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Texas Department of State Health Services

Pediatric Dose Reporting

Poor Data Quality & Potential Adverse Clinical Outcomes

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The Texas Immunization Registry (ImmTrac2)

Is secure, confidential, safely consolidates & stores immunization records from multiple sources.

29.3 Million Clients' immunization records

35,933 Organizations

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Agenda

- Background on COVID Pediatric Doses
- Correctly Reporting Pediatric Doses
- Issue-Incorrect Reporting and Consequences
- Approaches to Resolve Issue
- Challenges/Limitations
- Future Implications
- Questions

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Background on Pediatric COVID Doses

FDA Authorizes Pediatric Doses

- On October 29, 2021, U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) to permit the use of Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 in individuals 5 years of age and older.

5-11 Years of Age Recommendations

- Recommendations
  - Administered intramuscularly
  - 2 Dose Primary Series – second dose at least 21 days
  - **Dose size: 10 mcg**

  - For immunocompromised individuals ages 5-11, **an additional dose is authorized and recommended at least 28 days** after second dose is administered

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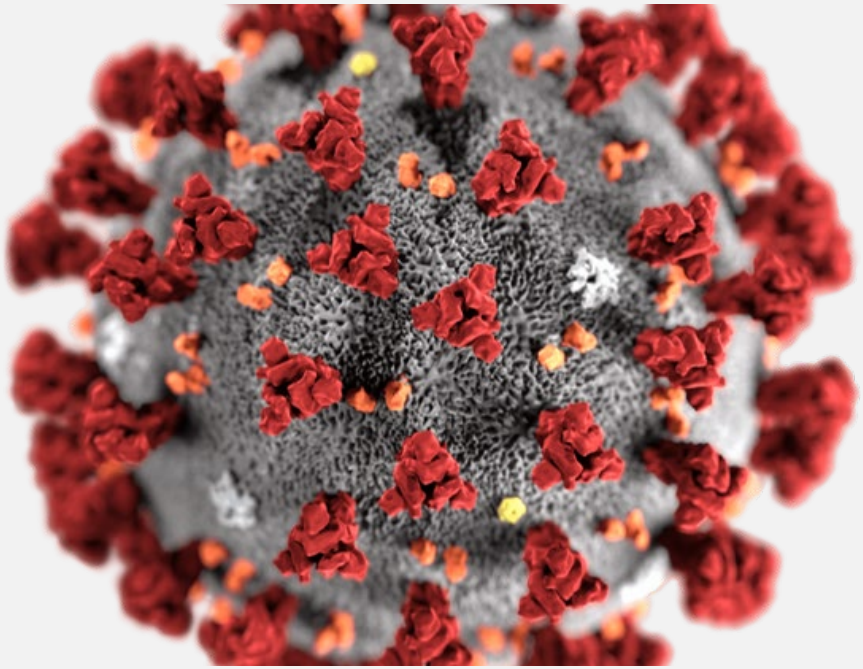
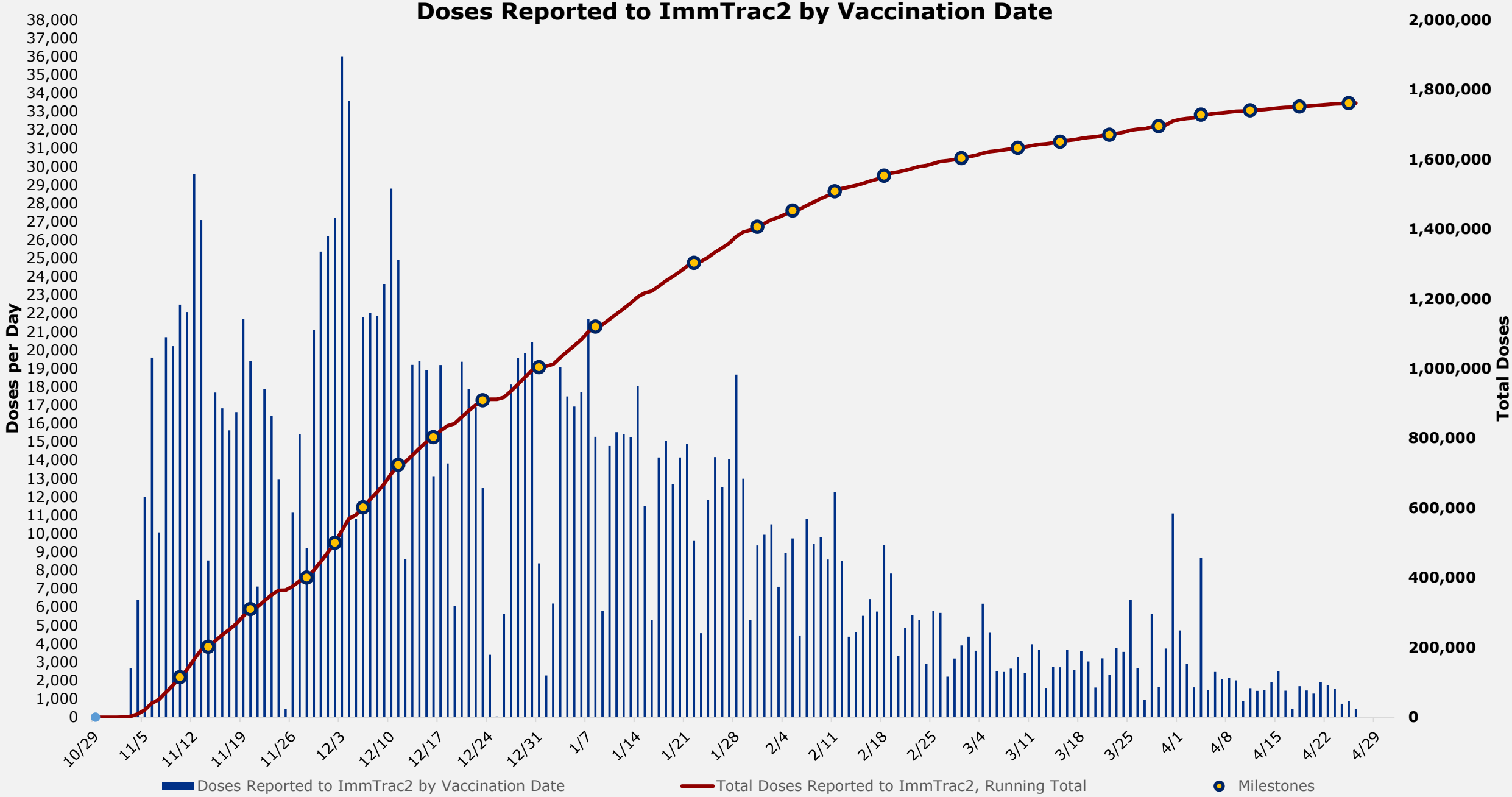
Pediatric COVID Dose Reporting in Texas

