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 & Surveillance (NCIRS)

Period of review: 03/09/2022 – 21/12/2022

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

Poliomyelitis (Polio)

- WHO recommended that all countries have polio outbreak response plans in place.
- JCVI advised that an inactivated polio vaccine (IPV) booster campaign should be commenced for children aged 1 – 9 years in London; the campaign began on 19 August 2022.

Pneumococcal

- ACIP provided clarification on the current guidance on pneumococcal conjugate vaccine (PCV) use:
  - Adults aged ≥65 years and/or adults with certain underlying disease who have not previously received 13v-, 15v-, or 20vPCV or whose previous vaccination history is unknown are recommended to receive 1 dose of 20vPCV or 15vPCV. When 15vPCV is used, it should be followed by a dose of 23vPPV.
  - Adults who have received 23vPPV only may receive either 20vPCV or 15vPCV, ≥1 year after their last 23vPPV dose.
- NACI has discussed updated guidance on 15vPCV and 20vPCV use – details not yet published.

Respiratory Syncytial Virus (RSV)

- ACIP reviewed evidence from phase III clinical trials investigating the safety and efficacy of GSK's RSVpreF3 vaccine and Pfizer's bivalent RSVpreF vaccine in older adults aged ≥60 years and older. High efficacy (>70%) was observed against infection and very high efficacy (>90%) observed against severe disease.
- ACIP reviewed evidence from clinical trials investigating Nirsevimab in infants (including preterm infants <35 weeks gestational age). GRADE review is being undertaken in early 2023. ACIP will vote by June 2023 if product is licensed by that time.
- JCVI is reviewing evidence on use of Nirsevimab and noted it may replace palivizumab.

Mpox (previously Monkeypox)

- UK will prioritise 2 doses to those in the existing target groups for pre-exposure vaccination (gay, bisexual and MSM at highest risk, and occupational vaccination) including efforts to maximise uptake of dose one within this group through engagement activities. These groups largely align with those risk groups recommended for vaccination by the WHO SAGE and ACIP.
- JCVI advised that once 2 doses of vaccine have been offered to those identified as being at high risk and uptake has plateaued, it may be reasonable to offer a single dose to those who are considered to be at an 'intermediate' risk of exposure to help increase resilience against further transmission.

Meningococcal

- ACIP advised a new one-vial presentation of Menveo will be available from Spring 2023, but is recommended for ages 10–55 years due to a lack of trial data in younger age groups and licensing in the USA (two-vial presentation is recommended for age 2 months to 55 years).
- ACIP is undertaking reviews of evidence on use of two MenABCWY vaccines.
- JCVI sub-committee agreed that the MenACWY booster after 5 years from previous dose should be recommended following a risk assessment for those who are travelling to an area with meningococcal outbreaks. There will be further advice for risk assessment for these travellers who are healthcare workers or will be in close contact with the local communities.

Chikungunya

- There are phase 2 and phase 3 clinical trials on several candidate Chikungunya vaccines.
- The US FDA has endorsed an accelerated approval pathway for chikungunya vaccines.

Contents

1 Advisory Committee on Immunisation Practices (ACIP), USA

1.1 ACIP meeting 19-20 October 2022

- Meeting agenda: https://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2022-10-19-20-508.pdf
- Presentation slides: https://www.cdc.gov/vaccines/acip/meetings/slides-2022-10-19-20.html

