Vaccine and Related Biological Products Committee Meetings

September 2022-January 2023

22 September 2022

The committee met in open session to discuss the Biologics License Application # 125739 (BLA - 125739) from Rebiotix Inc. for a product, Rebyota (Fecal Microbiota, Live), with a requested indication to "reduce the recurrence of *Clostridioides difficile* infection (CDI) in adults following antibiotic treatment for recurrent *Clostridioides difficile* infection." The committee voted 13 Yes vs 4 No in response to the question if the data are adequate to support the effectiveness of REBYOTA for the specific indication, and voted 12 Yes vs 4 No vs 1 abstain in response to the question if the data are adequate to support the effectiveness of REBYOTA for the specific indication.

06 October 2022

The committee met in open session to discuss the Strain Selection for the Influenza Virus Vaccines for the 2023 Southern Hemisphere Influenza Season. The committee voted unanimously for the inclusion of an A/Sydney/5/2021 (H1N1) pdm09-like virus, an A/Darwin/9/2021 (H3N2)-like virus, and a B/Austria/1359417/2021-like virus (B/Victoria lineage). For the Yamagata lineage the committee voted 12 Yes, 2 No, 2 Abstain to include B/Phuket/3073/2013-like virus as the 2nd influenza B strain in the vaccine.

26 January 2023

The committee will meet in open session to discuss the future vaccination regimens addressing COVID-19.

National Vaccine Advisory Committee (NVAC) – Public Health Agency of Canada (PHAC) Update

1. Government of Canada's COVID-19 Vaccine Response

Vaccine Supply

As of **January 30, 2023,** a total of **118,998,428** doses of vaccine have been distributed to Canada's provinces and territories who have altogether administered over **97** million vaccine doses. Information on vaccine distribution/forecasted allocations and administration is available on the Government of Canada website and is updated regularly.

Vaccination Coverage

As of January 1, 2023 , 87.0% of people in Canada 5 years and older eligible for vaccination have received at least one dose of a COVID-19 vaccine and 84.4% are fully vaccinated. COVID-19 vaccination coverage information by key demographics and vaccine product is updated monthly.

Vaccination status	0-4 years	5-11 years	≥5 years	Total population
At least 1 dose	9.0% (+4.3)	52.7%	87.0%	**83.3%**
Primary series completed	4.2% (+4.2%)	41.1%	84.4%	80.6%
Booster dose received since August 1, 2022	n/a	n/a	23.2% (+20.2%)	22.1% (+19.3)
Primary series completed or booster dose received in the last 6 month	n/a	n/a	26.0%	24.9%

- As of January 1, 2022:
  - 27.3% of the population 12 years+ has completed the primary series or received a booster dose in the last 6 months; 59.2% of 70 to 79 years and 59.2% of 80+ have completed the primary series or received a booster dose in the last 6 months .

Notes:

The "primary series completed" category excludes Quebec from August 14, 2022, and onward, due to changes in Quebec's vaccination status categories. For this reason, the cumulative percent of people in Canada who have completed their primary series, by report week, should be interpreted with caution.

The cumulative number and percent of people who received at least 1 dose decreased from July 17, 2022, to August 14, 2022, due to changes in Quebec's methodology

COVID-19 Vaccination Coverage Survey (CVCS)

> In spring 2021, the Public Health Agency of Canada (PHAC) in collaboration with Statistics Canada launched a COVID-19 vaccination coverage survey across all provinces and territories. The purpose being to measure self-reported coverage across different socio-demographic subgroups and collect more information about vaccine hesitancy in Canada to complement existing coverage data. Survey results are available online.

Childhood COVID-19 Immunization Coverage Survey (CCICS)

In 2022, the Public Health Agency of Canada (PHAC) launched the Childhood COVID-19 Immunization Coverage Survey (CCICS) across all provinces and territories that was implemented in collaboration with the Communications and Public Affairs Branch (CPAB) of Health Canada. CCICS provides annual data on COVID-19 and seasonal influenza immunization coverage among children in Canada and the intentions of parents to vaccinate children. It also gathers information on parental knowledge, attitudes and beliefs (KAB) towards their children's COVID-19 and influenza vaccination (e.g., vaccine hesitancy) and the barriers to immunization among children. The survey also collects information on chronic medical conditions, disability, and socioeconomic indicators in order to examine vulnerable children or those at higher risk of COVID-19 and influenza complications, by applying SGBA+ analysis, where possible. CCICS 2022 web summary is available on Canada.ca while the methodological report and detailed tables are available on Library and Archives Canada Website.

Results Highlights for receiving at least one dose of a COVID-19 vaccine among 5- to 17-year-olds:

- Among reported ethnicities, COVID-19 vaccine coverage was lower in Black (76%), Middle Eastern and North African (76%) and Indigenous (74%) children. Among Indigenous children, Inuit children had the highest coverage (97%), followed by Métis children (78%) and First Nations children (69%).
- Children living in urban areas had higher COVID-19 coverage than children living in rural areas (83% and 72%, respectively).
- COVID-19 vaccine coverage was higher among children whose parents reported that child had received all recommended routine childhood vaccines (84%), compared to those who received some routine vaccines (55%) or did not receive any (45%).
- The most common reason for not vaccinating children against COVID-19 was vaccine refusal (72%) followed by vaccine hesitancy (22%).

PHAC is currently performing in-depth analysis of the CCICS 2022 data to identify factors associated with non vaccination, parental vaccine hesitancy and intentions to vaccinate children among all children and subgroups such as, but not limited to, children with chronic medical conditions. Work is underway to implement the second cycle of CCICS in 2023.

Survey on Vaccination during Pregnancy (SVP)

The childhood National Immunization Coverage Survey (cNICS) has been conducted every two years since 1994; PHAC and Statistics Canada have been collaborating to implement the cNICS since 2011. cNICS collects information on vaccine coverage among children aged 2, 7, 14, and 17 and among pregnant women (Survey on Vaccination during Pregnancy (SVP)). SVP was first conducted in 2019 and again in 2021 as a component of cNICS. The impact of the pandemic on vaccine coverage in Canada was assessed by cNICS 2021. Results from SVP 2021 were released in December 2021 while results from the childhood component of cNICS will be released in spring 2023.

- The majority of women (77%) reported that the pandemic had no influence on their decision to vaccinate, while 6% reported they were less inclined and 17% reported that the pandemic made them more inclined to vaccinate against pertussis and influenza during pregnancy.
- Pertussis vaccine coverage during pregnancy has increased from 44% in 2019 to 65% in 2021, while influenza vaccine coverage increased from 45% in 2019 to 53% in 2021.

COVID-19 Vaccine Uptake

Based on data from the Canadian Community Health Survey (CCHS) collected between June 2021 and February 2022, PHAC examined inequalities in vaccine uptake and found:

- that the proportion of people having received at least 1 dose of a COVID-19 vaccine was lower among people who self-identify as off-reserve First Nation (81%), Black (82%) or Arab (85%), but higher among South Asian people (96%) than in White people (93%).

Vaccine Safety

Canada has a well-established vaccine safety surveillance system, which sees collaboration across provinces and territories, PHAC, Health Canada, and vaccine manufacturers. PHAC is receiving and reviewing reports of adverse events following COVID-19 immunization from provinces and territories through the Canadian Adverse Events Following Immunization Surveillance System (CAEFISS). This system has been enhanced to support the rollout of COVID-19 vaccines, expedite the timeliness, and share information with partners and report adverse events publicly. To promote transparency and ensure the public has access to COVID-19 vaccine safety information including developments on adverse events, PHAC posts weekly vaccine safety surveillance reports online.

As of early January 2023, over 96 million COVID-19 vaccine doses have been administered in Canada. Adverse events (side effects) have been reported by 53,611 people. **That's**

about 6 people out of every 10,000 people vaccinated who have reported 1 or more adverse events, of which **43,046** were considered non-serious (**0.045% of all doses administered**) and 10,565 were considered serious (**0.011% of all doses administered**).

2. Vaccine Confidence

In response to the various factors and barriers impacting an individual's trust and access to vaccines and immunization, the Government of Canada, in partnership with provincial and territorial governments, is undertaking a number of efforts to educate, engage, and empower Canadians to make informed vaccination decisions using evidence-based communications and program supports. This includes a robust communications strategy focused on public education resources, mass advertising, countering mis- and dis-information on social media channels, and expanding information hubs with credible vaccine information. Given health care providers' important role in the success of vaccine acceptance PHAC provides an online toolkit, webinars and regular information bulletins for healthcare providers to support vaccination choices.

While Canada has seen a steady increase in vaccine uptake within the general population, gaps in confidence and uptake remain, particularly among equity-deserving groups, such as Black Canadians and Indigenous Peoples. According to a recent public opinion survey, 86% of Black Canadians (18+) report they have received at least 2 doses and 42% report they have received at least one booster. As with earlier phases of vaccination, this is lower than the general population. Indigenous population (12+) reported receiving 2 doses at 90%, in line with the general population, and 40% a third dose.

As these populations often face multiple intersecting social, attitudinal and structural barriers to vaccination, the Government of Canada is funding innovative community-based vaccine confidence initiatives and outreach strategies through the Immunization Partnership Fund (IPF) and the Vaccine Community Innovation Challenge. These initiatives support vaccine confidence within a broad range of populations, including marginalized, under-served and at-risk populations through tailored interventions and approaches.

- Between 2020 and 2023, the Government of Canada is investing just over $50M in more than 100 projects through the IPF to support local, regional and national organizations combatting vaccine hesitancy, countering mis- and dis- information, supporting healthcare provider education and training, and mitigating access barriers. PHAC is investing additional funds in supporting fall 2022 vaccination campaigns including support Canadians in keeping up to date with COVID-19 vaccination (boosters/additional doses) with community, regional and national projects.

- In 2021-22, the Government of Canada delivered the Vaccine Confidence Innovation Challenge with community-based actors to design and carry out information campaigns to promote confidence in vaccination against COVID-19 and continued compliance with public health measures. More than 125 projects received micro-grants and a grand prize winner was announced in February 2022.

- June 1, 2022 marked the one year anniversary of the launch of the pan-Canadian Vaccine Injury Support Program, which provides fair and timely support for individuals vaccinated in Canada who experience a serious and permanent injury as

a result of receiving a Health Canada-authorized vaccine, including COVID vaccines, on or after December 8, 2020. The program is being independently administered by a third party.

3. National Advisory Committee on Immunization (NACI)

As Canada's national immunization technical advisory group, NACI provides independent advice to federal, provincial, and territorial governments on the use of authorized vaccines in Canada. NACI guidance is advisory in nature as provincial and territorial governments are responsible for their vaccine policies and immunization programs. NACI's recommendations can be found online on the NACI website

COVID-19
On January 20, 2023, NACI released updated guidance on the use of COVID-19 booster doses. This guidance reinforces existing fall 2022 booster dose recommendations and extends the program, meaning that individuals who were recommended to receive a booster in the fall of 2022 but have not yet received one are recommended to receive it now, provided it is six months after their last COVID-19 vaccine dose or SARS-CoV-2 infection. Bivalent Omicron-targeting mRNA COVID-19 vaccines continue to be the preferred booster products for all individuals 5 years of age and over. NACI is currently recommending only one COVID-19 booster since the start of fall 2022, and at this time, is not issuing guidance on an additional booster dose for individuals who will reach six months since their fall 2022 booster later this winter. NACI continues to monitor the evolving evidence and epidemiology and will provide updated guidance in the coming months as needed.