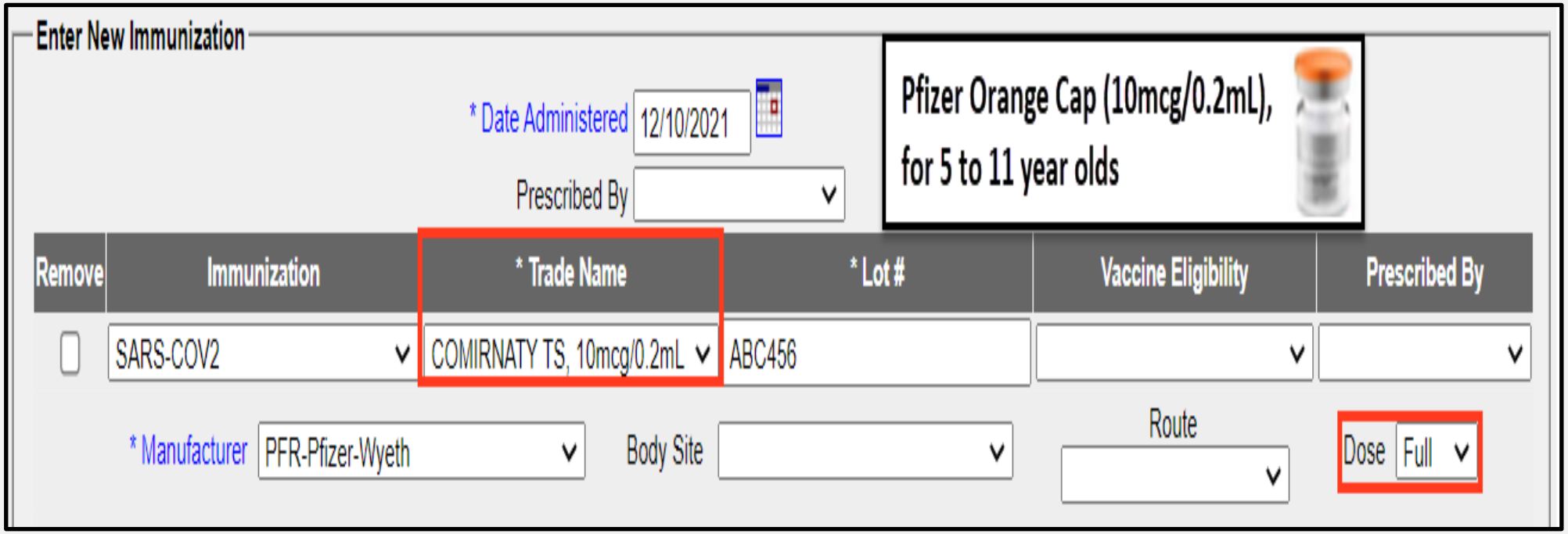


Doses Reported to ImmTrac2 by Vaccination Date



Reporting Pediatric Doses to Immtrac2

Reporting Online Through ImmTrac2



Reporting Through Data Exchange

- Provider/Organization must report the CDC