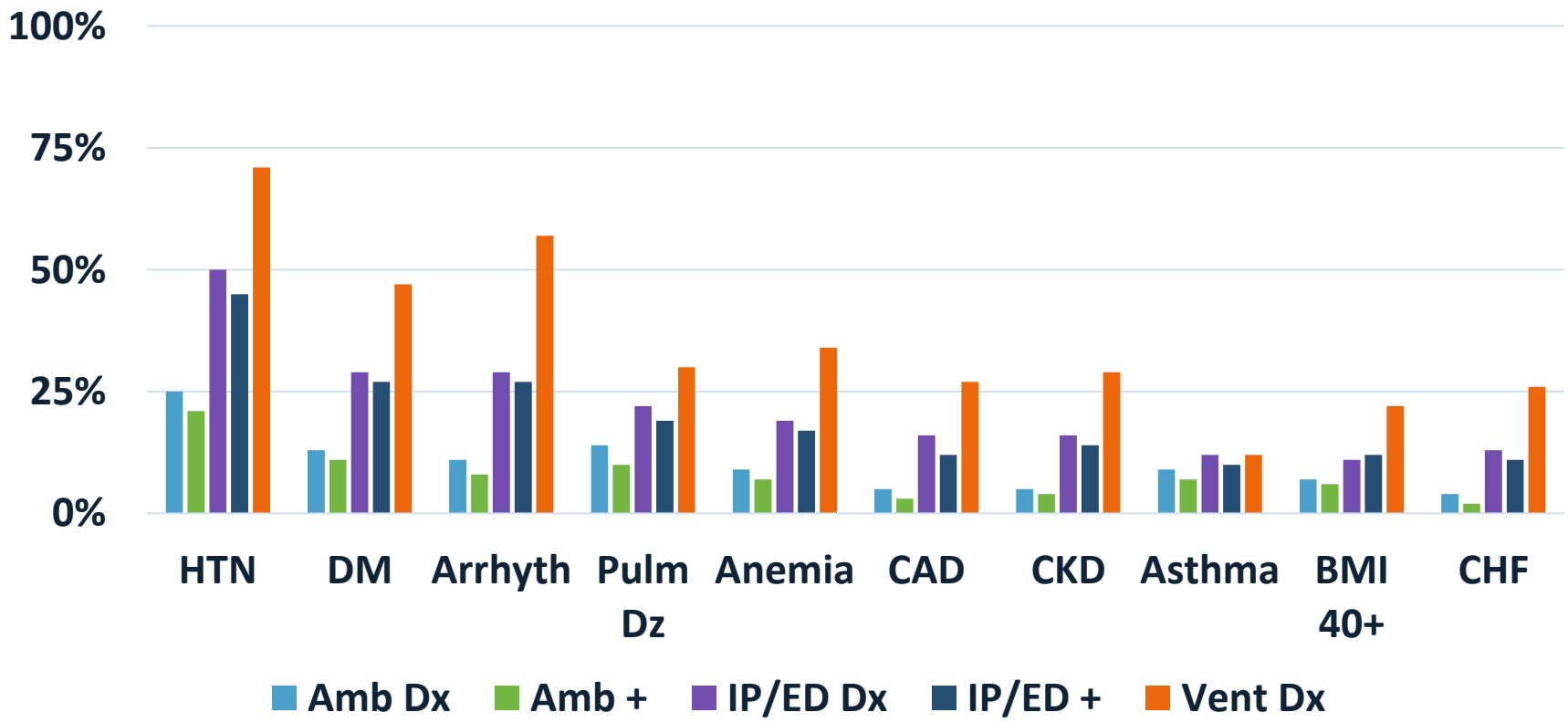
Race: COVID by Setting, Adult