Pneumococcal Vaccines

- Policy Question: Should a dose of 20vPCV be recommended for the following groups:
    1. Adults aged ≥19 years, who previously received 13vPCV only
    2. Adults aged 19–64 years with an immunocompromising condition, cerebrospinal fluid leak, or cochlear implant, who previously received both 13vPCV and 23vPPV
    3. Adults aged ≥65 years, who previously received both 13vPCV and 23vPPV
- Impact of 13vPCV use against pneumococcal disease in adults:
    - 13vPCV-type invasive pneumococcal disease (IPD) incidence among adults aged ≥65 years decreased after 13vPCV use in children but remained stable in 2014–2019.
    - Non-13vPCV-type IPD incidence among adults aged ≥65 years remained stable.
    - Pneumococcal serotypes contained in 20vPCV but not in 13vPCV caused 27% of IPD in adults in 2018–2019.
    - Reduction in incidence of hospitalised 13vPCV-type pneumococcal pneumonia was observed after routine 13vPCV use among a cohort of adults aged ≥65 years, but not over overall pneumococcal pneumonia hospitalisations.
    - In 2013–2016, additional serotypes contained in 20vPCV caused 3–4% of all-cause hospitalised community acquired pneumonia in adults.
    - Overall IPD incidence in both adults and children, and pneumococcal pneumonia hospitalisations among adults decreased early during the COVID-19 pandemic.
- GRADE assessment:
- Assessed 1 dose of 20vPCV vs currently recommended schedule of 23vPPV in U.S. adults aged 19–64 years with an immunocompromising condition, cerebrospinal fluid leak, or cochlear implant and/or adults aged ≥65 years who previously received 13vPCV.
- Based on 2, phase 3 clinical trials among adults of age ≥65 years who were not immunocompromised, immunogenicity was evaluated for 20vPCV by prior vaccine status (13vPCV, 23vPPV, 13vPCV+23vPPV), No 20vPCV vs 23vPPV comparison and post-hoc analysis assessing 20vPCV and quadrivalent inactivated influenza vaccine (QIV).
- Summary of immunogenicity findings:
    - Opsonophagocytosis assay (OPA) geometric mean titre (GMT) ratios defined as "[GMT (20vPCV, previous 13vPCV with or without 23vPPV)]/[GMT (20vPCV, previous 23vPPV only)]; blood draws occurred 1 month post-dose" were higher for the previous 13vPCV and previous 13vPCV+23PPSV compared to previous 23vPPV for all 20 serotypes and previous 23vPPV for 15 to 19 serotypes respectively.
    - Percentage of seroresponders (defined as "percentage of participants with a ≥4fold rise in OPA titres from before to 1 month after vaccination") was higher for the previous 13vPCV and previous 13vPCV+23vPPV compared to previous 23vPPV for 13 to 18 and 3 to 6 serotypes respectively.
- Evidence of benefits for disease outcomes (IPD incidence and pneumonia hospitalisations) not available.

- The safety profile of 20vPCV vs 23vPPV in 13vPCV group; 20vPCV in 13vPCV+23vPPV group was evaluated based on 1 phase 3 clinical trial.
    - Proportion reporting serious adverse events (SAEs) through 6 months after vaccination was similar across groups (13vPCV +20vPCV vs 13vPCV+ 23vPPV: 2.4% vs 1.6% respectively and 13vPCV + 23vPPV + 20vPCV vs no comparator group): 1.6%).
    - No vaccine-related SAEs and deaths reported.
- In comparison of benefits and harms, the WG concluded the evidence favoured the intervention (dose of 20vPCV) – desirable effects were considered moderate (groups 1 & 2) or small to moderate (group 3), and undesirable effects were minimal.
- In terms of certainty with respect to safety and effectiveness, the overall certainty of evidence was low for the group 1 and 2 and moderate for group 3.
- Based on two surveys of healthcare providers, providers were likely to support a recommendation of 20vPCV for people who have received 13vPCV
- Based on economic modelling conducted by three groups: benefits of recommending 20vPCV still outweigh the cost for adults who have received 13vPCV only. Variable responses among WG were reported for group 2 and 3.
- <u>WG interpretation</u>: Desirable consequences probably outweigh undesirable consequences in most settings, suggesting recommendation of 20vPCV in the groups mentioned above.
- 15vPCV has been approved for kids in June 2022 and the focus of the WG after this meeting is regarding the approval of 20vPCV that is anticipated in second quarter of 2023.
- Additional pneumococcal conjugate vaccines, 21vPCV and 24vPCV are currently being studied.
- <u>Economic Assessment of 20vPCV for Adults Vaccinated with 13vPCV only and 13vPCV +23vPPV</u>
- No policies or model simulations below <$126,640 / Quality adjusted life year (QALY)
- Q1: Adults 19+ who previously received 13vPCV only
    - 137k–557k / QALY (Base case)
- Q2: Immunocompromised adults 19-64 who previously received 13vPCV+23vPPV
    - 255k–341k / QALY (Base case)
- Q3: Adults 65+ who previously received 13vPCV+23vPPV
    - 188k– 874k / QALY (Base case)
    - Context from recent PCV modelling for adults at age 65:
        - Replacing 13vPCV (shared clinical decision making) + 23vPPV (all)
            - With 20vPCV(all): cost-saving
            - With 15vPCV(all)+ 23vPPV (all): cost-saving
        - Continuing to recommend 13vPCV (all) in 2019: $562k/QALY
- <u>Updates to Clinical Guidance on Pneumococcal Vaccine Use among Adults:</u>
- Clarification on the current guidance was provided as follows:
- Adults aged ≥65 years and/or adults with certain underlying disease who have not previously received 13vPCV, 15vPCV, or 20vPCV or whose previous vaccination history is unknown are recommended to receive 1 dose of 20vPCV or 15vPCV.
    - When 15vPCV is used, it should be followed by a dose of 23vPPV to complete the recommended vaccine series. If 23vPPV is inadvertently given before 15vPCV, a dose of 15vPCV or 20vPCV should be given at least 1 year later.