vaccination codes assigned to the vaccination. Providers can report either NDC (Use or Sale) or the CVX Code.

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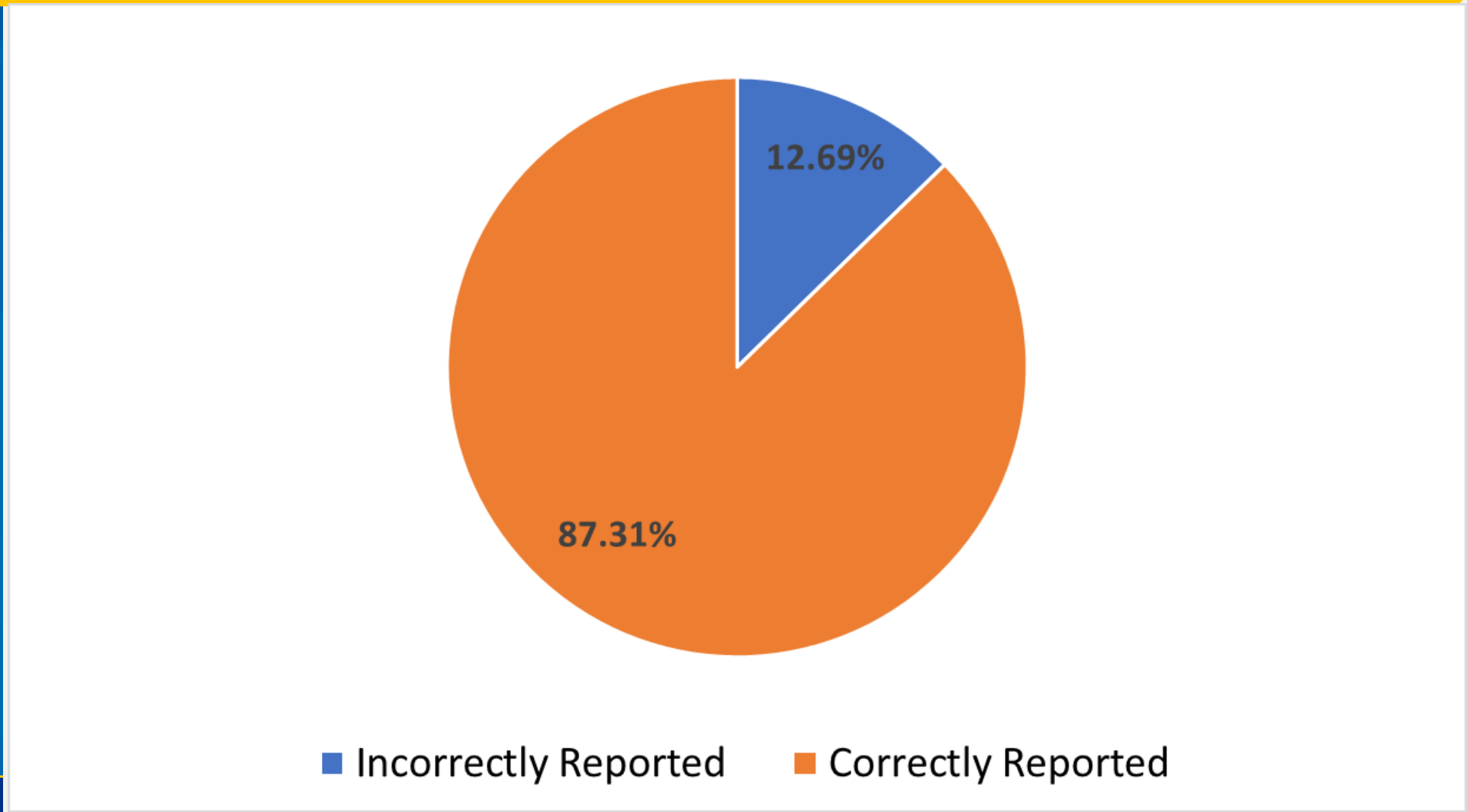
Incorrect Reporting of Pediatric Doses



