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: 19/05/2022 – 02/09/2022

Key updates in this NITAG summary on vaccine preventable diseases of interest to Australia

Monkeypox

- All countries (included in this summary document) discussed recommendations on use of the smallpox vaccines for preventing monkeypox, with updated published recommendations from ACIP, JCVI and UK Health Security Agency, and NACI.
- The USA recommended MVA-BN (JYNNEOS®) as an alternative option to ACAM2000® for vaccination against monkeypox in high-risk population groups already recommended for vaccination, while the UK preferentially recommended MVA-BN over ACAM2000.

Rabies

- ACIP updated rabies pre-exposure (PrEP) recommendations; the main changes included: A 2-dose (days 0 and 7) intramuscular (IM) rabies vaccination series replaced the 3-dose schedule; The minimum acceptable rabies antibody titre was changed to 0.5 IU/mL; Risk categories were redefined.
- ACIP recommended all persons for whom rabies PrEP is indicated receive 2 IM doses of HDCV or PCECV on days 0 and 7. In addition, persons in the newly defined risk category 1 should have rabies antibody titres checked every 6 months, and those in the newly defined risk category 2 should have rabies antibody titres checked every 2 years; a booster dose should be administered if titres are <0.5 IU/mL at the time of these titre checks. ACIP recommended persons in risk category 3 either have rabies antibody titres checked during years 1–3 after completion of the 2-dose primary series (and a booster dose if the titre is <0.5 IU/mL) or pre-emptively receive a one-time IM booster dose of rabies vaccine during day 21–year 3 after completion of the 2-dose primary series.
- These recommendations apply both to immunocompetent and immunocompromised persons; however, PrEP administered to immunocompromised persons requires additional considerations.

Pneumococcal disease

- ACIP recommended 15vPCV may be used as an option to 13vPCV for children aged <19 years according to currently recommended 13vPCV dosing and schedules.

Influenza

- ACIP recommended that adults aged ≥65 years preferentially receive any one of the quadrivalent high-dose, adjuvanted or recombinant influenza vaccines over standard inactivated influenza vaccine.
- The approved age indication for the Flucelvax Quadrivalent (cell-based QIV), was changed from ≥2 years to ≥6 months of age in the US.
- New Zealand expanded funded influenza vaccination eligibility to people with serious mental health and addiction needs, and all children aged 3-12 years inclusive.

HPV

- JCVI confirmed move to a 1 dose schedule for other groups in the routine HPV immunisation program (earliest date indicated is the academic year 2023 to 2024).
- JCVI to review proposed recommendations for all HIV-positive people aged up to and including 45 years be offered at least 3 doses of 9vHPV vaccination (currently MSM only).

Respiratory Syncytial Virus (RSV)

- The US ACIP reviewed the disease burden of RSV in children and older adults in the USA and the monoclonal antibody Nirsevimab for infants, in anticipation for its considerations regarding the use of various RSV vaccines in older adults and other special adult populations.

- In New Zealand, PTAC recommended that the monoclonal antibody palivizumab be funded for the next two RSV seasons (2022/2023), for RSV prophylaxis of children under the age of 12 months who are at high risk of developing RSV disease.
- In Canada, NACI published recommendations on use of palivizumab as prophylaxis against severe RSV in premature infants of <30 weeks gestational age and <6 months of age during the RSV season, children aged <24 months with certain medical conditions, and certain infants <6 months living in remote communities.

Updates to UK's childhood vaccination schedule

- Second dose of MMR brought forward to 18 months (from 3 years 4 months) of age, creating a new immunisation visit at 18 months.
- Additional dose of Hib-containing vaccine added (DTaP-IPV-Hib or DTaP-IPV-Hib-HepB) at 12 or 18 months.
- In the context of the discontinuation of Menitorix (Hib-MenC) vaccine by GSK, an infant dose of MenACWY will not be added at 12 months to replace HiB-MenC due to indirect protection from the teenage MenACWY dose. Modelling with a simple approach estimated that a maximum of ~20 cases in a single birth cohort over 5 years could be averted by giving a dose of MenACWY at age 3 months, with fewer cases prevented if given at age 12 months. With a dynamic approach model, it was predicted that the carriage prevalence would decline over time, with near elimination estimated by 2040 from the adolescent program, noting that cross-protection from the MenB vaccine was assumed, and it could not anticipate the introduction of new meningococcal strains.

Understanding the behavioural and social drivers of vaccine uptake

- The WHO published its first position paper on the behavioural and social drivers (BeSD) of vaccine uptake in May 2022. It summarised the development of new tools and indicators to assess the BeSD of vaccine uptake for childhood and COVID-19 vaccination, reported the main findings of a scoping review that examined existing systematic reviews and meta-analyses on interventions to improve vaccine uptake, made recommendations for using the new tools and the resulting data to prioritise local interventions, and concluded with future research directions.
- Countries are recommended to systematically collect and analyse data on behavioural and social drivers of vaccine uptake to guide program planning, implementation and evaluation, and to contribute to global tracking and reporting.

Contents

1 Advisory Committee on Immunisation Practices (ACIP), USA

1.1 ACIP meeting 22-23 June 2022

- Meeting agenda: https://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2022-06-22-23-508.pdf
- Presentation slides: https://www.cdc.gov/vaccines/acip/meetings/slides-2022-06-22-23.html
- Immunisation schedule: https://www.cdc.gov/vaccines/schedules/index.html

Influenza Vaccine

- Preliminary estimates of 2021-22 seasonal influenza vaccine effectiveness against medically attended influenza using test-negative design:
    - Of 6,782 people, 502 (7%) tested influenza RT-PCR positive; of 487 typed, 456 (94%) A/H3N2, 29 (6%) A unsubtyped, and 2 A(H1N1)pdm09.
    - Adjusted vaccine effectiveness (VE) against medically attended influenza A (any) in all ages ≥6 months was 34% (95% CI: 19 – 46).
    - Adjusted VE against medically attended influenza A/H3N2 in all ages ≥6 months was 35% (95% CI 19 – 47); VE by age – 6 months to 17 years: 44% (95% CI: 22 – 60), 18 to 49 years: 27% (95% CI: -3 to 48). Could not calculate adjusted VE for ≥50 years, but unadjusted VE was 29% (95% CI: -19 to 58).
- Vaccine safety update 2021-2022 influenza season – no new safety concerns identified.

- **Influenza vaccines for persons aged ≥65 years: Evidence to Recommendations (EtR) Framework**
- ACIP has previously expressed no preferential recommendation for any specific influenza vaccine(s) for this age group.
- Question: Do the relative benefits and harms of QIV-HD, aQIV, and RIV (FluBlok), as compared with one another and with other influenza vaccines, favour the use of any one or more of these vaccines over other age-appropriate influenza vaccines for persons ≥65 years of age?
- Final recommendation: ACIP recommends that adults aged ≥65 years preferentially receive any one of QIV-HD, RIV (FluBlok), or aQIV. If unavailable, then any other age-appropriate influenza vaccine should be used.
    - Current evidence is insufficient to inform a recommendation of any one over the others.
- Key considerations comparing the three vaccines with standard dose unadjuvanted QIV:
    - The most data are available to support QIV-HD, with evidence favouring its use for all outcomes and includes results of a large randomised trial. Evidence is less for aQIV and least for RIV.
    - Among outcomes, the most data are available for influenza hospitalisations.
    - Randomised trial of RIV (FluBlok) did not demonstrate benefit for primary outcome for 65 and older, but did for other outcomes in this subgroup and for those 50 and older.
    - Evidence that support superiority of adjuvanted vaccine over standard influenza vaccines against outcomes of influenza illness, influenza-associated outpatient/ER visits, influenza-associated hospitalisations, influenza-associated deaths, any solicited systemic adverse event Grade ≥3, and vaccine-associated Guillain-Barre syndrome from one cluster randomised and multiple observational studies.
    - Relative VE varies with season. Benefits of one vaccine compared to another are not static, relative benefit might not be observed in every season.

    - Increased frequency of some reactogenicity events in some studies of QIV-HD and aQIV compared with IV-SD, but most events were mild or moderate in severity. Certainty of evidence for safety outcomes was low or very low mainly due to downgrading for imprecision.
    - In cost-effective modelling: 20% of scenarios were cost-saving; 95% scenarios were under $195,000/ quality-adjusted life year (QALY). ICERs varied considerably based upon underlying VE and influenza season severity.
- Key considerations comparing higher dose and adjuvanted vaccines with one another:
    - Some observational studies of QIV-HD vs aQIV show greater benefit for one or other, but no differences in pooled analyses. No differences in safety outcomes of interest in one randomised study.
    - Some suggestion of greater benefit of RIV (FluBlok) relative to both QIV-HD and aQIV, but these data are from one observational study based on one season of data.
- **Other updates to recommendations for the 2022-2023 influenza season**
- USA influenza vaccine composition for 2022-23: All vaccines will be quadrivalent.
- The approved age indication for Flucelvax Quadrivalent (QIV [cell]) changed from≥2 years to ≥6 months; All standard-dose unadjuvanted QIVs now approved for ages ≥6 months.
- Recommendations for influenza vaccination of persons aged ≥65 years.