    - If 15vPCV or 20vPCV is not available, a dose of 13vPCV may be given followed by a dose of 23vPPV as previously recommended.
- Adults who have received 23vPPV only may receive a dose of either 20vPCV or 15vPCV, ≥1 year after their last 23vPPV dose. When 15vPCV is used in those with history of 23vPPV receipt, it need not be followed by another dose of 23vPPV.
- Proposed changes to address gaps in current adult pneumococcal vaccine recommendations
- Adults who received haematopoietic stem cell transplant (HSCT) were previously not included as part of the pneumococcal risk conditions but in the light of current evidences HSCT recipients are recommended to receive their due doses.

Chikungunya Vaccines

- Chikungunya, a mosquito-borne disease has caused large outbreaks with high attack rates. Outbreaks have occurred in Africa, Asia, Europe, Americas, and islands in the Indian and Pacific Oceans.
- No chikungunya vaccine ever licensed in United States or globally.
- Two single-dose intramuscular (IM), Coalition for Epidemic Preparedness Innovations (CEPI) co-funded vaccines, Valneva and Emergent BioSolutions, are in their phase III clinical trials. Additionally Merck (1 dose + booster) has completed the phase II trial and International Vaccine Institute/ Bharat Biotech (2-dose) has commenced phase II and phase III trials.
- FDA endorsed accelerated approval pathway for chikungunya vaccines due to unpredictable outbreaks of short duration, possibility of persistent arthralgia in some patients, and lack of chikungunya treatments.
- **Valneva-VLA1553 Chikungunya Vaccine Candidate:**
- Live-attenuated CHIKV vaccine candidate targeting long-lasting immunity with a single dose. It is based on La Reunion strain of East Central South African genotype. It is attenuated by reverse genetics resulting in 60aa deletion within the nsP3 protein.
- FDA has given Breakthrough Therapy designation allowing priority review for Valneva vaccine with completed phase III trials in adults ≥18 years; licensure is expected during 2023.
- Summary of immunogenicity findings: There were 622 adults in two phase III trials. High seroresponse rates were observed at 28 days post-vaccination (≥98%) and 6 months post-vaccination (96%). Similar seroresponse rates in older (≥65 years) and younger (18–64 years) adults reported; however, there is limited data among older subjects (N=59).
- Summary of safety findings: Available data for 3,490 adults in two Phase III trials. Overall, AEs and severe AEs occurred at significantly higher rates in vaccine vs placebo recipients. Solicited local AEs reported at low rate however, solicited systemic AEs reported by 50% of vaccinated subjects– Arthralgia reported by 17% vaccine recipients. Insufficient number of subjects to detect rare SAEs and therefore, WG will be reviewing data more fully during GRADE assessment.
- In 2023, WG aims to present to ACIP traveller epidemiology, sequelae data, and other data relevant to recommendations and relevant GRADE assessment. During mid-February 2024, ACIP will vote on vaccine recommendations.

Polio Vaccines

- Polio outbreaks continue to be identified globally with 249 laboratory confirmed cases this year.
- Polio topics under consideration by WG:

- Whether more specific guidance on adult vaccination, including use of adult booster doses, can be provided in the context of circulating poliovirus.
- Whether immunocompromised adults should be recommended an additional adult booster of a polio-containing vaccine.
- Whether fractional doses of the inactivated poliovirus vaccine (fIPV), as prequalified by WHO, should meet polio vaccination requirements, including for people immigrating to the U.S.
- Consider criteria under which the novel oral poliovirus vaccine (nOPV) might be used in areas with outbreaks or persistent circulation of poliovirus.

- Innovation in Polio vaccination Novel OPV2 (nOPV2)
  - nOPV2 is more genetically stable and less likely to be associated with the emergence of Circulating vaccine-derived poliovirus (cVDPV). It can provide mucosal immunity to limit the spread among IPV vaccinated people. Approved for use under WHO Emergency Use Listing (EUL) in 2020.
  - Review of safety data on the first million doses of nOPV2 used for outbreak response by the independent Global Advisory Committee on Vaccine Safety (GACVS) concluded that there were no obvious red flags or safety concerns.
- WHO Strategic Advisory Group of Experts on Immunisation (SAGE) recommends vaccine response to cVDPV:
  - Routine/catch-up immunisation with Bivalent oral poliovirus vaccine (bOPV) and/or IPV should continue
  - Countries consider use of nOPV2 if IPV response does not stop cVDPV
- Fractional dose IPV
  - Fractional IPV (fIPV), administered intradermally using one fifth of regular dose, stretches the limited supplies of inactivated polio vaccine (IPV).
  - WHO have recommended use of fIPV as a response strategy for VDPV2 outbreaks.
  - Currently fIPV are not recognised as a dose to satisfy immunisation requirements in the U.S.