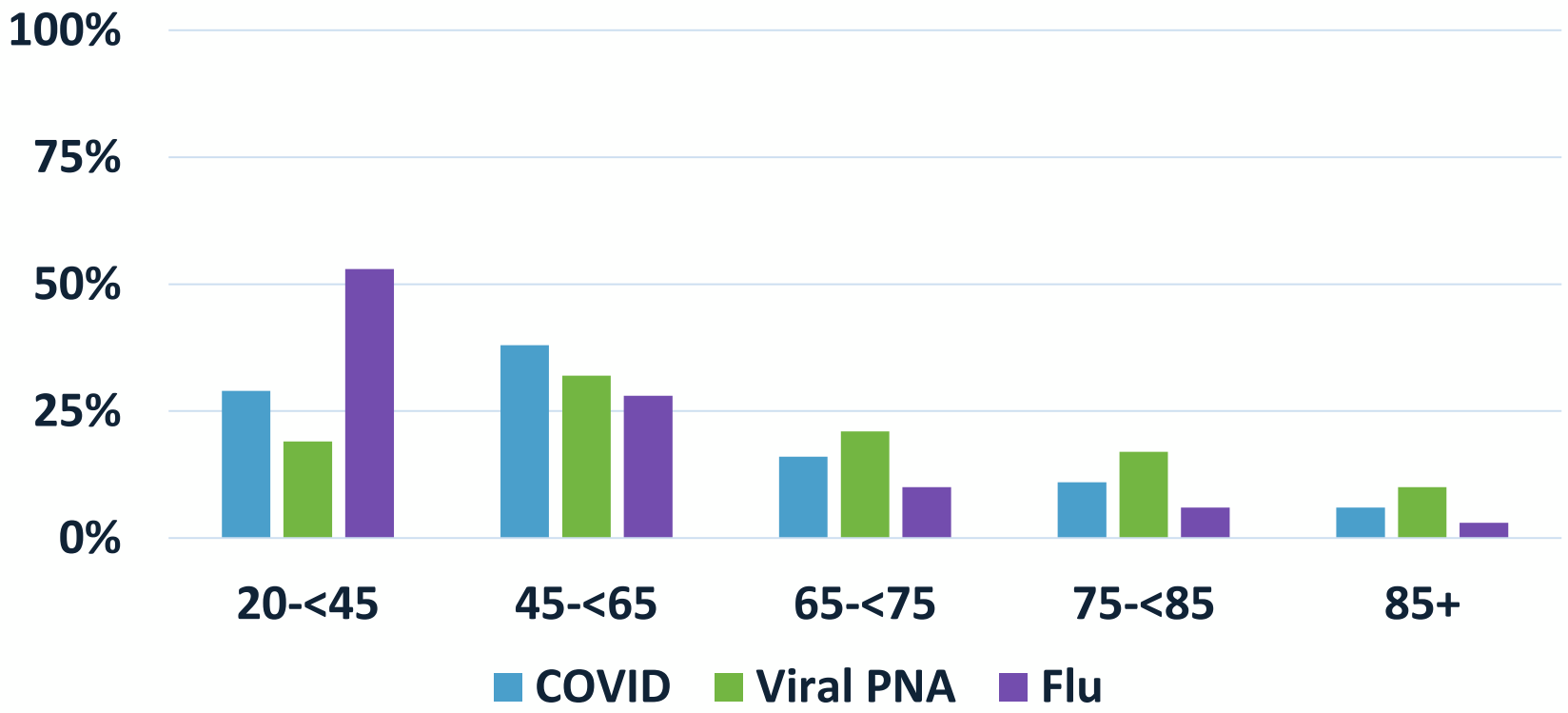
Race: COVID by Setting, Children



