Summary of recent issues considered by four national immunisation technical advisory groups (NITAGs) and WHO immunisation-related advisory committees

Prepared by the National Centre for Immunisation Research and Surveillance (NCIRS)

Period of review: 22/08/2021 – 20/01/2022

Contents

1 Advisory Committee on Immunisation Practices (ACIP), USA

1.1 ACIP meeting 29 September 2021

- Meeting agenda: https://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2021-09-29-508.pdf
- Presentation slides: https://www.cdc.gov/vaccines/acip/meetings/slides-2021-09-29.html
- Immunisation Schedule: https://www.cdc.gov/vaccines/schedules/index.html

Tick-borne Encephalitis (TBE) Vaccine

- 13 August 2021: FDA approved a TBE vaccine (manufactured by Pfizer as TICOVAC) (no TBE vaccine previously licensed in U.S)
- TBE Vaccine Work Group formed in September 2020, vote on recommendations planned for Feb 2022
- Immunogenicity after primary series
    - Measuring vaccine protection against TBE - TBE virus neutralizing antibodies believed to confer protection against disease – Neutralizing antibody titer ≥10 generally used in vaccine studies – No formal correlate of protection and no standardized reference reagents
        - Immunogenicity in observational study, 3-dose primary series (at intervals of 0.5/1 to 3 months [adults/children] and 5 to 12 months, respectively, after the previous dose): seropositivity was >99% 1-month post-dose 3 and 94–98% 3 years post-dose 3 in adults (16–64 years) and children/adolescents (1–15 years)
- Summary of immunogenicity after a booster dose (≥3 years) among adults and children:
    - high seropositivity rates (100%) at 1 month after booster dose;
    - high seropositivity rates (≥85%) persist through 10 years after booster dose;
    - moderate decrease in GMT initially followed by slow decrease through 10 years
- Safety (among adults and children)
    - After dose 1
        - Local adverse events: adults 36% and children and adolescents 25%
        - Systemic adverse events: adults 14% and children and adolescents 20%
        - Fever rates variable by age group but mainly mild and no fever >40ºC
    - Severe adverse events were uncommon; lower adverse events rates after subsequent doses
- Vaccine effectiveness
    - No VE study for Pfizer's TBE vaccine alone
    - VE study in Austria with partially relevant data with limitations
        - Most but not all vaccine in use was Pfizer's TBE vaccine (90–95%)
        - When TBE occurred in vaccinated person no information on which vaccine used

        - Most vaccinated persons would have had previous formulations of TBE vaccine
        - VE measured based on vaccination according to the recommended Austrian vaccination schedule (Updated VE estimate, 2018–2020 - VE all age groups: 96%)
- TBE disease and vaccination in special populations
    - Pregnant women and their babies – Pregnant women similar spectrum of illness to non-pregnant persons (transplacental transmission of TBE virus not established) - No studies assessed safety or immunogenicity in pregnancy.
    - Breastfeeding women - TBE virus transmission via breastfeeding – 2 reports show transmission with variable outcomes in infants. No studies have assessed safety of TBE vaccination in lactating women
    - Persons with altered immune status
        - Can have severe TBE and have higher risk of fatal outcome
        - Limited data on TBE vaccine use in persons with altered immunocompetence – Some studies used previous formulation of vaccine and/or modified schedule
        - Immunogenicity results were variable but typically lower in immunocompromised persons – When adequate response occurred, it was often delayed
        - Safety data suggested vaccination was well-tolerated
    - Older persons
        - Incidence and severity of disease are highest in older persons
        - High seropositivity rates after 3-dose primary series – 99% (136/137) of older adults ≥70 years seropositive at 1 month
        - Some concern about duration of seropositivity after booster dose over longer term (≥5 years) but very limited data
        - Adverse event rates comparable to younger persons
- Coadministration with other vaccines: no data

Zoster Vaccines

- Timeline of Recombinant Zoster Vaccine (RZV, Shingrix): July 2021 – FDA approved expanded RZV indication for use in immunocompromised adults ≥18 years
- **Policy Question:** Should adults ≥19 years of age who are or will be immunodeficient or immunosuppressed due to disease or therapy be recommended to receive two doses of recombinant zoster vaccine for the prevention of herpes zoster and its complications?
    - Including but not limited to:
        1. Hematopoietic stem cell transplant (HSCT) recipients
        2. Patients with hematologic malignancies (HM)
        3. Renal or other solid organ transplant (SOT) recipients
        4. Patients with solid tumour malignancies (STM)

5. People living with HIV
6. Patients with primary immunodeficiencies, autoimmune conditions, and taking immunosuppressive medications/therapies

- Preliminary Evidence to Recommendations (EtR) conclusion: the Work group recommended use of RZV in immunocompromised adults
  - Severity of HZ in immunocompromised individuals
    - Postherpetic neuralgia (PHN): ~6–10% vs ~4% overall in administrative claims databases; between 6% and 45% across immunocompromised conditions and studies
    - Disseminated HZ: ~3% of immunocompromised, exceedingly uncommon in healthy persons; 10–17% mortality associated with disseminated HZ among renal transplant recipients
    - Hospitalization: 8% of HSCT recipients with HZ vs ~<1% of overall Medicare beneficiaries with HZ.
  - Risk of HZ in immunocompromised (Group 6)
    - ~2 to 4-fold higher risk in patients with autoimmune conditions than in healthy individuals
    - ~1.5-fold higher risk for unvaccinated Medicare beneficiaries with autoimmune conditions vs not immunocompromised
  - Special Considerations
    - RZV Package Insert Contraindications, Warnings and Precautions
      - Contraindications: history of severe allergic reaction to any component of the vaccine or after a previous dose of Shingrix
      - Warnings and Precautions: increased risk of GBS observed (42 days following vaccination with SHINGRIX – post marketing observational study); Syncope (fainting) can be associated with the administration of injectable vaccines, including SHINGRIX
    - Special Considerations
      - Work group recommended delaying Shingrix in pregnant women given lack of data of its use in this population; no restrictions on vaccinating breastfeeding women
      - Individuals with History of GBS: providers and patients should discuss potential risk
      - Individuals who have received the varicella vaccine series: Laboratory testing not recommended to confirm vaccine-induced immunity
      - Individuals with no history of varicella or varicella vaccine: RZV not indicated for prevention of primary varicella infection; Laboratory testing not recommended to confirm naïve; Limited safety data
  - Next Steps: discuss feedback, finalize EtR; Final EtR and vote anticipated at ACIP meeting

Pneumococcal Vaccines

- Current Pneumococcal Vaccines: 23vPPV and 13vPCV
- New Pneumococcal Vaccines (Policy options: PCV15 and PCV20 use - evaluated separately)
  - 20vPCV: Licensed for use in adults aged ≥18 years on 8 June 2021
  - 15vPCV: Licensed for use in adults aged ≥18 years on 16 July 2021
- Proposed timeline: Oct – vote on recommendations for both newly licensed vaccines
- Summary of three economic models assessing pneumococcal vaccines in US adults
  - Age based strategies (PCV20)
    - PCV20 (65 years): health improving across all age-based results; most estimates cost-saving
    - PCV20 (50 years): health improving in many results; some estimates cost-saving
  - Risk based and combined strategies, PCV20
    - Improved health indicated in all risk-based strategies and models
    - PCV20 19-64: risk-based assessments indicate a broad range of possible values ($11,000 to $292,000 per QALY gained); indicate cost-savings in 2 of 2 models
    - PCV20 19-49: risk-based assessments indicate a broad range of possible value (cost-saving to $483,000 per QALY gained); indicate more favourable value (CDC and Pfizer model indicates cost-savings)
  - All strategies, PCV15+PPSC23
    - Age-based analysis: improved health indicated in all main results; cost-savings indicated by the CDC model (4 of 4 scenarios)
    - Risk-based: improved health and higher costs indicated in all main results; risk-based only strategies yield a broad range of possible value ($250,000 to $656,000 per QALY gained)
    - Combined age-and risk-based assessments indicate values that were more favourable than risk-based alone, CDC model ($338,000 per QALY gained)
- EtR Framework: Risk-based Use of 15-valent and 20-valent Pneumococcal Conjugate Vaccines in Adults
  - **Balance of consequences:** Desirable consequences clearly outweigh undesirable consequences in most settings
  - **Current PICO questions for PCV15**
    - Age-based: Should PCV15 be routinely recommended to US adults ≥65 years in series with PPSV23?
    - Risk-based: Should PCV15 in series with PPSV23 be recommended for U.S. adults aged 19–64 years with chronic medical conditions* or immunocompromising conditions**?
  - **Current PICO questions for PCV20**
    - If age-based recommendation at age ≥50 years:

- Should PCV20 be routinely recommended to US adults aged ≥50 years?
- Should PCV20 be recommended for U.S. adults aged 19–49 years with chronic medical conditions* or immunocompromising conditions**?