Pneumococcal Vaccines

- June 2022: FDA expanded approved 15vPCV (13vPCV types + 22F and 33F) to children 6 weeks through 17 years of age. 20vPCV licensure is anticipated in Q2 of 2023.
- Policy Question: Should 15vPCV be routinely recommended as an option for pneumococcal conjugate vaccination according to currently recommended dosing and schedules for: a) children <2 years of age, b) children 2–18 years of age with underlying medical conditions?
- **Additional data from the Phase 3 trial of 15vPCV in children 6 months to 17 years of age**
- Based on 7 clinical trials, the safety profile of 15vPCV is generally comparable to 13vPCV.
- No new safety concern was identified for 15vPCV with respect to post-vaccination body temperatures. The between-group differences were small and not statistically significant based on both weighted and unweighted analyses.
- FDA requested additional analyses based on concomitant administration of 15vPCV with 5-in-1 DTaP-IPV/Hib combination vaccine. The immunogenicity (based on IgG geometric mean concentrations) and safety of 15vPCV relative to 13vPCV in the ad-hoc subgroup analysis limited to participants who received 5-in-1 DTaP-IPV/Hib combination vaccine as a concomitant vaccine are consistent with the primary analysis in the overall population.
    - There was a narrow miss of the original pre-specified non-inferiority margin (-5.4 vs -5) for mumps in the subgroup; determined to be not likely clinically significant.
    - Mixed 13vPCV/15vPCV regimens were comparable to a complete 13vPCV regimen at dose 4.
- Economic analysis and public health impact of 15vPCV use in children:
    - Economic analysis demonstrated reduced direct medical costs and improved health (prevention of invasive pneumococcal disease (IPD), non-bacteraemic pneumonia (NBP), acute otitis media (AOM)); 15vPCV (vs. 13vPCV) was estimated to be cost-saving in two models (CDC & Merck).

        - Models assume 15vPCV prevents more disease than 13vPCV, 15vPCV costs approximately the same as 13vPCV.
        - Models assume that 15vPCV VE is equal to 13vPCV VE for 13vPCV-type disease, and provides protection for two additional, non-13vPCV serotypes.
- **Use of 15vPCV in children: Updates to the EtR Framework**
- PICO question: Should 15vPCV be recommended as an option for pneumococcal conjugate vaccination according to currently recommended dosing and schedules, for U.S. children?
- ACIP policy recommendation: 15vPCV may be used as an option to 13vPCV for children aged <19 years according to currently recommended 13vPCV dosing and schedules.
    - The balance between desirable and undesirable consequences was considered closely balanced or uncertain
- Key factors considered by ACIP:
    - Assessment of potential undesirable effects of 15vPCV use in children <2 years was "small". Uncertainty about higher reactogenicity (particularly fever ≥40.0◦C post dose 4) in children who received 15vPCV from a descriptive safety analysis reporting.
    - Assessment of potential benefits vs undesirable effects of routine use of 15vPCV in children <2 years of age or children 2-18 years with underlying medical conditions was "favours both". Uncertainty of the added impact from 15vPCV use (vs. 13vPCV use) given that there are no clinical efficacy data; uncertainty about reactogenicity from 15vPCV use compared with 13vPCV use.
    - Results from the cost-effectiveness analysis were 15vPCV use reduces direct medical costs and improves health (CDC model and Merck model). Only immunogenicity studies available, and there are uncertainties around clinical efficacy of 15vPCV. There are uncertainties about the actual vaccine price. Possibility of increased healthcare utilisation in the 15vPCV recipients due to increased reactogenicity (e.g. fever).
    - Pneumococcal disease burden remains higher in Native American/Alaskan Native (NA/AN) children. NA/AN experience cyclical outbreaks due to serotype 12F, which is not included in either 13vPCV or 15vPCV.
- **Clinical Considerations for Use of 15vPCV in Children:**
- Recommendations for each age group remained the same except for the addition of the option to use either 13vPCV or 15vPCV within the routine schedule (4-dose series with doses at ages 2, 4, 6, and 12–15 months).
- 13vPCV and 15vPCV can be used interchangeably.
- A supplemental dose of 15vPCV is not indicated for children who have received 4 doses of 13vPCV or another age-appropriate, complete 13vPCV schedule.
- Recommendations for use of 23vPPSV use for children aged 2–18 years who are at increased risk of pneumococcal disease remain unchanged.

Measles, Mumps, and Rubella (MMR) Vaccine

- June 2022: FDA approved GSK's vaccine Priorix. Previously only Merck's M-M-R-II vaccine was licensed in the USA.
- PICO and policy question: Should MMR vaccine (Priorix, GSK) be recommended as an option according to currently recommended schedules and off-label uses to prevent measles, mumps, and rubella in people ≥6 months of age? Comparison to M-M-R II (Merck).

- Given the similarities in dosage and vaccine components, evidence from clinical trials and literature review, Priorix may be administered in any situation in which a MMR vaccine is indicated and is fully interchangeable with M-M-R II including all off-label uses.
- Note: As Priorix and Priorix Tetra (MMRV) have been available and used in Australia for a number of years, the evidence reviewed by ACIP has not been summarised here. See ACIP slides for details.

Human Papillomavirus (HPV) Vaccine Informational Session

- ACIP reviewed current HPV vaccine coverage, impact of HPV vaccination on HPV-associated outcomes in US, and use of a single dose HPV vaccination schedule.
- Estimated national coverage as of 2020 was 75.1% for ≥1 HPV vaccine, and 58.6% for a completed HPV vaccination series. Coverage increasing but still lower than that for other routine adolescent vaccines. Disparities in vaccination coverage continue by race/ethnicity (lower in non-white Hispanics) and metropolitan statistical area (lower coverage in rural areas).
- Impact of the US HPV vaccination program on HPV-associated outcomes:
    - Genital 4vHPV (6/11/16/18) prevalence declined among both vaccinated (86-97%) and unvaccinated (65-87%) young females from 2015-2018 compared to pre-vaccine era.
    - Declines in incidence of juvenile onset recurrent respiratory papillomatosis (JORRP): 2.9 cases per 100,000 births in 2004-2005 vs 0.7 cases per 100,000 births in 2012-2013.
    - Declines in HPV16/18 prevalence have translated into declines in cervical precancer incidence in young women (8.6% lower in 2014 than 2008).
    - Early impact on invasive cancer might be occurring (Incidence rate was ~1.1 per 100,000 in 2005 compared to ~0.3 per 100,000 in 2017).
- **One-Dose Human Papillomavirus (HPV) Vaccination: Overview of Current Evidence:**
- ACIP reviewed evidence from studies of 1-dose HPV vaccination. This evidence has recently been reviewed by ATAGI and so is not summarised in detail in this document. For details, see ACIP slides. The following studies reviewed by ATAGI were reviewed by ACIP:
    - Costa Rica Vaccine Trial (CVT): 1, 2 or 3 doses of 2vHPV through 11 years
    - India IARC Trial: protection after 1, 2 or 3 doses of 4vHPV through 10 years
    - KEN SHE: RCT of 1 dose of 9vHPVor 2vHPV with meningococcal vaccine control, with clinical efficacy (HPV infection) results to 18 months
    - Dose Reduction Immunobridging & Safety Study (DoRIS): Randomised trial of 1, 2, 3 doses of 2vHPV or 9vHPV, with immunogenicity results to 24 months
- The following additional studies were discussed:
    - ESCUDO RCT in Costa Rica to evaluate efficacy. Objectives: 1) to evaluate non-inferiority of 1 versus 2 doses of bivalent and 9-valent vaccines for prevention of new cervical HPV16/18 infections that persist 6+ months, and 2) to evaluate 1 dose compared to unvaccinated. First results expected 2024.
    - Thailand Impact Study: Observational study of 1 dose and 2 doses of 2vHPV given to Grade 8 girls (age <15 years) in two similar Thai provinces. Outcome is vaccine-type HPV prevalence in years 2 and 4 post-vaccination. Results not yet available.
- Modelling and health economic data:
    - Impact and cost-effectiveness of adding a second dose is driven by duration of protection and, possibly, the ability to achieve higher coverage or expand catch-up with 1-dose versus 2 or 3 doses.

    - Projected impact and cost-effectiveness of 1-dose versus 2-dose 9vHPV vaccination in 192 countries using a comparative modelling approach (Public Health England, HPV-ADVISE, and Harvard models) has been conducted.
- Updated 2022 WHO SAGE recommendations noted: single-dose or 2 doses recommended for 9–14 year olds; at least 2 doses but ideally 3 doses for immunocompromised persons.
- ACIP noted no regulatory approval for 1-dose HPV vaccination in any age group or for 2-dose vaccination in age groups >14 years.