NACI published guidance on the use of the Pfizer-BioNTech Comirnaty (3 mcg) COVID-19 vaccine in children 6 months to 4 years on October 21, 2022. This guidance built on NACI's guidance on the use of the Moderna Spikevax (25 mcg) vaccine in children 6 months to 5 years of age that was released on July 14, 2022.

Monkeypox
On September 23, 2022, in light of the ongoing outbreaks at the time and after reviewing current evidence, NACI published updated Interim Guidance on the Use of Imvamune® in the Context of Monkeypox Outbreaks in Canada, which included guidance for pre-exposure vaccination as well as dose-sparing strategies to maximize coverage when supply is limited.

Influenza
NACI is expected to release guidance on repeated seasonal influenza vaccination in February 2023 after the committee was asked to assess the effects of repeated influenza vaccination on vaccine effectiveness, efficacy, and immunogenicity based on evidence published in the last decade suggesting that repeated seasonal influenza vaccination may reduce the protection provided by the vaccine in the last season.

Pneumococcal Disease
NACI is expected to release interim guidance on the use of pneumococcal 15-valent conjugate vaccine (PNEU-C-15) in pediatric populations and public health level recommendations on the use of pneumococcal vaccines in adults (including 15-valent and 20-valent conjugate vaccines) in March 2023.

Vaccine Horizon Scanning Industry Virtual Consultation

The Public Health Agency of Canada recently resumed its vaccine pipeline planning meeting and hosted two virtual consultations in early November 2022 which focused on prophylactic products for Respiratory Syncytial Virus and *Streptococcus pneumonia* bacteria.

Meetings

NACI will be resuming in-person meetings this year, with the first meeting scheduled for April 27-28, 2023. Due to the COVID-19 pandemic, NACI has not met in person since February 2020. Moving forward, NACI is planning to adopt a hybrid approach of both in-person and virtual meetings.

4. Other Vaccine Guidance

The following publicly available documents were updated to reflect new/updated NACI guidance and/or newly authorized COVID-19 vaccine formulations or age indications to support provinces and territories and health care providers with vaccine administration:

- November 17, 2022: Planning guidance for immunization clinics: Managing vaccine administration errors or deviations (COVID-19 vaccines)
- December 23, 2022: Planning guidance for immunization clinics: Vaccine product comparison and overview of key features (COVID-19 vaccines)

January 2023 DoD ex officio statement

COVID-19 vaccine efforts:

The Department of Defense (DoD) COVID-19 vaccine implementation plan encompasses Active Duty, US Coast Guard, Reserve and National Guard personnel, in addition to retirees, beneficiaries and additional individuals authorized to receive COVID-19 vaccine from DoD.

As of 3 January 2023, DoD has administered over 9.4M FDA-approved or authorized COVID-19 vaccines at ~400 immunization sites globally to those with an indication based on age and medical history in accordance with FDA guidance and CDC recommendations.

Similar to the civilian sector, DoD is eager to learn from VRBPAC's discussions WRT COVID vaccine schedule and formulation in late January 2023 and whether these vaccines will remain authorized or will be licensed in a method similar to the annual influenza vaccine. Additionally, DoD is interested in the processes/timeline to commercialize COVID-19 vaccines.

Monkeypox

DoD has received and is administering Jynneos vaccine for monkeypox prevention IAW CDC recommendations and is currently meeting demand.

Northern Hemisphere Influenza Vaccine

DoD continues to actively administer influenza vaccine. Influenza vaccine is a requirement for those Service Members and healthcare workers who don't have an approved exemption. DoD is encouraging sites administer influenza and appropriate COVID-19 vaccine, if indicated, at same visit.

National Vaccine Advisory Committee
National Institutes of Health Update
February 2023

COVID-19

- **PRE-PRINT**

  A. Branches *et al*. Immunogenicity of the BA.1 and BA.4/5 Bivalent Boosts: A Brief Report of Preliminary Results from the COVAIL Randomized Clinical Trial. *medRxiv* February 2, 2023. https://doi.org/10.1101/2023.01.31.23285306

Malaria

- **Monoclonal Antibody Prevents Malaria Infection in African Adults**

  One dose of an antibody drug safely protected healthy, non-pregnant adults from malaria infection during an intense six-month malaria season in Mali, Africa, a National Institutes of Health clinical trial has found. The antibody was up to 88.2% effective at preventing infection over a 24-week period, demonstrating for the first time that a monoclonal antibody can prevent malaria infection in an endemic region. These findings were published in *The New England Journal of Medicine* and presented at the American Society of Tropical Medicine & Hygiene 2022 Annual Meeting in Seattle.

  NIAID News Release, October 31, 2022: https://www.niaid.nih.gov/news-events/monoclonal-antibody-prevents-malaria-infection-african-adults

  K Kayentao *et al.* Safety and efficacy of a monoclonal antibody against malaria. *NEJM* November 17, 2022. DOI: 10.1056/NEJMoa2206966.
  https://www.nejm.org/doi/full/10.1056/NEJMoa2206966

Hepatitis B

- **Three-dose hepatitis B vaccine regimen protects people with HIV**

  A three-dose course of the hepatitis B vaccine HEPLISAV-B fully protected adults living with HIV who had never been vaccinated against or infected with the hepatitis B virus (HBV), according to study findings presented at the October 2022 IDWeek conference in Washington, D.C. NIAID sponsors the ongoing Phase 3 ACTG A5379 clinical study.

  NIAID News Release, October 20, 2022: https://www.niaid.nih.gov/news-events/three-dose-hepatitis-b-vaccine-regimen-protects-people-hiv

Ebola

- **Experimental NIH Sudan Virus Vaccine Protects Macaques**

  A National Institutes of Health research group with extensive experience studying ebolavirus countermeasures has successfully developed a vaccine against Sudan virus (SUDV) based on the licensed Ebola virus (EBOV) vaccine. The new vaccine, VSV-SUDV, completely protected cynomolgus macaques against a lethal SUDV challenge. The findings were published in the journal *The Lancet Microbe*.

  NIAID News Release, February 2, 2023: https://www.niaid.nih.gov/news-events/experimental-nih-sudan-virus-vaccine-protects-macaques

  A Marzi *et al*. Species-specific immunogenicity and protective efficacy of a VSV-based Sudan virus vaccine: a challenge study in macaques. *The Lancet Microbe.* DOI: 10.1016/S2666-5247(23)00001-0 (2023). https://doi.org/10.1016/S2666-5247(23)00001-0

- **Ebola Vaccine Regimen Safe, Immunogenetic in Adults and Children**
  Two randomized, placebo-controlled trials evaluating three Ebola vaccine administration strategies in adults and children found that all the regimens were safe in both age groups, according to results published today in the *New England Journal of Medicine*. The trials were conducted under the Partnership for Research on Ebola Vaccination (PREVAC) international consortium.
  NIAID News Release, December 14, 2022: https://www.niaid.nih.gov/news-events/ebola-vaccine-regimens-safe-immunogenic-adults-and-children
  M Kieh *et al*. Randomized trial of vaccines for Ebola virus disease. *New England Journal of Medicine*. DOI: 10.1056/NEJMoa2200072 (2022).
  https://www.nejm.org/doi/full/10.1056/NEJMoa2200072

Marburg virus (MARV)

- **Marburg Vaccine Shows Promising Results in First-in-Human Study**
  A newly published paper in *The Lancet* shows that an experimental vaccine against Marburg virus (MARV) was safe and induced an immune response in a small, first-in-human clinical trial. The vaccine, developed by researchers at NIAID, could someday be an important tool to respond to Marburg virus outbreaks.
  NIAID News Release, January 30, 2023: https://www.niaid.nih.gov/news-events/marburg-vaccine-shows-promising-results-first-human-study
  M Hamer *et al*. Safety, tolerability, and immunogenicity of the Marburg chimpanzee adenovirus vector vaccine (cAd3-Marburg) in healthy adults: a phase 1, open-label, dose-escalation trial. *The Lancet* DOI: 10.1016/S0140-6736(22)02400-X (2023).
  https://doi.org/10.1016/S0140-6736(22)02400-X
  NIH Release , January 30, 2023: https://www.nih.gov/news-events/news-releases/marburg-vaccine-shows-promising-results-first-human-study

HIV

- **Experimental HIV Vaccine Regimen Safe but Ineffective, NIH Study Finds**
  An investigational HIV vaccine regimen tested among men who have sex with men (MSM) and transgender people was safe but did not provide protection against HIV acquisition, an independent data and safety monitoring board (DSMB) has determined. The HPX3002/HVTN 706, or "Mosaico," Phase 3 clinical trial began in 2019 and involved 3,900 volunteers ages 18 to 60 years in Europe, North America and South America. Based on the DSMB's recommendation, the study will be discontinued. Participants are being notified of the findings, and further analyses of the study data are planned.
  NIAID News Release, January 18, 2023: https://www.niaid.nih.gov/news-events/experimental-hiv-vaccine-regimen-safe-ineffective-nih-study-finds

Influenza

- Researchers conducted a phase 2, multicenter, double-blind, randomized, controlled trial (Pediatric HCT Flu Study; ClinicalTrials.gov number, **NCT02860039)** that compared immunogenicity and safety between high-dose trivalent influenza vaccine (HD-TIV) and standard-dose quadrivalent influenza vaccine (SD-QIV) in children and adolescents 3 to 17 years of age who had received an allogeneic HCT 3 to 35 months earlier. They found that two doses of HD-TIV resulted in higher antibody responses to influenza A antigens than two doses of SD-QIV in pediatric recipients of HCT. The overall safety profile was similar, with a slightly higher

number of mild or moderate injection-site reactions after the second dose of HD-TIV than after the second dose of SD-QIV.
*New England Journal of Medicine***.** January 26, 2023.
https://www.nejm.org/doi/full/10.1056/NEJMc2210825

- Controlled human infection models (CHIMs) of influenza virus have been used since the 1930s to advance understanding of infection natural history, clinical characteristics, and immune responses. Researchers conducted a CHIM study with influenza A/Bethesda/MM2/H1N1, an A/California/04/2009/H1N1pdm-like virus, at four sites among healthy adults aged 18 through 49 years. The study was designed to assess clinical response, immunological response, and safety of the (H1N1)pdm09 viral challenge.
J.R. Ortiz *et al*. A Multi-Center, Controlled Human Infection Study of Influenza A (H1N1) pdm09 in Healthy Adults. *The Journal of Infectious Diseases.* 26 January 2023.
https://doi.org/10.1093/infdis/jiad021