▪ If age-based recommendation at age ≥65 years:
- Should PCV20 be routinely recommended to US adults aged ≥65 years?
- Should PCV20 be recommended for U.S. adults aged 19–64 years with chronic medical conditions* or immunocompromising conditions**?

*Alcoholism, chronic heart/liver/lung disease, diabetes, cigarette smoking
**Chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, human immunodeficiency virus infection, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplants, congenital or acquired asplenia, sickle cell disease, or other hemoglobinopathies, CSF leak, or cochlear implant

- At this time, revaccination strategies are not being considered

Hepatitis B Vaccines

- Post-licensure safety of an adjuvanted hepatitis B vaccine: Final results of the HEPLISAV-B acute myocardial infarction study
  - Objective: Compare occurrence of acute myocardial infarction (AMI) in recipients of Heplisav-B and recipients of Engerix-B; Real-world post-licensure safety study requirement as part of vaccine licensure (study design – non-randomised cluster design)
  - Study setting: Kaiser Permanente Southern California (KPSC) (large, diverse integrated health care system; 4.7 million members; 15 medical centres; 4.6 million vaccinations administered in 2019) and Kaiser Permanente HealthConnect® (comprehensive electronic health record system; ideal system in place to identify who can benefit from vaccination; Hep B vaccination alert for patients with diabetes)
  - Study design: Non-randomized cluster design, routine vaccine administration over 14 months (Aug 2018 - Oct 2019); Individuals passively followed through electronic health records for 13 months after first dose during study accrual period (index dose)
    - Heplisav-B became only available hepatitis B vaccine in family and internal medicine departments at 7 medical centres; Other 8 medical centres continued to use Engerix-B in family and internal medicine departments; Selection of medical centres primarily based on operational considerations
  - Outcome (primary): (1) Type 1 AMI (definite + probable); (2) First occurrence during 13-month follow-up after index date
  - Results: AMI rates (rate per 1000 person-years)
    - Heplisav-B: 1.67; Engerix-B*: 1.86; Total: 1.77

    *In Engerix-B group, a higher proportion of events came from claims, and a lower proportion of claims were adjudicated as AMI.
    *Background AMI rate among KPSC adults in 2020 is 1.74 per 1000 person-years.
  - Results: Hazard Ratio (HR) for confirmed type 1 AMI events, Heplisav-B vs. Engerix-B: Cox model with IPTW, adjusted HR (95%CI): 0.92 (0.63-1.32)

- Conclusion: There is no evidence of an increased risk of AMI associated with vaccination with Heplisav-B compared to Engerix-B.

- EtR Framework: Should all HepB-unvaccinated adults receive hepatitis B vaccination?
  - Evidence to Recommendations Framework: Should all HepB-unvaccinated adults receive hepatitis B vaccination?
    - Balance of consequences (work group judgement): Desirable consequences clearly outweigh undesirable consequences in most settings
  - Policy Options for ACIP Considerations: All adults previously unvaccinated for hepatitis B should receive hepatitis B vaccination
  - GRADE conclusions:
    - No studies comparing universal and risk-based adult hepatitis B vaccination
    - Cardiovascular events were more common in the Heplisav-B arms of RCTs compared to Engerix-B, but this difference was not statistically significant (Estimates were heterogeneous across trials and imprecise).
    - A lower rate of cardiovascular events was observed in the Heplisav-B group in an observational study, but this estimate was also imprecise.
    - The risk of serious adverse events was significantly lower in the Heplisav-B arms of RCTs (Estimates were heterogeneous across trials).

Orthopoxviruses Vaccines

- 2019: JYNNEOS® joined ACAM2000 as FDA-approved vaccine; Indication: for prevention of smallpox and monkeypox
- Work group goals:
  - Develop recommendations for newly licensed live, replication-deficient modified vaccinia virus vaccine, JYNNEOS®;
  - Merge all previous CDC recommendations about pre-exposure use of Dryvax/ACAM2000 so that these recommendations are consolidated with those for JYNNEOS®

ACAM2000 and JYNNEOS®

- Populations recommended: Persons at occupational risk for orthopoxviruses (i.e., diagnostic laboratorians, healthcare response teams); boosters recommended for those at continued or sustained risk (response teams to only receive boosters at time of event)
- Populations offered: Persons who administer ACAM2000 or care for patients with infection or after vaccination with replication competent virus
- Frequency of boosters (those working with smallpox and monkeypox):
  - ACAM2000: Every 3 years (had previously been every year)
  - JYNNEOS®: Every 2 years
- Frequency of boosters (those working with less virulent orthopoxviruses): At least every 10 years

- PICO questions:

  PICO 1, 2: Primary vaccination with JYNNEOS® in at-risk populations

1. Should JYNNEOS® be recommended for research and clinical laboratory personnel performing diagnostic testing for orthopoxviruses and for designated response teams at risk for occupational exposure to orthopoxviruses?
2. Should JYNNEOS® be recommended, for healthcare personnel who administer ACAM2000 or care for patients vaccinated with replicating orthopoxviruses

PICO 3, 4: Booster after primary JYNNEOS® series in person with continued risk

3. Should persons who are at continued risk for occupational exposure to more virulent orthopoxviruses such as variola virus or monkeypox virus receive a booster dose of JYNNEOS® every two years after the primary JYNNEOS series?
4. Should persons who are at continued risk for occupational exposure to replication-competent orthopoxviruses like vaccinia virus or cowpox virus receive a booster dose of JYNNEOS® at least every 10 years after the primary JYNNEOS series?

PICO 5: Change from booster with ACAM2000 to booster with JYNNEOS®

5. Should persons who are at continued risk for occupational exposure to orthopoxviruses, and who received an ACAM2000 primary vaccination, receive a booster dose of JYNNEOS® as an option to a booster dose of ACAM2000?

- EtR Frameworks for Use of JYNNEOS® - Summary of EtR #1-5: Balance of consequences: Desirable consequences probably outweigh undesirable consequences in most settings

1.2 ACIP meeting 20 October 2021

- Meeting agenda: https://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2021-10-20-21-508.pdf
- Presentation slides: https://www.cdc.gov/vaccines/acip/meetings/slides-2021-10-20-21.html

Pneumococcal Vaccines

- Introduction: Rationale for Harmonizing at Age ≥65 years
    - Due to potential waning of immunity, vaccination later in life may be favourable when risk of disease may be higher
    - Vaccination later in life is consistently cost-saving (lower cost and better health outcome compared to current recommendations) in cost-effectiveness analyses
    - Proposed risk-based and age-based options still provide an opportunity for higher PCV coverage, which may prevent more disease compared with current recommendations and may address some health equity concerns
    - Updated Policy Questions for Consideration

- Should **PCV20 alone <u>OR</u> PCV15 in series with PPSV23** be routinely recommended to US adults **aged ≥65 years?**
- Should **PCV20 alone <u>OR</u> PCV15 in series with PPSV23** be recommended for U.S. adults **aged 19–64 years** with certain underlying medical conditions or other risk factors*?

*alcoholism, chronic heart/liver/lung disease, cigarette smoking, diabetes mellitus, chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, human immunodeficiency virus, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplants, congenital or acquired asplenia, sickle cell disease or other hemoglobinopathies, CSF leak, or cochlear implant.