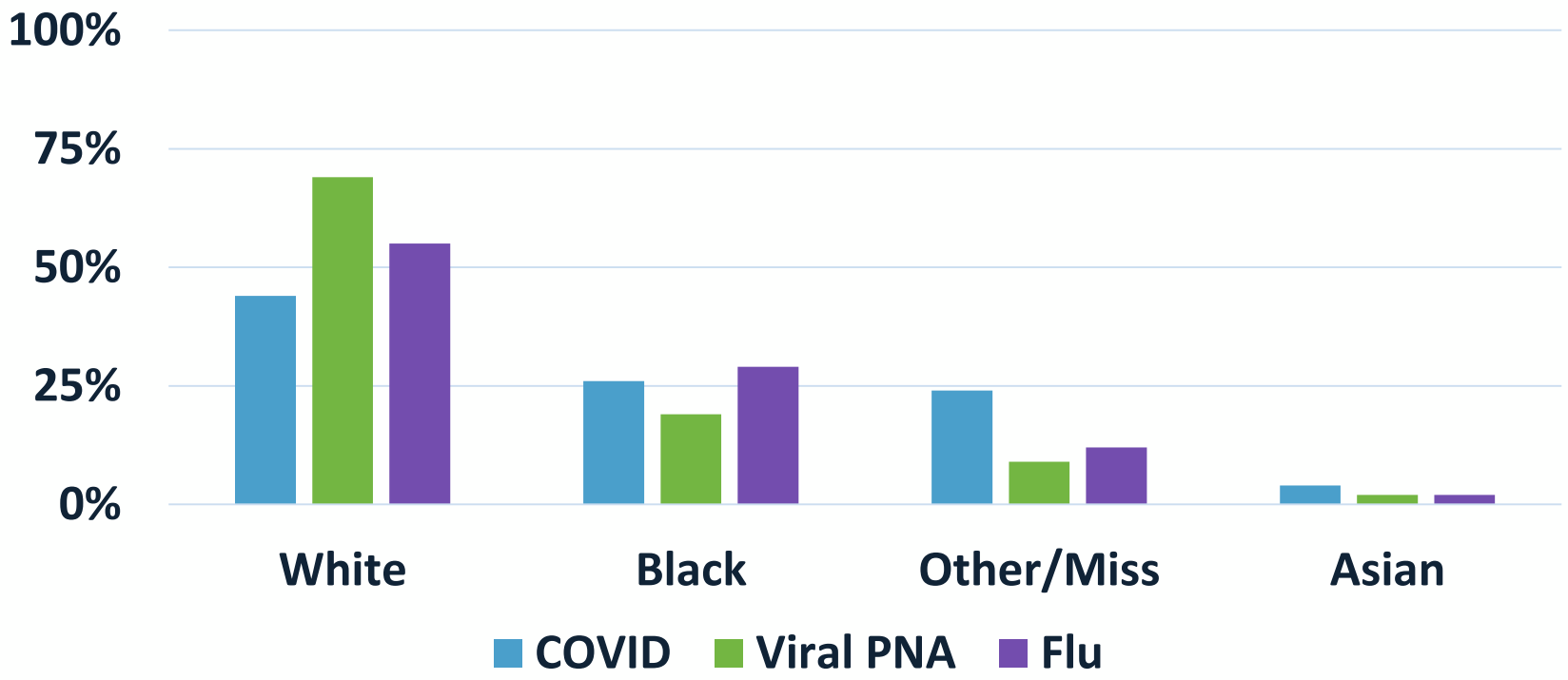
Comorbidities: COVID by Setting, Adults



