

DoD Influenza Surveillance and Mid-Season Vaccine Effectiveness

Armed Forces Health Surveillance Branch (AFHSB)

Naval Health Research Center (NHRC)

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) – 4 March 2020**

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****Representing the DoD CONUS and OCONUS lab-based influenza surveillance activities**



“Medically Ready Force...Ready Medical Force”

Briefing Outline



Purpose: Provide a concise update to the VRBPAC on DoD influenza surveillance activities for 2018-2019

1. Program Description
2. Strain Circulation
3. Molecular Analyses
4. Vaccine Effectiveness

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**
 - 1.4 Million Active Duty records (health care utilization, immunizations, deployment, reportable diseases, etc.)
 - Produce Medical Surveillance Monthly Reports, Ad-hoc requests, Studies/analyses,
 - Weekly influenza reports
 - Vaccine safety and effectiveness studies

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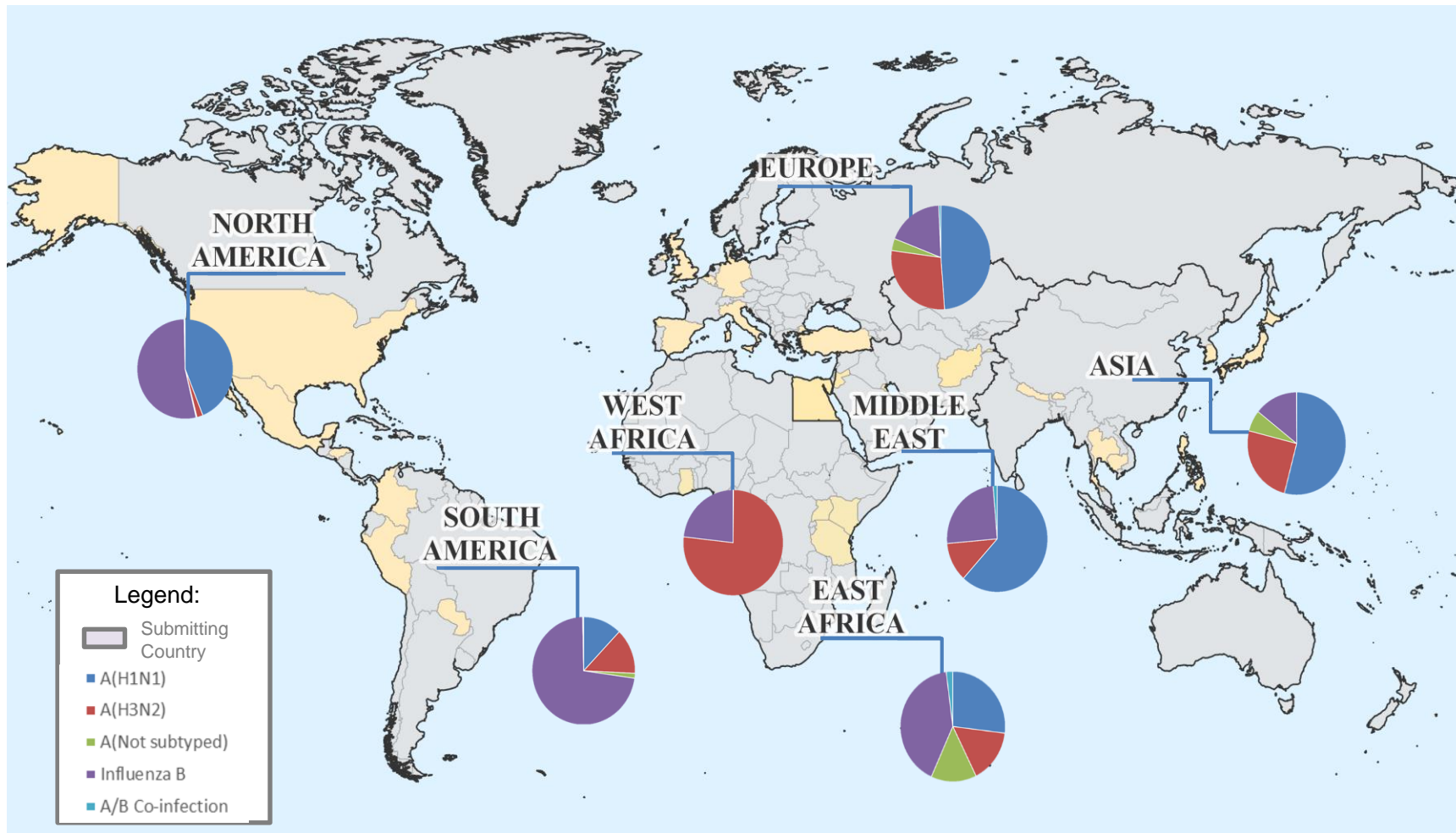
GEIS-Supported Influenza Surveillance Footprint



- ★ GEIS Core Partner Laboratory
- Darker shaded countries are where GEIS supports influenza surveillance

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Submitting Countries and Subtype Circulation 2019-2020 Season

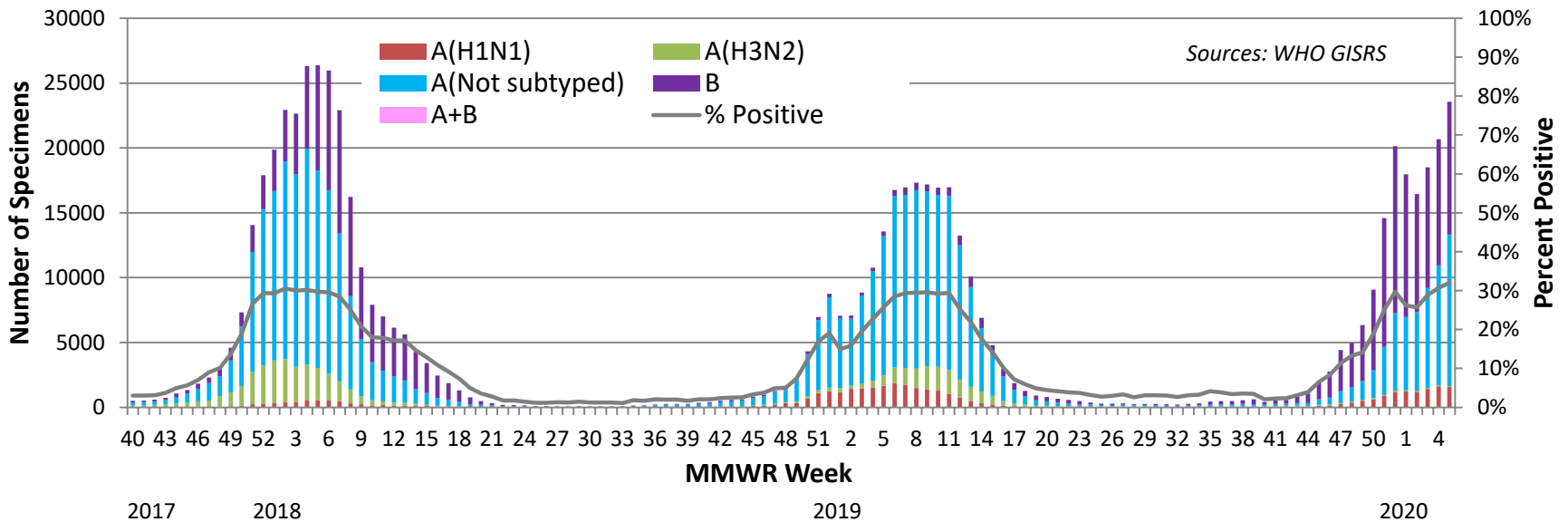
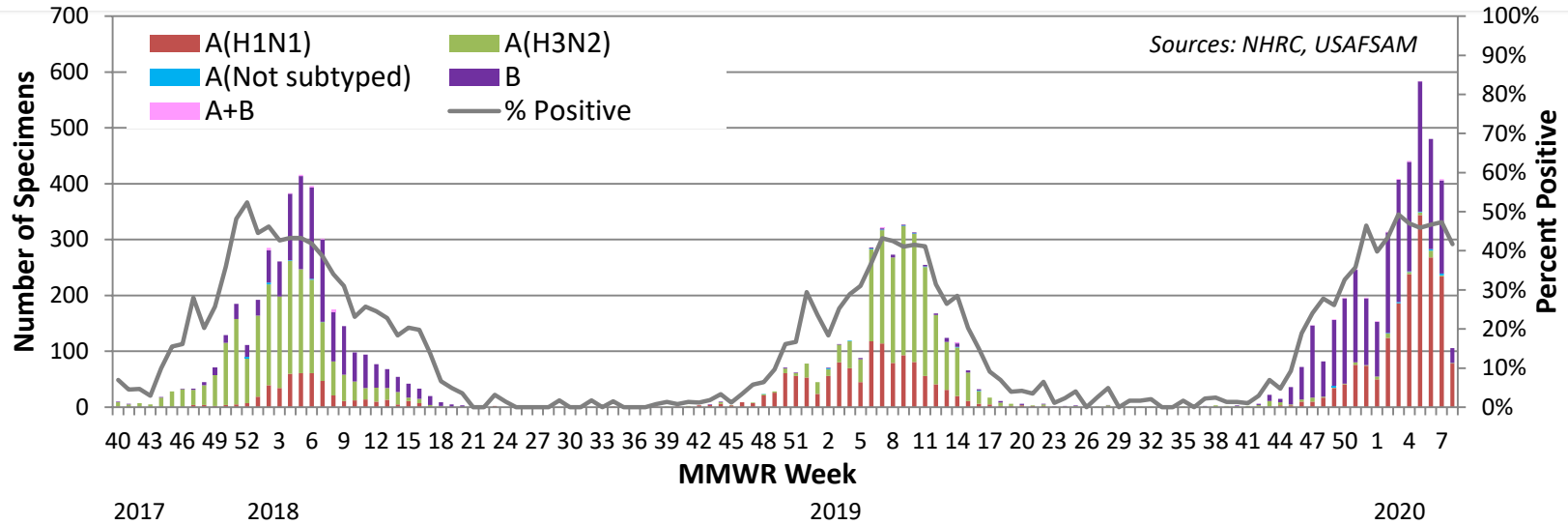


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Subtype Circulation: North America



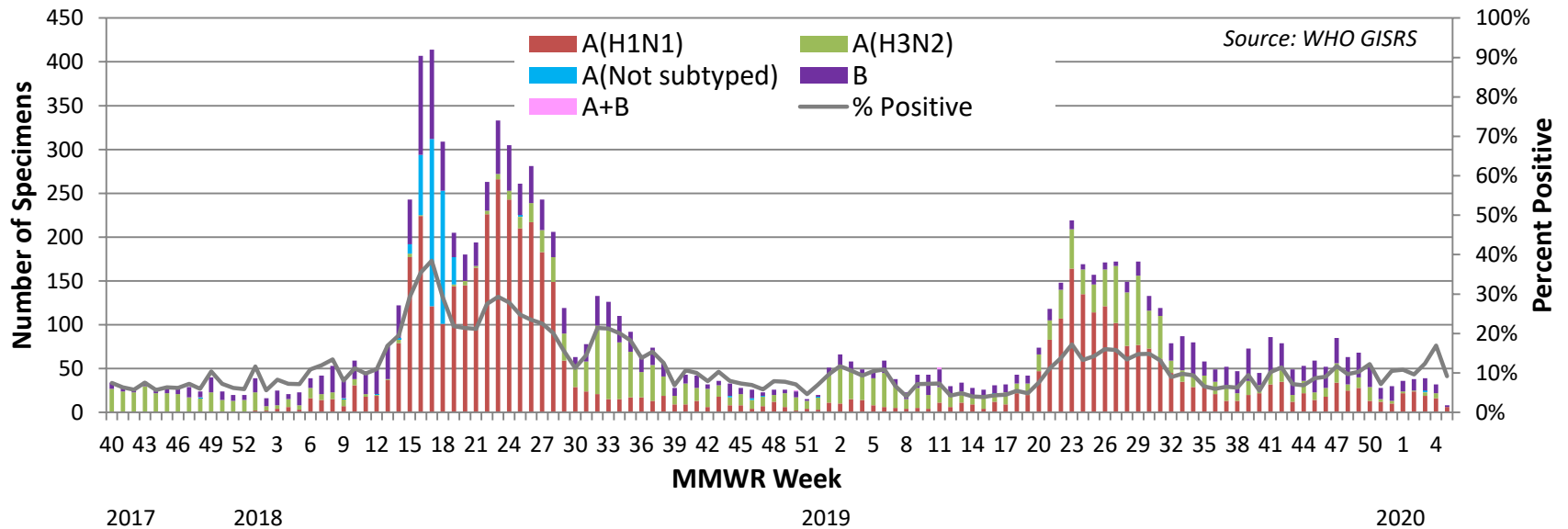
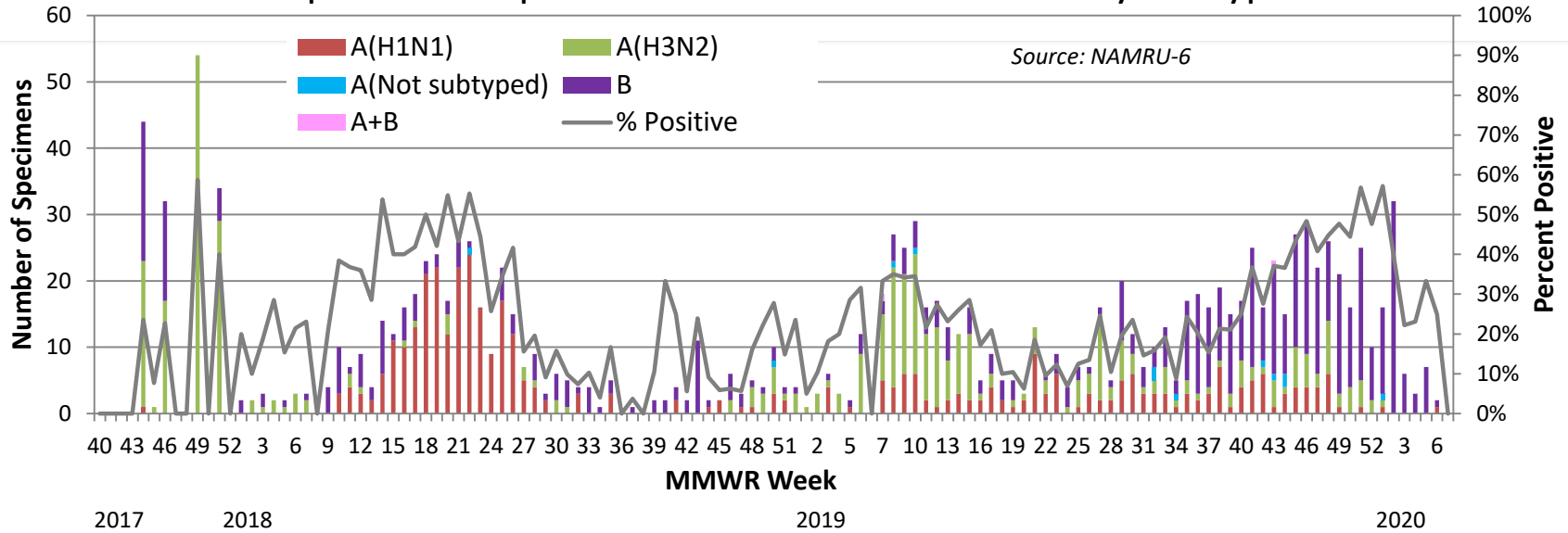
Number and Proportion of Specimens Positive for Influenza by Subtype