- Considerations for Age-Based and Risk-Based Use of PCV15 and PCV20 among U.S. Adults and Proposed Policy Options
  - Main Reasons Against the Proposed Options
    - Prefer an age-based recommendation at age 50 vs 65 years
      - May reduce disparity in disease burden in adults aged 50–64 years
      - May provide more opportunities to vaccinate adults before they develop underlying conditions
    - Concerns with PCV15 options given need to use in series with PPSV23
      - Logistically more challenging to administer different vaccines in series
      - Need to know the vaccination history to correctly complete series
      - Can result in lower serotype coverage if series not completed
  - Age-based recommendation age 50 vs. 65 years – reasons
    - Due to potential waning of immunity, vaccination later in life may be favourable when risk of disease is higher
    - Consistently cost-saving (lower cost and better health outcome compared to current recommendations) in cost-effectiveness analyses
    - Proposed risk-based and age-based options still provide an opportunity for higher PCV coverage, which may prevent more disease compared with current recommendations and may address some health equity concerns
  - Use of PCV15 in series with PPSV23 – reasons
    - Provides broad serotype coverage
    - Age-based use at age 65 was cost-saving (lower cost and better health outcomes compared to current recommendations) according to CDC's cost-effectiveness analysis
    - PCV13+PPSV23 series is currently used
      - Adults aged ≥19 years with immunocompromising conditions, cochlear implant, cerebrospinal fluid (CSF) leak
      - Adults aged ≥65 years* based on shared clinical decision-making

<u>Zoster Vaccines</u>

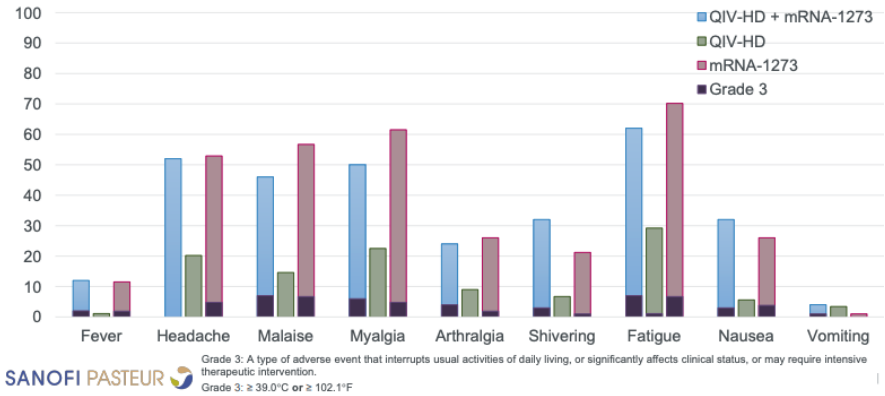
- WG Interpretation of the EtR Regarding Use of RZV in Immunocompromised Adults, Considerations for Use, and Proposed Policy Options

- **Policy Question:** Should adults aged ≥19 years who are or will be immunodeficient or immunosuppressed due to disease or therapy be recommended to receive two doses of recombinant zoster vaccine for the prevention of herpes zoster and its complications? (immunocompromising conditions as listed above)
- EtF Framework: work group interpretations
    - Balance of consequences: Desirable consequences clearly outweigh undesirable consequences in most settings
    - Type of recommendation: We (WG) recommend the intervention

Influenza Vaccines

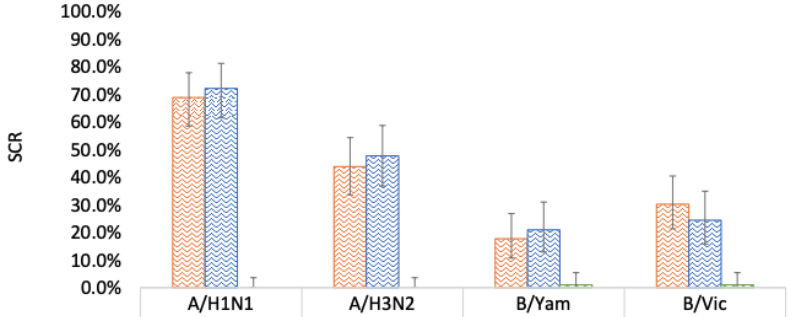
- Phase II, open-label study to assess the safety and immunogenicity of Fluzone® High-Dose Quadrivalent, 2021–2022 Formulation and a third dose (100 µg) of mRNA-1273 COVID-19 vaccine (Moderna) administered either concomitantly or singly in adults 65 years of age and older previously vaccinated (at least 5 months before enrolment) with a 2-dose schedule of mRNA-1273 vaccine
- 3 treatment groups (~100 participants per group): Group 1 - concomitant administration, QIV-HD first followed by mRNA vaccine; Group 2 – QIV-HD; Group 3 – mRNA vaccine.
- Study Code: QHD00028; https://clinicaltrials.gov/ct2/show/NCT04969276
- Safety summary, safety profile of QIV-HD and mRNA-1273 vaccine (concomitantly or singly)
    - Injection site reactions
        - QIV-HD and mRNA-1273: reaction frequency similar whether the vaccine was administered concomitantly or singly.
            - Solicited injection site reaction:
                - Group 1: QIV-HD, 61.0 (95% CI 50.7-70.6); mRNA-1273, 82.0 (95% CI 73.1-89.0)
                - Group 2: QIV-HD, 61.8 (95% CI 50.9-71.9)
                - Group 3: mRNA-1273, 91.3 (95% CI 84.2-96.0)
            - Injection site pain, the most frequently reported injection site reaction for both vaccines. The frequency of injection site pain tended to be lower following injection of QIV-HD (both QIV-HD alone and QIV-HD + mRNA-1273).
            - Frequency of Grade 3 injection site reactions tended to be lower following injection of QIV-HD compared to mRNA-1273.
    - Systemic reactions
        - Fatigue was most frequently reported in all treatment groups. Frequency was similar in the coadministration group and mRNA-1273 group and lower in QIV-HD group.
        - Frequency of Grade 3 systemic reactions was similar in the co-administration group and mRNA-1273 group and lower in QIV-HD group.

- Solicited systemic reactions (Day 1 - 8)



Reference: Graph from ACIP slides (slide 10), presented by Dr. R Izikson (Sanofi Pasteur)
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/02-influenza-izikson-508.pdf

  - No serious adverse events (SAEs), adverse events of special interest (AESIs) or deaths.
  - No adverse events (AEs) leading to study discontinuation.
  - Medically attended AE (MAAE): 1 participant in mRNA-1273 group (muscle spasm)
  - Unsolicited AEs and ARs: the frequency of unsolicited AEs and ARs was similar across treatment groups (most unsolicited AEs were systemic).
- Immunogenicity findings:
  - HAI immune response
    - All 3 treatment groups demonstrated similar GMT levels at baseline
    - Day 22, co-administration group and QIV-HD only group demonstrated similar GMT levels, proportions of participants with titers ≥ 1:40, and seroconversion rates for each influenza strain.
    - Seroconversion rate of influenza HA antibody response, by strain and by group



	A/H1N1	A/H3N2	B/Yam	B/Vic
Group 1 (QIV-HD+mRNA-1273)	68.8%	43.8%	17.7%	30.2%
Group 2 (QIV-HD only)	72.1%	47.7%	20.9%	24.4%
Group 3 (mRNA-1273 only)	0.0%	0.0%	1.0%	1.0%

SANOFI PASTEUR
Abbreviation: SCR=seroconversion rate
Definition: titer < 10 [1/dil] at D01 and post-vaccination titer ≥ 40 [1/dil] at D22, or titer ≥ 10 [1/dil] at D01 and a ≥ 4-fold-rise in titer [1/dil] at D22

Reference: Graph from ACIP slides (slide 18), presented by Dr. R Izikson (Sanofi Pasteur)
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/02-influenza-izikson-508.pdf

  - SARS-CoV-2 immune response
    - All 3 treatment groups demonstrated similar GMC levels at baseline.
    - Day 22, co-administration group and mRNA-1273 group demonstrated similar GMC levels and proportions of participants with ≥ 2- and ≥ 4-fold-rise of antibody titers.
- Overall interpretation: study results demonstrate that QIV-HD and mRNA-1273 vaccine (100µg) can be administered safely together without evidence of immunogenicity interference, supporting existing co-administration recommendations of COVID-19 and influenza vaccines.