Respiratory Syncytial Virus (RSV) Vaccines – Older Adults

- GSK RSV Older Adult (OA) candidate vaccine-Clinical trials:
- Three phase III clinical trials are available. Overall, RSVPreF3 OA provides high and consistent efficacy and safety across the full spectrum of RSV disease regardless of RSV A or RSV B.
- AReSVi004 study recruited adults ≥60 years and reported safety, reactogenicity, immunogenicity, persistence and revaccination. Findings suggested durable RSV-A, RSV-B neutralising antibody and CD4+ T cell response across all age groups, 12 months post vaccination.
- AReSVi-006: Phase 3, randomised, placebo-controlled, observer-blind, multi-country study to demonstrate the efficacy of a single dose and annual revaccination doses of GSK's RSVPreF3 OA investigational vaccine in adults aged 60 years and above.
  - Consistently high vaccine efficacy (71.7% for RSV-acute respiratory tract infection(ARI), 82.6% for RSV- lower respiratory tract disease (LRTD) and 94.1% for Severe RSV-LRTD%) across the full spectrum of RSV disease was reported over 6.7-month follow-up, supporting efficacy over the course of an RSV season.

- Very high (>92%) and consistent vaccine efficacy against severe RSV disease and in older adults at increased risk.
- Robust immune response to RSV-A and RSV-B regardless of age and frailty status.
- Most adverse events were mild to moderate and transient. The overall rate of SAEs, fatal SAEs, and PIMDs were balanced between the groups.

- RSV-007: Open-label, randomised, controlled, multi-country study to evaluate immune response, safety and reactogenicity of RSVPreF3 OA investigational vaccine when co-administered with FLU vaccines in adults aged 60 years and above. Co-primary endpoints met for both FLU-QIV and RSV.
- <u>Safety and Efficacy of Bivalent RSV Prefusion F Vaccine in Adults ≥ 60 Years of Age</u>
  - The RSV vaccine efficacy study in older adults immunised against RSV disease (RENOIR)- a phase III, multicentre study targeting 40,000 healthy adults of age 60 and above who were randomised to receive RSVpreF 120 µg or placebo (1:1). Immunogenicity was studied in the subset of 1050 participants.
  - Local and systemic events were mostly mild to moderate and short lived. No safety concerns identified.
  - RSVpreF was efficacious in reducing RSV associated LRTI (≥ 2 symptoms: 66.7%), ≥ 3 symptoms: 85.7%) and ARI (62.1%)
- <u>RSV WG Considerations Policy questions:</u>
  - Should vaccination with GSK RSVpreF3 vaccine and Pfizer RSVpreF vaccine (be recommended for all older adults (Age ≥60 years? Age ≥65 years? Other?)?
  - Two clinical trials (GSK, Pfizer) on adults described above reported significant efficacy against lower respiratory tract disease/illness caused by RSV- efficacy point estimates against the primary outcomes in both trials exceeded 60%.
  - Incidence of symptomatic RSV infection was low in both trials, it could be related to the recruitment of healthier population compared with the general U.S population, and secondly both trials were conducted during periods of atypical RSV seasonality in the U.S, attributable to the COVID19 pandemic.
  - Trials were underpowered to estimate efficacy against more severe RSV outcomes (e.g., hospitalisation, death).
  - Both trials are ongoing, with multiple years of follow up planned. However, data from only the first year will be available for consideration of the first policy recommendations.
  - There is no established immunologic correlate of protection for RSV. Need for revaccination, and the time interval, are yet to be determined.
  - Cases of Guillain Barré syndrome (GBS) were reported after vaccination with both investigational vaccines. Rates were 1 case of GBS / ~15,000 persons who received the investigational vaccine (GSK) and 2 cases of GBS / ~26,000 persons who received the investigational vaccine (Pfizer) respectively. .
  - Uptake of a novel RSV vaccine among older adults will depend on patient and clinician education.
  - Next steps: To inform recommendations and age threshold, WG will review GRADE evidence for both vaccines and a cost effectiveness analysis is needed.