Subtype Circulation: South America

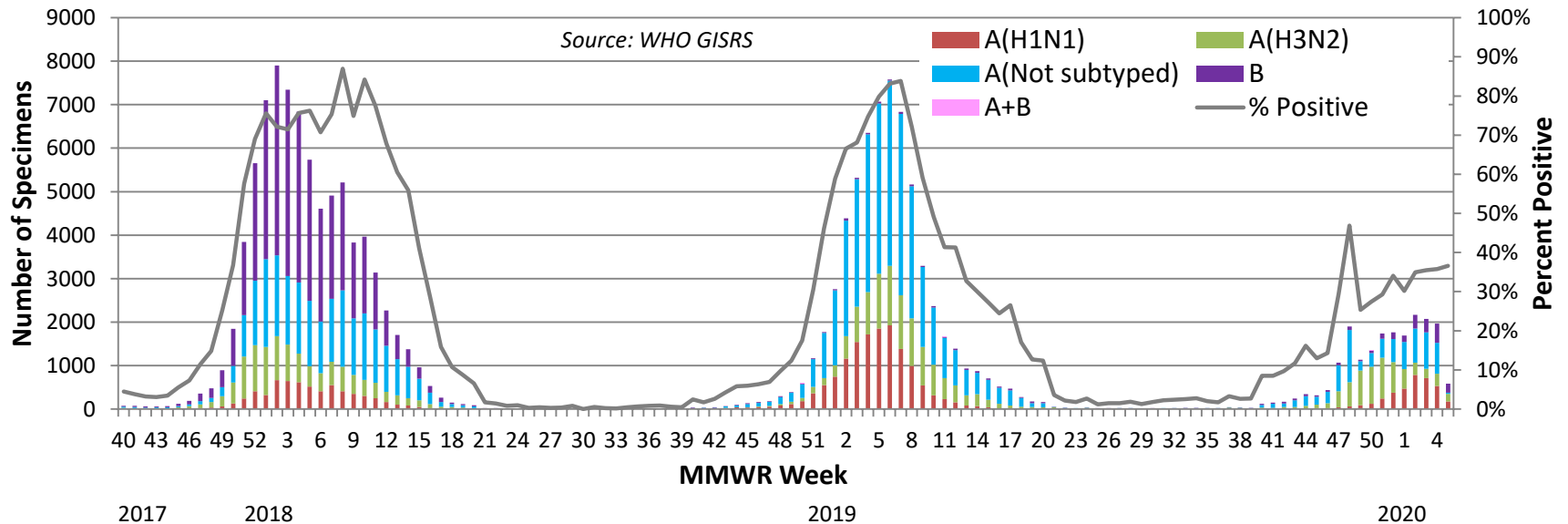
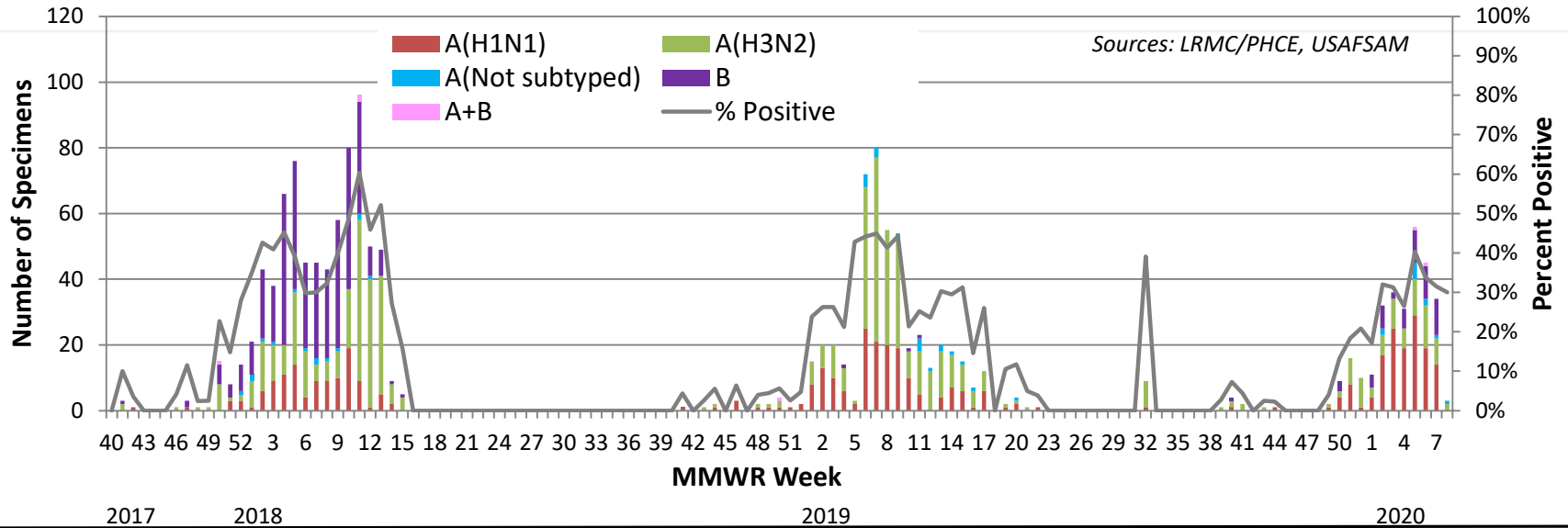


Number and Proportion of Specimens Positive for Influenza by Subtype



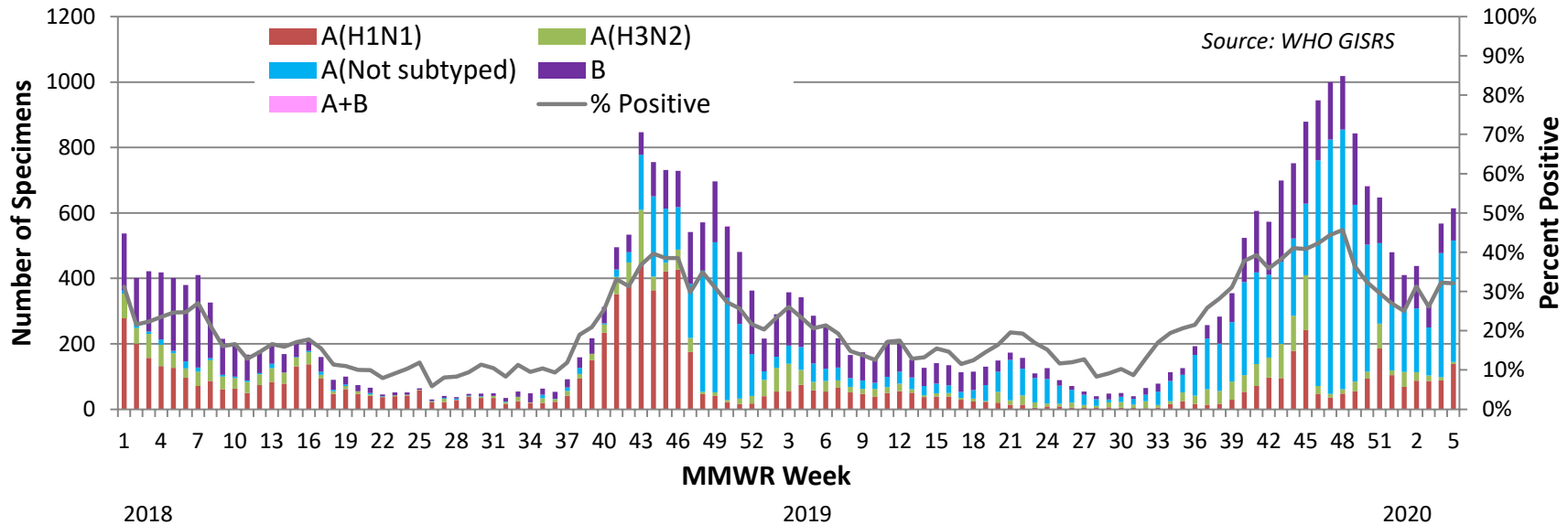
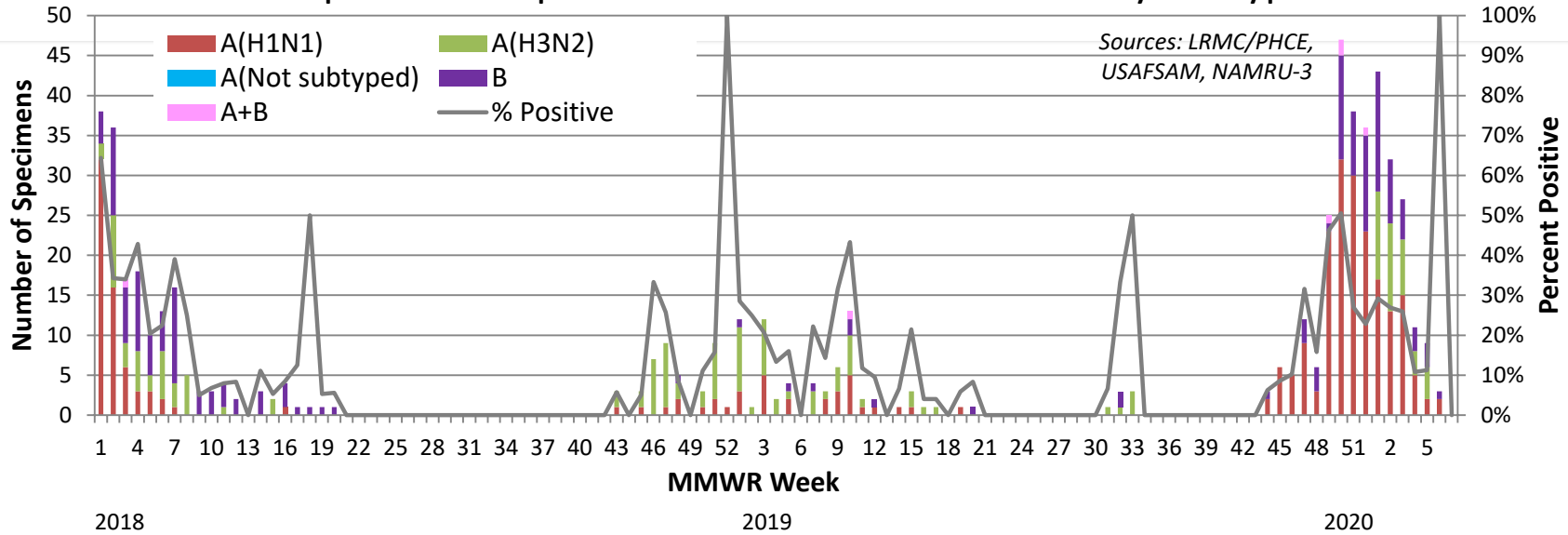
Subtype Circulation: Europe