- **Change in Age Indication for Flucelvax Quadrivalent** (cell culture, inactivated)
  - Age indication changed from ≥4 years to ≥2 years (approved by FDA in March, 2021).
  - **14 October 2021, FDA approved for ages ≥6 months.**
  - Data presented at June 2021 ACIP meeting:
  - Randomized trial of immunogenicity and safety compared to licensed egg-based quadrivalent inactivated influenza vaccine (Afluria Quadrivalent), among 2,402 children ages 6 to ≤47 months
    - Flucelvax Quadrivalent: 0.5 mL/dose
    - Afluria Quadrivalent: 0.25 mL/dose (6 to 35 months); 0.5 mL/dose (36 to 47 months)
  - Prespecified non-inferiority criteria met for Geometric Mean Titer (GMT) ratios and difference in seroconversion rates for all four viruses
  - Rates of solicited and unsolicited adverse events similar between groups
- Inactivated Influenza Vaccines for Children 6 through 35 months: 5 vaccines are now approved for this age group. Dose volumes vary.
  - Fluarix Quadrivalent 0.5 mL/dose; FluLaval Quadrivalent 0.5 mL/dose; Flucelvax Quadrivalent 0.5 mL/dose; Afluria Quadrivalent 0.25 mL/dose; Fluzone Quadrivalent 0.25 mL/dose or 0.5 mL/dose

1.3 ACIP meeting 2-3 November 2021

- Meeting agenda: https://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2021-11-2-3-508.pdf
- Presentation slides: https://www.cdc.gov/vaccines/acip/meetings/slides-2021-11-2-3.html

Hepatitis Vaccines

- ACIP Hepatitis Work Group Deliberations: The ACIP Hepatitis Vaccine Work Group unanimously agreed that the current risk-based recommendations need revision, with the majority preferring a universal adult HepB strategy with no upper age limit.
- Universal Adult Hepatitis B Vaccination: Work Group Considerations
    - New recommendations (proposed): simplify adult HepB vaccination schedule
        - **All adults previously unvaccinated for hepatitis B should receive hepatitis B vaccination**
        - All infants; Unvaccinated children <19 years (no change)

Immunisation Schedules

- Recommendations from the Combined Immunisation Schedule WG for the 2022 Immunisation Schedules for Children/Adolescents and Adults
    - Combined Immunisation Schedules Work Group updates schedules annually
        - Immunisation schedule: recommendations for persons 18 years of age or younger
        - Adult immunisation schedule: recommendations for persons 19 years of age or older

Orthopoxviruses Vaccines

- Timeline: MMWR publication; Recommendations become official (early/mid 2022)
- Clinical Guidance – Proposed ACIP Contraindications for ACAM2000 and JYNNEOS
    - Household contacts: JYNNEOS is a replication-deficient vaccine and therefore should not present a risk of transmission to household contacts
    - Atopic dermatitis / eczema and other active exfoliative skin conditions: Studies evaluating JYNNEOS in persons with atopic dermatitis have demonstrated immunogenicity in eliciting a neutralizing antibody response and did not reveal any significant safety concerns
    - Conditions associated with immunosuppression: Immunocompromised persons may have a diminished immune response to JYNNEOS
    - Pregnancy - available human data on JYNNEOS administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy. However, animal models, including rats and rabbits, have shown no evidence of harm to a developing foetus.
    - Aged <1 year
        - Vaccination of infants aged <1 year is contraindicated for ACAM2000
        - JYNNEOS is not licensed for persons <18 years and has not been rigorously evaluated in this population
        - Caution should be used when considering the administration of ACAM2000 or JYNNEOS to children and adolescents aged <18 years
    - Breastfeeding

        - Safety and efficacy of JYNNEOS has not been evaluated in breastfeeding women
        - It is not known whether JYNNEOS is excreted in human milk and data are not available to assess the impact of JYNNEOS on milk production or the safety of JYNNEOS in breastfed infants
        - However, JYNNEOS vaccine is replication deficient and therefore should not present a risk of transmission to breastfeeding infants.
        - Caution when considering the administration of JYNNEOS to breastfeeding women
    - Three or more known major cardiac risk factors
        - Clinical studies have not detected an increased risk of myopericarditis in recipients of JYNNEOS
        - Persons with underlying heart disease or ≥3 major cardiac risk factors should be counselled on the theoretical risk of myopericarditis given the uncertain aetiology of myopericarditis associated with replication-competent smallpox vaccines
- Summary of Evidence to Recommendations Frameworks for Use of JYNNEOS
    - Proposed clinical guidance
        - If recipients change from ACAM2000 to JYNNEOS®, recipients should
            - Receive subsequent boosters with JYNNEOS®
            - Adhere to the booster schedule for JYNNEOS®
        - Changes from JYNNEOS® to ACAM2000 are expected to occur less frequently

Ebola Vaccines

- WG Activities and Discussions Since February 2021
    - Elicited the support of Council of State and Territorial Epidemiologists (CSTE) to define/enumerate state-designated Ebola Treatment Centres
    - Discussions on risk of exposure to Ebola virus for both groups
    - Discussions on proposed policy options
- Pre-Exposure Vaccination with -ZEBOV-GP Ebola Vaccine for Special Pathogens Treatment Centres (SPTC) and Laboratory Response Network Facilities
    - SPTCs have been defined as: Healthcare facilities that intend to receive and are able to provide care for a suspect or confirmed patient with Ebola virus disease (EVD) for the duration of their illness, as assessed by their state health department. In addition to EVD, these facilities may also be designated by the states to treat other high consequence pathogens.
    - Evidence for Expansion of Recommendations
        - Benefits and Harms:
            - How substantial are the desirable anticipated effects? Large
                - RR: 0.04 [95%CI: 0.0001 – 0.74]) = 96% risk reduction
            - How substantial are the undesirable anticipated effects? Moderate

        - Arthralgia more commonly reported among vaccine recipients (RR: 2.55)
        - Severe arthralgia more commonly reported among vaccine recipients; overall uncommon (RR: 6.40)
        - Arthritis is more commonly reported among vaccinees (RR: 1.80)
        - Vaccine-related SAEs uncommon (3 events/17,119 vaccine recipients)
    - Balance of consequences: Desirable consequences probably outweigh undesirable consequences in most settings
    - Type of recommendation: we recommend the intervention
- Proposed text for policy options:
    - 1: Pre-exposure vaccination with rVSVΔG-ZEBOV-GP vaccine is recommended for healthcare personnel* involved in the care and transport of suspect or confirmed Ebola virus disease patients at Special Pathogens Treatment Centres
    - 2: Proposed Text: Pre-exposure vaccination with rVSVΔG-ZEBOV-GP vaccine is recommended for laboratorians and support staff at Laboratory Response Network (LRN) facilities that handle specimens that may contain replication-competent Ebola virus (species Zaire ebolavirus) in the United States

1.4 ACIP meeting 12 January 2022

- Meeting agenda: https://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2022-01-12-508.pdf
- Presentation slides: https://www.cdc.gov/vaccines/acip/meetings/slides-2022-01-12.html

Cholera Vaccine

- Policy topic under consideration: Should ACIP recommend CVD 103-HgR for children and adolescents aged 2–17 years traveling to an area with active cholera transmission?
- Vaxchora® Vaccine - Paediatric Dose Development
    - Vaxchora vaccine is comprised of two packets that are reconstituted in 100mL of water*
        - Buffer Component packet: Contents: 4.5 g of white to off-white powder
        - Active Component packet: Contents: 2.0 g of white to beige powder (V. cholerae CVD 103-HgR attenuated vaccine strain)
    - Clinical Development Program (Paediatric Phase 4 006) - Well-tolerated serum vibriocidal antibody (SVA) 98.5%(D11) Non-inferior to 004 (Healthy adults, aged 18-45 years. Ref - McCarty JM, et al. Vaccine. 2018;36:833-840)
    - Conclusion: Vaxchora is well tolerated and effective in children age 2 to 17 years; compatible with both sugar (sucrose) and stevia powder/crystals

