Vaccines and Related Biological Products Advisory Committee Meeting

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DoD Influenza Surveillance and Mid-Season Vaccine Effectiveness

Armed Forces Health Surveillance Division (AFHSD)
Naval Health Research Center (NHRC)
Naval Medical Research Center (NMRC)
United States Air Force School of Aerospace Medicine (USAFSAM)
DoD Global Respiratory Pathogen Surveillance Program Partners

Presentation to the Vaccines and Related Biological Products Advisory Committee (VRBPAC) – 3 March 2022

LCDR Courtney Gustin, DrPH, MSN**

**Representing the DoD CONUS and OCONUS lab-based influenza surveillance activities
Purpose: Provide an update to the VRBPAC on DoD influenza surveillance activities for 2022 - 2022

1. Program Description
2. DoD Influenza Subtype Circulation
3. Antigenic Characterization
4. Vaccine Effectiveness in US Service Members
5. Vaccine Strain Recommendations
Breadth of DoD Influenza Surveillance

• Global Influenza Surveillance
  ▪ Approximately 400 locations in over 30 countries
    ✓ Military; local government/academic
  ▪ Extensive characterization capabilities within the DoD
    ✓ Culture, PCR, sequencing, serology
  ▪ Rapid sharing of results with CDC and/or regional WHO reference centers
    ✓ Yearly average: ~30,000 samples collected and analyzed each year

• Comprehensive Epidemiology and Analysis Capabilities
  ▪ 1.33 Million Active Duty records (health care utilization, immunizations, deployment, reportable diseases, etc.)
    ✓ Produce Medical Surveillance Monthly Report (MSMR), ad-hoc requests, studies/analyses,
    ✓ Weekly influenza reports
    ✓ Vaccine safety and effectiveness studies
DoD Influenza Subtype Circulation
DoD Influenza Subtype Circulation

- **Common themes for the 2021-2022 season**
  - ALL laboratories and nations continued to be affected by the SARS-CoV-2 pandemic
  - Concurrent testing and assay validation for SARS-CoV-2 and influenza
  - While surveillance estimates for DoD on the next few slides are lower than usual, influenza was detected in all GCCs (in some places for the first time since the beginning of the pandemic)

- **Region-specific examples**
  - North America: installation-wide influenza A outbreaks
  - Africa: frequent detection of Influenza A Virus (IAV) and Influenza B Virus (IBV), including A(H1N1) in West Africa
  - Southeast Asia: persistent influenza in Nepal
Subtype Circulation: North America
Number and Proportion of Specimens Positive for Influenza by Subtype

Sources: NHRC, USAFSAM

Source: WHO GISRS
Subtype Circulation: South America
Number and Proportion of Specimens Positive for Influenza by Subtype

Source: NAMRU-6

Source: WHO GISRS

DoD Surveillance

WHO Surveillance

Medically Ready Force… Ready Medical Force
Subtype Circulation: Europe

Number and Proportion of Specimens Positive for Influenza by Subtype

Sources: LRMC/PHCE, USAMRD-G

DoD Surveillance

WHO Surveillance

Medically Ready Force… Ready Medical Force
Subtype Circulation: Asia

Number and Proportion of Specimens Positive for Influenza by Subtype

Sources: AFRIMS, NAMRU-2, USAFSAM

DoD Surveillance

WHO Surveillance

Medically Ready Force... Ready Medical Force
Subtype Circulation: Middle East

Number and Proportion of Specimens Positive for Influenza by Subtype

Sources: LRMG/PHCE, USAFSAM, NAMRU-3

DoD Surveillance

WHO Surveillance

Medically Ready Force… Ready Medical Force
Subtype Circulation: East Africa

Number and Proportion of Specimens Positive for Influenza by Subtype

Source: USAMRD-A

Source: WHO GISRS
Subtype Circulation: West Africa (Ghana)
Number and Proportion of Specimens Positive for Influenza by Subtype

Source: NAMRU-3

Source: WHO GISRS

DoD Surveillance
WHO Surveillance

Medically Ready Force… Ready Medical Force
<table>
<thead>
<tr>
<th>Reference Viruses</th>
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<td>A/Tasmania/503/2020 Egg</td>
<td>1810 80 640 640 40 40 57 80 113 160</td>
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<tr>
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<tr>
<td>A/Darwin/9/2021 Egg</td>
<td>160 226 3620 2560 160 160 160 80 80</td>
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<td>A/Darwin/6/2021 Cell</td>
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<td>160 113 3620 5120 80 80 160 80 80 57</td>
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Antigenic Cartography Map Generated using ACMACS Program
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</tbody>
</table>
Summary of Circulating Subtype 2021-2022 Influenza Season

- Influenza surveillance has continued during the 2021-2022 season and influenza activity has been detected in all regions after a period of relative inactivity in 2020-2021.