<u>Respiratory Syncytial Virus (RSV) Vaccine – Maternal/Paediatric</u>

- <u>Nirsevimab for the prevention of RSV in all infants</u>

- A development program conducted across all infants. Three clinical trials were discussed. Two clinical trials, phase III pivotal (MELODY trial), phase IIb POC/pivotal recruited term, preterm healthy infants 29+ wGA, and compared Nirsevimab to placebo (2:1). The third Phase II/III pivotal clinical trial (MEDLEY) recruited preterm Infants <35 wGA infants with (chronic liver and heart disease) CLD/CHD and compared the same.
- Primary endpoint of MELODY trial reported on 1490 infants, with incidence of RSV confirmed medically attended lower respiratory tract infection (MA-LRTI) through 150 days after dosing with 74.5% (95% CI: 49.6, 87.1) efficacy.
- Efficacy against other endpoints (n=2009):
  - MA RSV LRTI: 76.4% (95% CI: 62.3-85.2);
  - MA RSV LRTI with hospitalisation: 76.8% (95% CI: 49.4-89.4);
  - Very severe MA RSV LRTI: 78.6% (95%CI: 48.8-91.0).
- No SAEs (including anaphylaxis or serious allergic reactions) or deaths attributable to vaccine.
- Primary endpoint of phase II b POC/Pivotal reported on 1453 infants. Incidence of RSV confirmed MA-LRTI through 150 days after dosing with 70.1% (95% CI: 52.3, 81.2) efficacy.
- Primary endpoint of MEDLEY trial reported on 615 preterm infants <35wGA and 310 infants with CLD/CHD. Safety profile of Nirsevimab was similar to Palivizumab.
- Pooled MELODY All Subjects AND Phase 2b recommended dose
- *Efficacy through Days 151*: Pooled analysis reported that Nirsevimab (n=2579) had 79.0% (95%CI: 68.5-86.1), 80.6% (95%CI: 62.3-90.1) and 86.2% (95%CI: 68.1-94.0) efficacy against MA RSV LRTI, MA RSV LRTI with hospitalisation and very severe MA RSV LRTI respectively.
- *Efficacy against MA LRTI for RSV A and RSV B through Days 151*: Pooled analysis reported that Nirsevimab (n=2579) had 78.1% (95%CI: 61.1-87.7) and 80.0% (95% CI: 63.7-89.0) efficacy against MA LRTI for RSV A and RSV B respectively.
- 2nd season RSV incidence Days 361 – Days 511 after single dose prior to 1st season
- A low incidence of RSV LRTI was observed during season two with no hospitalised cases.
- Cases of any cause MA RSV LRTI were balanced by group
- Duration of protection:
- Primary and secondary endpoints for MELODY evaluated the efficacy of Nirsevimab through 150 days
- Efficacy did not decline over the time period of this evaluation
- There is some evidence that suggests that this protection extends beyond 150 days although the degree of this protection is yet to be determined.
- An analysis of the data from the South African cohort, that experienced a delayed RSV season, showed a hazard ratio of 0.491 (95% CI 0.158, 1.523).
- Neutralising antibody titres where 7x higher than baseline at day 361 in Nirsevimab treated subjects and were significantly higher than those with natural infection
- Implementation of an all infant program for Nirsevimab would be a combination of office administration for those born before the season and in-hospital administration for those born during the season.
- RSV WG Considerations
- Policy questions:

- Should Nirsevimab be recommended for all infants <8 months of age entering their first RSV season and all infants born during the RSV season?
- Should Nirsevimab be recommended for children <24 months of age entering their second RSV season who remain at increased risk of severe disease?

- Early next year (2023), WG needs to review GRADE evidence to identify children <24 months of age entering their second RSV season who remain at increased risk of severe disease for recommendations. Cost effectiveness analysis to be conducted by WG in February 2023. ACIP will give their vote by June 2023 if product is licensed by that time.

Meningococcal Vaccines

- Menveo One-Vial Presentation
- GSK has a newly licensed one-vial presentation of Menveo (MenACWY vaccine) that will be available in spring 2023.
- Products are licensed for different age ranges, raising important provider communication and use challenge.
- Two vials original MenCYW-135 requires liquid and MenA lyophilised to be reconstituted in a 0.5mL dose. It is recommended for age 2 months to 55 years. While the single vial (0.5mL/dose) has all components in a liquid presentation ready to use. It is suitable for age 10-55 years (unclear if/when product may be studied in children <10 years). Compared to the original Menveo, single vial has all the excipients except potassium dihydrogen phosphate and sucrose. Active substances are similar in both the vaccines.
- GSK plans to maintain a consistent but limited supply of Menveo Two-Vial for children <10 years. To overcome the challenge of ensuring that providers reserve Menveo Two-Vial for children <2 years as this is the only currently registered vaccine for this age group.
- Meningococcal Vaccines WG Plan for Assessing the MenABCWY Vaccines
- Two new MenABCWY vaccines currently in clinical trials, GSK and Pfizer.
- Each vaccine is a combination of an existing MenACWY vaccine and an existing MenB vaccine.
- WG will assess each pentavalent vaccine separately to have votes on use of these vaccines at the October 2023 ACIP meeting.
- GSK MenABCWY Vaccine
- Comprised of Menveo 1 Vial (serogroups ACWY) and Bexsero (serogroup B). Clinical trial is anticipated to assess 1) a two-dose schedule (0,6 months), 2) studying 10 through 25 years of age, 3) MenACWY primed and naive subjects and 4) Longer interval studies underway (not available in time for initial product licensure).
- Pfizer MenABCWY Vaccine
- Comprised of Nimenrix (serogroups ACWY) and Trumenba (serogroup B). Clinical trial is anticipated to assess same as GSK except 1) two doses (0,6 m and 0,12 m apart), 2)two doses at 11–12 years and a booster at 16 years and 3) a single dose of pentavalent as an alternative to MenACWY vaccine.
- Policy questions to be considered by WG:
- Should the pentavalent vaccine be included as an option for people aged ≥10 years:
  - Currently recommended to receive both MenACWY and MenB vaccines? E.g. adolescents 16 years

- Currently recommended to receive MenACWY only? E.g. 11 year olds
- Currently recommended to receive MenB only? – E.g., during a serogroup B outbreak.