- Evidence to Recommendations: CVD 103-HgR among children and adolescents aged 2–17 years: We recommend the intervention*

Tick-borne Encephalitis Vaccine

- Immunogenicity and safety updates
    - Summary of seropositivity rates and GMTs
        - After 1 dose: Seropositivity rates and GMTs are low
        - After dose 2: Seropositivity rates and GMTs initially increase then decrease in following months; variability by age group with lower rates and GMTs in older age groups; concerning that GMTs close to seropositivity cut off
        - After dose 3: Increase in seropositivity rates and notable increase in GMTs
    - Work Group conclusions: Important to recommend a 3-dose primary series be completed prior to departure, in line with FDA-approved schedule; Include data on immunogenicity after 1 or 2 doses in MMWR to enable counselling of individual travellers unable to complete full series
- EtR for TBE vaccine use among travellers
    - Policy question: Should TBE vaccine be recommended for use in persons aged ≥1 year traveling to or residing in TBE risk areas?
    - Proposed policy option category: TBE vaccination for persons who travel abroad based on shared clinical decision-making
- EtR for TBE vaccine use among laboratory workers
    - Policy question: Should TBE vaccine be recommended for use in laboratory staff working with TBE virus?
    - Proposed policy option category: TBE vaccination is recommended for laboratory workers

Influenza Vaccines

- Influenza Vaccines for Older Adults
    - High-dose Inactivated Influenza Vaccine: TIV-HD (Fluzone High-Dose) and Fluzone HD (Fluzone High-Dose Quadrivalent)
        - TIV-HD approved in 2009; replaced with Fluzone HD in 2020-21
        - Contains four times the quantity of hemagglutinin per vaccine virus compared with standard-dose inactivated vaccines (60 µg vs. 15 µg).
        - TIV-HD demonstrated superior efficacy to standard-dose Fluzone in a randomized trial conducted among 32,000 participants ages ≥65 years over 2011-12 and 2012-13 seasons.
        - Fluzone HD demonstrated noninferior immunogenicity to TIV-HD for the three viruses common to both vaccines, and superior immunogenicity to the additional influenza B viruses not present in the trivalent comparators
    - ACIP Recommendations Concerning Influenza Vaccines for Older Adults
        - Provide descriptive summary of efficacy and effectiveness data.

- No preference is expressed for any one vaccine over another; any IIV or RIV is appropriate.
- Vaccination should not be delayed to find a specific vaccine when an appropriate one is available.

- Relative VE (rVE) of different influenza vaccines varies
  - Izurieta et al analyses of CMS data: 12-13 million people aged ≥65 years each season; VE against influenza-associated hospital encounters (inpatient stays and ER visits), defined by ICD influenza codes.
    Relative Vaccine effectiveness (%)

	Relative VE compared with egg-based SD-IIV4		
Vaccine	**2017-18**	**2018-19**	**2019-20**
HD-IIV3	**9.0 (7.2, 10.6)**	**4.9 (1.7, 8.1)**	**6.8 (3.3, 10.1)**
aIIV3	**3.9 (1.4, 6.3)**	**7.7 (3.9, 11.4)**	**8.2 (4.2, 12.0)**
RIV4	-	-	**13.3 (7.4, 18.9)**
ccIIV4	**11.0 (7.9, 14.0)**	0.8 (-4.6,5.9)	2.8 (-2.8,8.2)

Hepatitis B Vaccines

- Introduction: Evaluation of the use of a three antigen HepB vaccine candidate (PREHEVBRIO) for adult vaccination
- Safety & Immunogenicity of a 3-Antigen (S, pre-S1, pre-S2) Hepatitis B Vaccine, PreHevbrio™ [Hepatitis B Vaccine (Recombinant)]
  - Reactogenicity: Solicited Local and Systemic Adverse Events
    - Higher rates of mild-to-moderate pain and tenderness at injection site and myalgia for PreHevbrio – generally resolved without intervention in 1-2 days
    - No increase in reactogenicity symptoms over the 3-dose vaccination schedule
    - Very low rates of vaccine discontinuation due to AEs (0.4% for PreHevbrio; 0.3% for Engerix-B)
  - Unsolicited Adverse Events: no unexpected safety signals associated with either vaccine and no unusual patterns or concerning clusters of SAEs, medically-attended AEs, or New Onset of Chronic Illness (NOCI)
  - Adults vaccinated with PreHevbrio, data demonstrated: a well-established safety profile; higher rates of seroprotection in adults; robust immunogenicity regardless of age; rapid onset of protection; higher immunogenicity in key high-risk populations
    - Seroprotection rate (SPR) at Day 196, 4 weeks post third vaccination
      1. Non-Inferiority of SPR achieved in all subjects age 18+ years
         - PreHevbrio 10µg (n=718): 91.4%
         - Engerix-B 20µg (n=723): 76.5%
         - Difference: 14.9% 95% CI [11.2% to 18.6%]
      2. Statistical and clinical superiority, as defined in the protocol, achieved in subjects age 45+ years
         - PreHevbrio 10µg (n=625): 89.4%

        - Engerix-B 20µg (n=627): 73.1%
        - Difference: 16.4% 95% CI [12.2% to 20.7%]
    - On average, ~90% of adults age 18-45 vaccinated with PreHevbrio attained seroprotection after 2 doses (Day 168) vs. ~40 -50% of those who received Engerix-B

Respiratory Syncytial Virus Vaccines

- Introduction to ACIP's Maternal/Paediatric RSV Work Group
- Purpose of the Work Group
    - Respiratory syncytial virus (RSV) is a major cause of lower respiratory illness, particularly among infants and children and among older adults and adults with chronic medical conditions.
    - RSV vaccine and monoclonal antibody development has progressed in the past decade with over 40 candidate vaccines and monoclonal antibodies currently in development.
    - Target populations for whom these products are intended include infants and young children, pregnant women, and older adults.

Pneumococcal

- Updates from the Pneumococcal Vaccines Work Group
    - Clinical Guidance on the PCV15–PPSV23 Interval
        - When PCV15 is used, the recommended interval between PCV15 and PPSV23 is ≥1 year. A minimum interval of 8 weeks can be considered for adults with an immunocompromising condition*, cochlear implant, or cerebrospinal fluid leak to minimize the risk for IPD caused by serotypes unique to PPSV23 in these vulnerable groups.

          **chronic renal failure, nephrotic syndrome, immunodeficiency, iatrogenic immunosuppression, generalized malignancy, human immunodeficiency virus infection, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplants, congenital or acquired asplenia, sickle cell disease, or other hemoglobinopathies, CSF leak, or cochlear implant*
    - Clinical Guidance for Those Who Previously Received PPSV23 Only: Adults who have only received PPSV23 may receive a pneumococcal conjugate vaccine (either PCV20 or PCV15) at least 1 year after their last PPSV23 dose
    - Clinical Guidance for those who previously received PCV13 (with/without PPSV23)
        - In favour of providing an opportunity to administer higher-valent PCVs to those who have already received PCV13 (with/without PPSV23).
        - Incremental public health benefits of providing PCV15 or PCV20 to adults who have received PCV13 only or both PCV13 and PPSV23 have not been evaluated by ACIP.
        - MMWR policy note expected to be published on January 28th, 2022 does not include a recommendation on PCV15/PCV20 use in adults who previously received PCV13 (with/without PPSV23)

1.5 Additional ACIP meetings focused on COVID-19 vaccines

Additional meetings were held on:

- 30 August 2021: https://www.cdc.gov/vaccines/acip/meetings/slides-2021-08-30.html
- 22 – 23 September 2021: https://www.cdc.gov/vaccines/acip/meetings/slides-2021-09-22-23.html
- 20 – 21 October 2021: https://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2021-10-20-21-508.pdf
- 2 – 3 November 2021: https://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2021-11-2-3-508.pdf
- 19 November 2021: https://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2021-11-19-508.pdf.pdf
- 16 December 2021: https://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2021-12-16-508.pdf
- 05 January 2022: https://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2022-01-05-508.pdf