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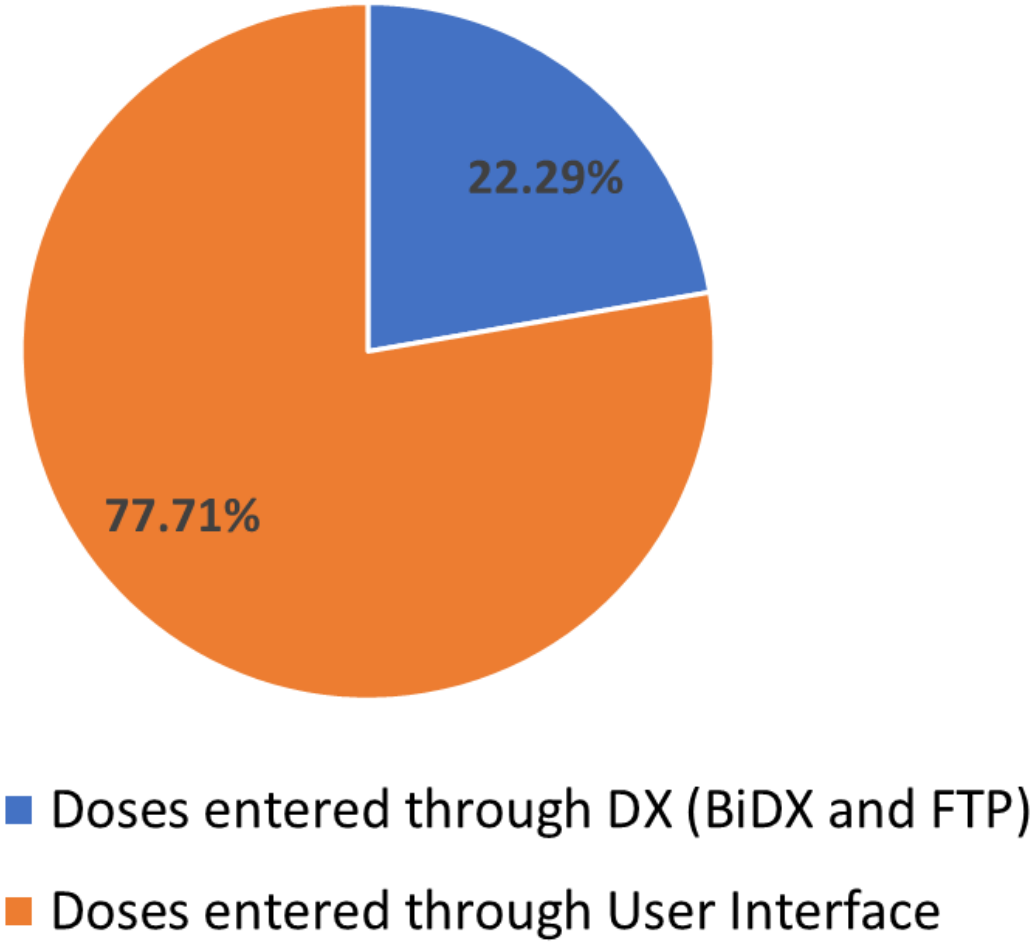
Incorrect Reporting By Record Source



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Let's get all the tools!