Number and Proportion of Specimens Positive for Influenza by Subtype



Subtype Circulation: Middle East

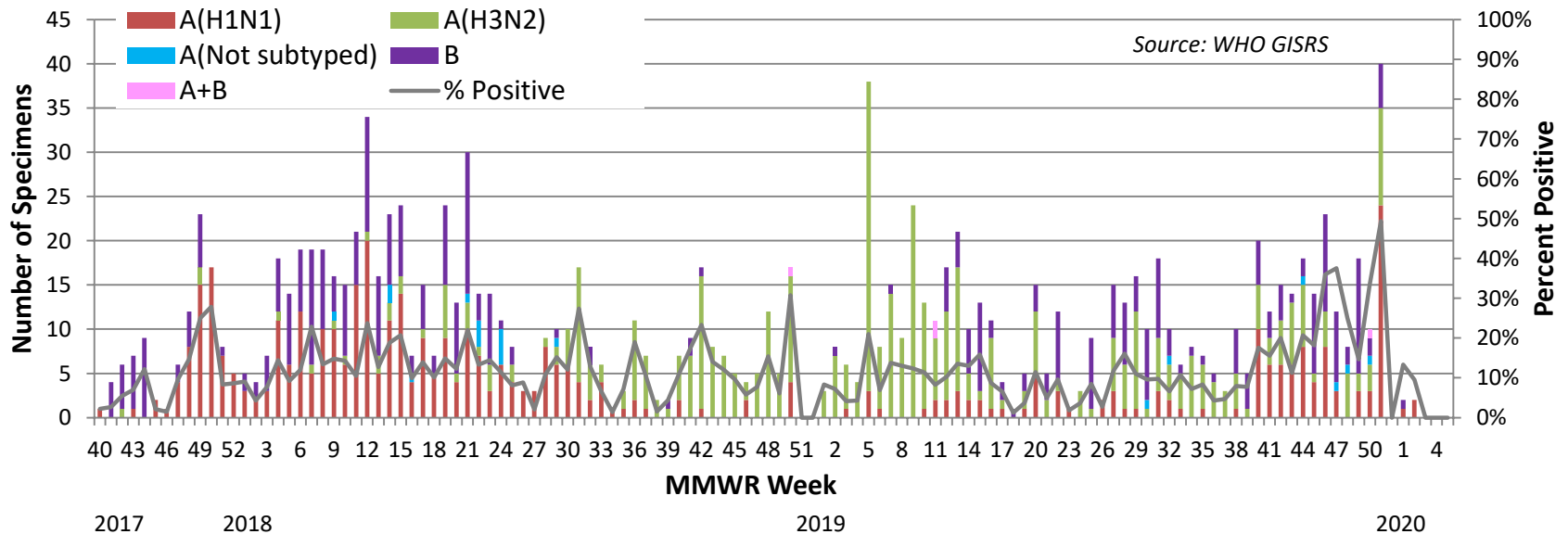
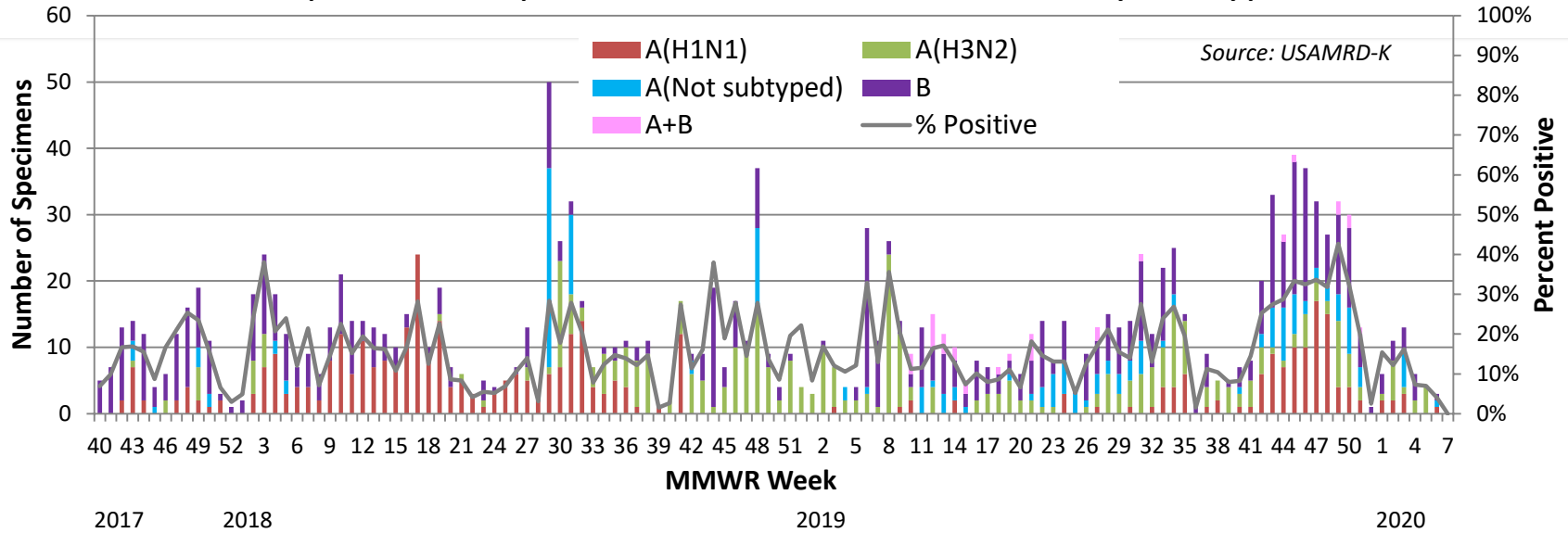
Number and Proportion of Specimens Positive for Influenza by Subtype



Subtype Circulation: East Africa



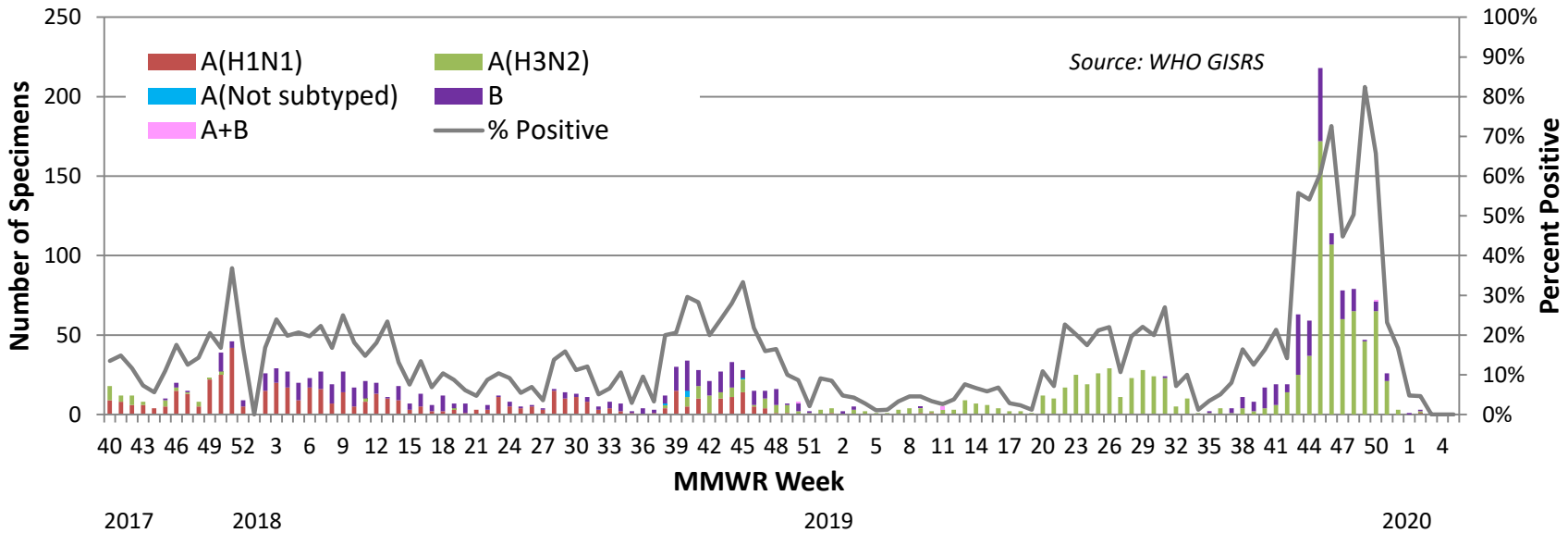
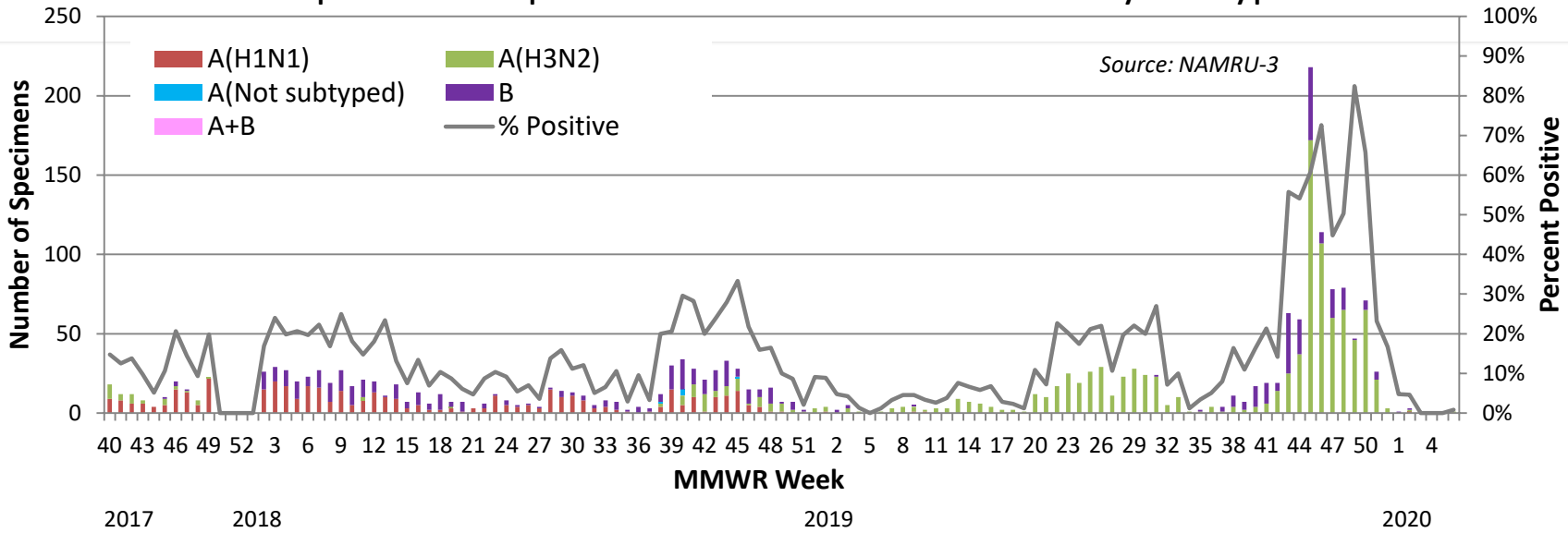
Number and Proportion of Specimens Positive for Influenza by Subtype



Subtype Circulation: West Africa (Ghana)



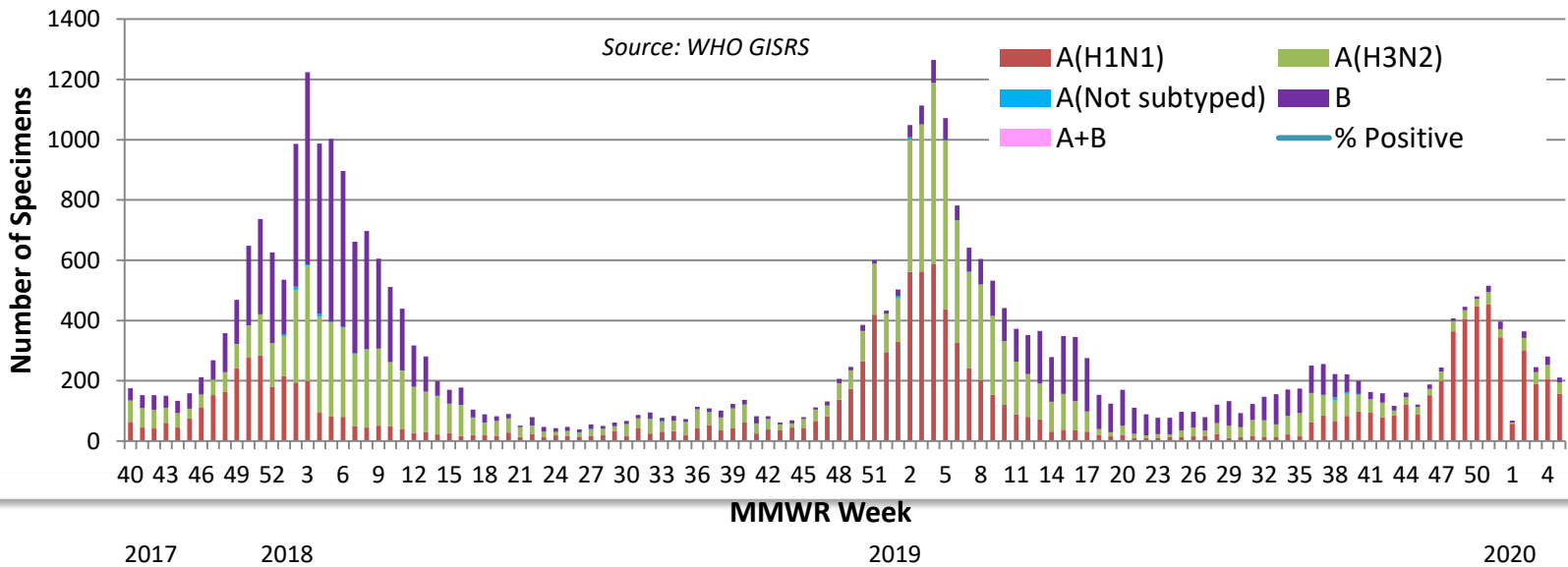
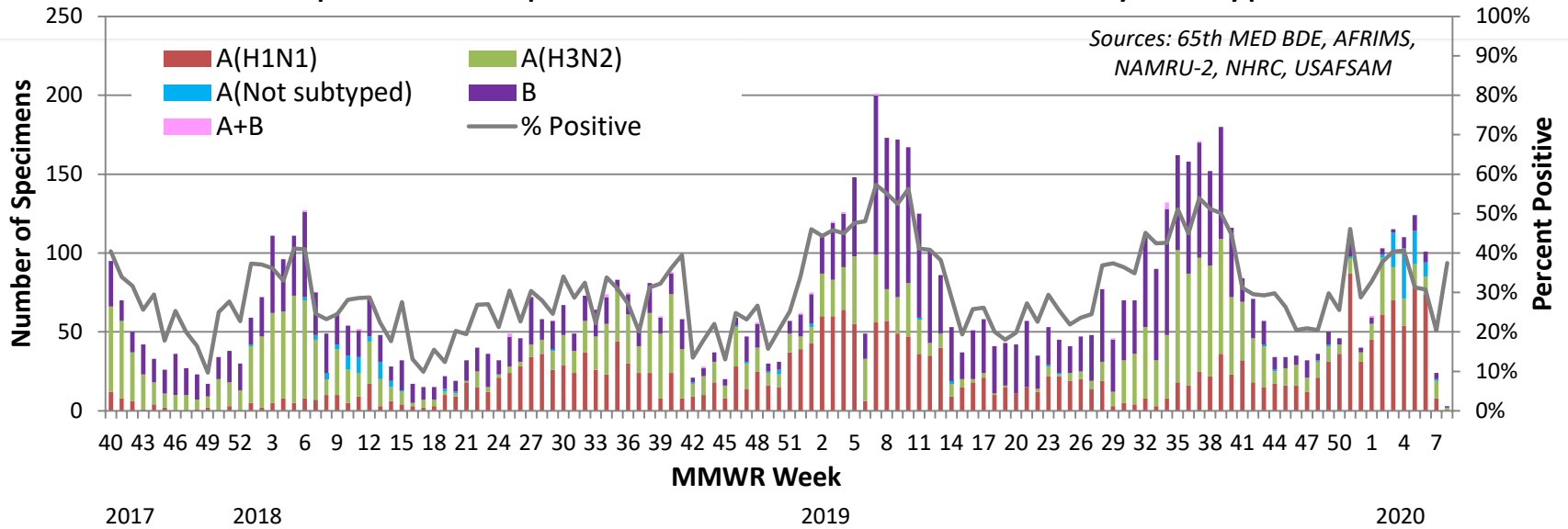
Number and Proportion of Specimens Positive for Influenza by Subtype