Briefly, the following topics were covered in these meetings:

- Pregnancy: Safety monitoring in v-safe; Safety monitoring in VSD;
- Vaccine Safety Technical (VaST) assessment; VaST summary
- Immunity and SARS-CoV-2
- Vaccine effectiveness studies in the US; COVID-19 vaccine effectiveness, primary series
- Safety update for COVID-19 vaccines: VAERS; VSD
- Updates on Thrombosis with Thrombocytopenia Syndrome (TTS)
- Benefit-risk discussion for use of Pfizer-BioNTech COVID-19 vaccine in individuals ≥16 years
- GRADE: Pfizer/BioNTech COVID-19 vaccine; EtR Framework: Pfizer-BioNTech COVID-19 vaccine; BNT-162b2 COVID-19 vaccine BLA safety and efficacy data
- Myocarditis: VAERS; VSD; adolescents and young adults
- Children
    - Pfizer-BNT162b2 use in children aged 5-11 years
    - SARS-CoV-2 Epidemiology in children; Vaccine safety surveillance in children
    - Implementation of COVID-19 vaccine paediatric program
    - Clinical considerations for COVID-19 vaccination in children
    - EtR Framework: Pfizer-BioNTech COVID-19 vaccine in children aged 5-11 years + Updates regarding booster
- Booster doses

- Framework COVID-19 booster doses; benefit/risk discussion; safety; immunogenicity
- Booster dose data: Moderna; Janssen
- Modelling the potential impact of booster doses in nursing home residents
- Early safety monitoring for third doses of mRNA vaccines
- EtR Framework: Booster doses of Pfizer-BioNTech COVID-19 vaccine; Updates to the EtR Framework: Pfizer-BioNTech and Moderna COVID- 19 vaccine booster doses; Safety, immunogenicity for a 3rd dose of BNT162b2; Efficacy and safety of BNT 162b2 booster dose; National Institutes of Health, Mix and Match booster study
- v-safe and VAERS – third dose and simultaneous vaccination

- Update on Omicron

1.6 Newly published or updated recommendations

1.6.1 ACIP recommendations:

- These recommendations have been adopted by the CDC Director and will become official once published in MMWR.
- CURRENT Influenza Vaccine Recommendations
  - MMWR; 27 August 2021: https://www.cdc.gov/mmwr/volumes/70/rr/rr7005a1.htm
  - Summary document: https://www.cdc.gov/flu/pdf/professionals/acip/acip-2021-22-summary-of-recommendations-updated.pdf
- ACIP recommends:
  - Routine annual influenza vaccination is recommended for all persons aged ≥6 months who do not have contraindications. No preferential recommendation for a specific vaccine when more than one licensed, recommended, and age-appropriate vaccine is available.
  - The following types of vaccines are expected to be available (2021–22 influenza season): inactivated influenza vaccines (IIV4s), recombinant influenza vaccine (RIV), live attenuated influenza vaccine (LAIV), and cell culture-based influenza vaccine (cIV).
  - Primary Updates:
    - All seasonal influenza vaccines (2021–2022) are expected to be quadrivalent.
    - Flucelvax Quadrivalent (cIV): approved age indication expanded from ≥4 years to ≥2 years.
    - Administration of influenza vaccines with other vaccines includes considerations for coadministration of influenza vaccines and COVID-19 vaccines. Vaccines given at the same time should be administered in separate anatomic sites.
    - Guidance concerning timing of influenza vaccination:

        - Pregnant women in their third trimester and children who need 2 doses should receive vaccination as soon as possible after vaccine becomes available. For nonpregnant adults, vaccination in July and August should be avoided unless later vaccination might not be possible.
    - Contraindications and precautions to the use of cIV and RIV have been modified, specifically with regard to persons with a history of severe allergic reaction (e.g., anaphylaxis) to an influenza vaccine.
        - History of a severe allergic reaction to a previous dose of any egg-based IIV, LAIV, or RIV of any valency is a precaution to use of cIV.
        - History of a severe allergic reaction to a previous dose of any egg-based IIV, cIV, or LAIV of any valency is a precaution to use of RIV.
        - Use of cIV and RIV in such instances should occur in an inpatient or outpatient medical setting under supervision of a provider who can recognize and manage a severe allergic reaction.
        - cIV, history of a severe allergic reaction (e.g., anaphylaxis) to any cIV of any valency or any component of cIV is a contraindication to future use of cIV.
        - RIV, history of a severe allergic reaction (e.g., anaphylaxis) to any RIV of any valency or any component of RIV is a contraindication to future use of RIV.
- Dengue Vaccine Recommendations - Dengvaxia vaccine
    - MMWR; 17 December 2021: https://www.cdc.gov/mmwr/volumes/70/rr/rr7006a1.htm?s_cid=rr7006a1_e&ACSTrackingID=USCDC_921-DM72052&ACSTrackingLabel=This%20Week%20in%20MMWR%20-%20Vol.%2070%2C%20December%2017%2C%202021&deliveryName=USCDC_921-DM72052
- ACIP recommends:
    - Dengvaxia is FDA licensed for use among children and adolescents aged 9–16 years.
    - **ACIP recommends vaccination with Dengvaxia for children and adolescents aged 9–16 having evidence of a previous dengue infection and living in areas where dengue is endemic**. Evidence of previous dengue infection, such as detection of anti-DENV immunoglobulin G with a highly specific serodiagnostic test, will be required for eligible children before vaccination.
    - Areas where dengue is endemic in the United States and its territories and freely associated states include Puerto Rico, American Samoa, the U.S. Virgin Islands, the Federated States of Micronesia, the Republic of Marshall Islands, and the Republic of Palau.

2 Immunisation Advisory Centre (IMAC), New Zealand

2.1 PTAC Considerations

Meetings were held on:

- 19 – 20 August 2021 (no vaccine specific considerations): https://pharmac.govt.nz/assets/2021-08-PTAC-meeting-record-.pdf

2.2 Other updates

Updates related to immunisation in New Zealand: https://www.health.govt.nz/our-work/preventative-health-wellness/immunisation/updates-immunisation

2.2.1 Immunisation Update – 10 August 2021

- Maintaining and catching up on childhood immunisations - Inclusion of the new MMR event at 12 months (from 1 October 2020) has also resulted in some missed doses.
- HPV recalls - encourage GPs to continue recalling those aged 14 year who may not be fully protected against HPV. Some children have missed out through the disruptions that lockdowns caused to school-based programmes during 2020 and 2021. GPs also encouraged to discuss HPV vaccination with people up to 27 years of age.

2.2.2 Immunisation Update – 14 September 2021

- Update related to Online CPR training, Childhood immunisations and wearing PPE in Alert Level 4, Administering immunisations in carparks, Updated HepB consent form

2.2.3 Immunisation Update – 14 October 2021

- Concomitant administration of vaccines – updated advice on timing of routine vaccines in relation to COVID-19 vaccine.
    - Influenza, MMR, HPV, diphtheria/ tetanus/ pertussis combination vaccine (Boostrix), and majority of other routine vaccines can now be administered before, after, or at the same time as Pfizer COVID-19 vaccine, without concern for the spacing of vaccinations.
    - Only exception to this advice is for the Zostavax (shingles) vaccine where a 7-day interval, before or after administering the Pfizer COVID-19 vaccine, is advised.
    - Minimum gap between dose 1 and dose 2 of the COVID-19 vaccinations is 3 weeks.
    - Updated guidance: https://www.health.govt.nz/your-health/healthy-living/immunisation
- Reminder about the 2020 childhood immunisation schedule change: MMR vaccines are now given at ages 12 months and 15 months rather than at 15 months and 4 years.