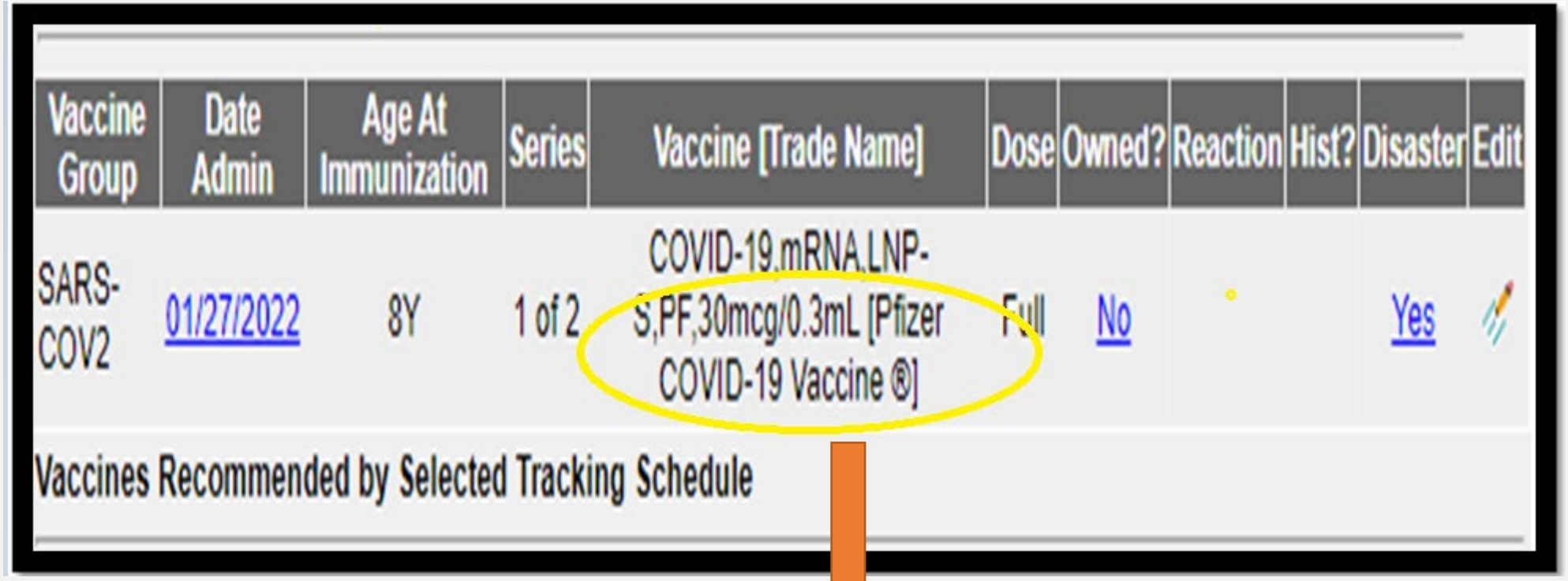
Software Used:

- ImmTrac2 Application
- SQL Developer
- Tableau
- Excel

Three Major Underlying Issues

- Reporting doses with an Incorrect Tradename
- Reporting Incorrect Date of Vaccination
- Client received **adult** formulation instead of **child** formulation

Example of Incorrect Trade Name



Vaccine Group	Date Admin	Age At Immunization	Series	Vaccine [Trade Name]	Dose	Owned?	Reaction	Hist?	Disaster	Edit
SARS-COV2	01/27/2022	8Y	1 of 2	COVID-19,mRNA,LNP-S,PF,30mcg/0.3mL [Pfizer COVID-19 Vaccine ®]	Full	No			Yes	
Vaccines Recommended by Selected Tracking Schedule										