Respiratory Syncytial Virus (RSV) Vaccine

- RSV vaccine and immuno-prophylaxis 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.
- Adult RSV vaccine products expected be reviewed by the WG: protein based with adjuvant candidate (GSK), protein-based candidate (Pfizer), adenovirus vector with soluble protein candidate (Janssen Pharmaceutical), mRNA candidate (Moderna), vaccinia vector candidate (Bavarian Nordic).
- Planned timeline for review: Manufacturer presentations and GRADE for vaccine products from October 2022 to June 2023, ACIP votes on vaccine products and policy options from June 2023 to October 2023.
- RSV virion structure: Attachment (G) protein and fusion (F) protein are targets for neutralising antibodies. Upcoming products against RSV target F protein alone, or have targets for both F and G proteins. RSV G gene is the most variable in the genome, F is more conserved. F sequence variability in circulating viruses will affect different types of products difference.
- Vaccine products: Live attenuated/chimeric, protein-based (inactivated, particle, subunit), nucleic acid, recombinant vectors; Immunoprophylaxis: Monoclonal antibodies.
- **Burden of RSV in children in the USA**
- RSV is the leading cause of hospitalisation in infants (2-3% of all infants hospitalised for RSV), most (68%) infants are infected in the first year of life and nearly all (97%) by age 2.
- Premature infants born at <30 weeks gestation had hospitalisation rates ~3x higher than term infants.
- 79% of children <2 years hospitalised with RSV had no underlying medical conditions.
- Each year in children aged <5 years, RSV is associated with ~1,500,000 outpatient visits, ~520,000 emergency department visits, 58,000 to 80,000 hospitalisations, 100-300 deaths.
- Currently licensed prevention product (Palivizumab [Synagis®]) – only 5% of US infants eligible; ~2% of the annual birth cohort receive one or more doses.
    - Monoclonal IgG directed against F protein, monthly administration due to short half-life.
    - Efficacy against RSV-associated hospitalisation 55% in preterm infants and infants with chronic lung disease; 45% in infants with congenital heart disease.
- **Burden of RSV in older adults in the USA**
- Among adults ≥65 years of age, RSV is associated with: ~2,200,000 symptomatic illnesses per year, ~177,000 hospitalisations per year, ~14,000 deaths per year.

- Burden of severe disease may be comparable to influenza, with variability across seasons (~177,000 RSV hospitalisations per year vs. 128,000-467,000 influenza hospitalisations per year).
- Adults with co-morbidities, immunocompromised adults, and long-term care facility residents may be particularly at risk for severe illness. In adults aged ≥60 years, rates of incidence of medically attended outpatient visits for RSV were nearly 2x higher in patients with chronic cardiopulmonary disease (CPD) compared with those without underlying disease. Nearly 94% of RSV-hospitalised adults have underlying medical conditions.
- **Safety and efficacy of Nirsevimab (AstraZeneca and Sanofi) in infants**
- Recombinant human IgG monoclonal antibody, targeting the prefusion RSV F protein.
- Phase 2-3 MELODY RCT in infants ≥29 weeks gestational age (N=3,568), randomised 2:1 to receive a single intramuscular dose of nirsevimab.
    - Primary endpoint: Incidence of medically attended lower respiratory tract infection (LRTI) (inpatient and outpatient) caused by RT-PCR confirmed RSV over 5 months.
    - Efficacy against medically attended RSV LRTI (95%CI): 79.5% (65.9-87.8) overall; 77.3% (50.3-89.7) with associated hospitalisation; 86.0% (62.5-94.8) of very severe severity.
    - Efficacy was consistent over 150 days (5 months).
    - Relative risk reduction (RRR) compared to placebo for outpatient visits for all-cause medically attended LRTI: 41.9 (95%CI: 25.7–54.6).
    - RRR compared to placebo for antibiotic course: 23.6 (95%CI: 3.8–39.3).
    - Safety: None of the serious adverse events or deaths were considered as related; overall incidence of antidrug antibody was low across studies with no safety concerns; 3 adverse events of special interest overall (hypersensitivity, maculopapular rash, heparin-induced thrombocytopenia) – only hypersensitivity was considered related to treatment.
- Implementation designed to be simple and with hospital dosing at birth during the RSV season and office dosing before the RSV season integrated with routine infant immunisations.

Monkeypox Informational Session

- 2022 outbreak: first suspected US case identified on 17 May; 155 cases diagnosed in the USA as of 22 June.
- Vaccines: JYNNEOS®, ACAM2000®.
- Treatments: Tecovirimat, Vaccinia Immune Globulin Intravenous (VIGIV), Cidofovir.
- JYNNEOS licensed by FDA in September 2019:
    - Live vaccine produced from the strain Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN), an attenuated, non-replicating orthopoxvirus.
    - Indicated for 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. CDC is developing an Expanded Access Investigational New Drug Protocol to allow the use of JYNNEOS for monkeypox in paediatric populations.
- ACAM2000 licensed by FDA in August 2007:
    - A live vaccinia virus vaccine. Replaced Dryvax - license withdrawn by manufacturer and remaining vaccine destroyed.
    - Indicated for active immunisation against smallpox disease for persons determined to be at high risk for smallpox infection. CDC-held Emergency Access Investigational New

Drug Protocol allows use for Non-Variola Orthopoxvirus Infection (e.g., monkeypox) during an outbreak.

- Greater supply available of ACAM2000 than JYNNEOS (~7.9 million doses JYNNEOS which could be filled upon governmental request vs. >100 million doses of ACAM2000).
- Pre-exposure prophylaxis (PrEP) – People who should get PrEP include:
    - Clinical laboratory personnel who perform testing to diagnose orthopoxviruses, including those who use polymerase chain reaction (PCR) assays for diagnosis of orthopoxviruses, including Monkeypox virus.
    - Research laboratory workers who directly handle cultures or animals contaminated or infected with orthopoxviruses that infect humans, including Monkeypox virus, replication-competent Vaccinia virus, or recombinant Vaccinia viruses derived from replication-competent Vaccinia virus strains.
    - Certain healthcare and public health response team members designated by public health authorities to be vaccinated for preparedness purposes.
    - At this time, most clinicians in the United States and laboratorians not performing the orthopoxvirus generic test to diagnose orthopoxviruses, including monkeypox, are not advised to receive orthopoxvirus PrEP.
- Vaccination of close contacts (PEP) based on risk exposure assessment.
    - High degree of exposure: PEP recommended
    - Intermediate degree of exposure: Informed clinical decision making recommended on an individual basis to determine whether benefits of PEP outweigh risks
    - Brief interactions and those conducted using appropriate PPE in accordance with Standard Precautions are not high risk and generally do not warrant PEP
- Jurisdictions with larger numbers of cases are reporting that high percentages of contacts cannot be identified. Currently limited supply of JYNNEOS. Some jurisdictions have expressed concerns about potential serious adverse events with use of ACAM2000, especially considering that milder disease is typically being reported.

Please refer to Appendix 8.2 for details on and topics covered in the additional ACIP meetings focused on COVID-19 vaccines.

1.2 Newly published or updated recommendations

1.2.1 Rabies Vaccine Recommendations

- MMWR; 6 May 2022: https://www.cdc.gov/mmwr/volumes/71/wr/mm7118a2.htm
- Updates reflect changes to preexposure prophylaxis (PrEP) recommendations agreed to at 24 February 2021, 5 May 2021, and 24 June 2021 meetings.
- Primary updates:
    - A 2-dose (days 0 and 7) intramuscular rabies vaccination series replaced the 3-dose schedule. ACIP recommends all persons for whom rabies PrEP is indicated receive 2 intramuscular doses of human diploid cell vaccine (HDCV; Imovax/Sanofi Pasteur) or purified chick embryo cell vaccine (PCECV; RabAvert/Bavarian Nordic) on days 0 and 7.
    - The minimum acceptable rabies antibody titre was changed to 0.5 IU/mL.

- Risk categories were redefined. ACIP recommends persons in the newly defined risk category 1 should have rabies antibody titres checked every 6 months, and those in the newly defined risk category 2 should have rabies antibody titres checked every 2 years; a booster dose should be administered if titres are <0.5 IU/mL at the time of these titre checks.
- A one-time titre or booster dose was advised for persons with risk for only recognised rabies exposures. ACIP recommends persons in risk category 3 either have rabies antibody titres checked during years 1–3 after completion of the 2-dose primary series (and a booster dose if the titre is <0.5 IU/mL) or pre-emptively receive a one-time intramuscular booster dose of rabies vaccine during day 21–year 3 after completion of the 2-dose primary series.
- These recommendations apply both to immunocompetent and immunocompromised persons. ACIP recommends that, when possible, vaccination be delayed until a temporary immunocompromising condition has resolved or immunosuppressive medications can be withheld. If an immunocompromising condition cannot be temporarily reversed, rabies vaccines can be administered, but antibody titre should be checked no sooner than 1 week (preferably 2–4 weeks) after completion of the 2-dose PrEP series and all booster doses (including those administered within 3 years of the primary series and in response to a low titre during the serial titre checks recommended for risk categories 1 and 2).
- Clinicians might consider avoiding chloroquine when rabies vaccine is being administered. If avoidance is not possible, ensuring that a patient's rabies antibody titre is ≥0.5 IU/mL no sooner than 1 week (preferably 2–4 weeks) after completion of the series will confirm that vaccination was effective.