Other Headlines

- **NIH Awards $12 Million for Antiviral Therapeutic Development**
NIAID recently awarded more than $12 million to three institutions for the development of antiviral therapies to treat diseases caused by viruses with pandemic potential. NIAID may award approximately $61.5 million total over five years if all contract options are exercised. The new product development contracts are part of the Antiviral Program for Pandemics (APP), which aims to accelerate the discovery, development and manufacturing of antiviral medicines.
NIAID News, November 21, 2022: https://www.niaid.nih.gov/news-events/nih-awards-12-million-antiviral-therapeutic-development
- **Experimental Cancer Vaccine Shows Promise in Animal Studies**
NIAID researchers report an experimental therapeutic cancer vaccine induced two distinct and desirable immune system responses that led to significant tumor regression in mice. The approach achieves an important goal in the quest for more effective immunotherapeutic vaccines for cancer. The study demonstrates that intravenous (IV) vaccine delivery enables and enhances T-cell immunity by overcoming tumor-induced immunosuppressive activity.
NIAID News Release, November 10, 2022: https://www.niaid.nih.gov/news-events/experimental-cancer-vaccine-shows-promise-animal-studies
- **Developing Mucosal Vaccines for Respiratory Viruses**
Vaccines that provide long-lasting protection against influenza, coronaviruses and respiratory syncytial virus (RSV) have proved exceptionally difficult to develop. In a new review article in *Cell Host & Microbe*, researchers from the National Institute of Allergy and Infectious Diseases (NIAID), part of the NIH, explore the challenges and outline approaches to improved vaccines. Anthony S. Fauci, M.D., former NIAID director, is an author along with Jeffery K. Taubenberger, M.D., Ph.D., and David M. Morens, M.D.
NIAID News Release, January 11, 2023: https://www.niaid.nih.gov/news-events/developing-mucosal-vaccines-respiratory-viruses
DM Morens *et al*. Rethinking next-generation vaccines for coronaviruses, influenza viruses, and other respiratory viruses. *Cell Host & Microbe* DOI: 10.1016/j.chom.2022.11.016 (2023).
https://www.cell.com/cell-host-microbe/fulltext/S1931-3128(22)00572-8

NACCHO
National Association of County & City Health Officials
The National Connection for Local Public Health

National Vaccine Advisory Committee (NVAC) Update
National Association of County and City Health Officials (NACCHO)
February 2023

Organization Updates

• In response to the COVID-19 pandemic, NACCHO maintains its operations in an Incident Management structure – Level 2. NACCHO's primary objectives for the response are to: maintain situational awareness at the national/federal and local level, support all stakeholders through information sharing, facilitate the sharing of information from the federal to the local level, advocate for federal funding, and convey the critical role of local public health departments during the ongoing pandemic. NACCHO has established and continues to maintain a COVID-19 webpage, online virtual community, data lab, contact tracing tools, and vaccine resources for COVID-19 response.

• NACCHO is also operating under an Incident Management structure – Level 2 for the mpox outbreak, though will likely be scaling back to Level 1 in the near future. Like COVID-19, NACCHO's primary objectives are to: maintain situational awareness at the national/federal and local level, support all stakeholders through information sharing, facilitate the sharing of information from the federal to the local level, advocate for federal funding, and convey the critical role of local public health departments.

• NACCHO is hosting the 2023 Preparedness Summit as a hybrid (in-person and virtual) event April 24-27, 2023, in Atlanta, Georgia. Each year, the Summit offers a unique learning and networking opportunity for current and aspiring emergency management, public health and healthcare professionals, and their partners, to share perspectives and engage in dialogue on key public health preparedness and response issues. As the first and longest running national preparedness conference, the Preparedness Summit is the best place for public health and preparedness professionals to gain the knowledge, resources, and relationships necessary to prepare for and respond to public health emergencies. Registration is now open.

• On July 10-13, 2023, NACCHO will host its annual NACCHO 360 Conference in Denver, Colorado. This year's theme, ***Elevating Public Health Practice for Today and Tomorrow***, will explore how the local public health workforce and its stakeholders can move forward in the midst of an ongoing crisis while implementing traditional and innovative approaches to restructure a system built to protect the health of communities nationwide. Conference tracks include Behavioral Health; Climate Change; Communications and Messaging; Health Equity and Social Justice; Leadership, Management, and Workforce Development; Public Health Policy and Law; and Surveillance, Informatics, and Data Systems. Registration is now open.

Immunization Project Updates

• On July 11 and 12, 2022, NACCHO held a National Stakeholder Consultation Meeting on Influenza Vaccination in Older Adults. This meeting was a follow-up to a convening held in 2021 and included a number of partner organizations in the older adult vaccination space. The sessions included presentations from CDC, local health departments, and other organizations. The group discussed goals in the areas of access, communication, data & reporting, and policy. A summary report of the meeting was developed and is available here.

• NACCHO continues to regularly convene the Immunization Workgroup (advisory group) comprised of local health officials, programmatic local health department (LHD) staff, and immunization coalition members. The group continues to serve in an advisory role in providing NACCHO guidance regarding local public health's role in increasing routine immunization rates, addressing vaccine confidence, and the planning and administration of the COVID-19 vaccine.

- The Workgroup is updating NACCHO's policy statement on School and Childcare Immunization Requirements.
- The Workgroup has contributed to a social media toolkit to promote routine vaccinations.

• NACCHO continues to participate in the *Equipping Local Health Departments to Address Vaccine Hesitancy* project. Through the project health departments are provided technical assistance (TA) and capacity building assistance to build immunization program workforce capacity, implement work to address vaccine hesitancy and misinformation, build partnerships with other local organizations, and identify areas of need to improve vaccine confidence.

- A second cohort of three local health departments participated in a focus group on their experience completing CDC's Rapid Community Assessment (RCA) and aggregated results will be shared via NACCHO's communications platforms.
- Three additional sites were selected to participate in a third cohort of the project and conduct RCAs in their communities. A training on the RCA was held on January 3 and cohort two sites were available to share their lessons learned in conducting the assessment with the new sites.
- On December 2 sites participated in a Community of Practice on working with minority owned businesses to increase vaccine uptake.
- The second cohort of three local health departments submitted an abstract and we selected to present on their projects at NACCHO's Preparedness Summit in April 2023.
- In December 2022, the second cohort completed their projects. This included developing resources at assist other LHDs in addressing vaccine hesitancy which will be shared on NACCHO's website.

• Through the Partnering for Vaccine Equity (PAVE) project, NACCHO aims to increase LHDs' capacity to improve adult vaccination coverage by identifying and implementing strategies to reduce racial and/or ethnic disparities. LHDs in this project receive training, technical assistance, and other resources to address vaccine uptake among adult populations experiencing disparities in influenza and COVID-19 vaccination coverage.

- Participating PAVE sites were highlighted in a blog post during National Influenza Vaccination Week. National Influenza Vaccination Week - #FightFlu: Protecting Our Adult Communities from Influenza Through Vaccination - NACCHO

    - A second cohort of sites completed the Rapid Community Assessment (RCA) and learned from the first cohort 's experience with the assessment to inform their planning and implementation of the assessment.
    - The second cohort sites are developing and implementing vaccine education/communications campaigns.
    - The NACCHO team is meeting with CoVAC (The Campus COVID-19 Vaccination and Mitigation Initiative) to discuss ways we can further promote and connect colleges and universities with LHDs to support public health initiatives.

- Through the *Equipping Local Health Departments to Build COVID-19 Vaccine Confidence* project, NACCHO aims to support LHDs to improve COVID-19 vaccine confidence and address misinformation at the community level in partnership with local trusted community messengers.
    - NACCHO partnered with Johns Hopkins University (JHU) on Lets Talk COVID Vaccines to select five sites to assist in developing a COVID-19 vaccine communications plan. On September 29th, these five sites presented on how they combat misinformation, identify and engage credible sources, and combat COVID fatigue in their communities.
    - NACCHO also partnered with JHU to select 3 local health departments to launch an AI chatbot, VIRA, to counter COVID-19 vaccine misinformation in state, city, or county, at no cost to health departments. More information can be found in the press release here.
    - On October 25th, NACCHO hosted a community of practice call on Building Effective Communication to Help Increase Vaccine Confidence Using the AIMS (Announce, Inquire, Mirror, and Secure) Model focused on promoting influenza vaccination. Recording here.
    - On November 17th, three sites highlighted their resources developed to address misinformation and increase COVID-19 vaccine confidence. The group heard from Partnership for Public Health in New Hampshire on tailored videos created that addressed the most common hesitancies in their communities. Van Buren/ Cass Health District in Michigan highlighted how they utilized Canva Pro to create social media messaging to reach their populations. Lastly, South Central in Pennsylvania spoke to their library education series where they have been working with parents and children to educate around the COVID vaccines. Recording here.
    - Sites participating in the project are currently completing a SOWT analysis and engaging partners to participate in a communications workshop lead by the Public Health Foundation.

- From April – November 2022, NACCHO participated in the *Vaccine Access and Training (VAT)* along with AIM, the Center for Global Health Innovation, and Johns Hopkins University. The project deployed over 100 community health workers across Alabama, Arizona, Florida, Georgia, Kentucky, Michigan, and Texas to build COVID-19 vaccine confidence in vulnerable and medically underserved communities. NACCHO's collaboration with others on the project has resulted in a very concise and organized resource repository housed in a micro website that is now available to all CHWs, partners, and the public in English and Spanish. The microsite features toolkits, training and resources for the community health workers.

- NACCHO promotes immunization awareness and education through its communication platforms.
    - NACCHO sends out a weekly COVID-19 Vaccine Round-up with all the latest news and resources regarding COVID-19 vaccines.

- NACCHO has resumed sending out a monthly Transmission Digest, which highlights immunization and infectious disease activities, news, and resources.
- NACCHO started sending an Mpox Digest to local health departments to ensure they are receiving news regarding mpox in a timely manner.
- Sign on Letter: Letter to Congressional Appropriators Supporting Full Funding for Immunization-related Activities in FY23
- Blog Post: Understanding and Responding to a Recently Published Study on Vaccine Associated Aluminum and Risk of Asthma
- Blog Post: CDC's Updated Pneumococcal Vaccine Recommendations for Adults - NACCHO
- Podcast: Monkeypox Response Podcast featuring 3 LHDs
- Sign-on Letter: Coalition To Stop Flu Applauds Introduction Of Legislation To Better Protect America From Seasonal And Pandemic Influenza
- Blog Post: Staying Up to date on CDC's MPOX Technical Reports
- Blog Post: National Influenza Vaccination Week - #FightFlu: Protecting Our Adult Communities from Influenza Through Vaccination
- Blog Post: Addressing Mpox by Utilizing COVID-19 Funds
- Blog Post: NACCHO Recognizes Second Anniversary of First COVID-19 Vaccination
- Blog Post: Inflation Reduction Act: Improving Adults Enrolled in Medicaid and Medicare Access to Recommended Vaccines – NACCHO

For more information, contact Katie Waters at kwaters@naccho.org, or visit the NACCHO Immunization program webpage.

Indian Health Service
NVAC Update, February 02, 2023

The Indian Health Service continues to confront the SARS-CoV-2 pandemic and its significant impact on tribal communities. Collaborating with our federal, tribal, and Urban Indian Organization partners, the IHS has prioritized equitable access to COVID vaccines throughout Indian Country. To date, participating federal, tribal, and urban facilities within the IHS jurisdiction have administered over 2.3 million COVID vaccines.

