The Thing About Boosters

This meeting will be recorded and will be available at www.fmda.org/journalclub.php
The Thing about Boosters

Swati Gaur MD MBA CMD
AGSF
• Dr Gaur has no financial disclosures
Objectives

• Discuss the current guidance and clinical research surrounding 3\textsuperscript{rd} shots/boosters

• Unpack the ethical considerations associated with boosters

• Identify how we in the PALTC community should be approaching boosters for our PALTC residents and geriatric patients
What is the vaccination percentage in your community?

- <30%
- 30-50%
- 50-70%
- >70%
SARS-CoV-2 Infections and Hospitalizations Among Persons Aged ≥16 Years, by Vaccination Status — Los Angeles County, California, May 1–July 25, 2021

Jennifer B. Griffin, PhD; Meredith Haddix, MPH; Phoebe Danz, MPH; Rebecca Fisher, MPH; Tae Hee Koo, MPH; Elizabeth Traub, MPH; Prabhu Gounder, MD; Claire Jar...
What is the rate of vaccination in your staff?

- 0-44%
- 45-59%
- 60-75%
- >75%
Why is rate of vaccination important?

66% reduction in cases if staff vax is >60-75%vs <44% staff vax
Why does it happen? Immunity in older adults

Canaday et al
Real world data on immunity over time

ACIP meeting, August 13, 21
Immunity of the same LTC group in 6 months

Supplemental Table 1. Proportion at the lower limit of detection (LLD, 1:12 titer) with pseudovirus neutralization assay (pNT50).

<table>
<thead>
<tr>
<th></th>
<th>2 weeks post-vaccination</th>
<th>Fisher's exact test</th>
<th>6 months post-vaccination</th>
<th>Fisher's exact test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>p-value</td>
<td></td>
<td>p-value</td>
</tr>
<tr>
<td><strong>Naïve</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>1/64 (2%)</td>
<td>0.005</td>
<td>10/64 (16%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>NH resident</td>
<td>11/73 (16%)</td>
<td></td>
<td>51/73 (70%)</td>
<td></td>
</tr>
<tr>
<td><strong>Prior infection</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Control</td>
<td>0/26</td>
<td>NS</td>
<td>5/26 (19%)</td>
<td>0.19</td>
</tr>
<tr>
<td>NH resident</td>
<td>0/43</td>
<td></td>
<td>15/43 (35%)</td>
<td></td>
</tr>
</tbody>
</table>

Israel data:

https://www.medrxiv.org/content/10.1101/2021.08.24.21262423v1.full-text
Israel Study: VRBPAC hearing Sept 17
Implications for LTC: residents and HCW

**Table 2. Primary Outcomes of Confirmed Infection and Severe Illness.***

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Nonbooster Group</th>
<th>Booster Group</th>
<th>Adjusted Rate Ratio (95% CI)†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confirmed infection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of cases</td>
<td>4439</td>
<td>934</td>
<td>11.3 (10.4 to 12.3)</td>
</tr>
<tr>
<td>No. of person-days at risk</td>
<td>5,193,825</td>
<td>10,603,410</td>
<td></td>
</tr>
<tr>
<td>Severe illness</td>
<td></td>
<td></td>
<td>19.5 (12.9 to 29.5)</td>
</tr>
<tr>
<td>No. of cases</td>
<td>294</td>
<td>29</td>
<td></td>
</tr>
<tr>
<td>No. of person-days at risk</td>
<td>4,574,439</td>
<td>6,265,361</td>
<td></td>
</tr>
</tbody>
</table>

* Listed are the results of the Poisson regression analysis in participants who received a booster vaccine and in those who did not receive a booster. The booster group includes data that were obtained at least 12 days after receipt of the booster dose.

† The rate ratio is the estimated factor reduction in the rate in the booster group as compared with the rate in the nonbooster group.
VRBPAC hearing Sept 17: Pfizer data

Exploratory Immunogenicity Analysis of Neutralization Activity Against USA_WA1/2020 Strain and Delta Variant

P1 participants 18-55 years of age (n= 11)

- Reference strain 1 Month post Dose 1: 310.1
- Reference strain 1 Month post Booster Dose: 1546.4
- Delta strain 1 Month post Dose 1: 241
- Delta strain 1 Month post Booster Dose: 1321

P1 participants 65-85 years of age (n= 12)

- Reference strain 1 Month post Dose 1: 195.8
- Reference strain 1 Month post Booster Dose: 1612.7
- Delta strain 1 Month post Dose 1: 123.4
- Delta strain 1 Month post Booster Dose: 1478.9

Limitations in the interpretation of the data include: small sample size and use of a non-validated SARS-CoV-2 plaque reduction neutralization assay with the USA_WA1/2020 and Delta variant input virus.
Safety: Local Reactogenicity (7 Days After Each Dose)

Injection Site Pain

| Phase 2/3 | Phase 2/3 | Phase 2/3 | Phase 1 |
| Dose 1 | Dose 2 | Booster | Booster |
| 16-55 years | 16-55 years | 18-55 years | 65-85 years |
| N=2899 | N=2682 | N=289 | N=12 |