  - **North America:** A(H3N2) has been the dominant type detected
  - **South America:** positivity increased in recent months (A/H3N2)
  - **Europe:** low levels of influenza detected
  - **Asia:** moderate influenza driven recently by A(H3N2) and influenza B
  - **Middle East:** low levels of influenza detected, primarily influenza A
  - **East Africa:** moderate influenza with all subtypes detected
  - **West Africa:** primarily detecting influenza A; one of the only regions with A(H1N1) circulating
DoD / USAFSAM Phylogenetic Analysis
2021-2022 Influenza Season
Geographical Distribution of Influenza Sequences, 2021-2022

Contributors:
- Eglin AFB (1)
- LRMC (5)
- NAMRU-6 (15)
- NHRC (21)
- Sentinel Sites (408)

Countries:
- Germany
- Italy
- Peru
- United Kingdom
- United States

A(H1N1)pdm09:
- 419

A(H3N2):
- 14

B/Yamagata:
- 15

Total: 450
2021-2022 A(H3N2) HA Phylogenetic Tree

- 448 influenza A(H3N2) HA sequences
- All in clade 3C.2a1b.2a2
- The majority from NORTHCOM and sharing D53G/D104G/L157I/S262N/K276R
- D53N/N96S/I192F/N378S group mostly from EUCOM and SOUTHCOM
- One major addition and two single losses of glycosylation motifs
- 2020-2021 and 2021-2022 NH vaccine strains and 2022 SH vaccine strains indicated on tree by stars
- A/Maryland/02/2021 most closely related reference strain
- Virus with S205F and A212T showed antigenic distinction from reference vaccine viruses
428 influenza A(H3N2) NA sequences

- NA phylogenetic tree similar in structure to HA
- Addition of glycosylation motif by S329N
- Again, A/Maryland/02/2021 most closely related reference strain
A total of 450 influenza sequences were available for analysis from the DoD, including contributions from LRMC, NHRC, NAMRU-6, and USAFSAM.

Only one influenza A(H1N1)pdm09 specimen from NORTHCOM was sequenced and was clade 6B.1A-5A.1, the same clade as the 2020-2021 influenza vaccine A(H1N1)pdm09 strain and shares the substitutions R113K and H399N similar to reference virus A/Pennsylvania/02/2021.

Only one influenza B specimen from EUCOM was sequenced and was a B/Yamagata lineage in clade Y3, the same clade as the 2021-202 influenza vaccine B/Yamagata strain.

448 influenza A(H3N2) sequences were analyzed and were all clade 3C.2a1b.2a2, with 6% sharing substitutions D53N/N96S/I192F/N378S and 90% sharing D53G/D104G/L157I/S262N/K276R.

One HA substitution in the first group, N96S, causes the addition of a glycosylation motif.

Four sequences (0.9%) that were not in the D53N or D53G groups, shared S205F and A212T. One representative from this group displayed the most antigenic distinction from reference and vaccine strains.
Service Member Vaccine Effectiveness Estimates
Analysis Overview

- Mid-year estimates provided by:
  - AFHSD AF Satellite - US Air Force School of Aerospace Medicine (USAFSAM)
  - Naval Health Research Center (NHRC)
  - AFHSD Epidemiology and Analysis Section (E&A)
- Case test-negative control studies used to estimate VE
  - All studies used case test-negative control method
  - Each influenza infection from USAFSAM and NHRC was confirmed by RT-PCR or viral culture; AFHSD also used positive rapid tests (but excluded rapid test negatives)
  - Analyses performed for influenza types and subtypes
Service Members: Study Design

- Case / Test-negative control design
- Population: Active component Service Members
  - Army, Navy, Air Force, Marines
  - CONUS and OCONUS
- Time Period: September 1, 2021 – February 12, 2022
- Lab-confirmed flu cases: positive by rapid, RT-PCR, or culture assays
- Test-negative Controls: negative by RT-PCR or culture assays (subjects with negative rapid excluded)
- Models adjusted for sex, age category, prior vaccination, and month of diagnosis
- Overall and type-specific VE calculated
Service Members: Vaccination Information & Case Subtypes

- **Vaccination**
  - IIV was the only vaccine type among the study subjects
  - 85% of subjects had prior flu vaccine in previous 5 years

- **Cases**
  - Influenza A (any subtype) = 1,303
  - Influenza A(H3N2) = 155
  - Influenza A(H1N1) = 1
  - Influenza B = 165
Service Members: Cases and Controls by Age Group

Age Strata of Cases and Controls

- **18-24**
  - Cases: 48
  - Controls: 37

- **25-29**
  - Cases: 24
  - Controls: 24

- **30-39**
  - Cases: 23
  - Controls: 29

- **40+**
  - Cases: 5
  - Controls: 9
Service Members: Interim VE Estimates 2021-2022