3 Joint Committee on Vaccination and Immunisation (JCVI), UK Department of Health

3.1 JCVI meeting: 22 June 2021

- A summary of the JCVI meeting held in October is provided below
- Agenda: https://app.box.com/s/9f24lity6bqso9b6qi7c/file/819801673473
- Draft minutes of the 22 June 2021 meeting has not yet been published. Topics covered in that meeting were:
    - Horizon scanning
    - Coverage
    - Infant schedule
    - RSV
    - Influenza
    - Shingles
    - HPV
    - Pneumococcal
    - Vaccine strategy
    - UK HAS

4 National Advisory Committee on Immunisation (NACI), Canada

4.1 NACI Meetings

The most recent meeting was conducted virtually on 18 January 2022; however, the summary of discussions has not yet been released.
https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/meetings.html

Meeting dates since previous NITAG summary:

- 2021:
    - 1 September; 7 September; 14 September; 21 September; 28 September
    - 12 October; 15 October; 26; October; 27 October
    - 2 November; 9 November; 16 November; 23 November
    - 7 December; 14 December
- 2022: 11 January; 18 January

4.2 Newly published or updated statement/recommendations

4.2.1 Recommendations on the use of COVID-19 vaccines

- Current vaccine statement: Published 22 October 2021

https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html

- Table of updates: Recommendations on the use of COVID-19 vaccines: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines/table-updates.html

---

5 Immunisation updates from the World Health Organization (WHO)

5.1 WHO Position Papers

- No updates

5.2 Strategic Advisory Group of Experts (SAGE) on Immunisation, WHO

Many documents on COVID-19 vaccine recommendations or technical guidance have been updated. See Appendix 8.1 for current list.

Meeting landing page: https://www.who.int/groups/strategic-advisory-group-of-experts-on-immunization/meetings

Meeting date: 4 – 8 October 2021

- Meeting details**:** https://www.who.int/news-room/events/detail/2021/10/04/default-calendar/sage_meeting_october_2021
- Agenda: https://cdn.who.int/media/docs/default-source/immunization/sage/2021/october/sage_agenda_04-08_oct2021_v05oct.pdf?sfvrsn=987cf605_5
- Highlights: https://cdn.who.int/media/docs/default-source/immunization/sage/2021/october/sage_oct2021_meetinghighlights.pdf?sfvrsn=3dcae610_15https://www.who.int/news-room/events/detail/2021/05/27/default-calendar/extraordinary-meeting-of-the-strategic-advisory-group-of-experts-on-immunization-(sage)-27-may-2021

- Poliomyelitis
  - SAGE endorsed the transition of the novel oral poliovirus vaccine (OPV) type 2 vaccine (nOPV2) from initial to wider use under WHO Emergency Use Listing, based on the findings of the independent safety and genetic stability assessment.
  - Countries in polio-free regions with high vaccination coverage may consider switching to Inactivated Poliovirus Vaccine (IPV) only schedules, including a 2-dose IPV schedule. Once adequate supply is available, the use of whole-cell pertussis hexavalent vaccines containing IPV will facilitate the use of IPV-only schedules.

- The RTS,S/AS01 malaria vaccine
    - Recommended that vaccine be used for prevention of *P. falciparum* malaria in children living in regions with moderate to high transmission as defined by WHO. Schedule of 4 doses in children from the age of 5 months. Countries may consider providing the RTS,S/AS01 vaccine seasonally, with a 5-dose strategy in areas with highly seasonal malaria or areas with perennial malaria transmission with seasonal peaks.
    - Further information about the WHO malaria vaccine recommendation is available here: https://www.who.int/news/item/06-10-2021-who-recommends-groundbreaking-malaria-vaccine-for-children-at-risk

Meeting date: 7 December 2021

- Meeting details: https://www.who.int/news-room/events/detail/2021/12/07/default-calendar/extraordinary-meeting-of-the-strategic-advisory-group-of-experts-on-immunization-(sage)-7-december-2021
- Agenda: https://cdn.who.int/media/docs/default-source/immunization/sage/2021/april/sage_agenda_29april2021_virtual_final.pdf?sfvrsn=e6906937_5
- No meeting minutes are available yet.

5.3 Extraordinary meeting of the Strategic Advisory Group of Experts (SAGE) on Immunisation

A number of meetings of SAGE occurred where the use of COVID-19 vaccines was discussed. There were no discussions related to the use of other vaccines.

9 September 2021: https://www.gov.uk/government/publications/sage-95-minutes-coronavirus-covid-19-response-9-september-2021

14 October 2021: https://www.gov.uk/government/publications/sage-96-minutes-coronavirus-covid-19-response-14-october-2021

29 November 2021: https://www.gov.uk/government/publications/sage-97-minutes-coronavirus-covid-19-response-29-november-2021

7 December 2021: https://www.gov.uk/government/publications/sage-98-minutes-coronavirus-covid-19-response-7-december-2021

5.4 Meeting of the Global Advisory Committee on Vaccine Safety (GACVS)

- No meetings have been held since the last NITAG summary was released.

5.5 WHO Regional Committee for the Western Pacific meeting

- Regional Committee meeting page: https://www.who.int/westernpacific/about/governance/regional-committee

- **25 – 29 October 2021, 72nd session (Himeji, Japan):** https://www.who.int/westernpacific/about/governance/regional-committee/session-72
- Agenda: https://www.who.int/docs/default-source/wpro---documents/regional-committee/session-72/wpr-rc72-01_provisional_agenda.pdf/
- No meeting minutes are available yet.

5.6 Global immunisation news and other items and resources

- Latest news: https://www.who.int/news-room/fact-sheets/detail/immunization-coverage

5.7 COVID-19 related reports, guidelines and publications

- Recent COVID-19 publications published by WPRO: https://iris.wpro.who.int/handle/10665.1/14505
- Disease Outbreak News (DONs): https://www.who.int/emergencies/disease-outbreak-news

Many documents on COVID-19 vaccine recommendations or technical guidance have been updated. See Appendix 8.1 for current list.

---

6 Other items

6.1 Published information on assessment and registration of vaccines in Australia by TGA

6.1.1 Public summary documents

Provisional Registrations of COVID-19 vaccines: https://www.tga.gov.au/covid-19-vaccine-provisional-registrations

6.1.2 TGA media releases

- Media releases and statements landing page: https://www.tga.gov.au/media-releases-statements Note: only key updates are provided in this summary
- Updates related to COVID-19 vaccines can be found here: https://www.tga.gov.au/covid-19-vaccine-news-and-updates
- COVID-19 vaccines undergoing evaluation (page updated 20 January 2022): https://www.tga.gov.au/covid-19-vaccines-undergoing-evaluation
- TGA provisionally approves Novavax (Biocelect Pty Ltd's) COVID-19 vaccine NUVAXOVID (20 January 2022): https://www.tga.gov.au/media-release/tga-provisionally-approves-novavax-biocelect-pty-ltds-covid-19-vaccine-nuvaxovid
- TGA recognises the Gamaleya Institute vaccine (Sputnik V, Russian Federation) for international travel to Australia (17 January 2022): https://www.tga.gov.au/media-release/tga-recognises-gamaleya-institute-vaccine-sputnik-v-russian-federation-international-travel-australia

- Pfizer's COVID-19 vaccine (COMIRNATY) provisionally approved for use in individuals 5 years and over (5 December 2021): https://www.tga.gov.au/media-release/pfizers-covid-19-vaccine-comirnaty-provisionally-approved-use-individuals-5-years-and-over
- TGA recognises two more COVID-19 vaccines not registered in Australia but used widely internationally (1 November 2021): https://www.tga.gov.au/media-release/tga-recognises-two-more-covid-19-vaccines-not-registered-australia-used-widely-internationally
- TGA Provisional Approval of Moderna COVID-19 vaccine to include 12-17 years age group (4 September 2021): https://www.tga.gov.au/media-release/tga-provisional-approval-moderna-covid-19-vaccine-include-12-17-years-age-group
- Joint statement on COVID-19 and COVID-19 vaccines from nation's regulators - The following is a joint statement from the TGA, Ahpra, Office of the Health Ombudsman and the Health Care Complaints Commission (30 August 2021): https://www.tga.gov.au/media-release/joint-statement-covid-19-and-covid-19-vaccines-nations-regulators
- TGA provisionally approves Pfizer COVID-19 vaccine (27 August 2021): https://www.tga.gov.au/media-release/tga-provisionally-approves-pfizer-covid-19-vaccine
- TGA approves name change of COVID-19 Vaccine AstraZeneca to VAXZEVRIA (19 August 2021): https://www.tga.gov.au/media-release/tga-approves-name-change-covid-19-vaccine-astrazeneca-vaxzevria