1.2.2 Orthopoxviruses (Smallpox and Monkeypox) Vaccine Recommendations – JYNNEOS

- MMWR; 3 June 2022: https://www.cdc.gov/mmwr/volumes/71/wr/mm7122e1.htm
- ACIP recommends: JYNNEOS preexposure prophylaxis as an alternative to ACAM2000 for certain persons at risk for exposure to orthopoxviruses.
- Primary updates:
  - ACIP recommends use of JYNNEOS (as an alternative to ACAM2000) for laboratory personnel and designated response team members, and for health care personnel who administer ACAM2000 or care for patients infected with orthopoxviruses
  - A booster dose of JYNNEOS is recommended:
    - Every 2 years for persons who received the 2-dose JYNNEOS primary series and who are at ongoing risk for occupational exposure to more virulent orthopoxvirus (e.g., Variola virus and Monkeypox virus)
    - At least every 10 years for persons who receive the 2-dose JYNNEOS primary series and who are at ongoing risk for occupational exposure to less virulent orthopoxviruses, (e.g., Vaccinia virus or Cowpox virus)
    - As an alternative to ACAM2000 for those who received an ACAM2000 primary vaccination with ongoing risk for occupational exposure to orthopoxviruses.
  - Persons who previously received ACAM2000 should decide before their next booster dose whether to receive ACAM2000 (booster every 3 years) or JYNNEOS (booster

every 2 years). Persons who transition to receiving JYNNEOS boosters are expected to continue receiving JYNNEOS boosters and to not revert to ACAM2000.
    - Fewer persons are expected to transition from JYNNEOS to ACAM2000 compared to persons transitioning from ACAM2000 to JYNNEOS. If this transition is approved by public health authorities, vaccinees should be advised that the expectation is that they will receive ACAM2000 for all future vaccine booster doses.
    - Due to the documented risk for myocarditis after receipt of both ACAM2000 and mRNA COVID-19 vaccines, and the unknown risk for myocarditis after JYNNEOS, persons might consider waiting 4 weeks after either JYNNEOS or ACAM2000 before receiving an mRNA COVID-19 vaccine, particularly adolescent or young adult males.

1.2.3 Influenza Vaccine Recommendations – 2022-2023 Influenza Season (Northern Hemisphere)

- MMWR; 26 August 2022: https://www.cdc.gov/mmwr/volumes/71/rr/rr7101a1.htm
- Updates reflect changes to recommendations agreed to at 20 October 2021, 12 January 2022, 23 February 2022, and 22 June 2022 meetings.
- Primary updates are based on recommendations discussed above (see influenza discussion):
    - Flucelvax Quadrivalent (QIV [cell]) approved from ≥6 months of age.
    - Adults aged ≥65 years should preferentially receive any one of QIV-HD, RIV (FluBlok), or aQIV.

2 Immunisation Advisory Centre (IMAC), New Zealand

2.1 PTAC Considerations

Meetings were held on:

- 17 – 18 February 2022; Minutes (published 12 May 2022): https://pharmac.govt.nz/assets/2022-02-PTAC-meeting-record-web-version.pdf
    - **Pneumococcal vaccines**
        - The Committee noted that the Immunisation Subcommittee recommended that 13vPCV should be included in the Childhood Immunisation Schedule rather than 10vPCV currently listed. The factors leading to this decision are detailed below.
        - The rate of 19A cases reached 13.1 per 100,000 children in June 2021, breaching the threshold (9.1 per 100,000) for the first time since monitoring began. Māori and Pacific peoples were over-represented in the 19A cases in 2020 in children <5 years.
        - Data published since the Schedule change from 13vPCV to 10vPCV vaccine in 2017 suggests that the cross protection afforded by 10vPCV against 19A is not as strong as initially thought.
        - Evidence from several countries (USA and UK) suggest that use of 13vPCV resulted in a decline of serotype 19A cases in all age groups.
        - Given additional information now available, PTAC considered that IMAC should review this topic again with some urgency to provide an updated view.
    - **Palivizumab for respiratory syncytial virus (RSV) prophylaxis in the context of COVID-19**
        - Recommendation: The Committee recommended that palivizumab be funded for the next two RSV seasons (in calendar years 2022 and 2023), with a view to reviewing funding

and eligibility criteria following the 2023 RSV season, for RSV prophylaxis of children under the age of 12 months who are at high risk of developing RSV disease.
    - Considerations: RSV disproportionately impacts premature infants who are Maori, Pacific, or living in areas with low socio-economic status in their first year of life; Seasonal characteristics of RSV are uncertain in the next two years in the context of the COVID-19 pandemic; The evidence for palivizumab prophylaxis in the infant population supports a reduction in hospitalisation in the target population who are vulnerable.
- 19 – 20 May 2022; Minutes (published 15 August 2022): https://pharmac.govt.nz/assets/2022-05-PTAC-Record.pdf
    - No vaccine specific considerations were discussed.
- 18 – 19 August 2022; Minutes are not yet available: https://pharmac.govt.nz/about/expert-advice/pharmacology-and-therapeutics-advisory-committee-ptac/
    - No vaccine specific applications were listed for review.

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 – 19 May 2022

- There is no stand-down period following COVID-19 infection; influenza vaccination may be administered as soon as the person is symptom-free and feeling well.
- Pharmacists to administer influenza vaccination to people aged 3 years and older.
- Catch-up efforts for routine vaccines continue, particularly MMR and HPV.

2.2.2 Immunisation Update – 11 August 2022

- Influenza vaccination update: In late June eligibility for funded influenza vaccines was extended to cover people with serious mental health and addiction needs, and children aged 3-12 years inclusive.
- COVID-19 vaccination: A second COVID-19 booster is now available and is recommended for certain high-risk groups including: Anyone ≥65 years; Māori and Pacific peoples ≥50 years; People ≥16 years who are severely immunocompromised or have high medical needs; All residents of aged care and disability care ≥16 years. The second booster is also available for all people ≥50 years, and all health, aged-care and disability workers ≥30 years.
- MMR and HPV vaccine catch-up program continues to be promoted.

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

3.1 Extraordinary JCVI monkeypox meeting: 25 May 2022

- A summary of the Extraordinary JCVI monkeypox meeting held in May is provided below
- Agenda: No agenda provided.
- Draft minutes, 25 May 2022: https://app.box.com/s/iddfb4ppwkmtjusir2tc/file/993199078522

- Epidemiology

- As of 24 May 2022 there were 74 confirmed cases of monkeypox in the UK. Cases were mainly gay, bisexual, and other men who have sex with men (GBMSM) without a documented history of travel to endemic areas, ranged in age from 20s to 50s, and mostly mild. No confirmed cases in household contacts of cases among GBMSM have been reported.
- The current UK outbreak is the West African clade which is usually associated with milder disease than the Central African clade.
- Case numbers were showing rapid increase with no signs of the outbreak curtailing.
- Greater severity of disease in children was noted. A case series from Nigeria showed that deaths related to monkeypox were predominantly in people living with HIV and in children.
- The age at which individuals are susceptible to contracting monkeypox is slowly increasing due to smallpox vaccinated populations aging.

- United Kingdom Health Security Agency (UKHSA) Guidance
  - Guidance "Recommendations for the use of pre and post exposure vaccination during a monkeypox incident" has been published. This was originally developed in 2019 for the use of the MVA-BN vaccine in the context of previous experience of use of this vaccine in contacts of monkeypox cases in the UK, and approved by the JCVI. The available evidence had been reviewed based on experience of use of the vaccine and subsequently updated. This current guidance is about managing the ongoing incident and using the vaccine available in the best possible way to curtail the epidemic.
  - One of the key recommendations in the guidance is pre-exposure vaccination (two doses, minimum 28-day interval) for individuals at risk of occupational exposure for both those working in high consequence infectious disease (HCID) units with patients and those undertaking environmental decontamination.
  - A single dose is recommended for those with a history of single dose live smallpox vaccine with the priority to offer a first dose to naïve individuals and to complete the course for those who are at ongoing risk.
  - UKHSA guidance on groups recommended for pre-exposure vaccination, and guidance on groups and timeframes recommended for post-exposure vaccination reflected what JCVI discussed and agreed, summarised below.
  - Once post-exposure vaccination has been completed, if sufficient supplies allow, vaccine should be offered to individuals completing their second or booster dose as part of a pre-exposure vaccination course.
  - The JCVI noted that the MVA-BN vaccine was much less reactive than the live vaccine however there is limited or no data on reactogenicity in people who are pregnant. Guidance is given on the principle of theoretical risk based on the vaccine not being a live vaccine and that it will only be considered in pregnant women with significant exposure and based on a risk-benefit assessment. As this is a non-replicating vaccination, it is expected to be safe in pregnancy and in immunocompromised individuals.
- Vaccine Strategy
  - Agreed that the strategy aim to interrupt transmission to bring the outbreak under control. A preventative strategy was not considered as the disease was not endemic in the UK.
  - Agreed that a selective deployment strategy would be the most appropriate rather than a mass vaccination strategy, targeting individuals with an elevated risk of exposure or severe disease. A potential ring vaccination approach was discussed.

- Based on the current epidemiology, JCVI recommends targeted pre-exposure vaccination of GBMSM with a history of high-risk behaviours for acquiring monkeypox. Healthcare workers at higher risk of exposure are also a key target group.
- Agreed that post-exposure vaccination should be limited to 4 days post exposure, unless in individuals at high risk of severe disease for whom this timeframe is 14 days post-exposure. This includes children, individuals who are pregnant or immunosuppressed.
- The Committee also considered the option of using the live smallpox vaccine, given the supply constraints of the MVA-BN vaccine. Considering the high rate of adverse reactions with the live vaccine and that disease was currently mild, this was not preferred. If this was needed, it should be used as a booster after MVA-BN or by use of vaccinia immunoglobulin to mitigate adverse reactions.
- Antivirals may have a much greater post-exposure effect. Members noted that brincidofovir (licensed CMV prophylaxis) and teciviromat (licensed for monkeypox treatment) could be considered. Vaccinia immunoglobulin could also provide rapid protection in those who are at high risk or for whom vaccination is contraindicated. Antivirals have been used on a compassionate basis to treat cases of pox virus disease, but there is no experience with post-exposure prophylactic use.