Following regulatory actions by the FDA and CDC, the IHS rapidly communicated information regarding bivalent COVID vaccine boosters. The IHS federal, tribal, and urban facilities are actively engaged in implementing the bivalent COVID boosters. As of January 15, 2023, nearly 146,300 bivalent booster doses have been administered throughout Indian Country.

Across its three surveillance systems to date, IHS COVID vaccine safety monitoring has demonstrated a reassuring safety profile consistent with other national vaccine safety surveillance systems. Meanwhile, the IHS routinely collaborates with the CDC and engages with Tribal leaders to support vaccine confidence among the American Indian and Alaska Native service population.

Beginning this past Spring, IHS has also been working proactively to ensure access to Jynneos vaccine to mitigate the risks of Mpox in tribal communities. Over 10,000 doses of Jynneos were prepositioned across our 12 IHS Areas. On September 9, IHS announced a Mpox PrEP Initiative to expand eligibility for Jynneos vaccine to include not only PEP and PEP++ but also pre-exposure prophylaxis for at-risk populations. In collaboration with our federal and tribal partners, IHS implemented a simple process for onboarding sites to participate in the national Mpox Equity Pilot Program to further expand access to our vulnerable service population. We continue collaborating with federal, tribal, and urban facilities to implement additional targeted strategies to improve uptake in the second dose of the vaccine.

The IHS routinely surveils for Influenza-like Illness (ILI) through the IHS Influenza Awareness System. The 2022–2023 influenza season shows unusually high ILI activity. The ILI activity showed an early rapid increase that peaked at week 50 at 5.6%, followed by a steep decline. The ILI activity documented in the past 11 weeks are more elevated than the previous six influenza seasons. The system also indicates that IHS regions with very high influenza vaccination coverage rates reported lower ILI activity than regions with low vaccination coverage rates. The IHS immunization program continues to collaborate with our federal and tribal partners to promote influenza and all recommended vaccines.

Finally, I am pleased to report that in November 2022, the IHS rolled out a new national vaccine strategy. The "E3" Vaccine Initiative is designed to promote access for Every Patient at Every Encounter to Every Recommended Vaccine when clinically indicated. This includes all ACIP-recommended vaccines in all age groups. We are working with federal, tribal, and urban facilities and leadership of tribal communities for a "bottom-up" approach to operationalizing this vaccine strategy. The bottom-up approach includes communication, stakeholder engagement, and

collaboration, building a resource bank, quality improvement through cross-pollination, champions challenge, and data tracking to measure success.

We look forward to continued collaboration with our tribal, urban, and federal partners to ensure access to safe and effective vaccines across the age spectrum for American Indians and Alaska Natives served by the Indian Health Service.

HRSA Bureau of Primary Health Care
National Vaccine Advisory Committee Updates – February 2023

The Health Center Program provides comprehensive, culturally competent, and quality primary health care services to medically underserved people across the nation. Nearly 1,400 health center grantees operate more than 14,800 health center sites, serving more than 30 million people, including 1 in 3 people living in poverty and 8.6 million children in our country. Health centers provide critical preventive and chronic disease management services. In addition to ensuring access to primary and preventive care, health centers' model of care includes the provision of non-clinical enabling services, including translation, transportation, outreach and education, care coordination, and eligibility assistance, that recognize and help to address the social and environmental barriers to health and to health care experienced by their patients.

COVID-19 Vaccine Updates

- **Overall Vaccine Administration:** As of January 13, 2023, **22,996,240 COVID-19 vaccine doses** have been administered by all health centers; 70 percent to racial and/or ethnic minority patients. Specifically, nearly 9.5M patients initiated a vaccination series, over 8.9M patients completed a vaccination series, and over 4.6M received an additional booster dose.
    - Since April 3, 2021, health centers have administered COVID-19 vaccines through **102,760 community-based events**, including through school-based clinics, family vaccination clinics, and community and faith-based events.
    - In the most recent reporting period (December 31, 2022-January 13, 2023) health centers held **1,022 vaccination events**.

- **HRSA Health Center COVID-19 Vaccine Program:** As of January 13, 2023, total of **9,475,425 COVID-19 vaccine doses** have been administered through the HRSA Health Center COVID-19 Vaccine Program; 76 percent to racial and/or ethnic minority patients.
    - Special Populations: Through January 13, 2023, health centers participating in the Health Center COVID-19 Vaccine Program have administered:
        - **26,290 doses** to patients with limited English proficiency
        - **5,858 doses** to public housing residents
        - **331,886 doses** to migratory and seasonal agricultural workers
        - **2,246 doses** to patients experiencing homelessness
        - **19,507 doses** administered to patients less than 18 years old

- **Expanding COVID-19 Vaccination (ECV) Funding for Health Centers:** On December 9, 2022, HRSA awarded approximately $350 million in one-time ECV funding for a six-month period of performance to more than 1,400 health centers and look-alikes. Health centers will use these funds, with an emphasis on activities within three months of award, on outreach and education, community engagement, and coordinated partner events to increase updated COVID-19 vaccinations among underserved populations.

- **Emerging Priorities:** Bivalent Boosters:
    - On September 1, 2022, CDC recommended the updated (bivalent) Pfizer-BioNTech booster for patients ages 12 and older and Moderna booster for patients ages 18 and older. By December 8, 2022, the updated bivalent vaccine was authorized and CDC-recommended for all children down to six months of age. HRSA has deployed tailored

technical assistance to increase confidence in and promote uptake of the updated bivalent COVID-19 vaccines focusing on the importance of partnering with key organizations with a strong presence in health center communities.

- On October 4, 2022, HRSA convened health centers, stakeholders, and other federally-funded community partners to participate in the *Partnerships Through the Pandemic: Strategies for Promoting COVID-19 Vaccine Booster Uptake* Town hall. The town hall featured opening remarks by HRSA's Administrator as well as expert panelists from the Administration for Community Living (ACL), Department of Housing and Urban Development (HUD), and HRSA's Health Systems Bureau's Community Based Workforce for COVID-19 Vaccine Outreach (CBO) Program, and Maternal and Child Health Bureau (MCHB). The presenters provided insights for health centers and other federal grantees to pursue local counterparts, connect, and collaborate on promoting COVID-19 vaccine boosters in their community. The Town Hall was well-received and as a follow up HRSA circulated a resource guide capturing key takeaways and examples of partnerships that have made an impact in health center communities. The resource is provided here- Bivalent Booster Town Hall Resource Guide.

- **Technical Assistance:**
  - The CDC supports coadministration of the COVID-19 vaccines with other immunizations, including influenza. HRSA is amplifying the Clinical Guidance for Coadministration of COVID-19 Vaccines from the CDC as well as other resources on bivalent boosters, product guides, social media content, and manufacturer training webinars across all HRSA communication platforms.
  - The Health Center COVID-19 Vaccine Program continues to collaborate with HRSA's Community-Based Outreach for COVID-19 Vaccine Outreach (CBO) Program to strengthen health center's engagement with community-based organization. The CBO team was featured in the Town Hall mentioned above, and the Health Center COVID-19 Vaccine Program team members provided an overview of the program and highlighted opportunities for collaboration at the CBO program Office Hours.

- **Partnerships:** HRSA continues to partner with over 60 federal, state, and local partners to strategize on increasing the COVID-19 vaccination rate. Partnerships include: the Centers for Disease Control and Prevention, Food and Drug Administration, Administration for Community Living, Administration for Children and Families, Department of Housing and Urban Development, Department of Education, Veterans Health Administration, National Association of State Departments of Agriculture, National Association of Community Health Centers and Door Dash, Direct Relief, Encore AARP, National Head Start Association, United Fresh, and others.

Calendar Year (CY) 2021 Uniform Data System (UDS) Immunization Data

- Health centers administered seasonal flu shots to 4,028,003 patients.
- Health centers administered select immunizations doses to 3,233,342 patients for: hepatitis A, haemophilus influenzae B (Hib), pneumococcal, diphtheria, tetanus, pertussis (DTaP) (DTP) (DT); measles, mumps, rubella (MMR); poliovirus; varicella; and hepatitis B.
- Please note CY 2021 UDS data is available online. HRSA is currently collecting and reviewing health centers' UDS data for CY 2022, which will be made available by fall 2023.

Summary of Health Resources and Services Administration (HRSA), Division of Injury Compensation Programs Activities for February 2-3, 2023, National Vaccine Advisory Committee

National Vaccine Injury Compensation Program Update

The National Vaccine Injury Compensation Program (VICP) continues to process an increased number of claims. In FY 2022, petitioners filed 1,029 claims with the VICP, nearly $196 million was awarded to petitioners, and $34 million was awarded to pay attorney's fees and costs for compensated and dismissed cases.

In FY 2023, as of December 1, 2022, petitioners filed 192 claims with VICP, and approximately $29 million was awarded to petitioners, including their attorney's fees/costs. In addition, as of December 5, 2022, the VICP had a backlog of 1,546 claims alleging vaccine injury awaiting review. More data about the VICP can be obtained at https://www.hrsa.gov/vaccine-compensation/data/index.html.

Countermeasures Injury Compensation Program Update

As of December 1, 2022, 10,889 claims alleging injuries/deaths from COVID-19 countermeasures have been filed with the Countermeasures Injury Compensation Program (CICP), including 7,624 claims alleging injuries/deaths from COVID-19 vaccines. Sixty-eight claims have been denied compensation. Twelve claims have been determined medically eligible for compensation, including one claim which has been partially compensated. More information about the CICP can be found at https://www.hrsa.gov/cicp.

CDC Update for National Vaccine Advisory Committee (NVAC)
February 2-3, 2023

Advisory Committee on Immunization Practices (ACIP) Updates

October 19-20, 2022, ACIP Meeting
A two-day virtual ACIP meeting was held on October 19-20. The topics for the meeting included Pneumococcal disease, chikungunya, COVID-19, Poliovirus, Respiratory Syncytial Virus, Meningococcal disease, influenza, dengue and Monkeypox. The committee also reviewed and voted on revisions to the 2023 vaccine schedules for children, adolescents and adults.

September 1, 2022, ACIP Meeting
A one-day virtual ACIP meeting was held on September 1. The meeting focused on COVID-19 related topics including SARS-CoV-2 variants; updates to COVID-19 vaccine effectiveness (VE) and vaccine safety; Evidence to Recommendations (EtR) Framework assessment of bivalent COVID-19 booster doses; and votes on Moderna COVID-19 bivalent vaccine in individuals ≥18 years of age and Pfizer-BioNTech COVID-19 bivalent vaccine in individuals ≥12 years of age.