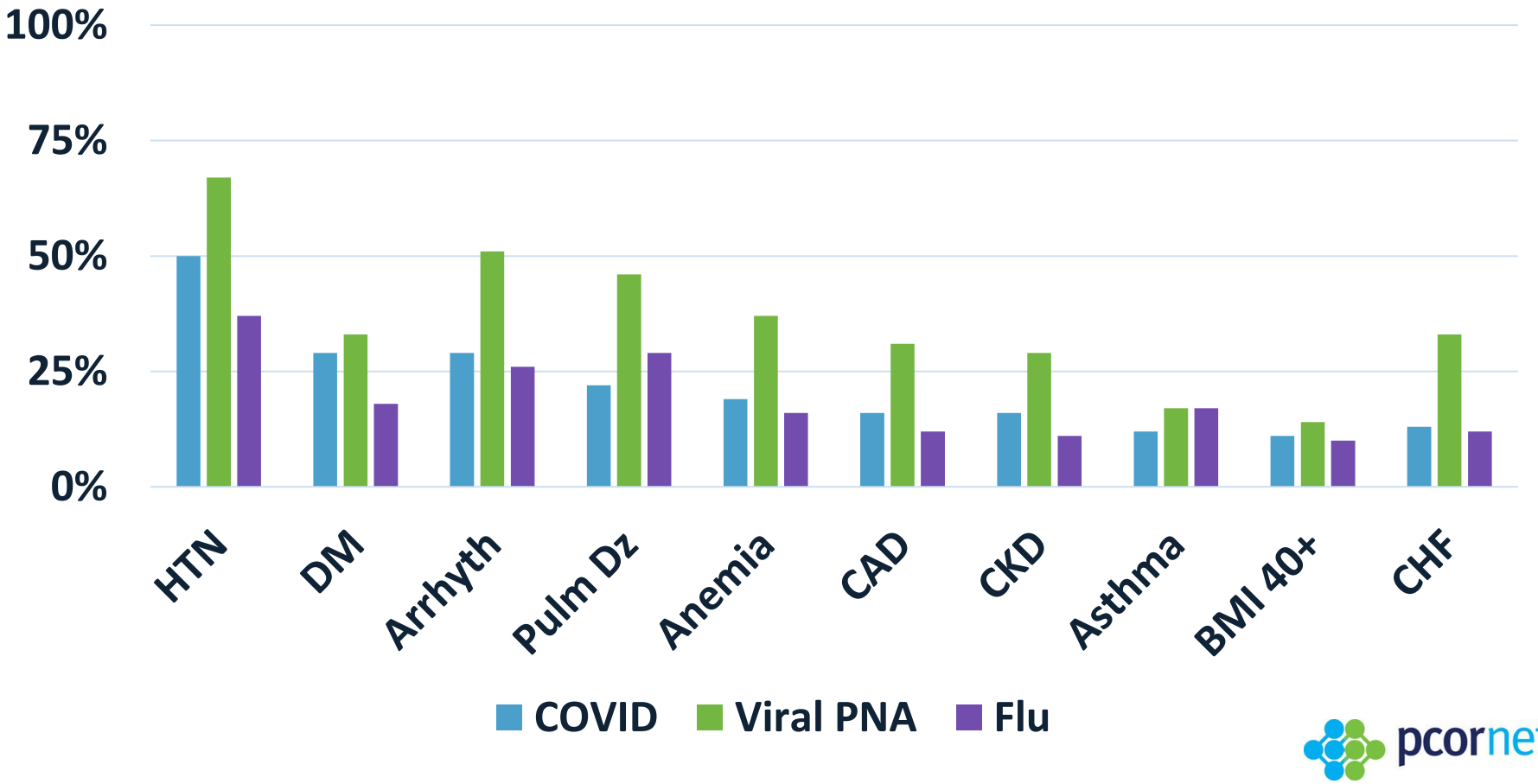
Age, Inpatient/ED: COVID, Viral PNA, Flu