3.2 JCVI meeting: 17 June 2022

- A summary of the JCVI meeting held in June is provided below
- Agenda: https://app.box.com/s/9f24lity6bqso9b6qi7c/file/972444882986
- Draft minutes, 17 June 2022: https://app.box.com/s/iddfb4ppwkmtjusir2tc/file/993200326824

- Infant Schedule
  - In December, JCVI noted the lower pneumococcal vaccine response at 5 months when 13vPCV was coadministered with Vaxelis compared to when coadministered with Infanrix Hexa in the Oxford Vaccine Group trial. At 13 months (following the second dose) this trend was not as evident. In a letter to JCVI, Sanofi noted that this study was not powered to look at the difference in pneumococcal sub-types.
  - Modelling on the potential use of MenACWY vaccine in infancy and in toddlers, compared to the indirect protection provided by the teenage MenACWY dose was presented in the context of the discontinuation of Menitorix (Hib-MenC) vaccine by GSK (currently given as single dose at 12 months).
    - Infant immunisation was modelled with a dose of MenACWY given at either 3 months or 12 months combined with the teenage programme and compared with MenACWY vaccination in teenagers only.
    - Results from simple approach model: a maximum of ~20 cases in a single birth cohort over five years could be averted by giving the dose at 3 months, with fewer cases prevented if given at 12 months.
    - Results from a dynamic approach model: Overtime it is predicted that the carriage prevalence will decline, with near elimination estimated by 2040 from the adolescent program. The model assumes that there is cross-protection from the MenB vaccine, and cannot anticipate the introduction of new meningococcal strains which may have increased transmissibility or virulence. Indications are that the incremental cost-effectiveness ratio would be >£100,000 per QALY.

Noted that the current cohort of teenagers would have been primed for MenC in infancy.
        - A recent paper (Ladhani et al.) suggests that improving the timeliness of 4CMenB vaccine could prevent more cases than adding a dose of MenACWY at 3 or 12 months. (DOI: 10.1016/j.vaccine.2021.12.010)
    - The JCVI agreed that due to the demonstrated decline in MenACWY cases and predicted near elimination; there are therefore low number of cases to prevent, there was not a need for a MenACWY dose at 3 or 12 months. Indirect protection from the teenage MenACWY dose could be relied on.
        - Following the announcement from GSK that Menitorix (Hib/MenC) will be discontinued, UK stocks were checked and it was estimated that the current routine schedule can continue until 2025.
    - Varicella modelling: New model will be developed due to lack of an existing UK model; will include studies on quality of life impact on children and families, seroprevalence work by the UKHSA, and experience data from 25 years in the USA. JCVI varicella sub-committee is planned to be held in autumn.
    - Infant schedule discussion:
    - JCVI agreed that an additional dose of Hib-containing vaccine (multivalent, DTaP-IPV-Hib or DTaP-IPV-Hib-HepB) should be added at 12 or 18 months, as well as bringing forward the second dose of MMR forward to 18 months from 3 years 4 months. This would create a new immunisation visit at 18 months. An interim statement is available.
        - Considerations for bringing forward the second MMR dose: Concern was expressed about the current coverage of MMR vaccine especially as measles cases are being observed in Europe. Data from London showed improvements in coverage when MMR is brought forwards to 18 months.
    - The Committee discussed the potential for review of the preschool booster (dTaP-IPV) timing. Giving a dose of DTaP-IPV-Hib or DTaP-IPV-Hib-HepB at 18 months will shorten the gap between doses of pertussis-containing vaccine. When the preschool booster was initially added, whole cell pertussis was used for the primary course with an acellular booster. Currently acellular pertussis is used for both doses which is likely to have shorter longevity. Other considerations were:
        - The pre-school immunisation visit is also used to catch up on other immunisations which may have previously been missed. If this dose was moved later, it could potentially be given in school.
        - A school-based programme would reduce socio-economic differences in coverage seen in primary care programmes. The Committee agreed that operational colleagues should be asked about the possibility of the dTaP-IPV vaccine becoming a school-based program.
        - These changes would also leave space in the schedule for varicella vaccination, should future modelling and discussion lead to a JCVI recommendation for this.
- Travel sub-committee update
    - Yellow Fever Green Book: Confusion around the wording about incidental thymectomy during cardiac surgery; was not clear how often thymus tissue would be removed during procedures. A meeting with cardiothoracic surgeons will be arranged to discuss.
    - Takeda will present data on dengue virus vaccine at the next travel sub-committee.

- MHRA Yellow Card update for non-COVID-19 vaccines, 1 April 2019 to 31 March 2022
  - Increases in reports of non-COVID vaccines had been mainly driven by an increase in inactivated seasonal influenza reports. This may be due to the expansion of the adult flu vaccine program and increased uptake. No new safety issues have been identified.
  - A statistically significant increase in the estimated reported rate for pneumococcal conjugate vaccine was seen in 2021 compared with previous years. This may either be due to an underestimation of exposure, or a genuine increase in reports. There was also an increase in the proportion of reports with serious reactions, mainly reported infections including pneumococcal infection. This was not seen with other childhood vaccines.
  - Overall, no new safety signals have been identified in this report.
- Polio
  - Increased paralytic cases of wild poliovirus observed in Pakistan, Mozambique, Afghanistan and Malawi, and detection of poliovirus type 2 (all linked to the Sabin 2 vaccine strain) in sewage in the UK were discussed.
  - The JCVI considered evidence on the use of novel oral polio vaccine type 2 (nOPV2). The data so far show that more than 80% of countries who used nOPV2 did not show any evidence of breakthrough infection. nOPV2 looks to be able to interrupt transmission.
  - In 2020/21 nationally primary polio vaccination did not hit the WHO 95% vaccination target at one year (92.6%) or two years (94.3%), however this is reached as children turn 5 years.
  - Guidance will be updated for immunosuppressed individuals and to enhance clinical sampling and opportunistic sampling of patients who have recently returned from areas with OPV immunisation is planned.
  - The JCVI noted that any planned immunisation programmes will be able to be stood up quickly should the incident escalate, however deployment of nOPV would have a significant lead in time for deployment including regulatory approvals.
  - Members commented that an inactivated polio vaccine (IPV) campaign to raise antibody levels in everyone rather than just in those who may have missed immunisation could be considered if there was evidence that a specific location or age group were affected.
  - The JCVI agreed that improved coverage was needed regardless. The JCVI also endorsed the current preparations underway to allow use of nOPV2 if needed.
- Influenza and RSV update
  - Analysis of vaccine effectiveness showed high effectiveness against emergency department attendance for the live attenuated influenza vaccine (LAIV) above 70% in children and adolescents from 2 years to under 18 years of age. In adults over 50 the mid-point VE estimate was 26% for influenza vaccines overall (non-LAIV) with both VE estimates confidence intervals not spanning zero. For adults, efficacy was higher against the A(H1N1)pdm09 subtype than the A(H3N2) subtype which was broadly in line with expectations.
  - Surveillance of RSV was showing another unseasonal spell of activity in June with a rise in RSV positivity testing in <5 year olds and an uptick in the rate of hospitalisation.
  - JCVI advised to go back to the core risk groups recommended for palivizumab. Noted that this early seasonal activity might impact on planned studies for the new monoclonal antibody nirsevimab which was being trialled in a large safety study over the winter.
- HPV

- JCVI summarised key discussions around moving to a one-dose schedule. Additional unpublished evidence and findings of modelling studies were reviewed. A statement on a one-dose schedule for the routine HPV immunisation programme is available.
- Key concerns raised by stakeholders were the impact on coverage and widening health inequalities, the perception that there was insufficient evidence to support the schedule change, and lack of evidence of one-dose HPV vaccine schedules in boys. The need for clear communication, sufficient lead time for implementation and ongoing HPV surveillance were noted.
- Following consideration of the evidence and stakeholder concerns, JCVI considered the evidence to be in strong support of moving to a single dose schedule and intends to implement the program in the 2023-24 academic year. The advice was for the schedule to be one dose up to the 25th birthday and a two dose schedule from the age of 25.
- A three dose schedule should continue to be offered to individuals who are immunosuppressed and those known to be HIV-positive in the absence of further evidence.
- Draft guidelines by the British HIV Association (BHIVA) for HPV vaccination for persons living with HIV (PLWH): BHIVA's draft recommendations were that previously unvaccinated men and women with HIV aged up to and including 45 years be offered HPV vaccination regardless of CD4 cell count, ART use, and viral load. Other considerations:
  - Since the programme for MSM had been introduced, coverage was relatively low and was 49% for the first dose in the pilot study; having to disclose sexual orientation for vaccination was considered a problem.
  - The recommendation was for three doses in PLWH as there was insufficient evidence on fewer doses and in some instances a fourth dose might be advised for those at highest risk. There was also the suggestion that the bivalent vaccine was more immunogenic in PLWH than the quadrivalent vaccine, however, BHIVA would be recommending the 9vHPV vaccine be used.
- Current recommendations are for MSM up to the age of 45 years including those HIV positive to be vaccinated (recommendation does not include women). Due to catch up programs, there is likely a small cohort of HIV positive women aged 30-45 years who may be offered vaccination under BHIVA's guidelines. The Committee had agreed to keep under review the number of doses for PLWH as data was expected for South Africa soon.