Upcoming Meetings:
- February 22-24
- June 21-22
- October 25-26

CDC Agency Updates

COVID-19 Vaccine Implementation Updates
- CDC provides weekly updates on COVID-19 vaccine distribution and administration on the CDC COVID Data Tracker website. As of January 26, 2023, more than 953 million doses have been delivered, and more than 668 million doses have been administered, with more than 229 million individuals being fully vaccinated.
- Since the recommendation of the Pfizer-BioNTech COVID-19 vaccine for children aged 5–11 years more than a year ago, more than 11 million individuals aged 5-11 years old have received at least 1 dose of COVID-19 vaccine, with more than 9 million individuals aged 5-11 being fully vaccinated.
- On October 12, 2022, the CDC director signed a decision memo recommending updated (bivalent) COVID-19 boosters for children 5 years of age and older. This announcement expands on CDC's previous recommendation issued September 1, 2022, for updated COVID-19 boosters for people ages 12 years and older.
    - This action followed the Food and Drug Administration (FDA)'s granting of emergency use authorization for the Pfizer-BioNTech updated COVID-19 booster for children ages 5 through 11 years, and the Moderna updated COVID-19 booster for children and adolescents ages 6 through 17 years.
- Updated COVID-19 boosters protect against the original COVID-19 strain and the most recent Omicron subvariants, BA.4 and BA.5. These subvariants are more transmissible and are more likely to be able to

evade antibodies made against earlier subvariants. The FDA advised manufacturers earlier this year to add these subvariant components to their COVID-19 vaccine boosters.

- This new recommendation expands updated booster eligibility to about 9 million children ages 5 through 11 years who have already completed the COVID-19 primary series vaccines in the United States.
- CDC disseminated documents to inform jurisdictional planning of a COVID-19 vaccination program for this age group. This included information on ordering and delivery of this vaccine and At-A-Glance fact sheets on the Moderna and the Pfizer-BioNTech COVID-19 vaccine products with information on storage, preparation, scheduling, administration, and dosage. Communications between CDC, jurisdiction, and partners are ongoing to ensure a smooth and swift rollout. The documents are available at COVID-19 Vaccination for Children | CDC.

Current Efforts on Maintaining Childhood Vaccination Coverage

- In January, CDC published 2 MMWR articles addressing childhood vaccination coverage:
    - *Vaccination Coverage with Selected Vaccines and Exemption Rates Among Children in Kindergarten — United States, 2021–22 School Year;*
    - *Vaccination Coverage by Age 24 Months Among Children Born in 2018 and 2019— National Immunization Survey–Child, United States, 2019–2021*
- The report on vaccination coverage among children in kindergarten reveals an additional 1% drop in nationwide coverage of measles, mumps and rubella vaccine (MMR), diphtheria, tetanus, and acellular pertussis vaccine (DTaP), poliovirus vaccine (polio) and varicella (chickenpox) vaccines.
- Vaccination coverage has dropped a total of 2% since the start of the pandemic – from 95% reported in the 2019-20 school year to 93% in the 2021-22 school year. This decline is significant because it means there are more than 275,000 kindergartners are not completely protected against common, and sometimes very serious, vaccine-preventable diseases.
- The second report found that while coverage with most childhood vaccines increased by the age of 24 months when comparing children born during 2018–2019 with those born during 2016–2017, children without insurance were more than eight times as likely to be unvaccinated by age 24 months compared to privately-insured children. The report also shows differences in vaccination coverage among children living below poverty or in rural areas, with a 4 to 5% decrease in coverage among these groups during the pandemic. The report also found children without insurance were more than eight times as likely to be unvaccinated by age 24 months compared to privately insured children.
- These reports add to previous data that highlight the lingering impact of the COVID-19 pandemic on routine childhood vaccinations as well as disparities in coverage that have continued to persist, or even widen, among some groups.
- To help address pandemic-related declines in routine immunizations, CDC is launching Let's RISE, an effort to equip partners and health care providers with actionable strategies, resources, and data to support getting all Americans back on schedule with their routine immunizations. More information about Let's RISE and access to routine immunization resources and data can be found on CDC's website: https://www.cdc.gov/vaccines/partners/routine-immunizations-lets-rise.html

Influenza Updates

Seasonal influenza

- The season is ongoing, but at this time, key indicators used to classify severity indicate a moderately severe flu season. This may change as the season progresses.
- According to the most recent FluView report, seasonal influenza activity continues to decline across the country.
- As of January 14, 2023, 171.52 million doses of influenza vaccine have been distributed in the United States this season.
- A total of 91 pediatric deaths have been reported during the 2022-2023 season.

- For the 2022-2023 influenza season, there are three influenza vaccines that are preferentially recommended for people 65 years and older: Fluzone High-Dose Quadrivalent vaccine, Flublok Quadrivalent recombinant flu vaccine, and Fluad Quadrivalent adjuvanted flu vaccine.
- For the 2022-23 season, based on claims data for adults 18 and older: approximately 66.7 million flu vaccinations have been administered in pharmacies and physician medical offices this season, compared with an estimated 68.03 million at the same time in January 2022. This is about 1.3 million fewer vaccinations by this measure than at the same time last season, which represents a decrease of approximately 2%.
- CDC has partnered with the AD Council and the American Medical Association (AMA) for their annual Get My Flu Shot campaign. The campaign encourages the American public, with emphasis on Black and Hispanic audiences, to get vaccinated against the flu for the 2022-2023 season.

Polio

- A case of paralytic polio caused by vaccine-derived poliovirus type 2 (VDPV2) was confirmed in an unvaccinated person in Rockland County, New York, on July 21, 2022.
- No new paralytic polio cases have been identified in the U.S. for more than 115 days.
- Wastewater samples collected from New York (Rockland, Orange, Sullivan, and Nassau Counties, and New York City) are positive for poliovirus type 2; several of the genome sequences are VDPVs with a genetic linkage to the virus from the case patient and thus meet the World Health Organization (WHO) criteria for circulating vaccine-derived poliovirus (cVDPV).
- New York State Department of Health (NYSDOH) is leading the response to the case of polio and is working with the local health departments, and CDC, to mitigate risks and increase polio vaccine uptake.
- CDC has had staff deployed to NY since August 4th to assist with investigation and vaccination efforts in Rockland and Orange Counties. CDC's actions include:
    - Providing direct assistance in Rockland and Orange Counties, NY to:
        - support enhanced passive surveillance for poliovirus in stool through testing by healthcare provider
        - increase vaccination through physician specific reminder-recall for under-vaccinated children
        - support community vaccination for adults and children to catch-up on recommended polio vaccination
        - help develop and distribute information to promote safe recreational water use
    - Conducting testing for poliovirus in wastewater samples in NY and neighboring states, as well as providing confirmatory testing for clinical specimens.
    - Collaborating with Israel, UK, and WHO to understand the origins and relatedness of the case patient VDPV2 to those in other countries.
    - Ensuring safe and secure handling and transport of potentially infectious material (PIM) through National Authority for Containment (NAC).
    - Working with State and Local Departments of Health to run and refine syndromic surveillance for paralytic polio.
    - Facilitating the procurement of polio vaccine (single antigen and combination vaccine) for affected areas.
    - Working closely with NYSDOH and county staff on long-term strategies for improving vaccine confidence and demand in areas of low inactivated polio vaccine (IPV) coverage.
- CDC expanded wastewater testing for poliovirus in 5–6 additional jurisdictions.
- The MMWR on the latest wastewater testing results is available here.

Measles

- As of January 27, 2023, provisional data indicate that there have been 2 cases of measles in the United States in 2023 in 2 jurisdictions.
- As of January 19, 2023, provisional data indicate that there were 121 cases of measles in the United States in 2022.

- Jurisdictions at risk for measles continue to be those with persistently low vaccination coverage and importations from locations with poliovirus circulating.
    - In 2022, 100% of confirmed cases was associated with importation by individuals with travel history to Kenya, Somalia, and Tanzania, where measles outbreaks are ongoing.

Respiratory Syncytial Virus

- National trends in RSV activity continue to indicate the peak of seasonal activity has passed in all HHS Regions. RSV activity remains elevated in some regions but is decreasing or stable across all regions.
- RSV-associated hospitalizations and emergency department visits among people of all ages have peaked, continue to decrease, and are nearing typical end-of-winter-season levels.
- As typically seen throughout the year, children ages 4 years and younger, especially those aged <6 months, have the highest RSV-associated hospitalization rates currently. Compared to previous years, there are also more RSV-associated ED visits and hospitalizations among older children.
- In preliminary analyses among hospitalized children, there continue to be no indications of increased severity of disease among children who tested positive for RSV this year compared to the 4 pre-pandemic seasons, even when accounting for co-infections.

National Vaccine Advisory Committee Meeting – February 2-3, 2023

Report from the Biomedical Advanced Research and Development Authority (BARDA)

BARDA is located within the Administration for Strategic Preparedness and Response (ASPR) that leads the nation's medical and public health preparedness for, response to, and recovery from disasters and public health emergencies. BARDA is the premier advanced research and development organization within the US Government and supports the advanced development, manufacturing, and acquisition of medical countermeasures against chemical, biological, radiological, and nuclear (CBRN) threats, pandemic influenza, COVID-19, and other emerging infectious diseases. BARDA supports the ASPR mission to prepare for and respond to public health emergencies and disasters through partnerships with pharmaceutical and biotechnology companies, the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Departments of Defense (DOD) and Homeland Security (DHS) and other governmental, non-governmental, and international partners.

COVID-19 Vaccine Update

BARDA continues close coordination and collaboration with its private sector and interagency partners to support the federal COVID-19 response for vaccines. These efforts include supporting the advanced development and ongoing manufacturing and procurement of multiple vaccine candidates. Updates on progress since the last report are as follows:

AstraZeneca

- AZD1222 vaccine, developed in conjunction with the University of Oxford, consists of a replication-deficient adenovirus vector with the SARS-CoV-2 spike protein.
- The Phase 3 clinical study reported out primary efficacy results of 76% against symptomatic COVID-19.
- AstraZeneca has reported it will not pursue U.S. approval of its COVID-19 vaccine
- AstraZeneca's COVID-19 vaccine has been granted a conditional marketing authorization or emergency use in more than 50 countries, with the WHO EUL now accelerating the pathway to access in up to 145 countries through the COVAX Facility.

Janssen (a Johnson & Johnson Company)

- AD26-based vaccine technology platform that provided a significant domestic and global vaccine manufacturing capability. Through BARDA support, this same approach was used to develop and manufacture Janssen's investigational Ebola vaccine, which is in Phase 3 clinical development.
- Emergency use authorization was provided by the FDA on February 17, 2021. Recommendations from the FDA in May 2022 have restricted the use of this vaccine to those allergic to mRNA-based vaccines, those who are uncomfortable with mRNA vaccines and otherwise wouldn't be vaccinated, and those who may not have access to mRNA vaccines.
- The delivery of doses to the USG is complete unless any additional procurements are placed in the future.

Moderna

- mRNA-based COVID-19 vaccine (monovalent mRNA-1273 and bivalent mRNA-1273.222) encoding the SARS-CoV-2 spike protein.
- This effort continues the partnership between Moderna and BARDA to rapidly respond to emerging infectious diseases that was initiated with development of a mRNA Zika vaccine.
- On January 31, 2022, the FDA announced approval of the Moderna COVID-19 Vaccine, and is marketed

as SPIKEVAX, for the prevention of COVID-19 in individuals 18 years of age and older.