Correct Trade Name: ComirnatyTS 10mcg/0.2 ml

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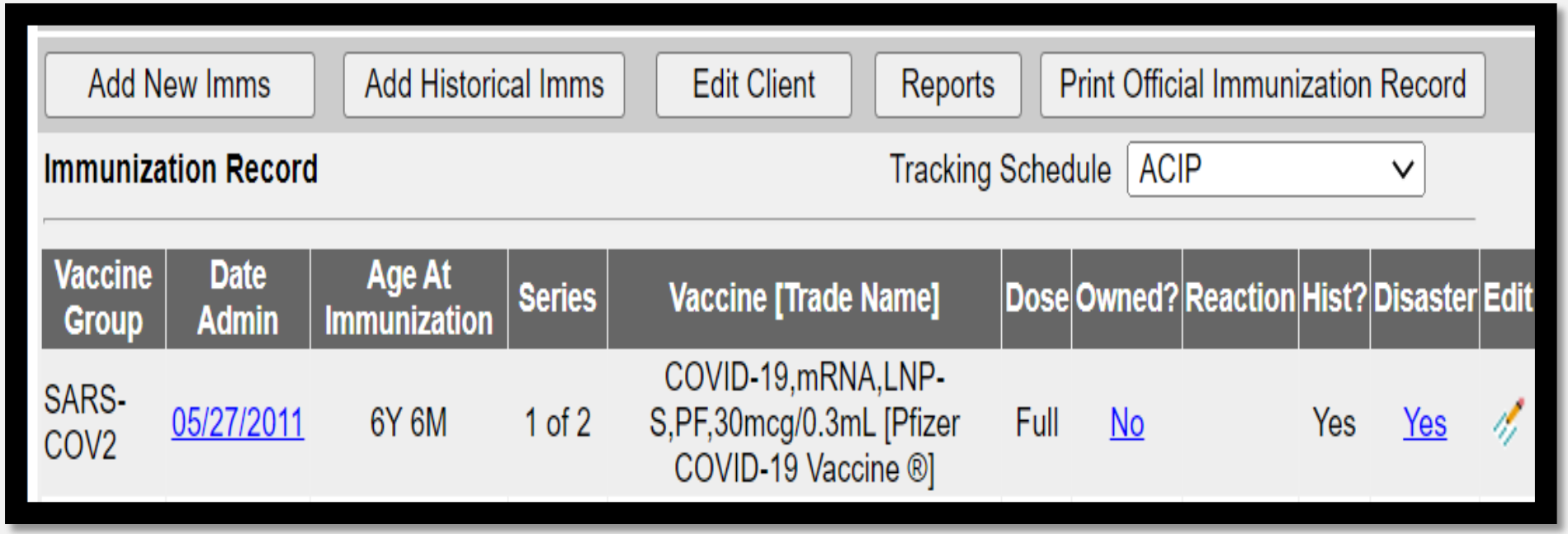
Example of Incorrect Date of Vaccination

- Year of Birth for Client is 2004
- Year of Administration is 2011



Add New Imms | Add Historical Imms | Edit Client | Reports | Print Official Immunization Record

Immunization Record Tracking Schedule: ACIP

Vaccine Group	Date Admin	Age At Immunization	Series	Vaccine [Trade Name]	Dose	Owned?	Reaction	Hist?	Disaster	Edit
SARS-COV2	05/27/2011	6Y 6M	1 of 2	COVID-19,mRNA,LNP-S,PF,30mcg/0.3mL [Pfizer COVID-19 Vaccine ®]	Full	No		Yes	Yes	

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Child gets the incorrect dose!

BUT WHY IS THIS
IMPORTANT?

Consequences of Incorrect Reporting

- Poor Data Quality
- Undercounting/Under reporting of pediatric doses administered in Texas
- Potential adverse clinical outcomes due to incorrect administration issues

Approaches to Resolve the Issue

Approach 1: Gov Delivery

- Registry sends a mass gov delivery email to all the providers, ImmTrac2 registry contacts and EHR vendors

Approach 2: Provider Webinars

- Providers educated on correctly reporting pediatric doses correctly through a series of 6 provider webinars.

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Approach 3: Customized Reports

- Team developed a SQL script that extracted doses given by a particular organization to clients, ages 5-11, with the following filters:

```
WHERE O.SHORT_NAME IN ()
AND Vaccination date ≥ '29-OCT-2021'
AND CVX code =208
```

Customized Client Level Reports

- **Client Demographics**
  - Client ID
  - Name
  - Date of birth
  - Address
- **Immunization Information**
  - Date of vaccination
  - Date Entered in ImmTrac2
  - Trade Name, Manufacturer and CVX code
  - Historical/Not historical
  - Lot Number

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Securely Data Sharing Client Data

If DX Provider	• Add the reports to their secure FTP folder • Send follow up email
If Manual/Online reporter	• Create FTP folder • Send credentials to point of contact • Add the customized report