Injection Site Redness

Injection Site Swelling

Mild — Moderate — Severe

Phase 2/3 Dose 1 and 2 participants from reactogenicity subset; N= number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose.
Safety: Systemic Reactogenicity (7 Days After Each Dose)

**Fatigue**
- Phase 2/3 Dose 1: 16-55 Years (N=2899)
- Phase 2/3 Dose 2: 16-55 Years (N=2682)
- Phase Booster: 18-55 Years (N=290)
- Phase 1 Booster: 65-85 years (N=12)

**Headache**
- Phase 2/3 Dose 1: 16-55 Years (N=2899)
- Phase 2/3 Dose 2: 16-55 Years (N=2682)
- Phase Booster: 18-55 Years (N=289)
- Phase 1 Booster: 65-85 years (N=12)

**New/worsened muscle pain**
- Phase 2/3 Dose 1: 16-55 Years (N=2899)
- Phase 2/3 Dose 2: 16-55 Years (N=2682)
- Phase Booster: 18-55 Years (N=289)
- Phase 1 Booster: 65-85 years (N=12)

**New/worsened joint pain**
- Phase 2/3 Dose 1: 16-55 Years (N=2899)
- Phase 2/3 Dose 2: 16-55 Years (N=2682)
- Phase Booster: 18-55 Years (N=289)
- Phase 1 Booster: 65-85 years (N=12)

**Chills**
- Phase 2/3 Dose 1: 16-55 Years (N=2899)
- Phase 2/3 Dose 2: 16-55 Years (N=2682)
- Phase Booster: 18-55 Years (N=289)
- Phase 1 Booster: 65-85 years (N=12)

Phase 2/3 Dose 1 and 2 participants from reactogenicity subset

N= number of participants reporting at least 1 yes or no response for the specified reaction after the specified dose

**Mild**= does not interfere with activity; **Moderate**= some interference with activity; **Severe**= prevents
Ethical Considerations
Understanding Breakthrough Cases

- Less vaccination = less community level protection
- More transmission
- More Unvaccinated
- Some vaccinated
- More hospitalization
- More deaths
Understanding Breakthrough Cases

- Less vaccination = less community level protection
- More transmission
- More unvaccinated
- Some vaccinated
- More hospitalization
- More deaths

Vaccination is our #1, 2, 3 strategy

Protecting our residents

- Vaccinated Resident
- Vaccinated staff
- Vaccinated Community

Protecting our staff

- Vaccinated Staff
- Vaccinated community
Staff COVID-19 rates: US vs FL

Confirmed COVID-19 Cases among Staff and Rate per 1,000 Resident-Weeks in Nursing Homes, by Week—United States

* Data are likely occurring, all data can be modified from week to week by facilities.

For the purpose of creating this time series graph, data that fail certain quality checks or appear inconsistent with surveillance protocols are assigned a value based on their patterns for data entry or excluded from analysis. Differences in how each facility implements this COVID-19 data collection, including variation in which staff collect the data, may affect facility reporting patterns.

Data source: Centers for Disease Control and Prevention, National Healthcare Safety Network.
Resident COVID-19 cases: US vs FL

[Graphs showing confirmed COVID-19 cases among residents and rate per 1,000 resident-weeks in nursing homes by week—United States for both the US and FL.]

*Data are likely scoring, all data can be modified from week to week by facilities.*

For the purpose of creating this time series graph, data that fail certain quality checks or appear inconsistent with surveillance protocols are assigned a value based on their patterns for data entry or excluded from analysis. Differences in how each facility implements the COVID-19 data collection, including variation in which staff collect the data, may affect facility reporting patterns.

Data source: Centers for Disease Control and Prevention, National Healthcare Safety Network
Resident COVID-19 deaths: US vs FL
How we prepare: Boosters in LTC
Unanswered questions:

• Does the data of Pfizer vaccine apply to Moderna?
• Do we give the same vaccine or a different vaccine is acceptable?
Coadministration of Influenza and COVID-19 vaccine

Coadministration of Influenza Vaccines with COVID-19 Vaccines

- ACIP influenza statement cites current *Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States*:
  - States that COVID-19 vaccines may be administered without regard to timing of other vaccines.
  - Vaccines administered at the same visit should be given at different sites (separated by an inch or more, if possible).
  - If COVID-19 vaccines are given with vaccines that might be more likely to cause a local reaction (e.g., high-dose or adjuvanted influenza vaccines), administer in separate limbs, if possible.

- Notes that providers should check current CDC COVID-19 vaccination guidance for updated information concerning coadministration.

Vaccine logistics

Your team
1. Consultant pharmacist
2. DON/ Nurse leadership
3. Medical director

- Tabulate the type of prime vaccine series – (data on heterologous?)
- Coordinate with consultant pharmacist on vaccine supply
- Schedule date of ‘vaccine clinic’
- Consents/ Assent
- Staffing logistics
- Educate staff on observation and assessment of anaphylaxis
- E Kit for vaccine
- Vaccine reporting

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html
Thank You!

Questions...
This meeting has been recorded and will be available at www.fmda.org/journalclub.php