- SPIKEVAX is a monovalent COVID-19 vaccine that is approved for use as a two-dose primary series for the prevention of COVID-19 in individuals 18 years of age and older. It is also authorized for emergency use to provide:
    - A two-dose primary series to individuals 12 years through 17 years of age.
    - A third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise.
- Moderna COVID-19 Vaccine currently is a monovalent COVID-19 vaccine that is authorized for emergency use to prevent COVID-19 as a:
    - Two-dose primary series for individuals 6 months of age and older.
    - Third primary series dose for individuals 6 months of age and older who have been determined to have certain kinds of immunocompromise.
- On August 31, 2022 Moderna COVID-19 Vaccine, Bivalent was authorized for use in individuals 18 years of age and older as a single booster dose administered at least 2 months after either:
    - Completion of primary vaccination with any authorized or approved monovalent COVID-19 vaccine, or
    - Receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.
- On October 12, 2022, Moderna COVID-19 Vaccine, Bivalent was authorized for administration at least two months following completion of primary or booster vaccination in children down to 6 years of age.
- On December 8, 2022, Moderna COVID-19 Vaccine, Bivalent was authorized for administration in individuals 6 months through 5 years of age as a single booster dose at least two months after completion of primary vaccination with the monovalent Moderna COVID-19 Vaccine.

Novavax

- NVX-CoV2373 vaccine consisting of Matrix-M™ adjuvant and the SARS-CoV-2 spike recombinant protein.
- The Phase 3 interim study report indicated efficacy of approximately 90 percent.
- NVX-CoV2373 COVID-19 vaccine achieved EUA on July 13 with a positive ACIP recommendation on July 19. The vaccine is now authorized for emergency use to provide:
    - A two-dose primary series to individuals 12 years of age and older.
    - A first booster dose to the following individuals at least 6 months after completion of primary vaccination with an authorized or approved COVID-19 vaccine:
        - Individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate.
        - Individuals 18 years of age and older who elect to receive the Novavax COVID-19 Vaccine, Adjuvanted because they would otherwise not receive a booster dose of a COVID-19 vaccine.

Sanofi & GSK

- Recombinant SARS-CoV-2 spike protein with transmembrane region deleted, produced using Sanofi's FDA-licensed seasonal influenza vaccine Flublok® facilities, adjuvanted with GSK's AS03.
- Data from Phase 2 and Phase 3 booster trials show that adjuvanted vaccine administrated as a third dose induces titers against virus variants, regardless of which vaccine was used for primary immunization. Post-boost titers were enhanced if the booster formulation included the Beta variant either as part of a bivalent formulation or as a monovalent vaccine.
- Phase 3 efficacy trial with a monovalent vaccine consisting of the original prototype SARS-CoV-2 Spike antigen, and the second with a bivalent formulation of the original plus the Beta variant antigen completed enrollment and results were submitted to FDA in support of a potential EUA or BLA application.

    - Phase 3 crossover / booster trial is ongoing.
- Sanofi's VidPrevtyn Beta is now authorized across the EU. The European Commission granted a market authorization on November 10, 2022.

Pfizer

- mRNA-based COVID-19 vaccine (BNT162b2) delivered in protein-free lipid nanoparticles, developed by Pfizer and BioNTech.
- On August 23, 2021, FDA announced approval of the Pfizer-BioNTech COVID-19 Vaccine, and the approved vaccine is marketed as Comirnaty, for the prevention of COVID-19 in individuals 12 years of age and older.
- Comirnaty is a monovalent COVID-19 vaccine that is approved for use as a two-dose primary series for the prevention of COVID-19 in individuals 12 years of age and older. It is also authorized for emergency use to provide a third primary series dose to individuals 12 years of age and older with certain kinds of immunocompromise.
- Pfizer-BioNTech COVID-19 Vaccine is a monovalent COVID-19 vaccine that is authorized for emergency use to prevent COVID-19 as:
    - The first two doses of the three-dose primary series for children 6 months through 4 years of age.
    - A two-dose primary series for individuals 5 years of age and older.
    - A third primary series dose for individuals 5 years of age and older who have been determined to have certain kinds of immunocompromise.
- Pfizer-BioNTech COVID-19 Vaccine, Bivalent is authorized for emergency use to prevent COVID-19 as:
    - The third dose of the three-dose primary series following two doses of the monovalent Pfizer-BioNTech COVID-19 Vaccine in children 6 months through 4 years of age.
    - A single booster dose at least two months after completion of either primary vaccination with any authorized or approved COVID-19 vaccine or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine in individuals 5 years of age and older.

- On December 8, 2022, FDA/CBER reissued the EUA for the Pfizer-BioNTech COVID-19 Vaccine. In this letter of authorization, the Pfizer-BioNTech COVID-19 Vaccine, Bivalent is authorized for emergency use to prevent COVID-19 as:
    - The third dose of the three-dose primary series following two doses of the monovalent Pfizer-BioNTech COVID-19 Vaccine in children 6 months through 4 years of age.
    - A single booster dose at least two months after completion of either primary vaccination with any authorized or approved COVID-19 vaccine or receipt of the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine in individuals 5 years of age and older.

For the most recent updates and to learn more about all the lifesaving technologies BARDA is supporting to combat the COVID-19 pandemic, please visit our COVID-19 MCM Portfolio page.

Filovirus Vaccine Update

Merck's single dose Ebola vaccine

- ERVEBO® received Conditional Marketing Authorization in the European Union on November 11, 2019 and received licensure by the Food & Drug Administration on December 19, 2019.

- Ongoing clinical development of ERVEBO® is generating data in pediatric subjects and HIV+ subjects that may enable expansion of the label indication to include those populations.
- BARDA entered into an agreement with Merck to procure 1 million doses of ERVEBO®; BARDA is also coordinating closely with WHO, GAVI, and UNICEF on the global supply of Ebola vaccines.

Sudan ebolavirus response

- BARDA is supporting the Sabin Vaccine Institute and IAVI for the development of ChAd3-Sudan and VSV-Sudan respectively. Both efforts also include Marburg vaccine candidates (as separate monovalent vaccines)
- BARDA worked with both vaccine sponsors to expedite manufacturing of doses that could be used in clinical trials to include ring vaccination in Uganda.
- WHO convened an advisory committee ahead of a potential ring vaccination study, recommending both the Sabin and IAVI vaccines for use in such a trial along with a third candidate from the University of Oxford. Doses for all three candidates arrived in country, but the Sudan ebolavirus outbreak ended prior to the ring vaccination protocol being implemented. BARDA, however, will continue its plans to support manufacturing efforts to improve preparedness for the next outbreaks.

Smallpox Vaccine Update

- On September 24, 2019 the FDA announced the approval of Bavarian Nordic's JYNNEOS vaccine, a live, non-replicating vaccine for the prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection. It is the only currently FDA-approved vaccine for the prevention of mpox disease.
- The mpox outbreak that started in May 2022 is still ongoing as of January but has waned in terms of case numbers per day.
- Over 900K vials of JYNNEOS vaccine procured by BARDA have been deployed in response to the mpox outbreak. This includes vials shipped directly to jurisdictions, provided to Americans through federal partners (DoD, IHS, HRSA and others) and to support special events throughout the country to increase vaccine equity.
- BARDA is continuing to act on its plans to fill 5.5M vials to bolster preparedness for future outbreaks.
- BARDA awarded a contract to Grand River Aseptic Manufacturing (GRAM) in September 2022 to accelerate technology transfer of the JYNNEOS fill/finish manufacturing process to GRAM's facility in Michigan.

Anthrax Vaccine Update

- A Biologics License Application for AV7909 was completed in June 2022.
- The Prescription Drug User Fee Act goal date for a decision by the FDA was in April 2023 but will likely be delayed by at least three months.
- Doses of this vaccine are being purchased in preparation for potential licensure by the FDA.

Zika Vaccine Update

Moderna mRNA Vaccine

- BARDA is supporting the development of Moderna's mRNA Zika vaccine and manufacturing platform through clinical development towards licensure. Phase 1 data shows that two 30ug doses given 28 days apart were well tolerated and stimulated a neutralizing antibody response in both flavivirus seropositive and seronegative individuals of ages 18-49 years. A Phase 2 study to assess the mRNA-1893 vaccine in adult participants living in endemic and non-endemic flavivirus areas is ongoing. The Zika vaccine candidate was also granted fast track status by the FDA.

Takeda Purified Inactivated Vaccine

- BARDA is supporting the development of Takeda's purified, inactivated, alum adjuvanted Zika Virus vaccine towards licensure. The Phase 1 clinical trial has been completed. This Zika vaccine candidate was granted fast track status by the FDA.

Pandemic Influenza Vaccine Update

- BARDA continues its partnerships to develop better and more rapidly produced next-generation pandemic influenza vaccines that shorten pandemic influenza response timelines and increase vaccine accessibility to ensure the Nation is prepared to respond to the next influenza pandemic.
- In addition to ongoing support of currently approved recombinant, cell, and egg-based vaccine, BARDA is continuing to support development of additional platforms that may further accelerate the response to a pandemic, such as mRNA

Alternative Routes of Administration Program

- BARDA continues to support several programs focused on alternative routes of administration. These efforts range from product formulation up through phase 1 clinical. BARDA is currently awaiting data read outs from these ongoing programs, as well as programs funded by others, to inform next steps.

Report of ASTHO Immunization Activities
Prepared for the National Vaccine Advisory Committee (NVAC)

The Association of State and Territorial Health Officials (ASTHO) is the national non-profit organization representing the public health agencies of the United States, the U.S. Territories, and the District of Columbia, as well as the 100,000 public health professionals these agencies employ. ASTHO members, the chief health officials of these jurisdictions, are dedicated to formulating and influencing sound public health policy to promote excellence in state-based public health practice.

Current ASTHO Immunization Initiatives:

Vaccine Resource Development: ASTHO continues to play a critical role in the nation's response to, and recovery from, the historic COVID-19 Pandemic. ASTHO staff have supported our members by providing situational awareness and technical assistance. ASTHO has developed several vaccine resources, including podcasts on ACIP Immunization Decisions, Creative Vaccine Strategies, Promoting The New COVID Booster, Tracking Legislation and Teaching Vaccine Advocates. In addition, ASTHO promoted National Influenza Vaccination Week through both a National Influenza Vaccination Week and Flu Vaccination Coverage podcast, and an Evidence Based Policy Blog.

Policy Academy: ASTHO is conducting a vaccine hesitancy Policy Academy for state and territorial health leaders to improve their capacity to identify develop and implement policies to address vaccine hesitancy. These sessions are intended to educate and help leaders prepare legislators for vaccine related sessions, explore policy options, and communicate effectively to vaccine hesitant populations. The first two sessions focused on coalition building and preparing testimony. The second two sessions will be held in early Spring.

Reducing Disparities in Adult Immunization Programs: ASTHO is working with key professional organizations and local partners to reduce racial and ethnic disparities in vaccination rates, and increase knowledge and trust in vaccines, with the goal of improving health equity and reducing the burden of vaccine preventable disease among adults. Last year, ASTHO funded five community action agencies to form community action teams, who are using evidence-based strategies to increase vaccine equity in their communities. ASTHO recently published two blogs, partnering with community action agencies and promotion of influenza vaccination to promote the work and early lessons learned from these teams. This year, ASTHO plans to work with the same sites to continue to implement strategies to assist and support vaccine equity these five communities, with a particular focus on reaching people living with mental and/or physical disabilities.