<table>
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<tr>
<th>Influenza Type</th>
<th>Vaccination Status</th>
<th>Cases N (%)</th>
<th>Controls N (%)</th>
<th>Crude VE (95% CI)</th>
<th>Adjusted VE (95% CI)*</th>
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</thead>
<tbody>
<tr>
<td>Any Influenza</td>
<td>Vaccinated</td>
<td>946 (65) 33,851 (69)</td>
<td>513 (35) 14,962 (31)</td>
<td>18 (9, 27)</td>
<td>36 (28, 44)</td>
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<tr>
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<td>Unvaccinated</td>
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<tr>
<td>Influenza A</td>
<td>Vaccinated</td>
<td>862 (66) 33,851 (69)</td>
<td>441 (34) 14,962 (31)</td>
<td>14 (3, 23)</td>
<td>33 (24, 41)</td>
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<td>A/H3N2</td>
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<td>52 (34) 14,962 (31)</td>
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<tr>
<td>Influenza B</td>
<td>Vaccinated</td>
<td>87 (53) 33,851 (69)</td>
<td>78 (47) 14,962 (31)</td>
<td>51 (33, 64)</td>
<td>59 (42, 71)</td>
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</table>

*Adjusted for sex, age, and month of diagnosis
Among Service Members, the 2021-2022 influenza vaccine provided:

- Low to moderate protection against any influenza (36%), influenza A (33%) and A/H3N2 (32%)
- Moderate protection against influenza B (59%)
Notes on Vaccine Strain Recommendations

The WHO influenza vaccine strain recommendations for the 2022-2023 Northern Hemisphere season are:

- For the 2022-2023 influenza vaccine A(H1N1) component: A/Victoria/2570/2019-like virus for the egg-based vaccine and A/Wisconsin/588/2019-like virus for the cell- or recombinant-based vaccine
  
  Based on our 2021-2022 data, we cannot agree or disagree with this recommendation

- For the 2022-2023 influenza vaccine A(H3N2) component: A/Darwin/9/2021-like virus for the egg-based vaccine and A/Darwin/6/2021-like virus for the cell- or recombinant-based vaccine
  
  Based on our 2021-2022 genetic and antigenic data, we agree with this recommendation

- For the 2022-2023 influenza vaccine B/Victoria component: B/Austria/1359417-like virus for the egg-based and cell- or recombinant-based vaccines
  
  We do not have 2021-2022 data to agree or disagree with this recommendation

- The above three influenza strains are recommended for the trivalent vaccine, and for the quadrivalent vaccine to include these three in addition to the B/Yamagata component, B/Phuket/3073/2013-like virus for the egg-based and cell- or recombinant-based vaccines
  
  Based on our 2021-2022 data, we cannot agree or disagree with this recommendation
Acknowledgements

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- Mr. Kelvin Blade

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- Ms. Erica Duarte

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- Ms. Caroline Smith
- Mr. Jeffrey Thervil
- Mr. Bismark Kwah
- Dr. Wenping Hu
- Ms. Kayla Brown

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- Lt Col Kathryn Shaw
- Maj Peter Wasik
- Dr. Deanna Muehleman
- Mr. William Gruner
- Ms. Carol Garrett
- Mr. James Hanson
- Dr. Anthony Fries
- Dr. Elizabeth Mancias
- Ms. Pamela Bentley
- Ms. Denise Kramer
- Mr. Matthew Sanders
- Ms. Aleta Yount
- Ms. Debby Koontz
- Mr. Don Johnson
- Mr. Andrew Martin
- Ms. Renee Mayhew
- Mr. Donald Minnich
- Ms. Dannielle Parlett
- Mr. Andrew Rhinevault
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- SSgt Brandon Ray
- SSgt Jonathon Barton

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- Bassem Hamdy
- Omar Nowar
- Dr. Jae Dugan
- LCDR Rebecca Pavlicek, PhD
- MAJ Edgie-Mark Co, PhD
- LT Emily K. Stefanov, PhD

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- Ms. Victoria Espejo
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- Ms. Angélica Espinoza
- Ms. Gladys Carrion
- Mr. Julio Evangelista
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Medically Ready Force… Ready Medical Force
Acknowledgements

Recruit Surveillance Sites
Marine Corps Recruit Depot San Diego
Marine Corps Recruit Depot Parris Island
Recruit Training Command Great Lakes
Fort Leonard Wood
Fort Benning
Fort Jackson
Lackland Air Force Base
Coast Guard Training Center Cape May

CDC-California Department of Health Border Infectious Disease Surveillance Sites
Clinica de Salud del Pueblo Brawley
Clinica de Salud del Pueblo Calexico
Clinica de Salud del Pueblo El Centro
San Ysidro Health Center
Pioneers Memorial Healthcare
El Centro Regional Medical Center
Sharp Chula Vista Hospital
Mexicali General Hospital

DoD Beneficiary Surveillance Sites
Branch Health Clinic/ Marine Corps Air Station Yuma
Naval Hospital Camp Pendleton
Captain James A. Lovell Federal Health Care Center (Naval Hospital Great Lakes)
Robert E. Bush Naval Hospital Twenty Nine Palms
Naval Training Center San Diego
Naval Medical Center San Diego
Naval Branch Health Clinic Kearny Mesa
Naval Health Clinic Lemoore
Naval Hospital Yokosuka
Naval Branch Health Clinic Naval Base San Diego
Naval Medical Center Portsmouth
Boone Branch Health Clinic
Oceana Branch Health Clinic

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Dr. Chesnodi Kulanga
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