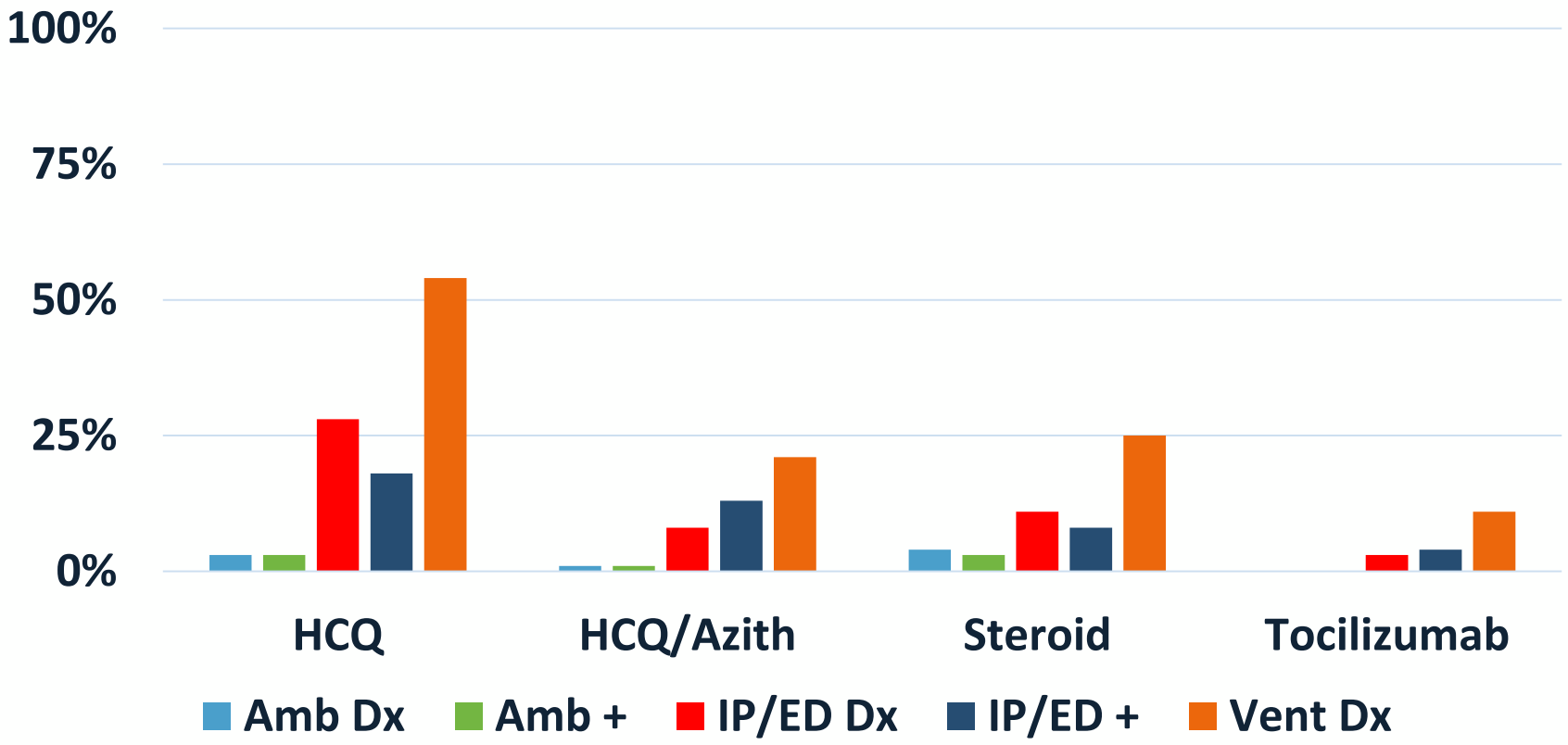
Race, Inpatient/ED: COVID, Viral PNA, Flu



Comorbidities, Inpatient/ED: COVID, Viral PNA, Flu



COVID Treatment



Other notes about data

- Asthma rates about 14% among children diagnosed with COVID
- 19 children with Kawasaki's/Toxic Shock among COVID Dx; 23 among viral pneumonia; 36 among influenza
- Among those with negative tests, % who are Black or African American is lower than for those testing +

Limitations

- Working on aggregate data in initial phase limits flexibility; extensive work to update modular programs
- Frequent ETLs limit ability to do data curation; questions regarding when to lock data for research
- Missing data on COVID diagnoses and labs
- Identifying best controls as move toward research
- Overlap in disease groups

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Next steps

- Continued development, execution of weekly queries
  - Refinement of care setting
  - “Flags” for institutional registries, ICU, ventilator status
- Data validation
  - Sensitivity/specificity analysis for the different methods of identifying patients (e.g., dx, labs) compared with institutional registries
- Establish research priorities and governance for use throughout network
  - Align with current Front Door practices
- Develop relationships with other agencies to leverage subset-CDM
  - CDC
  - FDA

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Discussion


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The National Patient-Centered Clinical Research Network