COVID-19 Immunization Data Exchange, Advancement and Sharing (IDEAS) Program: ASTHO, with support from the Office of the National Coordinator for Health Information Technology (ONC), launched a learning community to support data sharing and partnership between state immunization information systems (IISs) and health information exchanges (HIEs). Data exchange between these entities can support improved vaccine reporting and augment data available to inform public health decision-making. The IDEAS learning community will support cross-sector state teams in developing and implementing immunization data sharing plans and action steps. Subject matter experts from ASTHO, AIM, AIRA, Civitas Networks for Health, Guidehouse, and Mathematica are providing technical assistance and support dissemination of lessons learned from this effort.

Technical Assistance for Communication During Public Health Emergencies (COVID-19) Project: ASTHO, Harvard Opinion Research Program, NPHIC, and CDC are collaborating on a multi-year project to strengthen communication and messaging during the evolving COVID-19 pandemic. The goal is to support public health agencies with actionable data that can be used to enhance COVID-19 communication efforts. In 2022, four public opinion surveys were fielded to provide health agencies with robust, time sensitive data on the perspectives of the public related to trust in public health, changing COVID-19 recommendations, and vaccination. In addition, a learning community was established to provide capacity building and technical assistance to participating health agencies to enhance knowledge of and confidence to turn public health data into action using promising communication practices and strategies.

APhA
American Pharmacists Association

Report to the HHS National Vaccine Advisory Committee (NVAC)

From

American Pharmacists Association Liaison Representative
Jean-Venable "Kelly" R. Goode, Pharm.D., BCPS, FAPhA, FCCP
Professor and Director, Community-Based Residency Program
Virginia Commonwealth University School of Pharmacy
Past President, American Pharmacists Association

January 2023

Pharmacy providers continue to go beyond the call of duty to meet the needs of individuals and communities during the COVID-19 pandemic. The pandemic needs continue to evolve with the addition of newly enhanced bivalent booster vaccine recommendations for eligible patients and treatment options/recommendations. In addition to COVID-19 vaccines and boosters, pharmacy staff are answering the call to get pediatric and adolescent patient's routine vaccinations up to date and providing annual flu shots for eligible patients. Pharmacy personnel continue to be challenged with staff shortages, increasing patient and workload demands, and changing recommendations which increase concerns by pharmacists to meet the needs of their patients and communities.

Data from an article in press. Grabenstein JD. Essential Services: Quantifying the Contributions of America's Pharmacists in COVID-19 Clinical Interventions. Journal of the American Pharmacists Association (2022). https://doi.org/10.1016/j.japh.2022.08.010

- View this information on our website at https://pharmacist.com/Practice/COVID-19/The-Essential-Role-of-Pharmacy-in-Response-to-COVID-19
- Check out the infographic at https://pharmacist.com/Practice/COVID-19/The-Essential-Role-of-Pharmacy-in-Response-to-COVID-19/Infographic

Engagement

1) Vaccine Confidence
    a. Through a cooperative agreement with the CDC and other stakeholders, APhA has developed resources and information to support pharmacists' activities to build vaccine confidence among health care professionals, patients, and communities.
    b. Check out the recently refreshed website at: vaccineconfident.pharmacist.com.
2) Coloring Book
    a. APhA put out a call for coloring book pages and designs around vaccinations. These will be compiled into a book of 12 designs for distribution at pharmacies for children to color while waiting after receiving their vaccines.

Training and Education

1) Tips from the Field
    a. APhA created three CE webinars, moderated by Michael Hogue, PharmD, feature pharmacist immunizers who discuss how they have maintained immunization rates within their pharmacy or community during the pandemic and interventions they have put in place to increase immunization rates following a decline associated with the pandemic. Check out influenza, managing competing demands in a pandemic, and key considerations for safe and timely vaccinations at https://www.pharmacist.com/Practice/COVID-19/COVID-19-Vaccines/Tips-from-the-Field

2) What's New with the Flu 2022–2023 Season: This 3-part series of podcasts, hosted by Michael Hogue, PharmD, FAPhA, FNAP, will provide information to improve pharmacy teams' knowledge in appropriate influenza vaccine selection/administration during the 2022–2023 flu season.
    a. Episode 1 focuses on understanding the different types of influenza vaccines in the marketplace and how to select the appropriate age-based vaccine, particularly populations who are 50 years of age and older who have more risk.
    b. Episode 2 focuses on the current status of U.S. flu season, the importance of getting patients vaccinated, and the co-administration of other vaccines with the flu vaccine.
    c. Episode 3 will discuss how to have an effective and persuasive immunization consultation with your patients and how we can improve immunization rates.

Information and Resources

1) Pharmacist-administered vaccines
    a. In collaboration with the National Alliance of State Pharmacy Associations (NASPA), APhA has updated the resource containing a state-by-state analysis of pharmacist-administered vaccines. For information, visit: https://pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=EACvwV2aS-8%3d.
2) COVID-19
    a. APhA continues to update a COVID-19 vaccine algorithm to reflect the latest vaccine recommendations. Check out https://www.pharmacist.com/DNNGlobalStorageRedirector.ashx?egsfid=vUz7MhZHSZE%3d

AIRA
AMERICAN IMMUNIZATION REGISTRY ASSOCIATION

American Immunization Registry Association: NVAC Report

Summary September 2022 – January 2023

The following is a summary of the events and projects from September 2022, through January 2023. For additional information please contact Rebecca Coyle at (202) 552-0208.

At a glance (click to jump to the topic):

Measurement & Improvement (M&I)

Over the past several months members of AIRA and the Center for Disease Control and Prevention (CDC) collaborated to assess the processes to connect health care providers to immunization information systems (IIS), known as 'onboarding'. Five jurisdictions have now been invited to pilot a tool that will measure alignment across three provider onboarding best practice and characteristics categories:

(1) capability and capacity to onboard,
(2) stakeholder engagement and management, and
(3) process documentation and tools.

Improving IIS Data Quality

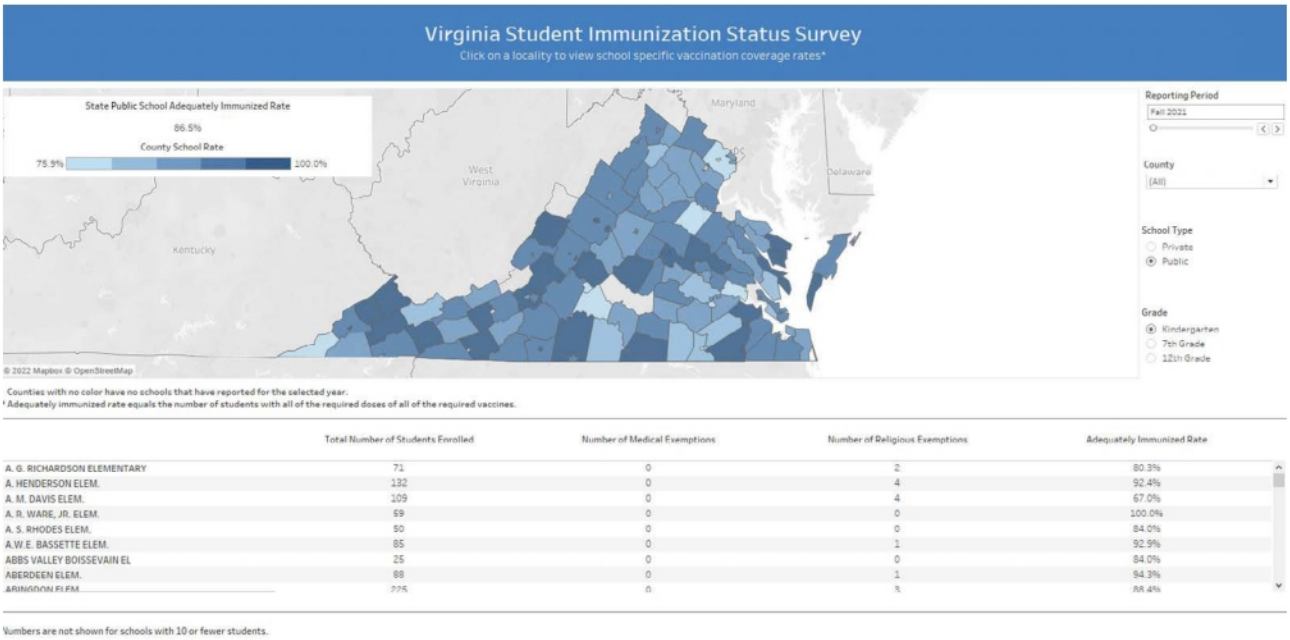
With IIS data now being utilized by a variety of stakeholders to inform outbreak response efforts and make important public health decisions, the need for IIS jurisdictions to focus on data quality has been brought to the forefront. Participation AIRA's Data at Rest (DAR) assessment provides an opportunity for IIS jurisdictions to measure the quality of the data that has been accepted into the IIS through an objective, independent testing process.

DAR results equip jurisdictions to better understand and identify opportunities to improve quality of the data that is "resting" in its IIS database. Participating IIS will receive usable and actionable reports that can help drive improvement of data quality from specific data senders. Participating in DAR assessment has become an increasingly important tool for identifying and addressing IIS data quality issues.

AIRA
AMERICAN IMMUNIZATION REGISTRY ASSOCIATION

Visualizing School Immunization Data: A Non-COVID Dashboard

AIRA's Tableau and Power BI User Groups are two outlets for IIS to share their successes and lessons learned, help members troubleshoot issues specific to each platform, and encourage the implementation of data visualization tools. Below are example snapshots of interactive dashboards shared by the Virginia Department of Health. Examples are shown for public and private schools, along with county-level data.



Using school immunization data to create visuals that are engaging, interactive, and easy to understand is a great way to share important immunization information. Seasonal influenza and routine immunization data are areas ripe with opportunity for creating interactive data visualizations.

Trainings

AIRA has a host of trainings and resources dedicated to supporting the advancements within the IIS community. We have launched several initiatives to support new-hire onboarding, training, and advancement of data analysis skills among IIS data analysts and epidemiologists.

Bulk Query Toolkit

AIRA, through the CDC, HIMSS and AIRA collaborative - the Immunization Integration Program (IIP) released its Bulk Query Toolkit, providing recommendations to IIS and their data exchange partners. The toolkit provides strategies to maintain core IIS functionality while expanding query capability to support large-scale population health efforts.

Association of Immunization Managers (AIM)

Executive Summary Report, National Vaccine Advisory Committee

February 2-3, 2023

2023 Vaccine Access Cooperative (VAC) In-Person Regional Meetings

AIM will convene eight (8) Vaccine Access Cooperative (VAC) in-person regional meetings (AIM Regions Map) during spring and summer of 2023. These meetings will bring together Immunization Program Directors, Medicaid Medical Directors, representatives of the American Academy of Pediatrics, the American Academy of Family Physicians, and pharmacy associations, along with other key partners to develop jurisdiction-specific strategies to improve participation in the Vaccines for Children Program and increase COVID-19 vaccination rates.

AIM Adult Immunization Committee

Established in January 2023, the AIM Adult Immunization Committee is intended to provide input to federal guidance and framework for adult immunization programmatic infrastructure, establish key messaging and advocacy priorities for AIM, and share information and resources to assist awardees in meeting adult immunization IPOM objectives. The Committee will provide input and feedback to CDC on the development of new guidance, as well as to NORC on the evaluation of the current adult programmatic activity. To learn more about the adult immunization committee, see the Adult Immunization Committee Charter.