- Vaccine coverage
  - England: Decrease in immunisation coverage at 12 months; decrease in adolescent MenACWY and Td-IPV (3-in-1 teenage booster [tetanus, diphtheria and polio]); prenatal pertussis coverage decreased since last year; shingles vaccination increased (particularly in older age groups).
  - Wales: Decrease in DTaP-IPV-Hib-HepB which dropped below 95% for the first time; decrease in uptake of MMR by age 2; similar uptake of flu vaccine to last year;
  - Scotland: Many efforts to keep vaccination rates stable during the pandemic; only school-based vaccination programs have been affected.
  - Northern Ireland: Decrease in MMR uptake; significant drop for shingles vaccine uptake; maternal pertussis vaccination remained static.
- UKHSA Incident Updates

- Diphtheria national incident actions include: A diphtheria serosurvey has been undertaken to estimate immunity in England. Preliminary results show there appears to be an increase in susceptibility in the older population in 2021 compared to 2009.
    - Some diphtheria cases seen were in unvaccinated and partially vaccinated individuals, noting poorer data quality of vaccination status in older adults.
- Update on invasive meningococcal disease (IMD): The number of lab confirmed IMD this year so far was much lower previous pre-pandemic years. Cases in the under 1s were still low; however cases in 15–19-year-olds have increased rapidly. A number of cases in the 16–24-year age group were seen in universities. It was not clear whether the MenB strain circulating is covered by Bexsero.

- Any Other Business
    - A varicella sub-committee is planned.
    - The pneumococcal sub-committee will review correspondence received from Pfizer about their pneumococcal conjugate vaccine.

4 National Advisory Committee on Immunisation (NACI), Canada

4.1 NACI Meetings

NACI meeting Summary of Discussion landing page:
https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/meetings.html

4.1.1 NACI meeting held on 10 May 2022

Summary of Discussion (now released) – 10 May 2022:

- Pneumococcal adult 15vPCV and 20vPCV evidence and context: The evidence-to-decision framework, full economic analysis and the proposed recommendations will be presented and discussed by the committee at a future meeting.

4.1.2 NACI meeting held on 24 May 2022

Summary of Discussion – 24 May 2022:

- Update on Monkeypox: The NACI Secretariat provided the committee with an update on upcoming High-Consequences Infectious Diseases (HCID) Working Group activities and next steps on vaccine guidance in the context of Monkeypox outbreaks in Canada.

4.1.3 NACI meeting held on 7 June 2022

Summary of Discussion – 7 June 2022:

- Update on Monkeypox: The NACI Secretariat provided the committee with an update on upcoming NACI interim guidance on the use of MVA-BN (Imvamune) in the context of Monkeypox outbreaks in Canada and discussed the longer-term workplanning for NACI and the High-Consequences Infectious Diseases (HCID) Working Group in relation to Monkeypox.

4.1.4 NACI meeting held on 4 July 2022

Summary of Discussion – 4 July 2022:

- Pneumococcal conjugate vaccines (15vPCV and 20vPCV) Overview of Evidence: The NACI Pneumococcal Working Group Chair provided remarks on the Working Group

deliberations for the recommended use of the two pneumococcal conjugate vaccines (PCV) that have been recently authorised for use in Canada in adults ≥18 years. The NACI Secretariat provided an overview of a cost-utility analysis comparing the use of 15vPCV or 20vPCV in scenarios including or compared to a 23vPPV in adults, and also provided an overview of the evidence, which included a summaries of the burden of pneumococcal disease, immunogenicity and safety, and key ethics, equity, feasibility and acceptability (EEFA) factors.

- Pneumococcal 15vPCV and 20vPCV Recommendations: Following the presentation of evidence, the committee discussed and voted on several elements of forthcoming guidance for the use of the new PCV vaccines in adults. The NACI Secretariat and Pneumococcal Working Group will update a draft statement to reflect decisions by the committee, and will bring to NACI for further discussion and approval at a future meeting where several outstanding decisions will be made. NACI recommendations not yet publicly available.

4.2 Newly published or updated statement/recommendations

Current vaccine statements:

- Published 1 June 2022: Canadian Immunization Guide Chapter on Influenza and Statement on Seasonal Influenza Vaccine for 2022–2023

https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2022-2023.html

  - Summary:
  - Influvac® Tetra and Flucelvax® Quad are authorised for use in people ≥6 months.
  - Administration of COVID-19 vaccines may occur at the same time as, or at any time before or after influenza immunisation (including all seasonal influenza vaccines or LAIV) for those aged 12 years and older as of September 2021.
  - Supemtek™ (RIV [FluBlok]) may be considered for use among the quadrivalent influenza vaccines offered to adults 18 years of age and older.
    - First authorised for use in Canada on 14 January 2021 in adults aged 18 years and older. Newly available (with NACI recommendations) from this year. Supplemental statement on recombinant influenza vaccines for 2022-2023 available.

- Published 8 June 2022: Recommended use of palivizumab to reduce complications of respiratory syncytial virus infection in infants

https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/palivizumab-respiratory-syncitial-virus-infection-infants.html

  - Summary:
  - The only means of prophylaxis against RSV disease is temporary passive protection with the monoclonal antibody preparation Palivizumab (Synagis™) (PVZ).
  - *PVZ should be offered to*: Premature infants of <30 weeks gestational age (wGA) and <6 months of age at onset of or during the RSV season; children aged <24 months with chronic lung disease of prematurity who require ongoing oxygen therapy within the 6 months preceding or during the RSV season; infants aged <12 months with haemodynamically significant CHD and infants born at <36 wGA and age <6 months old living in remote northern Inuit communities who would require air transport for

hospitalisation. For children with both CHD and chronic lung disease, recommendations for chronic lung disease should be followed.

- *PVZ may be considered for*: Premature infants of 30-32 wGA and age <3 months who are at high risk for exposure to RSV; selected children <24 months of age with severe chronic lung disease due to cystic fibrosis or other aetiology who require ongoing oxygen therapy or assisted ventilation in the 6 months preceding or during the RSV season; infants <12 months of age with haemodynamically significant chronic cardiopathy other than congenital; children aged 12-24 months awaiting heart transplant or having received a heart transplant within 6 months of onset of the RSV season; and children aged <24 months with severe immunodeficiency. It may also be considered for term infants aged <6 months living in remote Inuit communities with very high rates of hospitalisation for RSV among term infants and for infants of <36 weeks gestational age and age <6 months living in other remote communities with high rates of hospitalisation for RSV and where air transport would be required for hospitalisation.
- *PVZ should not be offered to*: Otherwise healthy infants born at or after 33 wGA; or to siblings in multiple births who do not otherwise qualify for prophylaxis. It should not be offered routinely for children <24 months of age with cystic fibrosis; for children <24 months of age with Down syndrome without other criteria for PVZ; or for healthy term infants living in remote northern Inuit communities, unless hospitalisation rates for RSV are very high.
- *PVZ should not be given* to prevent hospital-associated RSV infection in eligible children who remain in hospital. It may be considered when all other measures have failed to control an RSV outbreak in a neonatal intensive care unit.

- Published 10 June 2022: NACI Rapid Response: Interim guidance on the use of Imvamune® in the context of monkeypox outbreaks in Canada

https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/guidance-imvamune-monkeypox.html

- Summary: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/guidance-imvamune-monkeypox/summary-june-10-2022.html
- For post-exposure prophylaxis (PEP), NACI recommends:
- A single dose of the Imvamune® vaccine may be offered to people with high risk exposures (to be defined by PHAC) of a probable or confirmed case of monkeypox, or within a setting where transmission is happening. This dose should be offered as soon as possible, ideally within 4 days of exposure, but may be considered up to 14 days of last exposure. PEP should not be offered to people who have current monkeypox infection.
- A second dose may be offered after 28 days if an assessment indicates an ongoing risk of exposure.
- People with a history of myocarditis and/or pericarditis linked to a previous dose of an orthopoxvirus vaccine should discuss the benefits and risks of receiving Imvamune® with their doctor.
- Imvamune® shouldbe given at least 4 weeks before or after an mRNA COVID-19 vaccine, if possible. However, Imvamune® vaccination should not be delayed due to the receipt of an mRNA COVID-19 vaccine.

- For pre-exposure prophylaxis (PrEP), NACI recommends:
- Vaccination in routine laboratory research settings where replicating orthopoxviruses are studied. If Imvamune® is used, two doses should be given at least 28 days apart.

Please refer to Appendix 8.3 for new or updated recommendations from NACI on COVID-19 vaccines.

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5 Immunisation updates from the World Health Organization (WHO)

5.1 WHO Position Papers

- **Vaccines against influenza: WHO position paper – 13 May 2022**

https://www.who.int/publications/i/item/who-wer9719

- WHO recommends that all countries should consider implementing seasonal influenza immunisation programs.
- Individual national decisions on the use of influenza vaccines should take into consideration target groups, national immunization coverage goals, capacity to deliver services and resource availability.
- The following target groups should be considered for vaccination: health workers, individuals with comorbidities and underlying conditions, older adults and pregnant women. Additional groups include: people at high risk of severe influenza living in congregate-living settings, such as prisons, refugee camps and group homes.
- Programmes should pay particular attention to vaccine equity by considering disadvantaged populations and indigenous populations with a high burden of disease.
- Live attenuated influenza vaccines (LAIVs) are currently not recommended for children under 2 years of age and adults, including older adults and those with comorbidities, because VE has not been consistently demonstrated in these age groups.
- High-dose and adjuvanted vaccines may be used in older adults where they are available.