Subtype Circulation: Asia



Number and Proportion of Specimens Positive for Influenza by Subtype



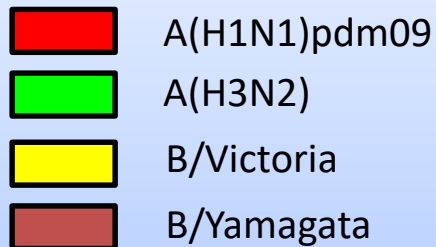
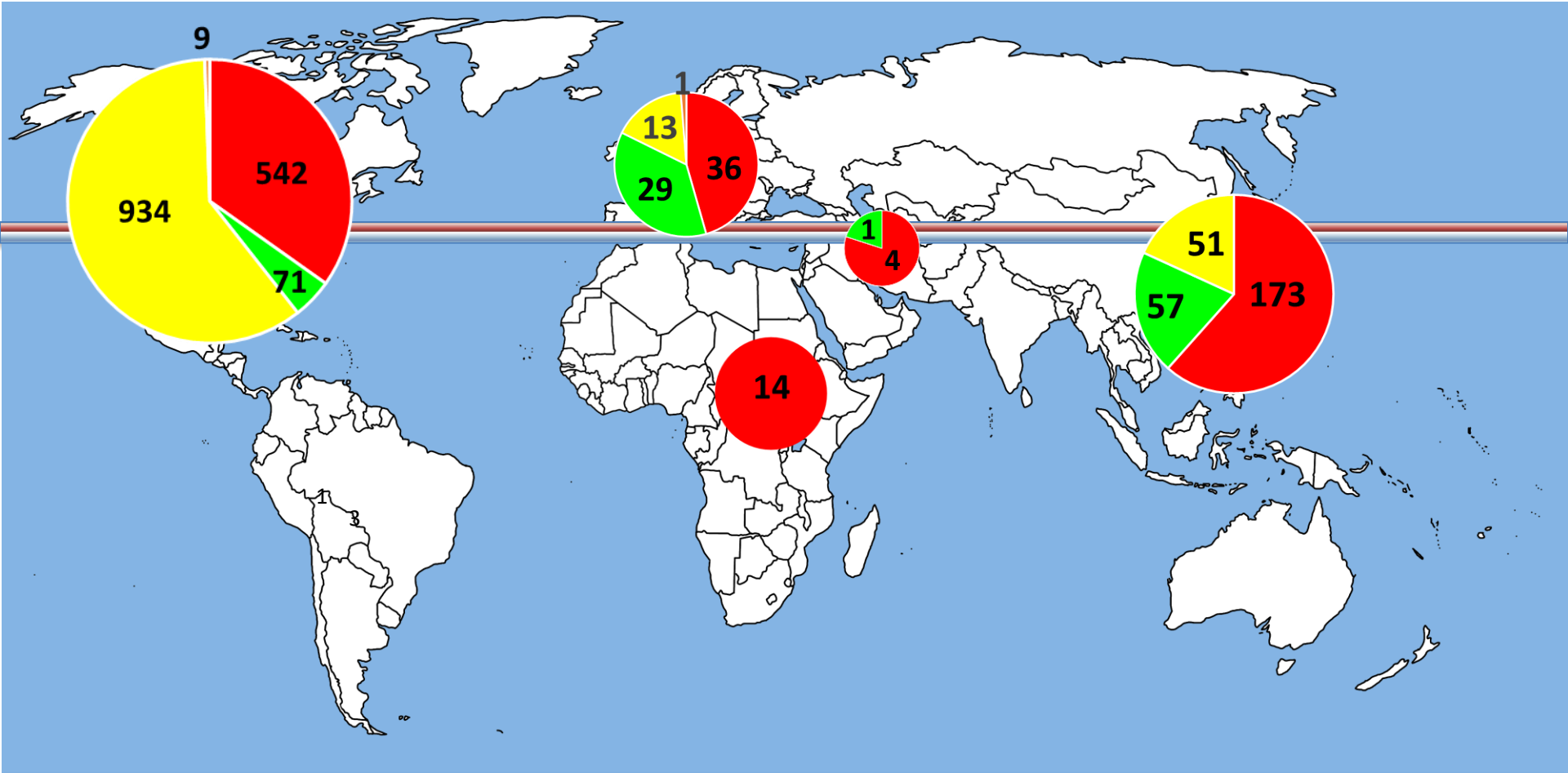
Summary of Circulating Subtype 2019-2020 Season



- In **North America** DoD surveillance is similar to national trends with a predominance of **Influenza B**; in recent surveillance **A(H1N1)** predominates
- Activity during the season in **South America** showed a predominance of **Influenza B***
- Activity in **Europe** shows **A(H1N1)** predominating
- **Asia** data show early predominance of **A(H3N2)** with recent predominance of **A(H1N1)***
- In the **Middle East** **A(H1N1)** predominates
- **East Africa** data show nearly evenly mixed predominance of **influenza B** with recent predominance of **A(H3N2)***
- Activity in **West Africa** shows **A(H3N2)** predominating

*Most data from tropics

DoD / USAFSAM Phylogenetic Analysis 2019-2020 Influenza Season

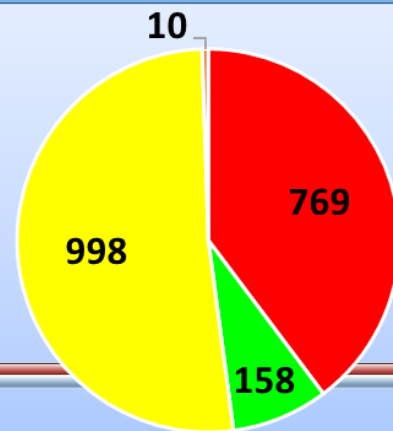


Contributors

- USAFSAM Sentinel Sites (1752)
- Deployed Locations (5)
- AFRIMS (64)
- NAMRU-2 (7)
- NHRC (93)
- USAMRD-K (14)
- Hospitalized Cases (34)

Countries

- | | |
|-----------|---------------|
| Cambodia | Mexico |
| Country 1 | Philippines |
| England | South Korea |
| Germany | Spain |
| Italy | Thailand |
| Japan | United States |
| Kenya | Guam |