AIM Letter to HHS: Considerations for Ensuring Timely Access to Vaccines After the COVID-19 Public Health Emergency

In November 2022, AIM sent a letter to HHS Secretary Becerra, making several recommendations for ensuring timely access to vaccines after the COVID-19 public health emergency ends. The letter also includes recommendations and requests for guidance on COVID vaccine commercialization.

AIM Sign On: Vaccinate Your Family (VYF) Letter on Coding RSV mAbs as Vaccine

In January 2023, AIM signed on to a letter authored by Vaccinate Your Family (VYF) encouraging the American Medical Association (AMA) to classify RSV mAbs as a vaccine and list those codes in the Vaccines, Toxoids section of the CPT code book. Coding this product as a vaccine will help ensure equal insurance coverage and access to a critical prevention tool. This letter was submitted to AMA directly by both VYF and AIM. Read the VYF letter here.

AIM Program Practices Database

In fall of 2022, AIM revamped the Program Practice Database – an online resource and idea sharing platform housed in the password protected portion of the AIM website intended to provide a forum for immunization program managers to share best practices and resources with each other. Program managers can submit resources from their jurisdiction such as infographics, fact sheets, newspaper articles, partnership tools, marketing materials, vendors, and other resources that other Program Managers may use or replicate in their jurisdiction.

Program Manager Knowledge Hub
Launching in January 2023, The Program Manager Knowledge Hub is a monthly webinar series for AIM members focused on collaborative problem solving and training. The goal is to foster knowledge-sharing among program managers, with a focus on managing the core immunization program and successfully transitioning from emergency response to recovery.

COVID-19 Pandemic Lessons Learned Project
AIM is collecting lessons learned from the COVID-19 pandemic. During the AIM Leadership in Action Conference in August 2022, 150+ conference attendees participated in a Pandemic Lessons Learned session where they shared successes, accomplishments, and challenges during the COVID-19 response from the state and jurisdictional perspective. AIM is utilizing this feedback to guide additional data collection. AIM is conducting an environmental scan of existing lessons learned reports, interviewing immunization program managers to gain additional insight, and collecting jurisdictional after-action reports.

COVID-19 Vaccine and VFC Community of Practice
AIM is currently recruiting up to 6 jurisdictions to work on COVID-19 vaccination rates for children 11 and under by assembling teams including the immunization program director, Medicaid medical director, state AAP or pediatric society member, state pharmacy association member, and up to 4 additional partners and working to break down barriers to pediatric vaccination. These teams will meet with AIM once a month from January through September 2023 to receive technical assistance and guidance to improve these rates. AIM will work as an extra set of hands researching best practices, connecting the teams with others that have had success in their areas of interest, assisting with developing materials, and more.

Member Assistance Program (MAP) Affinity Group Series: Capacity Building for Adult Immunization Programs
Started in 2021, The Member Assistance Program (MAP) is designed to provide programmatic assistance to support immunization programs in improving health equity, addressing vaccine hesitancy, and building robust adult immunizations programs. MAP began offering a new affinity group series on Capacity Building for Adult Immunization Programs in December 2022. This series addresses: staff onboarding and retention, strategies for continuous quality improvement, strategies for program success, and sustainable processes for a constantly changing environment.

Expanding the Role of Pharmacies in VFC
In Summer and Fall of 2022, AIM conducted an analysis of jurisdictional policies impacting participation in the Vaccines for Children (VFC) program. A webinar delved further into the successes and challenges of enrolling pharmacies in the VFC program. The AIM Pharmacies in VFC Work Group continues to meet, and is expected to draft a white paper and potential recommendations to increase pharmacy participation in VFC. AIM has also commissioned an environmental scan to understand barriers and facilitators of VFC program participation and administration of COVID-19 vaccinations to children.

AIM White Paper: Preventing Infant RSV - Examining Opportunities for Monoclonal Antibody Products in the Vaccines for Children Program
AIM authored a white paper on monoclonal antibodies and Respiratory Syncytial Virus (RSV). The white paper is intended to inform, provide recommendations, and guide discussion on RSV, and discussions considerations when exploring the addition of non-vaccine products to the VFC

program including collaborating with perinatal quality improvement organizations, developing educational materials for the medical community, examining the logistics of RSV mAb distribution, and identifying barriers to successful program implementation. (This white paper is for AIM members only and is password protected on our website).

AIM Celebration Webinar Marking the 2nd Year of COVID-19 Vaccine Distribution
On December 14, 2022, AIM held a webinar celebrating the second anniversary of COVID-19 vaccine distribution. Presenters included Dr. Cameron Webb, Senior Advisor to the White House COVID-19 Response Team, Dr. Anne Zink, Alaska SHO & ASTHO President, Dr. Georgina Peacock, CDC Director of the Immunization Services Division, and Chris Duggar, CDC Deputy Director of Distribution & Federal Partnerships, Vaccine Task Force, COVID Response. Watch the recording here and read the AIM press release.

AIM Reminder Recall Program
The goal of AIM's reminder/recall (RR) program is to increase immunization rates by assisting members in notifying individuals that they or their child(ren) are due for vaccinations or are late receiving a scheduled routine vaccination. AIM supports members by designing and coordinating reminder/recall postcard mailings. AIM is currently in the process of recruiting and working with jurisdictions interested in the reminder recall program.

RESOURCES & TOOLKITS

Communicating the Benefits of Influenza Vaccine During COVID-19
AIM and the Immunization Action Coalition (IAC) collaborated to create the *Communicating the Benefits of Influenza Vaccine During COVID-19* handout. The handout includes information on the burden of influenza from 2010 to 2022, benefits of seasonal flu vaccines, tips for discussing flu vaccine, and vaccination rate during the 2021-22 flu season.

COVID-19 Vaccination Social Media Toolkit
AIM updated the COVID-19 Vaccination Social Media Toolkit with messages about bivalent boosters and coadministration of COVID-19 and influenza vaccines. The social media templates provided in this toolkit help immunization programs create social media posts for Facebook, Instagram, LinkedIn, and Twitter. Each post is designed specifically for each platform and will fall within the platform's specifications. (This toolkit is designed for AIM members only and is password protected on our website).

Immunization Communications Resource Toolkit
AIM and the National Public Health Information Coalition (NPHIC) partnered to increase information sharing and collaboration between immunization program managers and public information officers related to COVID-19, flu, routine vaccination, and more. Find these resources here.

National Influenza Vaccination Week 2022 Social Media Toolkit
From December 5-9, AIM celebrated National Influenza Vaccination Week #NIVW. The CDC hosts this awareness week annually to remind everyone 6 months and older that there's still time to get a flu vaccine. AIM created a social media toolkit to help immunization programs and partners promote influenza vaccination nationwide.

Public Health Thank You Day 2022: November 21, 2022
To celebrate international Public Health Thank You Day (PHTYD) on November 21st 2022, AIM assembled easy-to-use resources for immunization program managers and partners, including social media activities and messages, thank you badges, and the AIM 2022 PHTYD video.

Vaccine Confidence Connecting the Dots
AIM's newest Connecting the Dots on Vaccine Confidence provides curated resources on vaccine confidence. This guide provides the necessary tools and information to build vaccine confidence across diverse communities. Resources include training and communications tools to engage with the public.

AIMing to Inform Podcast
AIM launched a limited series podcast *AIMing to Inform* in July 2022 and has since released 7 episodes. This series of conversations with immunization managers hopes to motivate and inspire public sector leaders, while helping them feel supported in their role. Short episodes hosted by AIM's Chief Policy and Government Relations Officer Brent Ewig talk to immunization managers across the US to understand how they have overcome challenges and become a champion for vaccines. Nearly 800 people have listened to the first season, and there have been 842 impressions, and 68 engagements on Twitter and 5,054 impressions and 327 engagements on LinkedIn. Listen to the AIMing to Inform Podcast here.

2022 Annual Survey Aggregate Report
Each year, AIM conducts this survey to assess and characterize immunization program policy, infrastructure, program activities, priorities, and the impact of funding changes (both federal and state) on IPs. Information gathered from the survey is used to generate reports and presentations on the status of immunization programs and to respond to inquiries from Congressional staff, partners, the media, and others. This year, the Annual Survey had an 83% response rate. Questions about the survey can be submitted to kdrumhiller@immunizationmanagers.org.

AIRA Discovery Session: Strategies & Tools to Increase Vaccination Rates Using Reminder/Recall
AIRA's January 2023 Discovery Session featured AIM's postcard reminder/recall program, as well as a presentation from the Nevada State Immunization Program (NSIP) about their efforts to partner with AIM to increase vaccination rates among racial/ethnic minority children and adolescents. NSIP and AIM mailed reminder/recall postcards to ~6k households with children 0-13 years of age, who reside in three counties in Nevada and were due for childhood 7-vaccine series; 6% received a vaccine within 12-weeks after mailing.

Summary of the
September 1, December 1, December 2, 2022 Advisory Commission on Childhood Vaccines Meeting
for the
February 2-3, 2022 National Vaccine Advisory Committee Meeting

The Advisory Commission on Childhood Vaccines (ACCV) conducted three meetings on Zoom during September – December 2022.

The September 1 and December 1, 2022 meetings provided updated with National Vaccine Injury Compensation Program from the Division of Injury Compensation Programs (DICP). The ACCV also received program updates from the Department of Justice (DOJ), Immunization Safety Office (CDC), the National Institute of Allergy and Infectious Disease (NIH), the Center for Biologics, Evaluation and Research (FDA) and the Office of Infectious Disease and HIV/AIDS Policy (OIDP).

After the updates provided at the September 1, 2022 ACCV meeting, the ACCV discussed the language of the draft recommendation to the Secretary. This recommendation supports increasing the annual appropriations for DICP, DOJ, and the Office of Special Masters of the U.S. Court of Federal Claims (Court) to provide the necessary resources to timely and efficiently implement the VICP. The recommendation also supports amending the National Childhood Vaccine Injury Act of 1986 to increase the number of special masters from the current cap of eight to no fewer than ten special masters. The ACCV voted to move the recommendation forward to the Secretary. The recommendation was sent to the Secretary in October 2022 and made publicly available on the ACCV website.

At the December 2, 2022, meeting, CAPT Karen R. Broder, Chief Medical Officer at the Centers for Disease Control and Prevention (CDC) presented on the Clinical Immunization Safety Assessment (CISA) Project. Kathleen Stratton, a staff member at the National Academies of Sciences, Engineering, and Medicine (NASEM) presented on the DICP and CDC jointly-funded contract to conduct a causality assessment of adverse events following (1) the delivery of vaccines intended for intramuscular administration; and (2) COVID-19 vaccination.

ACCV members previously expressed concerns about current vacancies on the ACCV. DICP is seeking ACCV nominations for each category and additional information is available on the ACCV website. We are actively trying to identify a practicing attorney, who is not employed by the Federal government, that is interested in vaccine-related issues. If there are any additional questions or interests in submitting in a nomination, please visit our website or email ACCV@hrsa.gov.