- **Understanding the behavioural and social drivers of vaccine uptake WHO position paper – 20 May 2022**

https://www.who.int/publications/i/item/who-wer9720-209-224

- The WHO published its first position paper on the behavioural and social drivers (BeSD) of vaccine uptake in May 2022. It summarised the development of new tools and indicators to assess the BeSD of vaccine uptake for childhood and COVID-19 vaccination, reported the main findings of a scoping review that examined existing systematic reviews and meta-analyses on interventions to improve vaccine uptake, made recommendations for using the new tools and the resulting data to prioritise local interventions, and concluded with future research directions.
- Countries are recommended to systematically collect and analyse data on behavioural and social drivers of vaccine uptake to guide program planning, implementation and evaluation, and to contribute to global tracking and reporting.
- National and Regional Immunisation Technical Advisory Groups are recommended to: i) analyse and use data from BeSD surveys and in-depth interview guides (in conjunction with other programme data, including digital listening insights) to guide planning and

prioritisation; and, ii) include individuals with social sciences expertise and representatives from civil society in their membership to strengthen work on vaccination.

- **Polio vaccines: WHO position paper – 24 June 2022**

https://www.who.int/publications/i/item/WHO-WER9725-277-300

  - For countries using oral polio vaccine (OPV) in their national immunisation programme, WHO recommends 3 doses of bOPV and 2 doses of IPV.
  - In polio-endemic countries and in countries at high risk for importation and subsequent spread of poliovirus, WHO recommends a bOPV birth dose (zero dose) followed by the primary series of 3 bOPV doses and 2 IPV doses.
  - The OPV appropriate to the outbreak poliovirus strain remains the vaccine of choice to interrupt transmission rapidly and to stop polio outbreaks. Based on epidemiological circumstances, bOPV, mOPVs, tOPV and IPV are available for outbreak response; additionally, nOPV2 is available under WHO EUL since November 2020.
  - Individuals with primary immunodeficiency disorders should not be vaccinated with OPV and, instead, should receive IPV alone. Both IPV or OPV may be administered safely to HIV-infected individuals who are clinically well and immunologically stable. bOPV is contraindicated in severely immunocompromised patients with known underlying conditions.

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

There have been no meetings since the 4 – 7 April 2022 SAGE meeting (reported in last summary).

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

Meeting of SAGE occurred where the use of COVID-19 vaccines were discussed. There were no discussions related to the use of other vaccines.

Meeting date: 11 August 2022

- Meeting details: https://www.who.int/news-room/events/detail/2022/08/11/default-calendar/extraordinary-meeting-of-the-strategic-advisory-group-of-experts-on-immunization-(sage)-11-august-2022
- Agenda: https://cdn.who.int/media/docs/default-source/immunization/sage/2022/august/sage_august_2022_agenda.pdf?sfvrsn=ad9f5ad6_3
- Topics covered: Update on COVID-19 vaccination and booster coverage; WHO revised guidance on emergency use listing; Valneva's VLA2001 COVID-19 vaccine (information, evidence for use as heterologous booster dose, evidence assessment and interim recommendations); Vaccine effectiveness of 1st and 2nd booster dose; SARS-CoV-2 protective effectiveness or prior infection and hybrid immunity (systematic review and meta-analysis); Good Practice Statement on the use of 2nd booster doses; New data for younger children (Pfizer

and Moderna); Interim recommendations for the use of mRNA vaccines (Pfizer and Moderna) against COVID-19.

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

- GACVS Committee Reports landing page: https://www.who.int/groups/global-advisory-committee-on-vaccine-safety/committee-reports
- **First joint GACVS and Advisory Committee on Safety of Medicinal Products (ACSoMP) meeting on 14 – 16 June 2022 (held online):**
- Full report (published 29 August 2022): https://www.who.int/westernpacific/publications-detail/who-wer9734-397-408
    - Monitoring safety in pregnancy: WHO has 3 ongoing initiatives to improve safety monitoring during pregnancy: 1) A collaboration between the Pharmacovigilance team and PATH to map and assess the strengths and limitations of pregnancy exposure registries available in LMICs; 2) An internal WHO project, to map various WHO initiatives to assess the availability of minimal data elements to study pregnancy and neonatal outcomes in LMICs and to propose methods to harmonize these data elements; 3) Monitoring the safety of COVID-19 vaccines during pregnancy, a collaboration with the WHO Sexual and Reproductive Health and Research team.
        - As of June 2022, over 10 000 women have been recruited in 8 countries, including about 4500 vaccinated women, of whom about 1700 and 1300 were exposed and unexposed, respectively, to SARS-CoV-2 infection.
    - WHO Listed Authorities (WLAs) will replace the definition of stringent regulatory authorities (SRAs).
    - The main difference in the definition is the replacement of the procurement-oriented concept of stringent regulatory authorities with regulatory authorities operating at an advanced level of performance using transparent and evidence-based pathways. SRA definition available here. WLA information available here.
    - Update on nOPV2 vaccine safety: as of the week of 12 June 2022, over 360 million doses of nOPV2 have been administered in 21 countries to stop type 2 outbreaks and another 16 countries have indicated that they are ready to respond to vaccine derived poliovirus (VDPV) with nOPV2, if necessary. No breakthrough cases have been reported in 14 of the 17 countries where nOPV2 has been used for type 2 VDPV outbreaks countries.
    - 6 adverse events of special interest (AESIs) were assessed as being consistent with a causal association with immunisation, all in Nigeria, where 88 million doses were administered between March and October 2021: 3 cases of suspected vaccine-associated paralytic poliomyelitis (VAPP), and one each of anaphylaxis, allergic reaction and meningoencephalitis. The reporting rates for these events were all well below the expected range, so did not generate any new safety signals.
    - Overview of COVID-19 vaccine safety:
    - Since the beginning of 2022, 4 safety topics have been reviewed by the GACVS COVID-19 sub-committee:
        - Interim results from a cohort event monitoring (CEM) study for safety signal detection after vaccination with different COVID-19 vaccines;

        - Safety of COVID-19 vaccines in children and adolescent groups including the risk of myocarditis;
        - Safety of COVID-19 vaccine booster doses, including heterologous vaccination;
        - COVID-19 vaccine safety during pregnancy and pregnancy outcomes.
    - The Pharmacovigilance team has been updating the emergency interim guideline for the case management of thrombosis with thrombocytopenia syndrome (TTS) following vaccination to prevent coronavirus disease (COVID-19).
    - Three emerging safety signals are being reviewed to assess if they should be presented to the GACVS COVID-19 sub-committee: Transverse myelitis; Hearing loss and tinnitus; Acute hepatitis.

5.4 WHO Regional Committee for the Western Pacific meeting

- No meetings held after 25 – 29 October 2021
- Next meeting: 24 – 28 October 2022 (People's Republic of China)
- Regional Committee meeting page: https://www.who.int/westernpacific/about/governance/regional-committee

5.5 Global immunisation news and other items and resources

- Latest news: https://www.who.int/news-room/fact-sheets/detail/immunization-coverage
- GIN May 2022 – June 2022: https://www.who.int/publications/m/item/gin-may-june-2022
- Publication of BeSD tools: https://www.who.int/publications/i/item/9789240049680

5.6 Other items of relevance to vaccine preventable diseases

- Second meeting of the International Health Regulations (2005) (IHR) Emergency Committee regarding the multi-country outbreak of monkeypox (23 July 2022): https://www.who.int/news/item/23-07-2022-second-meeting-of-the-international-health-regulations-(2005)-(ihr)-emergency-committee-regarding-the-multi-country-outbreak-of-monkeypox
    - Recommended public health measures included: targeted use of smallpox or monkeypox vaccines for PEP and PrEP in specific populations, convening NITAGs to decision making on use of monkeypox vaccines, and engaging communities at high risk of exposure in decision-making process regarding vaccine rollout
- Virtual Meeting of Regional Technical Advisory Group for dengue and other arbovirus diseases, New Delhi, India, 4-6 October 2021 (report published 25 July 2022): https://www.who.int/publications/i/item/sea-cd-331
    - Two vaccines are in the pipeline – Takeda vaccine, currently undergoing Phase 3 studies; and NIH vaccine, also currently in Phase 2/3. Dengvaxia has been registered in over 20 countries and WHO/Strategic Advisory Group of Experts on Immunization (SAGE) recommendations will be followed.
- Disease Outbreak News (DONs): https://www.who.int/emergencies/disease-outbreak-news

See Appendix 8.1 for updated COVID-19 vaccine recommendations or technical guidance.

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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 (non-COVID-19)

- Media releases and statements landing page: https://www.tga.gov.au/media-releases-statements

Note: only key updates are provided in this summary

- Influenza vaccine batch release for 2022 season (27 July 2022): https://www.tga.gov.au/news/media-releases/influenza-vaccine-batch-release-2022-season

A number of TGA media releases related to COVID-19 vaccines have been published. Please refer to Appendix 8.4.