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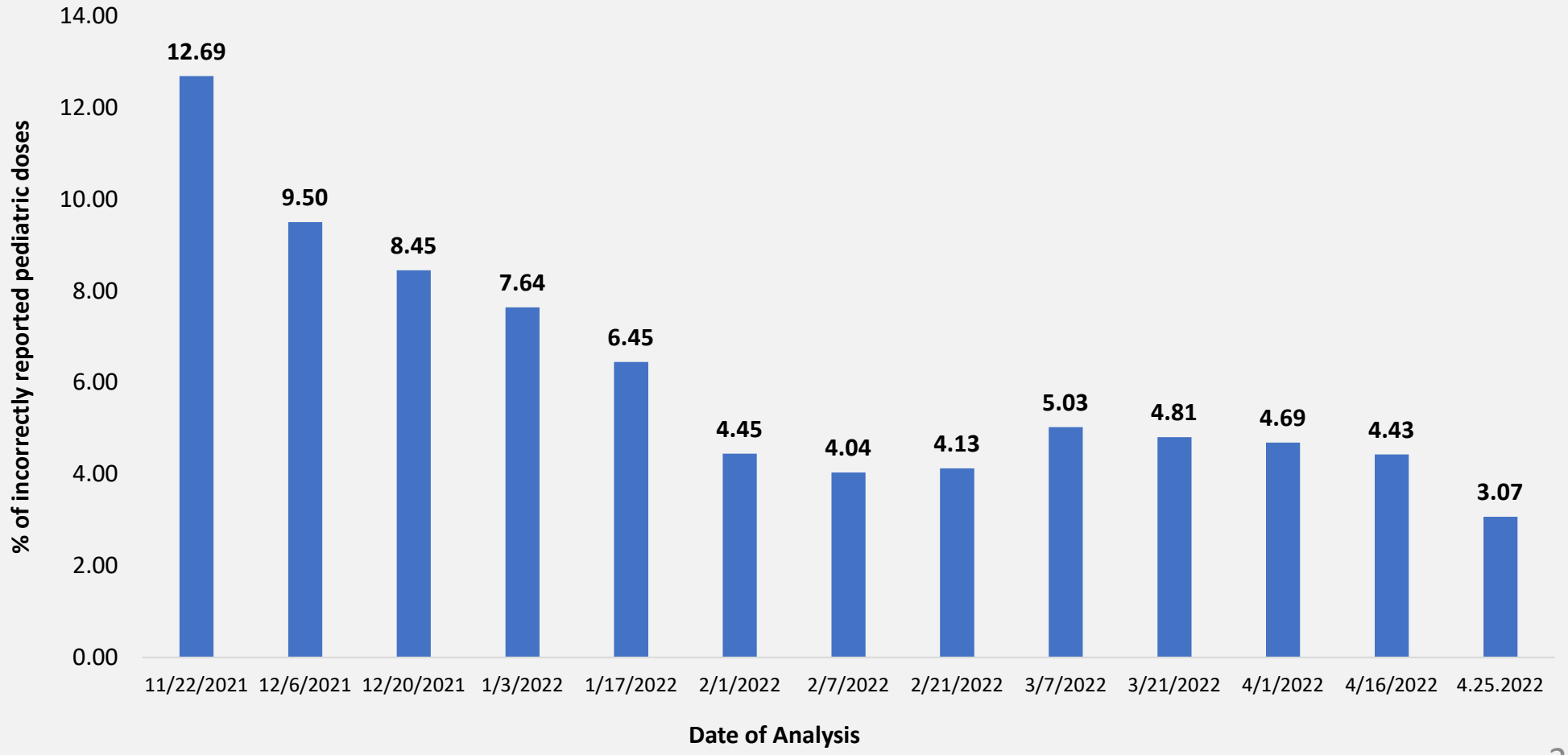
Outreach Strategy

- Providers were given a week to respond, post which another follow up was conducted.
- Met virtually through Teams/Zoom to resolve reporting issues
- Performed multiple rounds of aggressive team meetings/emails, and we continue to meet monthly