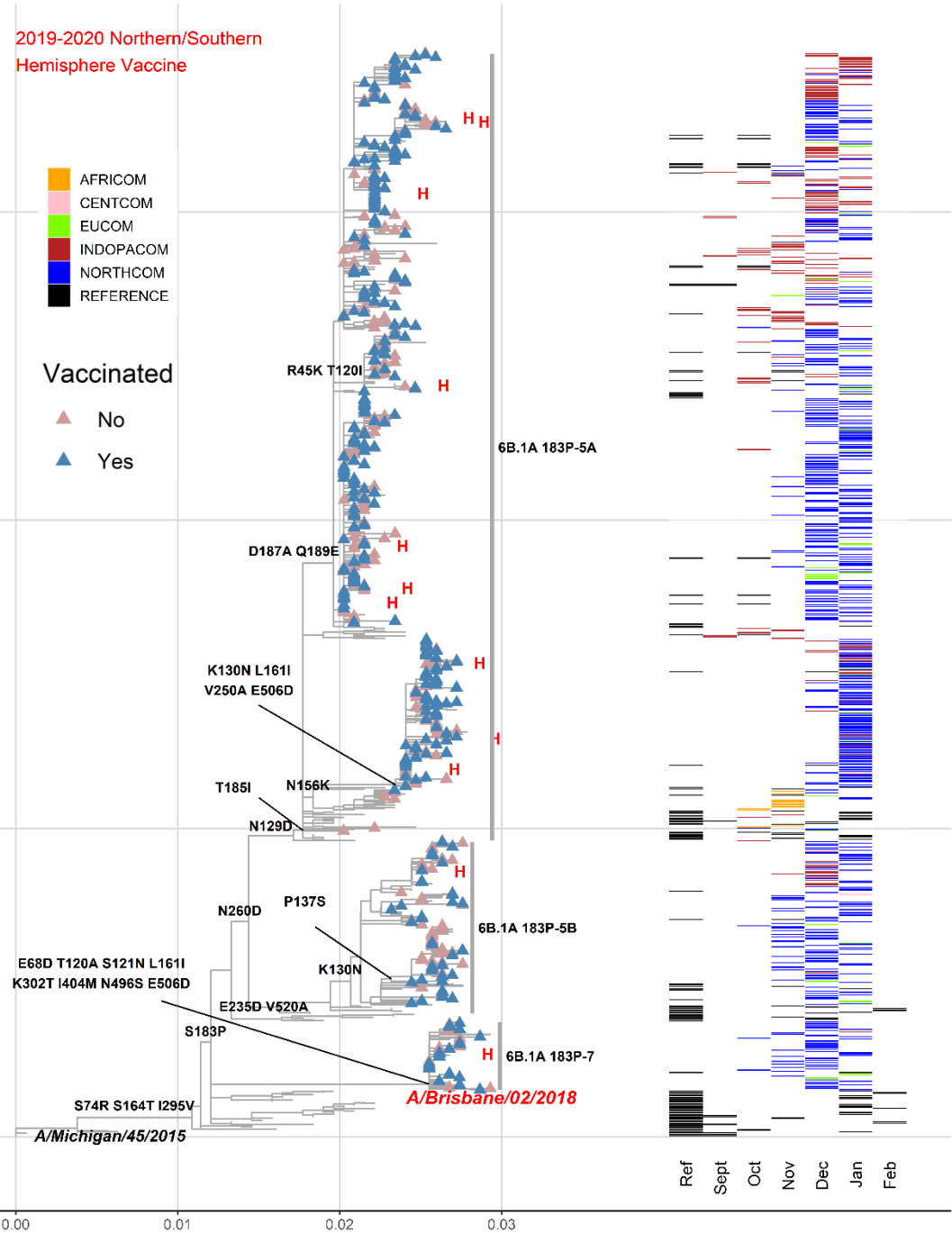
Total = 1935

2019-2020 Northern/Southern Hemisphere Vaccine

- AFRICOM
- CENTCOM
- EUCOM
- INDOPACOM
- NORTHCOM
- REFERENCE

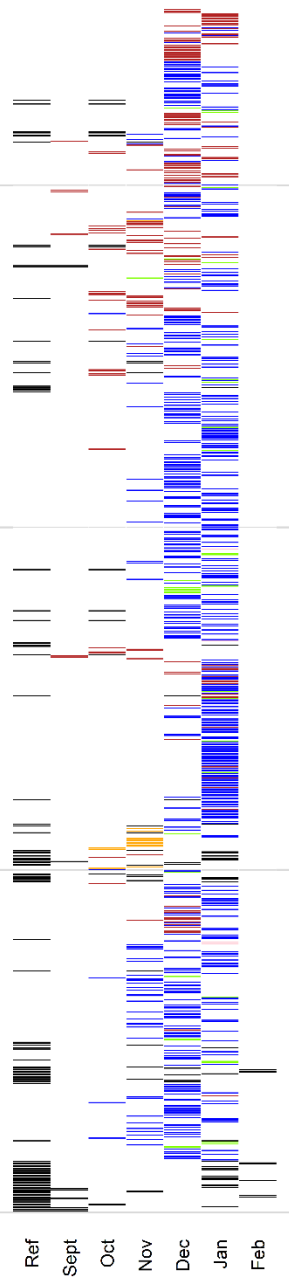
Vaccinated

- ▲ No
- ▲ Yes



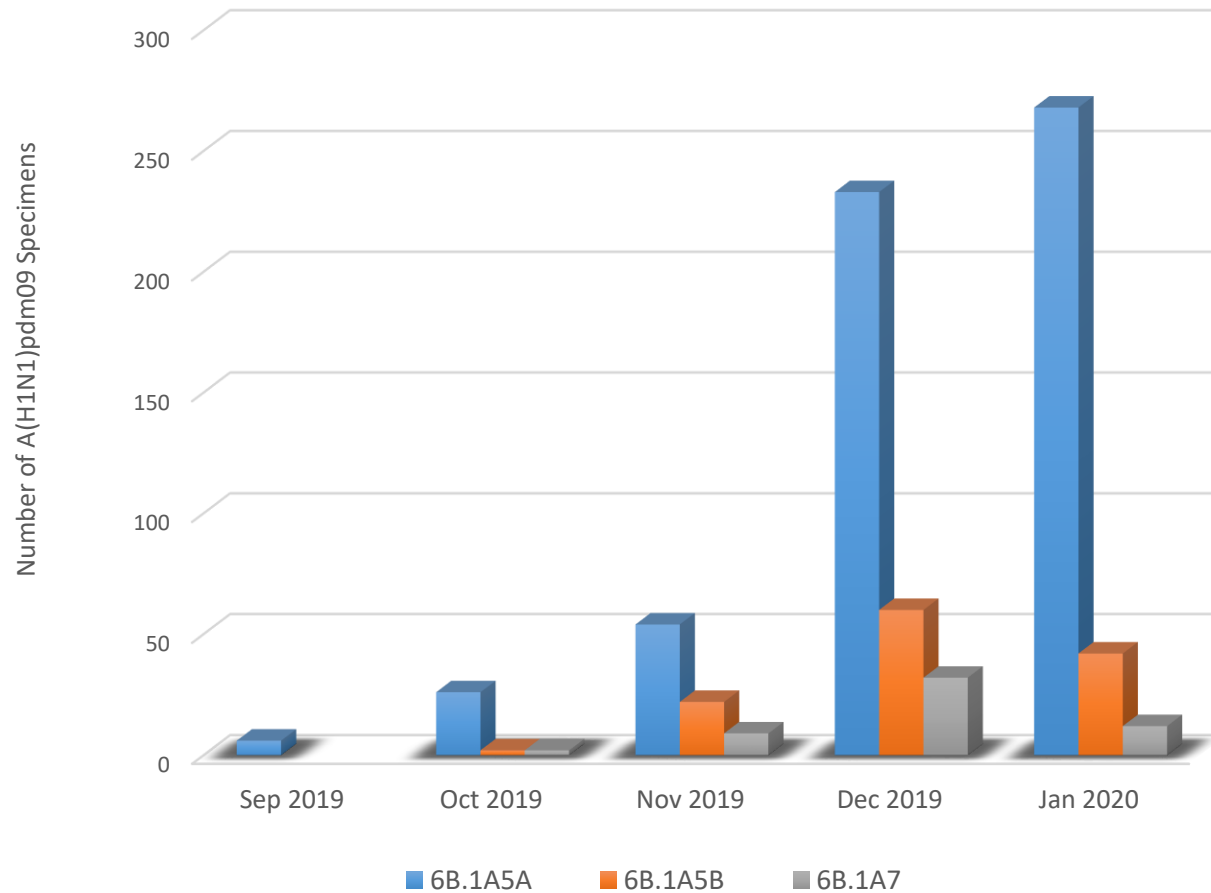
Influenza A(H1N1)pdm09

769 influenza A(H1N1)pdm09 specimens sequenced
 All clade 6B.1A with 183P substitution, with 76.5% in subgroup 5A, 16.4% in subgroup 5B, and 7.1% in subgroup 7
 15 A(H1N1)pdm09 specimens collected from hospitalized patients, with 13 (86.7%) in subgroup 5A, and 1 each in groups 5B and 7
 Among 6B.1A5A viruses, 91.1% had D187A and Q189E, and 23.9% had K130N
 Among 6B.1A5B viruses, 45.6% had P137S



A(H1N1)pdm09 HA Clades

Sep 2019-Jan 2020



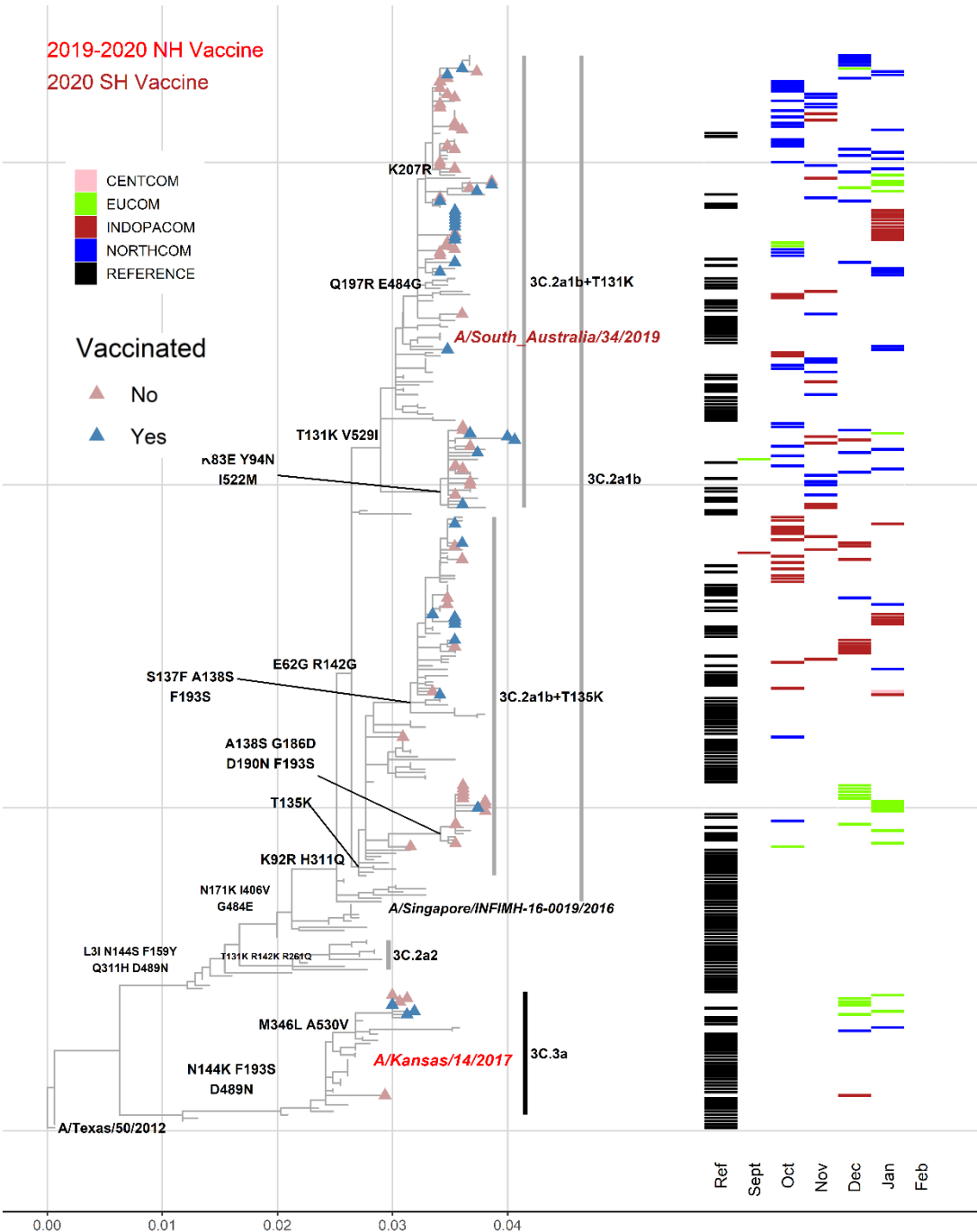
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2019-2020 NH Vaccine
2020 SH Vaccine

■ CENTCOM
■ EUCOM
■ INDOPACOM
■ NORTHCOM
■ REFERENCE

Vaccinated

▲ No
▲ Yes

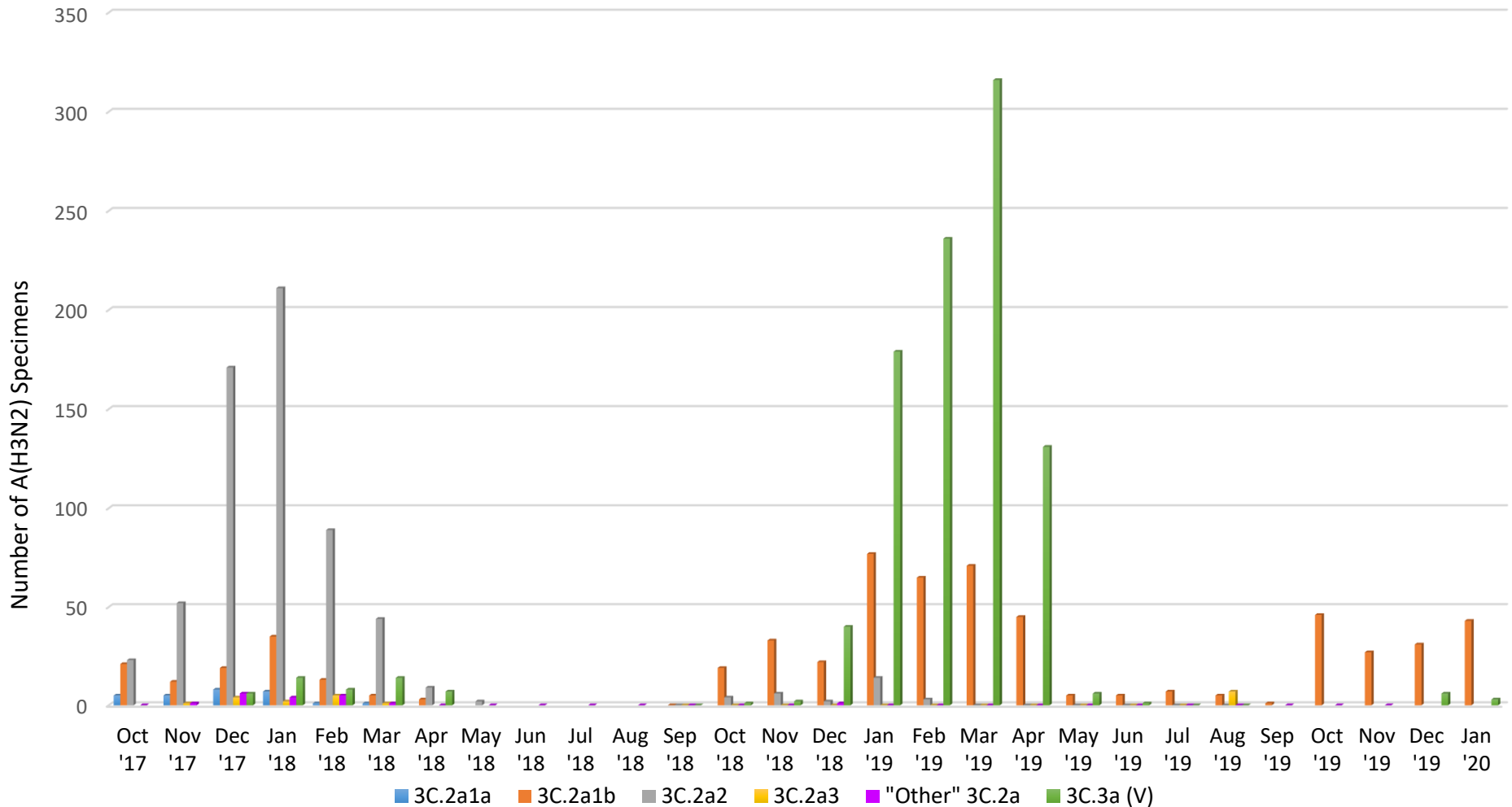


Influenza A(H3N2)

- 158 influenza A(H3N2) specimens sequenced
- 94.3% in clade 3C.2a1b and 5.7% in clade 3C.3a
- 73.0% of the 3C.2a1b viruses had the substitution T131K (same as 2020 SH vaccine strain A(South Australia/34/2019) and 44.9% had Q197R

A(H3N2) HA Clades

Oct 2017-Jan 2020



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2018-2020 NH Vaccine
2020 SH Vaccine

EUCOM
INDOPACOM
NORTHCOM
REFERENCE

Vaccinated

▲ No
▲ Yes

A217S

E128K

V1A.3

B/Washington/02/2019

G133R

162-164Del K136E

162-163Del I180V

I117V V146I

B/Colorado/06/2017

V1A.1

B/Brisbane/60/2008

0.000 0.005 0.010 0.015 0.020

Ref Sept Oct Nov Dec Jan Feb

Influenza B/Victoria Lineage

998 influenza B/Victoria specimens sequenced

96.6% in clade V1A.3 (3-del) and 3.4% in clade V1A.1 (2-del)