Influenza Vaccines

- Clinical Trial to compare safety of Recombinant Influenza Vaccine (RIV4) versus Quadrivalent Inactivated Influenza Vaccine (QIV) in Pregnancy:
- First randomised clinical trial to compare safety of RIV4 (n=190) and QIV (n=192) in pregnant women; enrolled 382 participants (89% of goal enrolment).
- RIV4 non-inferior to QIV for adverse birth outcomes, consistent with study hypothesis.
- Safety profile of RIV4 and QIV similar for moderate/severe reactogenicity events and maternal and infant health outcomes assessed.
- From the standpoint of safety, the study supports the ACIP recommendation to include RIV4 as option for pregnant persons.
- Influenza immunogenicity analyses is in progress.
- Influenza Surveillance Update
- Influenza activity remains low in the US overall, but is increasing with influenza A(H3N2) viruses predominance and the components selected for the 2022-23 Northern Hemisphere vaccine are appropriate for US flu season.
- ACIP reviewed southern hemisphere influenza epidemiology for 2022 season, noting predominance of A/H3 in Australia and other sentinel countries, but also noted significant circulation of A/H1N1 and B/Victoria viruses in South Africa
- Comparison of Influenza Vaccine Effectiveness against outpatient and inpatient illness in the USA 2021-22 season
- Three networks evaluate vaccine effectiveness (VE) against laboratory confirmed influenza associated department visits, and outpatient visits, emergency hospitalisation.
- In summary, preliminary findings suggested low to no significant protection against predominant influenza A/H3N2 illness of varying severity
  - 36% (95%CI: 20, 49) against outpatient illness aged ≥6 months (Flu VE)
  - 19% (95%CI: -12, 41) against paediatric ED visits (NVSN)
  - 31% (95%CI: -14, 58) against paediatric hospitalisation (NVSN)
  - 11% (95%CI: -19, 33) against adult hospitalisation (IVY)
- Protection was similar to pre-pandemic A/H3N2dominant seasons.
- Trend suggested higher VE in outpatient setting compared to paediatric hospitalisation/ED visits but not adult inpatient influenza.

Dengue Vaccines

- Dengvaxia™: Implementation of Dengvaxia™ has been challenging due to the prevaccination screening requirement, the two-test algorithm and reimbursement.
- In October 2022, European Medicine Agency recommended the approval of Takeda's dengue vaccine for the prevention of dengue (any serotype) in individuals ≥4 years. Final approvals are due in few months. However, it has been approved for use in Indonesia.
- The dengue vaccine WG has started review of the Takeda TAK-003 dengue vaccine.

Mpox (previously Monkeypox) Vaccines

- ACIP voted about primary vaccination with JYNNEOS (licensed attenuated, nonreplicating live virus vaccine produced from the strain Modified Vaccinia AnkaraBavarian Nordic [MVA]), also known as IMVAMUNE, IMVANEX, MVABN.
- Recommended in adults 18 years of age and older, with two doses administered 28 days (4 weeks) apart.
- Three components of the U.S national monkeypox vaccination strategy were discussed: post-exposure prophylaxis (PEP), expanded post exposure prophylaxis (PEP++) and pre-exposure prophylaxis (PrEP). PrEP, which is indicated for people in certain occupational risk groups, gay, bisexual and other men who have sex with men, transgender or nonbinary people, was discussed in detail.

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 Pneumococcal Vaccine Recommendations – 15vPCV in people aged <19 years