7 Upcoming meetings and agendas

ACIP, USA (http://www.cdc.gov/vaccines/acip/meetings/upcoming-dates.html)
- 2022: 23-24 February; 22-23 June; 19-20 October

PTAC, New Zealand https://pharmac.govt.nz/about/expert-advice/pharmacology-and-therapeutics-advisory-committee-ptac/)
- 2022 meeting dates: 17–18 February; 19–20 May; 18–19 August 17–18 November

JCVI, UK (https://www.gov.uk/government/policy-advisory-groups/joint-committee-on-vaccination-and-immunisation)
- Future meeting dates pending, but usually the 1st Wednesday of June and October

NACI, Canada (https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/meetings.html)
All meetings will be conducted virtually.
- 11 January 2022; 18 January 2022

SAGE WHO (https://www.who.int/groups/strategic-advisory-group-of-experts-on-immunization/meetings)

- 2022: 5-7 April; 4-6 October
- 2023: 21-23 March; 26-26 September
- 2024: 19-21 March; 24-26 September

WHO-GACVS (https://www.who.int/vaccine_safety/committee/en/)

- 15 - 16 December 2021

WPRO

- Future meeting dates pending

ACV

- 2022: 2 February; 30 March; 1 June; 3 August; 5 October; 30 November

8 Appendix

8.1 COVID-19 related reports, guidelines and publications by WHO

Technical Guidance Publications: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance-publications

Pfizer BioNTech COVID-19 Vaccine COMIRNATY

- Interim recommendations for use of the Pfizer–BioNTech COVID-19 vaccine, BNT162b2, under Emergency Use Listing (19 November 2021): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1
- Annexes to the recommendations for use of the Pfizer–BioNTech vaccine BNT162b2 against COVID-19 (21 January 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-BNT162b2-GRADE-ETR-annexes
- Pfizer-BioNTech COVID-19 Vaccine, COMIRNATY® (Tozinameran), COVID-19 Vaccine Explainer (21 September 2021): https://www.who.int/publications/m/item/comirnaty-covid-19-mrna-vaccine

Moderna mRNA-1273 vaccine against COVID-19

- COVID-19 Vaccine Moderna (mRNA-1273) (24 August 2021): https://www.who.int/publications/m/item/covid-19-vaccine-moderna-mrna-1273
- Interim recommendations for use of the Moderna mRNA-1273 vaccine against COVID-19, 7 December 2021 - https://www.who.int/publications/i/item/interim-recommendations-for-use-of-the-moderna-mrna-1273-vaccine-against-covid-19

- Annexes to the recommendations for use of the Moderna mRNA-1273 vaccine against COVID-19 (19 November 2021): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-mrna-1273-GRADE-ETR-annexes

CoronaVac, developed by Sinovac

- Interim recommendations for use of the inactivated COVID-19 vaccine BIBP developed by China National Biotec Group (CNBG), Sinopharm, Interim Guidance (7 May 2021, updated 28 October 2021): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BIBP-2021.1
    - Annexes to the recommendations for use of the Sinovac-CoronaVac vaccine against COVID-19: Grading of evidence, EtR tables (21 October 2021): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-Sinovac-CoronaVac-annexes-2021.1
- Interim recommendations for use of the inactivated COVID-19 vaccine, CoronaVac, developed by Sinovac, 21 October 2021 - https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-Sinovac-CoronaVac-2021.1
    - Annexes: https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-Sinovac-CoronaVac-annexes-2021.1
- Background document: https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-Sinovac-CoronaVac-background-2021.1

BIBP developed by China National Biotec Group (CNBG), Sinopharm

- Interim recommendations for use of the inactivated COVID-19 vaccine BIBP developed by China National Biotec Group (CNBG), Sinopharm, Interim guidance, 7 May 2021 (updated 28 October 2021) - https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BIBP-2021.1
    - Annexes: https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BIBP-annexes-2021.1
    - Background document: https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BIBP-background-2021.1
    - Annexes to WHO interim recommendations for use of the COVID-19 vaccine BIBP: GRADE and Evidence to Recommendations tables - https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-COVID-19-vaccine-BIBP-GRADE-ETR-annexes

Bharat Biotech BBV152 COVAXIN® vaccine

- Interim recommendations for use of the Bharat Biotech BBV152 COVAXIN® vaccine against COVID-19, Interim guidance (3 November 2021): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-bbv152-covaxin

- Annexes to the interim recommendations for use of the Bharat Biotech BBV152 COVAXIN® vaccine against COVID-19, Grading of evidence – Evidence to recommendations tables (3 November 2021): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-bbv152-covaxin-annexes
- COVAXIN® (BBV152) – Inactivated, COVID-19 vaccine, COVID-19 vaccine explainer (10 January 2022): https://www.who.int/publications/m/item/covaxin-(bbv152)-inactivated-covid-19-vaccine

Variants

- Guidance for surveillance of SARS-CoV-2 variants: Interim guidance (9 August 2021): https://www.who.int/publications/i/item/WHO_2019-nCoV_surveillance_variants
- **Omicron (B.1.1.529) -** Enhancing Readiness for Omicron (B.1.1.529): Technical Brief and Priority Actions for Member States (28 November 2021): https://www.who.int/publications/m/item/enhancing-readiness-for-omicron-(b.1.1.529)-technical-brief-and-priority-actions-for-member-states
- Enhancing response to Omicron SARS-CoV-2 variant, Technical document (21 January 2022): https://www.who.int/publications/m/item/enhancing-readiness-for-omicron-(b.1.1.529)-technical-brief-and-priority-actions-for-member-states

Immunocompromised

- Interim recommendations for an extended primary series with an additional vaccine dose for COVID-19 vaccination in immunocompromised persons, Interim guidance (26 October 2021): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-immunocompromised-persons

Children and Adolescents

- COVID-19 disease in children and adolescents: Scientific briefs (29 September 2021): https://www.who.int/publications/i/item/WHO-2019-nCoV-Sci_Brief-Children_and_adolescents-2021.1

Coadministration

- Coadministration of seasonal inactivated influenza and COVID-19 vaccines, Interim guidance (21 October 2021): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-coadministration-influenza-vaccines

Technical Documents

- How to manage COVID-19 vaccines without VVM at vaccination service points? (31 August 2021): https://www.who.int/publications/m/item/how-to-manage-covid-19-vaccines-withoutvvm-at-vaccination-service-points

- Antigen-detection in the diagnosis of SARS-CoV-2 infection, Interim guidance (6 October 2021): https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays
- WHO SPRP 2021 Mid-term Report - WHO Strategic Action Against COVID-19 (7 October 2021): https://www.who.int/publications/m/item/2021-mid-year-report---who-strategic-action-against-covid-19
- Injection safety in the context of coronavirus disease (COVID-19) vaccination (5 November 2021): https://www.who.int/publications/i/item/WHO-2019-nCoV-Policy-brief-Vaccination-Injection-safety
- Therapeutics and COVID-19, Living Guideline (7 December 2021): https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2021.4

Surveillance

- Acknowledgements: The Unity Studies for sero-epidemiological investigation of COVID-19, Evidence-based knowledge for public health response (19 October 2021): https://www.who.int/publications/m/item/acknowledgements-the-unity-studies-for-sero-epidemiological-investigation-of-covid-19

COVID-19 Vaccines

- WHO calls for comments on the revised Target Product Profile for COVID-19 vaccines, Meeting Report (20 January 2022): https://www.who.int/publications/m/item/who-calls-for-comments-on-the-revised-target-product-profile-for-covid-19-vaccines