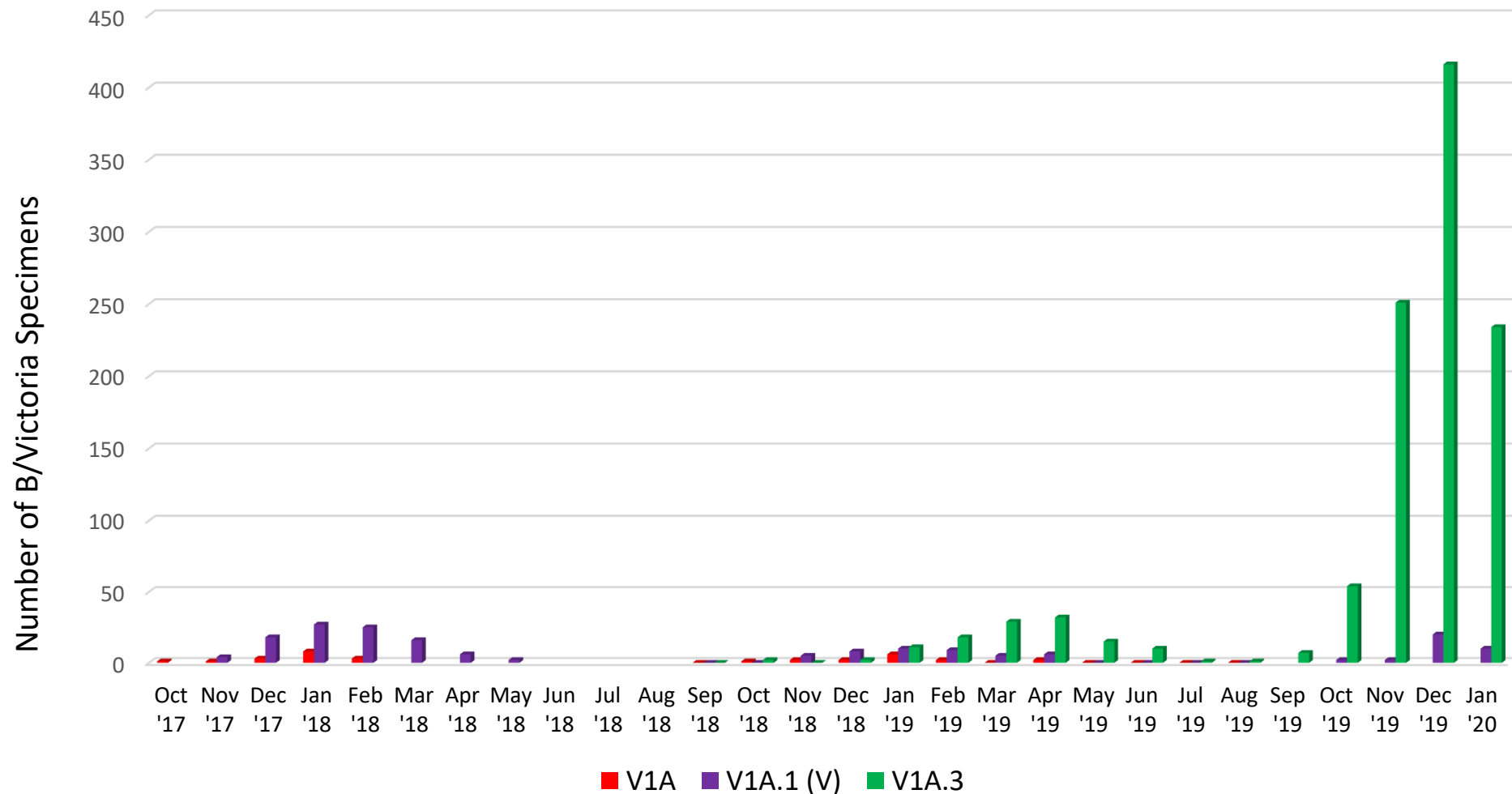
19 collected from hospitalized patients, with 18 (94.7%) in clade V1A.3 and 1 in V1A.1

Nearly all V1A.3 viruses had G133R (98.9%) and K136E (99.9%), and 49.1% had E128K

Additionally, 10 influenza B/Yamagata specimens were collected and all were clade Y3 (data not shown)

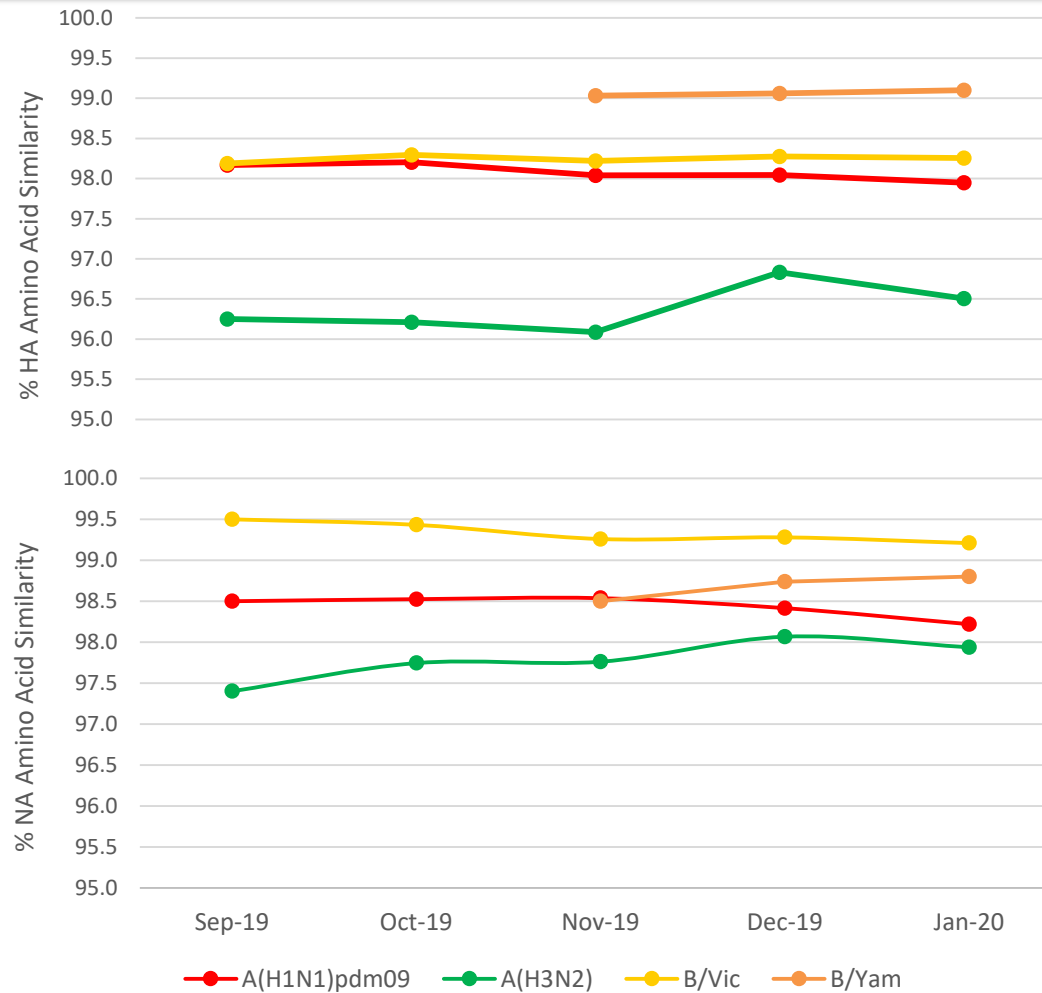
B/Victoria HA Clades

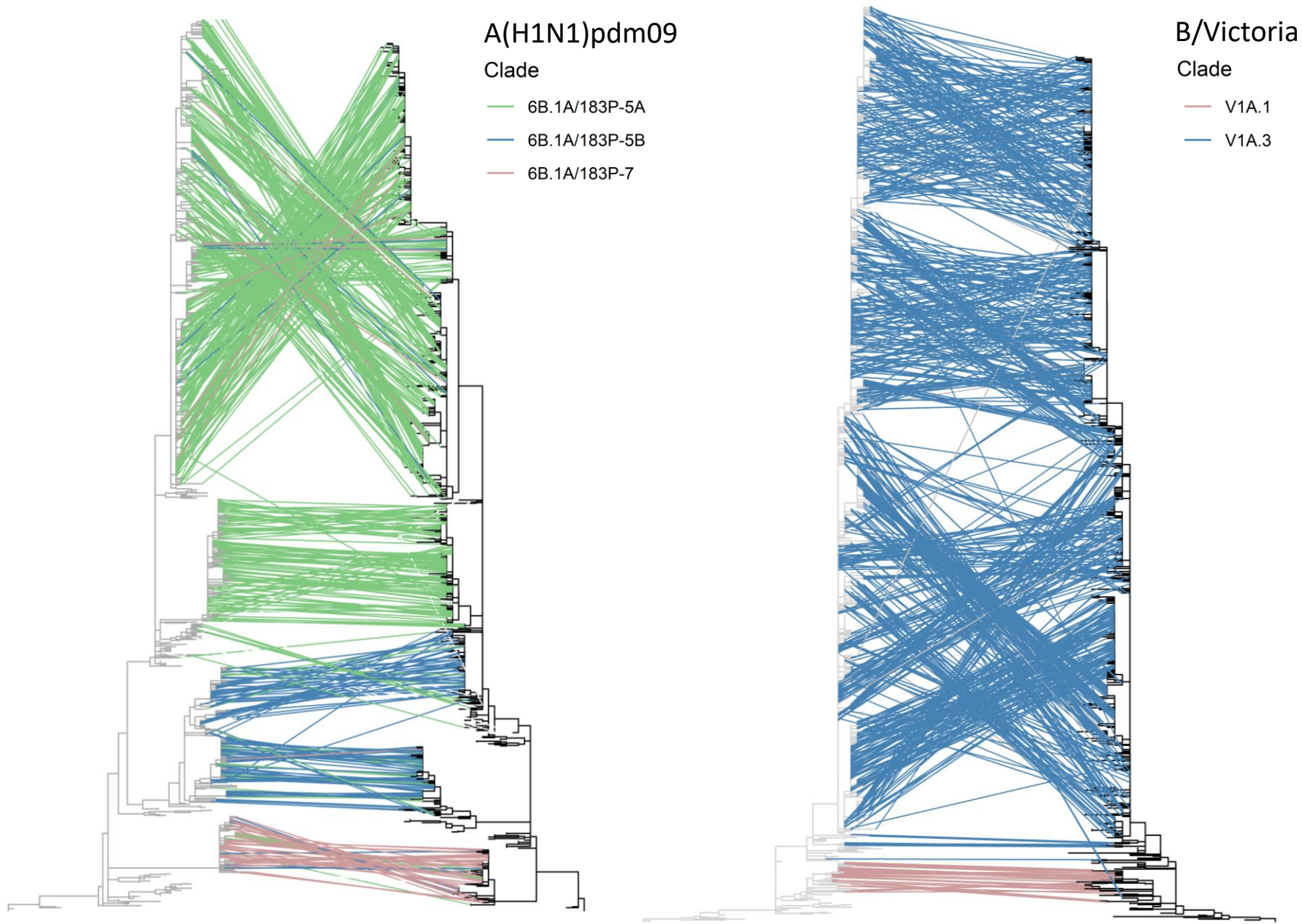
Oct 2017-Jan 2020



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Surface Protein Similarity





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Microneutralization Titers for Influenza Virus A (H1N1) samples



		Reference Antiserum			Passage
		A/Brisbane/2/2018	A/Michigan/45/2015	A/California/7/2009	
Reference Virus					
A(H1N1)pdm09	A/Brisbane/2/2018	20480	10240	5120	Egg
A(H1N1)pdm09	A/Michigan/45/2015	20480	10240	5120	Egg
A(H1N1)pdm09	A/California/7/2009	2560	1280	1280	Egg
Test Antigen					
A(H1N1)pdm09	A/Georgia/10013/2019	3620	2560	640	PMK
A(H1N1)pdm09	A/Washington/9902/2019	2560	1280	640	PMK
A(H1N1)pdm09	A/Colorado/9862/2019	2560	1280	640	PMK
A(H1N1)pdm09	A/Alabama/9860/2019	5120	2560	1280	PMK
A(H1N1)pdm09	A/Japan/10014/2019	3620	1280	320	PMK
A(H1N1)pdm09	A/Ohio/9894/2019	5120	2560	320	PMK
A(H1N1)pdm09	A/Guam/9874/2019	5120	2560	640	PMK
A(H1N1)pdm09	A/Georgia/9866/2019	3620	1280	320	PMK
A(H1N1)pdm09	A/Delaware/9864/2019	5120	2560	640	PMK
A(H1N1)pdm09	A/Virginia/9900/2019	1810	1280	320	PMK
A(H1N1)pdm09	A/Texas/9896/2019	2560	1810	640	PMK
A(H1N1)pdm09	A/Nevada/9885/2019	5120	2560	905	PMK
A(H1N1)pdm09	A/Alabama/9860/2019	2560	2560	453	SIAT1

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Microneutralization Titers for Influenza Virus A (H3N2) samples



		Reference Antiserum			
Reference Virus		A/Kanasas/14/2017	A/Singapore/INFIMH-16-0019/2016	A/Hong Kong/4801/2014	Passage
	A/Kanasas/14/2017	1280	160	1280	Egg
	A/Singapore/INFIMH-16-0019	5120	10240	10240	Egg
	A/Hong Kong/4801/2014	5120	7241	10240	Egg
Test antigens					
A(H3N2)	A/Nevada/10019/2019	320	160	<160	PMK
A(H3N2)	A/Japan/9879/2019	640	320	320	PMK
A(H3N2)	A/Virginia/9898/2019	452	320	160	PMK
A(H3N2)	A/England/9865/2019	1810	905	905	PMK
A(H3N2)	A/Maryland/9883/2019	226	160	<160	PMK
A(H3N2)	A/Virginia/9899/2019	640	320	640	PMK
A(H3N2)	A/Ohio/9893/2019	160	<160	<160	PMK
A(H3N2)	A/Colorado/10011/2019	320	160	160	PMK
A(H3N2)	A/Washington/9903/2019	320	320	160	SIAT1