Results from the Outreach

Decrease in Incorrectly Reported Pediatric Doses



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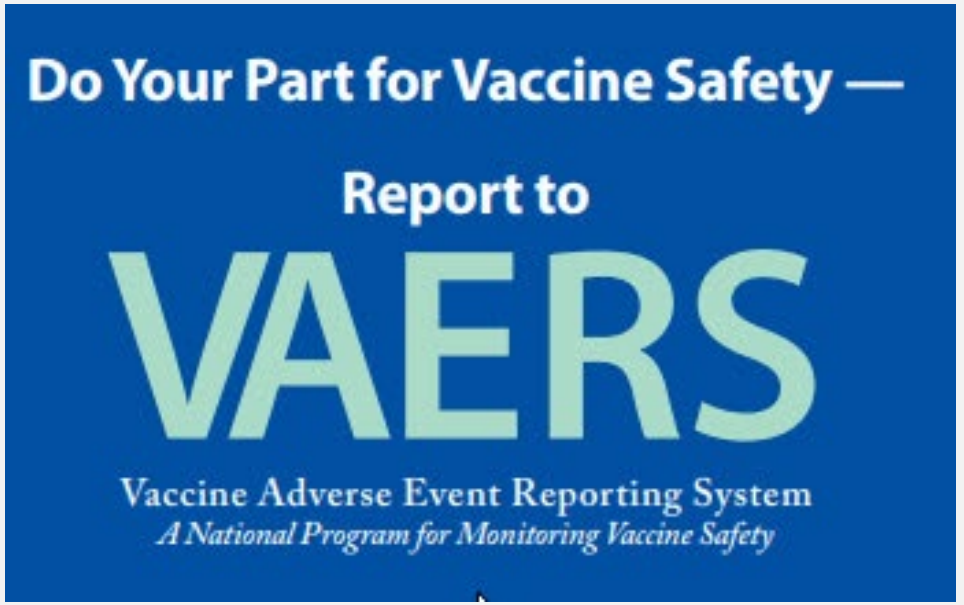
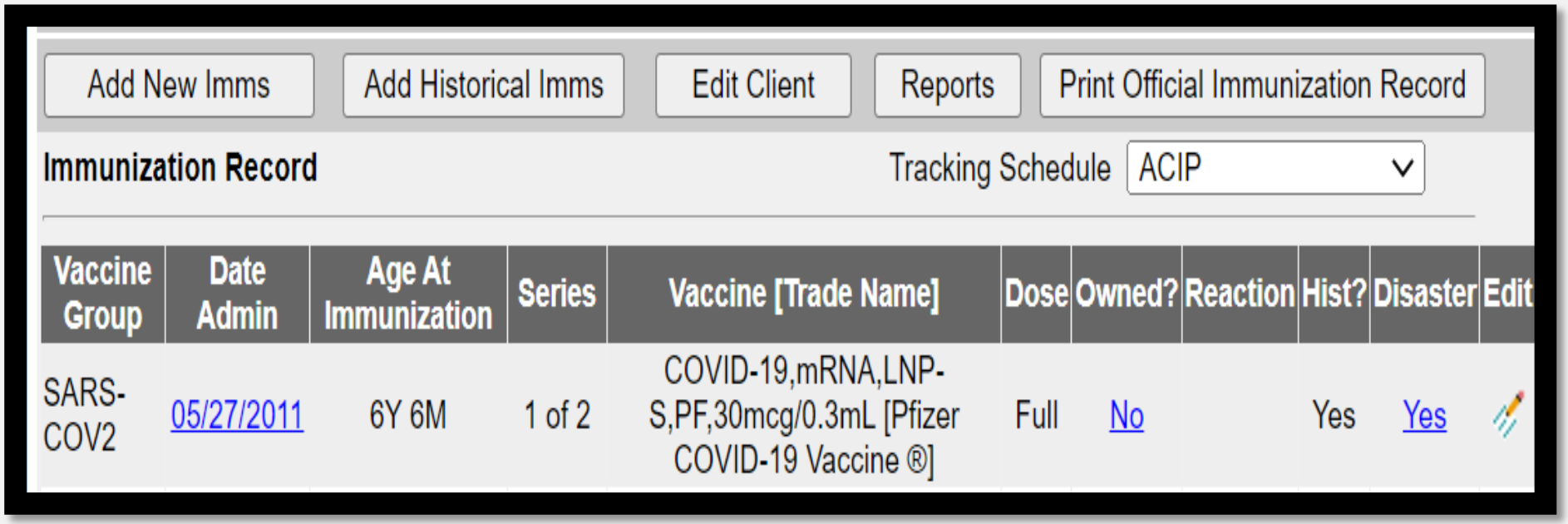
Results from Outreach Continued

In addition, providers started reporting this as an adverse event to Vaccine Adverse Event Reporting System.



Challenges and Roadblocks

Major Limitation: Dose Shows Valid!



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[Clinical Guidance for COVID-19 Vaccination | CDC]

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Other Limitations

- Lack of avenues to securely share the client level data
- Provider frustration on correcting trade names in Immtrac2
- Time consuming process
- Needs ongoing monitoring/outreach

Future Implications

- Educate and Empower providers to administer correct COVID formulations
- Reporting to VAERS
- Improved data quality

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Thank You!

From the Texas Department of State Health Services