- MMWR; 16 September 2022: https://www.cdc.gov/mmwr/volumes/71/wr/mm7137a3.htm
- Updates reflect changes to recommendations agreed to at 23-24 February 2022 and 22-23 June 2022 meetings.
- Primary updates:
    - ACIP recommends use of PCV (either 13vPCV or 15vPCV) for all children aged 2–59 months. In addition, risk-based PCV use is recommended for children aged 60–71 months with risk conditions, and persons aged 6–18 years with an immunocompromising condition, cerebrospinal fluid leak, or cochlear implant.
    - For all recommendations, 13vPCV and 15vPCV can be used interchangeably.
    - Interruption of the vaccination schedule does not require reinstitution of the entire series or the addition of extra doses.
    - Children aged ≥2 years with any risk conditions should receive 23vPPV after completing all recommended PCV doses (either 13vPCV or 15vPCV). These children should receive a single dose of 23vPPV at age ≥2 years and ≥8 weeks after the most recent PCV dose.
    - Children who have received 23vPPV but have not yet completed their recommended PCV doses should receive PCV ≥8 weeks after the 23vPPV dose. When elective splenectomy, immunocompromising therapy, or cochlear implant placement is being planned, PCV or 23vPPV vaccination should be completed ≥2 weeks before surgery or initiation of therapy, if possible.
    - Recipients of haematopoietic stem cell transplants are recommended to receive 3 sequential PCV doses followed by a dose of 23vPPV beginning 3–6 months after the transplant. In children with graft-versus-host disease, 23vPPV can be replaced with a fourth dose of PCV.
    - Either 13vPCV or 15vPCV can be administered at the same time as other routine childhood vaccinations, including COVID-19 vaccines, in separate syringes and using different injection sites.

- Coadministration of 15vPCV with meningococcal vaccines has not been studied. The same precautions used for coadministration of 13vPCV and meningococcal vaccines should be applied when 15vPCV is used. Risk for febrile seizures in children who received 15vPCV concurrently with an influenza vaccine has not been studied.

1.2.2 Cholera Vaccine Recommendations – CVD 103-HgR (Vaxchora)

- MMWR; 30 September 2022: https://www.cdc.gov/mmwr/volumes/71/rr/rr7102a1.htm
- Describes previously published ACIP recommendations about use of CVD 103-HgR for adults aged 18–64 years, and introduces a new recommendation for use in children and adolescents aged 2–17 years.
- ACIP recommends: CVD 103-HgR for prevention of cholera among travellers aged 2–64 years to an area with active cholera transmission.
- Primary updates:
  - ACIP recommends CVD 103-HgR for travellers aged 2–64 years to an area of active cholera transmission.
  - CVD 103-HgR is not recommended for travellers who are not visiting areas with active cholera transmission. No country requires vaccination against cholera as a condition for entry.
  - No data exist about the safety or efficacy of preventing cholera with booster doses of the currently licensed CVD 103-HgR. The duration of protection conferred by the primary dose beyond the 3-month period evaluated in adults aged 18–45 years is unknown. ACIP does not have a recommendation regarding use of booster doses.
  - CVD 103-HgR should not be given to patients who have received oral or parenteral antibiotics during the preceding 14 days. A duration of fewer than 14 days between stopping antibiotics and giving CVD 103-HgR might be acceptable under certain circumstances, such as if travel cannot be avoided before 14 days have elapsed after stopping antibiotics.
  - Antimalarial: Chloroquine might diminish the immune response to CVD 103-HgR. CVD 103-HgR should be administered ≥10 days before starting chloroquine. The optimal duration between completion of CVD 103-HgR and starting doxycycline is unknown.
  - No data are available on concomitant administration of the currently licensed CVD 103-HgR with other vaccines, including the enteric-coated oral live-attenuated typhoid vaccine (Ty21a). The expert opinion of the ACIP work group postulated that CVD 103-HgR buffer might interfere with the enteric-coated Ty21a formulation and concluded that taking the first Ty21a dose ≥8 hours after ingestion of CVD 103-HgR might decrease potential interference of the vaccine buffer with the Ty21a vaccine.

1.2.3 Measles, Mumps, Rubella Vaccine Recommendations – PRIORIX

- MMWR; 18 November 2022: https://www.cdc.gov/mmwr/volumes/71/wr/mm7146a1.htm
- Updates reflect changes to recommendations agreed to at 23 February 2022 and 23 June 2022 meetings.
- Primary updates:
  - PRIORIX is recommended according to the existing MMR recommended schedules and off-label uses as an option to prevent measles, mumps, and rubella.
  - PRIORIX and M-M-R II are fully interchangeable. ACIP General Best Practices states a preference that doses of vaccine in a series come from the same manufacturer; however,

vaccination should not be deferred when the manufacturer of the previously administered vaccine is unknown or when the vaccine from the same manufacturer is unavailable. Studies have shown that PRIORIX is safe and immunogenic when administered as a second dose after M-M-R II.
    - PRIORIX can be administered concomitantly, at different anatomic sites, with other routine childhood vaccines. Concomitant administration of PRIORIX with other live and non-live vaccines has been studied.
    - Contraindications for PRIORIX are the same as those for M-M-R II.