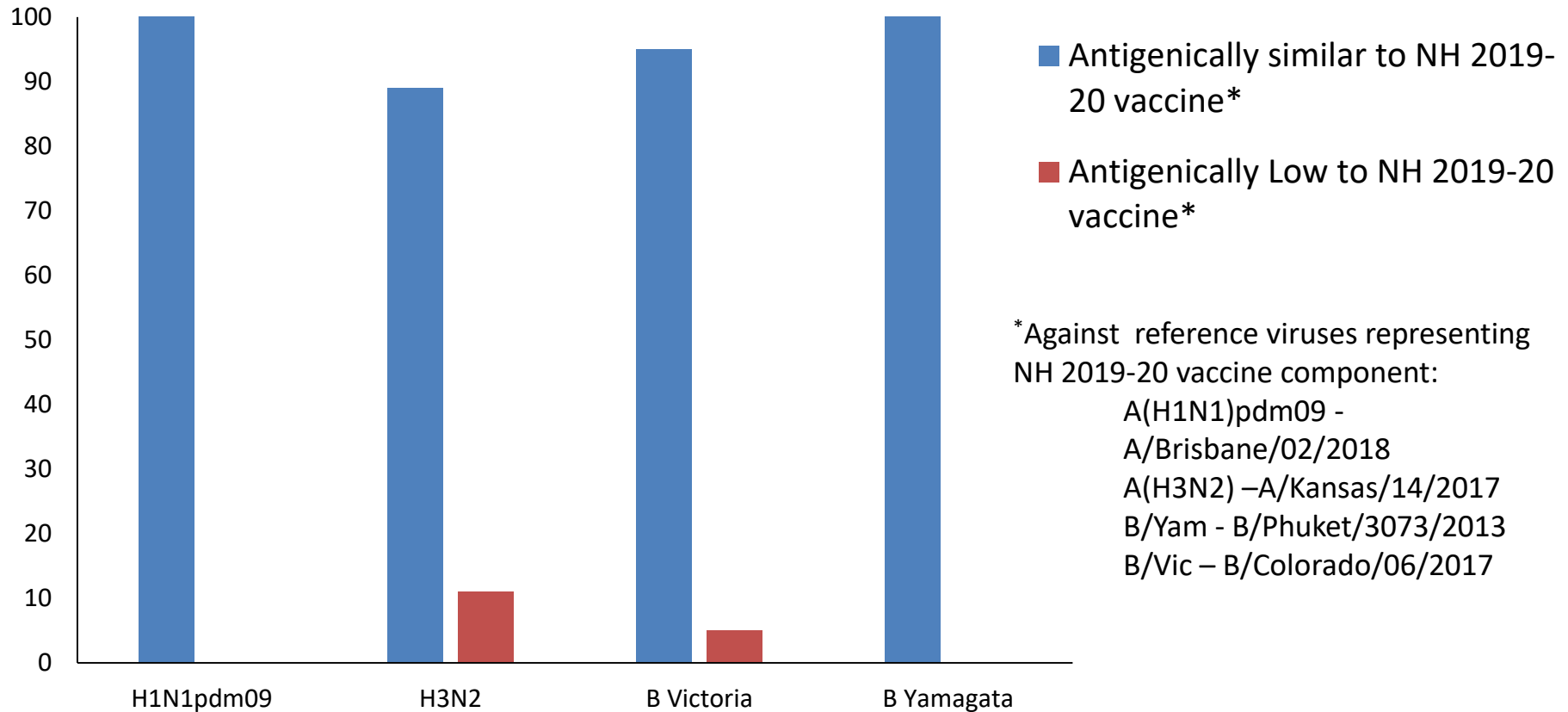
Microneutralization Titers for Influenza Virus B samples



		Reference Antiserum		
		B/Colorado/06/2017	B/Phuket/3073/2013	Passage
Reference Virus				
B/Vic	B/Colorado/06/2017	2560	40	Egg
B/Yam	B/Phuket/3073/2013	80	1280	Egg
Test Antigens				
B/Vic	B/Georgia/9912/2019	3620	<40	PMK
B/Vic	B/Kentucky/9915/2019	3620	<40	PMK
B/Vic	B/Kentucky/9914/2019	2560	<40	PMK
B/Vic	B/Kentucky/9917/2019	1280	<40	PMK
B/Vic	B/Washington/10133/2019	3620	<40	PMK
B/Vic	B/Texas/10099/2019	3620	<40	PMK
B/Vic	B/Texas/10098/2019	2560	<40	PMK
B/Vic	B/Nevada/10096/2019	2560	<40	PMK
B/Vic	B/Italy/9913/2019	3620	<40	PMK
B/Vic	B/Virginia/10132/2019	1280	<40	PMK
B/Vic	B/Texas/10100/2019	640	<40	PMK
B/Vic	B/South Carolina/10097/2019	1810	<40	PMK
B/Vic	B/Kentucky/10040/2019	905	<40	PMK
B/Vic	B/Colorado/10036/2019	2560	<40	PMK
B/Vic	B/Arizona/10034/2019	1810	<40	PMK
B/Yam	B/Nevada/9922/2019	<40	2560	PMK
B/Vic	B/Washington/10133/2019	640	<40	SIAT1
B/Vic	B/Colorado/10036/2019	320	<40	SIAT1
B/Vic	B/Florida/10037/2019	453	<40	SIAT1
B/Vic	B/Washington/10009/2019	905	<40	SIAT1
B/Vic	B/Washington/10010/2019	640	<40	SIAT1

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Antigenic Characterization Summary



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Midseason Vaccine Effectiveness (VE) Estimates

- Mid-year estimates provided by:
 - AFHSB AF Satellite - US Air Force School of Aerospace Medicine (USAFSAM)
 - Naval Health Research Center (NHRC)
 - AFHSB Epidemiology and Analysis Section
- 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; AFHSB also used positive rapid tests (but excluded rapid test negatives)
 - Analyses performed for influenza types and subtypes

AFHSB Air Force Satellite / USAFSAM Analyses

United States Air Force School of Aerospace Medicine (USAFSAM)



DoD Beneficiaries & U.S.-Mexico Border Civilians

- Adjusted Estimates of Vaccine Effectiveness
 - Population: DoD healthcare beneficiaries (excluding Service Members) and civilian populations at clinics near the U.S.–Mexico border (Border Infectious Disease Surveillance; BIDS)
 - Time period: November 3, 2019 – February 15, 2020 (Weeks 45-07)

- Analysis by influenza type/subtype

- Overall
- B
- A (any influenza A specimen)
- A(H1N1)pdm09
- A(H3N2)

- Analysis by population

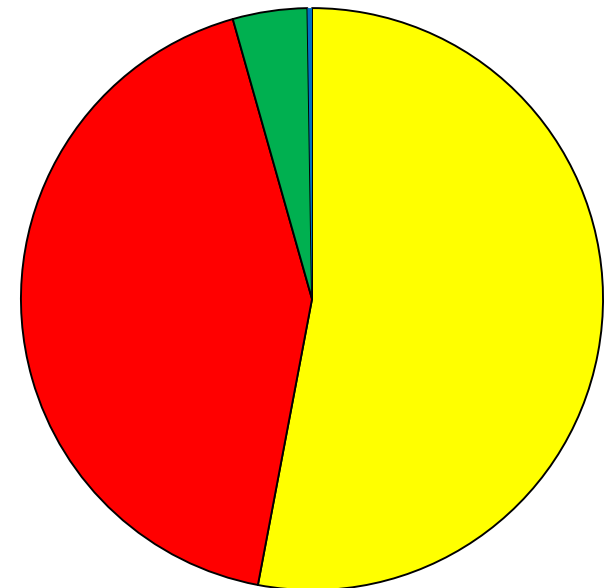
- Overall
- Children
- Adults

-
- Insufficient data for a 65+ age group & adult A(H3N2) analysis
 - Adjusted for age group, time of specimen collection, location, and gender

DoD Beneficiaries & U.S.-Mexico Border Civilians

- **Laboratories Contributing Specimens for VE Analysis (n=3,745)**
 - US Air Force School of Aerospace Medicine (USAFSAM) n = 3,375
 - Landstuhl Regional Medical Center (LRMC) n = 234
 - Naval Health Research Center (NHRC) n= 136

- **Adjusted Estimates of Vaccine Effectiveness**
 - Cases: n =1,595; confirmed by RT-PCR or viral culture
 - Controls: n=2,150; test-negative
 - Vaccination rates: cases **43%**, controls **57%**
 - Of total cases:
 - **23%** were influenza B
 - **18%** were influenza A(H1N1)pdm09
 - **2%** were influenza A (H3N2)
 - **0.1%** were influenza A/Not Subtyped



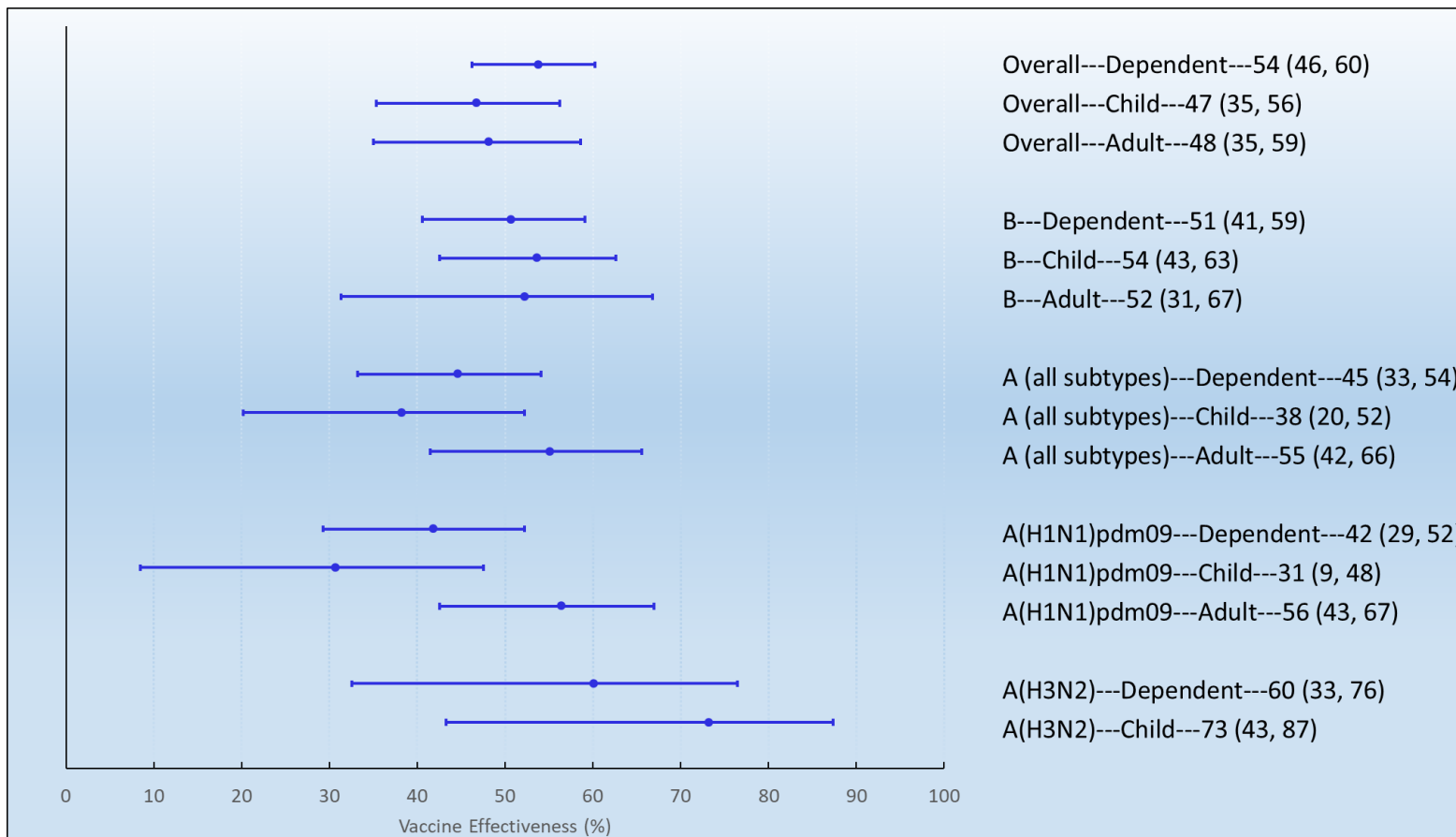
■ B ■ A(H1N1)pdm09 ■ A(H3N2) ■ A/Not Subtyped

Characteristic		Cases (n=1,595) No.(%)	Controls (n=2,150) No.(%)	p-Value
Gender	Male	715 (44.83)	828 (38.51)	<0.0001
	Female	880 (55.17)	1,322 (61.49)	
Age	2-8	624 (39.12)	747 (34.74)	<0.0001
	9-17	423 (26.52)	378 (17.58)	
	18-49	334 (20.94)	584 (27.16)	
	50-64	168 (10.53)	274 (12.74)	
	65+	46 (2.88)	167 (7.77)	
Month of illness	November	139 (8.71)	447 (20.79)	<0.0001
	December	375 (23.51)	643 (29.91)	
	January	732 (45.89)	732 (34.05)	
	February	349 (21.88)	328 (15.26)	
Geographic Region	Eastern CONUS	595 (37.30)	750 (34.88)	<0.0001
	Western CONUS	769 (48.21)	918 (42.70)	
	OCONUS	231 (14.48)	482 (22.42)	
Surveillance Hub	LRMC	56 (3.51)	178 (8.28)	<0.0001
	NHRC	52 (3.26)	84 (3.91)	
	USAFSAM	1,487 (93.23)	1,888 (87.81)	
Vaccination Status	Vaccinated	690 (43.26)	1,205 (56.05)	<0.0001
	Unvaccinated	905 (56.74)	945 (43.95)	
Flu	B	845 (52.98)	0 (0)	<0.0001
	A(H1N1)pdm09	680 (42.63)	0 (0)	
	A(H3N2)	66 (4.14)	0 (0)	
	A/Not Subtyped	4 (0.25)	0 (0)	
	Not Flu	0 (0)	2150 (100)	

CONUS=Continental United States; OCONUS=Outside Continental United States; LRMC=Landstuhl Regional Medical Center; NHRC=Naval Health Research Center; USAFSAM=United States Air Force School of Aerospace Medicine