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7 Upcoming meetings and agendas

ACIP, USA (http://www.cdc.gov/vaccines/acip/meetings/upcoming-dates.html)

- 2022: 19-20 October
- 2023: 22-23 February; 21-22 June; 25-26 October

PTAC, New Zealand https://pharmac.govt.nz/about/expert-advice/pharmacology-and-therapeutics-advisory-committee-ptac/)

- 2022 meeting dates: 17–18 November
- 2023 meeting dates: 16-17 February; 18-19 May; 17-18 August; 16-17 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 February, 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.

- 2022: 12-13 September; 3-4 October; 12-13 December

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

- 2022: 3-6 October
- 2023: 20-23 March; 25-28 September
- 2024: 18-21 March; 23-26 September

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

The date of the next GACVS meeting has not yet been announced.

WPRO
- 24 – 28 October 2022 (People's Republic of China)

ACV (https://www.tga.gov.au/committee/advisory-committee-vaccines-acv)
2022: 5 October; 30 November

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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 BNT162b2 vaccine against COVID-19
- Interim recommendations for use of the Pfizer–BioNTech COVID-19 vaccine, BNT162b2, under Emergency Use Listing (updated 18 August 2022): 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 (updated 18 August 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-BNT162b2-GRADE-ETR-annexes
- Vaccine explainer: Pfizer-BioNTech COVID-19 Vaccine, COMIRNATY® (Tozinameran) (3 June 2022): https://www.who.int/publications/m/item/comirnaty-covid-19-mrna-vaccine
- Vaccine explainer: Paediatric Pfizer-BioNTech COVID-19 vaccine COMIRNATY® (Tozinameran) (3 June 2022): https://www.who.int/publications/m/item/paediatric-comirnaty-covid-19-mrna-vaccine

Moderna mRNA-1273 vaccine against COVID-19
- Interim recommendations for use of the Moderna mRNA-1273 vaccine against COVID-19 (updated 18 August 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-mRNA-1273-2021.3
    - Annexes to the recommendations for use of the Moderna mRNA-1273 vaccine against COVID-19 (updated 18 August 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-mrna-1273-GRADE-ETR-annexes

Janssen Ad26.COV2.S (COVID-19) vaccine
- Interim recommendations for the use of the Janssen Ad26.COV2.S (COVID-19) vaccine (updated 6 June 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-Ad26.COV2.S-2021.1
    - Annexes to the interim recommendations for use of the Janssen Ad26.COV2.S vaccine (updated 6 June 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-Ad26.COV2.S-GRADE-ETR-annexes

Valneva VLA2001 inactivated vaccine against COVID-19

- Interim recommendations for use of the Valneva VLA2001 vaccine against COVID-19 (18 August 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-Valneva-VLA2001
    - Annexes to the interim recommendations for use of the Valneva VLA2001 vaccine against COVID-19 (18 August 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-Valneva-VLA2001-annexes
- Background document on the Valneva VLA2001 vaccine against COVID-19 (18 August 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-Valneva-VLA2001-background

Booster doses for COVID-19 vaccines

- Good practice statement on the use of second booster doses for COVID-19 vaccines (18 August 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-good-practice-statement-second-booster

Technical Documents

- Maintaining infection prevention and control measures for COVID-19 in health care facilities: Policy brief, 7 June 2022 (7 June 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-Policy_brief-IPC-HCF-2022.1
- Therapeutics and COVID-19: living guideline (14 July 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2022.4

Surveillance

- Contact tracing and quarantine in the context of COVID-19: interim guidance, 6 July 2022 (6 July 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-Contact_tracing_and_quarantine-2022.1
- Public health surveillance for COVID-19: interim guidance (22 July 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-SurveillanceGuidance-2022.2
- WHO COVID-19 Case definition (22 July 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-Surveillance_Case_Definition-2022.1
- Revised case report form for confirmed Novel Coronavirus COVID-19 (report to WHO within 48 hours of case identification) (22 July 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-SurveillanceCRF-2022.1
- Global surveillance of COVID-19: WHO process for weekly reporting aggregated data (22 July 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-surveillance_aggr_CRF-2022.1

Toolkits

- WHO mass gathering COVID-19 risk assessment tool: generic events, version 3 (16 June 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-Mass-gathering-RAtool-2022.1

Ethical considerations

- COVID-19 and mandatory vaccination: Ethical considerations (30 May 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-Policy-brief-Mandatory-vaccination-2022.1

COVID-19 publications published by WPRO: https://apps.who.int/iris/discover?search-result=true&query=&scope=&filtertype_0=mesh&filter_relational_operator_0=contains&filter_0=COVID-19&rpp=10&sort_by=dc.date.accessioned_dt&order=desc

8.2 Additional ACIP meetings focused on COVID-19 vaccines

Additional meetings were held on:

- 19 May 2022: https://www.cdc.gov/vaccines/acip/meetings/slides-2022-05-19.html
- 17 June 2022: https://www.cdc.gov/vaccines/acip/meetings/slides-2022-06-17.html
- 18 June 2022: https://www.cdc.gov/vaccines/acip/meetings/slides-2022-06-18.html
- 23 June 2022: https://www.cdc.gov/vaccines/acip/meetings/slides-2022-06-22-23.html
- 19 July 2022: https://www.cdc.gov/vaccines/acip/meetings/slides-2022-07-19.html
- 1-2 September 2022: https://www.cdc.gov/vaccines/acip/meetings/slides-2022-09-01-02.html

Briefly, the following topics were covered in these meetings:

- COVID-19 Vaccine Safety Technical (VaST) Work Group updates
- Epidemiology of COVID-19 and COVID-19 vaccine coverage; updates on variants
- Updates on vaccine-associated myocarditis
- Updates on vaccine effectiveness and safety in USA
- Paediatric COVID-19 vaccination:
  - Epidemiology of COVID-19 in young children
  - Updates on vaccine effectiveness in children and adolescents
  - COVID-19 vaccination in children aged 5 to 11 years:
    - Updates on vaccine effectiveness
    - Updates on vaccine safety
    - Safety and immunogenicity of a BNT162b2 (Pfizer) 10mcg booster in children
    - Updates to the Evidence to Recommendations (EtR) Framework on COVID-19 booster doses in children
    - mRNA-1273 (Moderna) vaccine safety, immunogenicity, and efficacy in children aged 6 to 17 years
    - EtR Framework on mRNA-1273 in children aged 6 to 17 years
  - COVID-19 vaccination in infants and children aged 6 months and older:
    - mRNA-1273 (Moderna) vaccine safety, immunogenicity and efficacy
    - BNT162b2 (Pfizer) vaccine safety, immunogenicity and efficacy
    - Recommendations, clinical and implementation considerations, and EtR Framework for mRNA vaccination in young children
- NVX-CoV2373 (Novavax) vaccine safety, immunogenicity and efficacy in adults aged 18 years and older; Recommendations, clinical and implementation considerations, and EtR Framework for NVX-CoV2373 vaccination in adults aged 18 years and older
- Bivalent COVID-19 vaccines:
  - Moderna COVID-19 bivalent vaccine; mRNA-1273.214 (Original/Omicron BA.1); mRNA-1273.222 (Original/Omicron BA.4/BA.5)

- Pfizer-BioNTech COVID-19 Omicron-modified Bivalent vaccine candidate
- EtR Framework and clinical considerations for Bivalent COVID-19 vaccine booster doses

- Burden and trends of long-term sequelae of SARS-CoV-2

8.3 Recommendations from NACI on the use of COVID-19 vaccines

- Summary of updates in the Canadian Immunization Guide (29 August 2022): Updated guidance on COVID-19 vaccines in Canada: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/summary-updates-canadian-immunization-guide-august-29-2022-covid-19-vaccines.html
- Current vaccine statements:
  - Published 1 September 2022: Recommendations on the use of bivalent Omicron containing mRNA COVID-19 vaccines

https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-bivalent-Omicron-containing-mrna-covid-19-vaccines.pdf

    - Summary: https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/naci-summary-september-1-2022.pdf
  - Published 19 August 2022: Recommendations on the use of a first booster dose of Pfizer-BioNTech Comirnaty COVID-19 vaccine in children 5 to 11 years of age

https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-first-booster-dose-pfizer-biontech-comirnaty-covid-19-vaccine-children-5-11-years.pdf

    - Summary: https://www.canada.ca/content/dam/phac-aspc/documents/services/immunization/national-advisory-committee-on-immunization-naci/naci-summary-august-19-2022.pdf
  - Published 14 July 2022: Recommendations on the use of Moderna Spikevax COVID-19 vaccine in children 6 months to 5 years of age

https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-moderna-spikevax-covid-19-vaccine-children-6-months-5-years.html

    - Summary: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-moderna-spikevax-covid-19-vaccine-children-6-months-5-years/summary-july-14-2022.html
  - Published 29 June 2022: Interim guidance on planning considerations for a fall 2022 COVID-19 vaccine booster program in Canada

https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/guidance-planning-fall-2022-covid-19-vaccine-booster.html

    - Summary: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/guidance-planning-fall-2022-covid-19-vaccine-booster/summary-june-29-2022.html

8.4 COVID-19 related TGA media releases

- 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 30 August 2022): https://www.tga.gov.au/covid-19-vaccines-undergoing-evaluation
- TGA COVID-19 vaccine weekly safety report landing page: https://www.tga.gov.au/news/covid-19-vaccine-safety-reports