USAFSAM

Summary of DoD Dependents and U.S.-Mexico Border VE Results



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USAFSAM

Adjusted VE Estimates 2019-2020



Type	Population	Vaccine Status	Cases (%)	Controls (%)	Crude VE (95% CI)	Adjusted VE* (95% CI)
Overall	All Dependents	Vaccinated	690 (18)	1205 (32)	40 (32, 48)	54 (46, 60)
		Unvaccinated	905 (24)	945 (25)		
	Children (2-17 yrs)	Vaccinated	459 (21)	632 (29)	39 (28, 49)	47 (35, 56)
		Unvaccinated	588 (27)	493 (23)		
	Adults (≥18)	Vaccinated	228 (15)	564 (36)	42 (29, 53)	48 (35, 59)
		Unvaccinated	317 (20)	452 (29)		
B	All Dependents	Vaccinated	323 (11)	1205 (40)	51 (43, 59)	51 (41, 59)
		Unvaccinated	522 (17)	945 (32)		
	Children (2-17 yrs)	Vaccinated	255 (14)	632 (35)	51 (40, 59)	54 (43, 63)
		Unvaccinated	402 (23)	493 (28)		
	Adults (≥18)	Vaccinated	66 (5)	564 (47)	56 (39, 68)	52 (31, 67)
		Unvaccinated	120 (10)	452 (38)		
A	All Dependents	Vaccinated	367 (13)	1205 (42)	25 (11, 36)	45 (33, 54)
		Unvaccinated	383 (13)	945 (33)		
	Children (2-17 yrs)	Vaccinated	204 (13)	632 (42)	14 (-8, 32)	38 (20, 52)
		Unvaccinated	186 (12)	493 (33)		
	Adults (≥18)	Vaccinated	162 (12)	564 (41)	34 (16, 48)	55 (42, 66)
		Unvaccinated	197 (14)	452 (33)		
A (H1N1)pdm09	All Dependents	Vaccinated	336 (12)	1205 (43)	23 (9, 36)	42 (29, 52)
		Unvaccinated	344 (12)	945 (33)		
	Children (2-17 yrs)	Vaccinated	188 (13)	632 (43)	11 (-14, 30)	31 (9, 48)
		Unvaccinated	164 (11)	493 (33)		
	Adults (≥18)	Vaccinated	147 (11)	564 (42)	35 (16, 49)	56 (43, 67)
		Unvaccinated	180 (13)	452 (34)		
A (H3N2)	All Dependents	Vaccinated	29 (1)	1205 (54)	39 (-1, 62)	60 (33, 76)
		Unvaccinated	37 (2)	945 (43)		
	Children (2-17 yrs)	Vaccinated	15 (1)	632 (54)	44 (-9, 72)	73 (43, 87)
		Unvaccinated	21 (2)	493 (42)		

CI=confidence interval; VE=(1-odds ratio) x 100.
 *VE Adjusted for age group, time of specimen collection, location, and gender

Summary of DoD Beneficiaries & U.S.-Mexico Border Civilians

- Overall VE was moderately protective and significant
- A(H1N1)pdm09: VE was highest among adults at 56%
- A(H3N2): VE was highest among children at 73%
- B: VE was highest among children at 54%

Service Member Vaccine Effectiveness Estimates

Service Members: Study Design



- Case / Test-negative control design
- Population: Active component Service Members
 - Army, Navy, Air Force, Marines
 - CONUS and OCONUS
- Time Period:
 - Influenza B and A(H1N1): Restricted to peak influenza months (Nov 1 – Feb 15)
 - Influenza A (any subtype) and A(H3N2): Restricted to peak Flu A months (Jan 1- Feb 15)
- 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, and month of diagnosis
- Type and sub-type VE calculated, if analysis supported by data

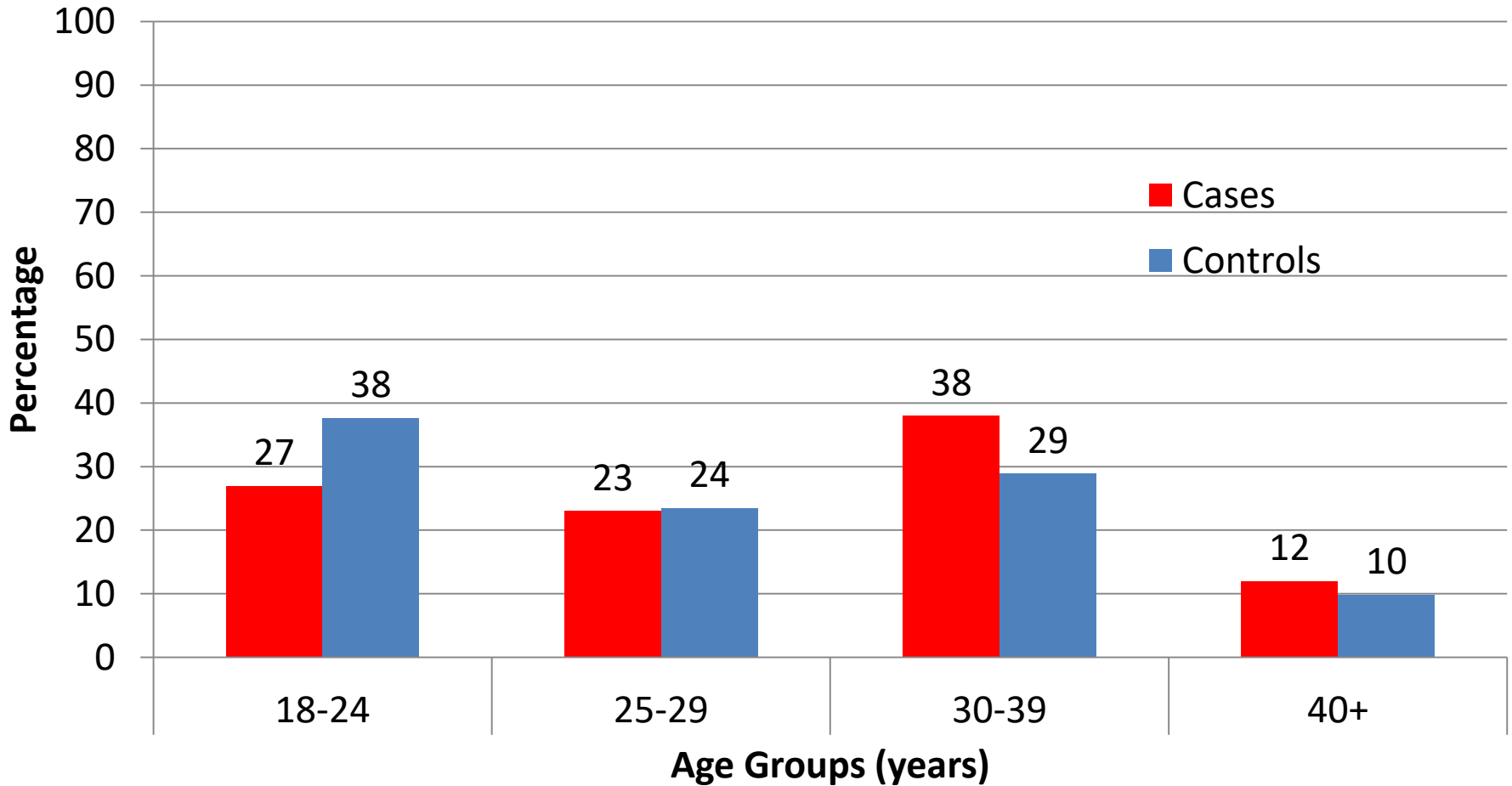
Service Members:

Vaccination Information & Case Subtypes



- Vaccination
 - IIV was the only vaccine type among the study subjects
 - 92% of subjects had prior flu vaccine in previous 5 years
- Cases
 - Influenza A (any subtype) = 1,911
 - Influenza A(H3N2) = 37
 - Influenza A(H1N1) = 347
 - Influenza B = 2,033

Service Members: Cases and Controls by Age Group



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Service Members: Interim VE Estimates 2019-2020



Influenza Type/Subtype	Time Period	Vaccine Type	Cases N (%)	Controls N (%)	Crude VE (95% CI)	Adjusted VE (95% CI)*
Influenza A (any subtype)	JAN-FEB	Vaccinated	1732 (91)	2038 (92)	13 (-8, 30)	12 (-10, 30)
		Unvaccinated	179 (9)	184 (8)		
A(H1N1)	JAN-FEB	Vaccinated	308 (89)	2038 (92)	29 (-3, 51)	28 (-5, 51)
		Unvaccinated	39 (11)	184 (8)		
A(H3N2)	NOV-FEB	Vaccinated	22 (59)	3699 (74)	49 (2, 74)	58 (9, 80)
		Unvaccinated	15 (41)	1283 (26)		
Influenza B	NOV-FEB	Vaccinated	1515 (75)	3699 (74)	-1 (-14, 10)	31 (20, 40)
		Unvaccinated	518 (25)	1283 (26)		

*Adjusted for sex, age, and month of diagnosis

Service Members: VE Summary



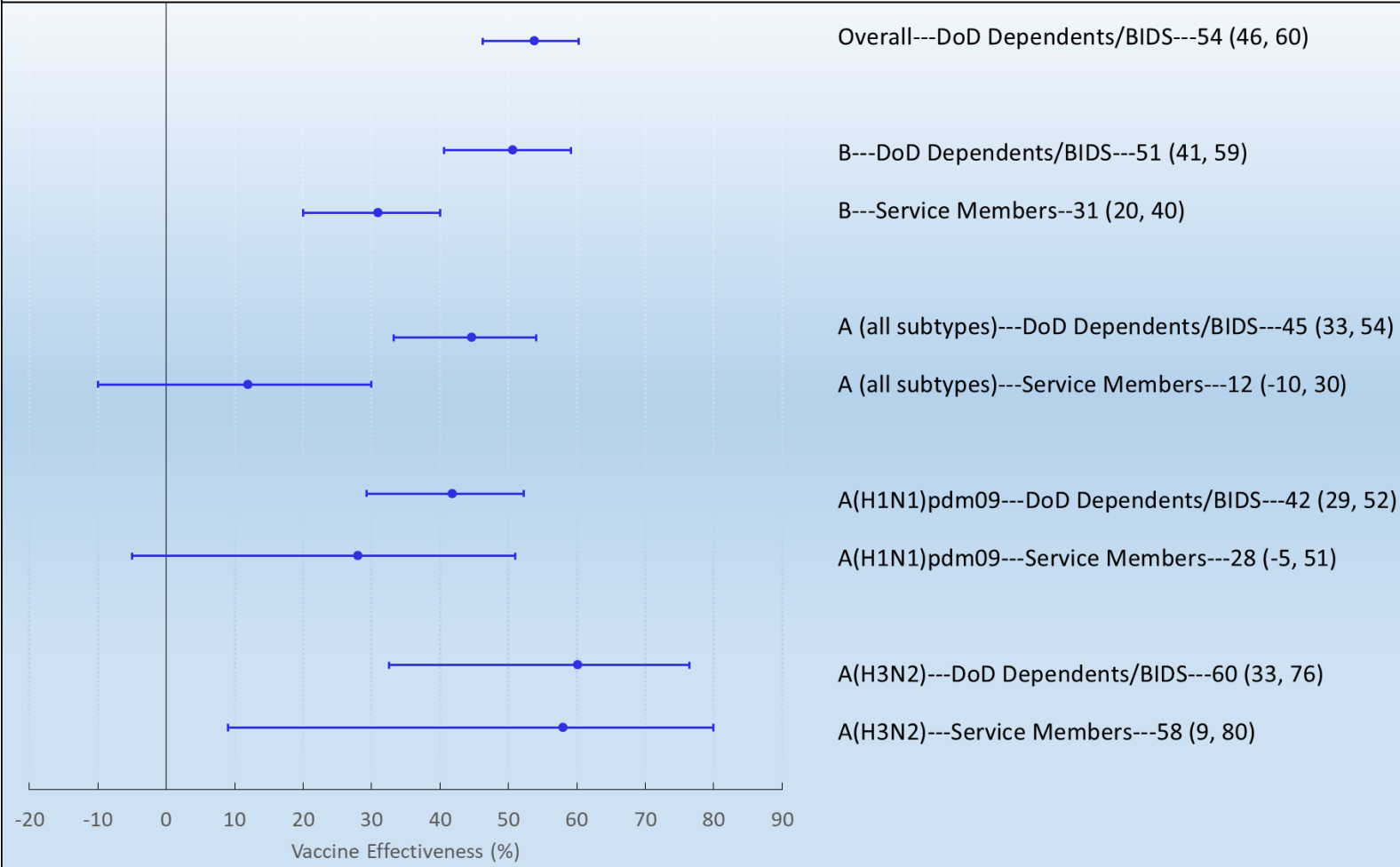
Among Service Members, the 2019-2020 influenza vaccine provided:

- Low to moderate protection against influenza B (31%)
- Moderate protection against A(H3N2) (58%)
- Non-statistically significant low protection against influenza overall (12%) and A(H1N1) (28%)

Summary of DoD VE Results



Influenza Midseason Vaccine Effectiveness 2019-2020



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Summary of DoD VE Results



- Statistically significant VE estimates indicated an overall midseason VE of 54%
 - VE for influenza A 45%, indicating moderate protection
 - VE for influenza B ranged from 31-51%, indicating low to moderate protection
 - VE for A(H1) and ranged 42%, indicating moderate protection
 - Protection was best for A(H3) and ranged from 58-60%, indicating moderate protection

Limitations



- Generalizability
 - Subjects were medically attended; did not assess vaccine impact on less severe cases
 - Active Duty military population is highly immunized; this could have a negative impact on VE (potential method issues and biological effects such as attenuated immune response with repeated exposures)
 - Populations are younger; did not assess vaccine impact in older, high-risk populations

Vaccine Strain Recommendations



- Based on the genetic and VE data, recommendations for the 2020-2021 influenza vaccine
 - For the 2019-2020 influenza vaccine A(H1N1) component: Consider alternate to A/Brisbane/02/2018-like virus, potentially a clade 6B.1A, subgroup 5A representative virus
 - For the 2019-2020 influenza vaccine A(H3N2) component: Consider transition to H3N2 3C.2a1b clade virus
 - For the 2019-2020 influenza vaccine B/Victoria component: Consider replacement of B/Colorado/06/2017-like virus with representative 3-deletion virus
 - 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: maintain the B/Phuket/3073/2013-like virus

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