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

2.1 Extraordinary JCVI meeting to discuss polio and meningococcal B: 25 July 2022

- A summary of the Extraordinary JCVI meeting to discuss polio and meningococcal B held in July is provided below *(included in this summary due to its publication on 1 November 2022)*
- Agenda: No agenda provided.
- Draft minutes, 25 July 2022: https://app.box.com/s/iddfb4ppwkmtjusir2tc/file/1054119657802

- Polio
    - JCVI discussed vaccination strategy options. It was agreed that the aim of any vaccine strategy is to prevent paralysis and to interrupt transmission of VDPV2 in the community. Prevention of paralysis is currently being actioned by the catch-up campaign in unvaccinated or under-vaccinated children.
    - JCVI noted that within areas of low maternal and infant vaccine coverage there are multiple communities with low uptake. These communities all present different challenges therefore interventions would need to be targeted.
    - Those who were vaccinated with IPV (routinely given since 2004) rather than OPV will not have any type 2 poliovirus mucosal immunity, shedding dynamics of the type 2 virus would have been different prior to the switch of the vaccine.
    - The maternal pertussis programme was introduced in 2012, and therefore this may apply to children under the age of 10. The pre-school booster may have mitigated some of the risk caused by the immunity gap; however, uptake of this vaccine is relatively low within London. Therefore, the booster campaign should cover children up to ten years old to prevent cases of paralysis.
    - At the current time it was unknown how transmission was occurring, globally younger children typically drive this. A campaign that offers a booster dose to all young children is likely to be more effective than specifically targeting only those who may have an immunity gap. However, widening to the whole of London would be beneficial due to the mobility of the population within London.
    - Bringing forward the planned changes for the additional hexavalent dose in the childhood programme earlier in London may save further effort in the future, this is still pending a final decision on whether the dose would be given at 12 or 18 months however a straight switch from Hib/MenC to DTaP/IPV/Hib/HepB may be possible.

- The Committee agreed that priority in immunisation programmes should be given to those which are time sensitive such as COVID-19, seasonal influenza and polio.

- Meningococcal B in 2021/22 academic year
  - The number of cumulative cases in the current academic year was still low compared to previous pre-pandemic years. Meningococcal cases by serogroup showed that these were almost entirely due to Group B. Outbreaks in certain university, causes of the outbreak, type of strain and preventive options were discussed.
  - There was no indication of emergence of a more virulent MenB strain, and incoming university freshers will have had more social mixing prior to entering university than the previous two academic years. Therefore, one option would be to not vaccinate.
  - The other option would be to offer two doses of vaccine as a preventative intervention. This would not prevent all cases in university students and would not prevent all university-linked cases.
  - The threshold to consider a cluster of cases to be an outbreak was for educational or residential settings two or more cases (confirmed or probable) of invasive meningococcal disease occurring within 28 days in the same setting. Cases that are within a common social network or with close geographical/temporal relationship would be considered a cluster. A rate of 40/100,000 is otherwise used. However identifying the denominator is difficult. Focused denominators should be used where possible such as if cases are linked to a hall of residence or specific education group/sports club. A subset may be immediately over the threshold therefore understanding the correct group for the denominator is crucial.
  - There may be the possibility of a mixed schedule in the future and vaccines may be modified in the future to reflect the strains circulating.
  - The meningococcal reference unit (MRU) will be looking at the herd immunity gap using a seroprevalence study for meningococcal B, looking both pre and post lockdown.
  - Appropriate recommendations should be made if there were further cases identified in universities.

2.2 JCVI meeting: 19 October 2022

- A summary of the JCVI meeting held in October is provided below
- Agenda: https://app.box.com/s/9f24lity6bqso9b6qi7c/file/1037449376214
- Draft minutes, 19 October 2022: https://app.box.com/s/iddf b4ppwkmtjusir2tc/file/1079270439367

- Mpox
  - JCVI advised on the use of intradermal administration as a dose sparing approach. Second doses will be offered to those who are at an ongoing high risk of exposure. The JCVI published a statement advising on the prioritisation for the allocation of the remaining doses of vaccine.
  - Declining number of cases were reported in UK and other European countries. Majority of these cases were males, identified as gay, bisexual or other men who have sex with men (GBMSM).

- Similar decreases in shigella and lymphogranuloma venereum (LGV) were seen just after monkeypox case decreases indicating there may have been changes in behaviour of sexual network which contributed.
- The Committee heard an update on vaccine effectiveness (VE). Studies reported VE of 78-79%.
- Challenges of evaluating vaccine programme, sero-evaluation and challenges in delivering the vaccination operationally were discussed.
- No safety issues had been identified for the MVA-BN vaccine as a result of the reports received and the data was considered to be reassuring.
- No severe cases reported therefore no further analysis. However, committee will review further updates next year.

- Diphtheria
  - Since the last update at the June JCVI meeting a pattern of travel related Corynebacterium diphtheria had been observed predominantly amongst asylum seekers, mainly presenting with cutaneous lesions or wounds. The JCVI noted that most migrant arrivals are not able to give a vaccination history and are therefore assumed to be unvaccinated.
  - A briefing note has been circulated across the health system to improve case finding, early diagnosis and to promote use of diphtheria anti-toxin for respiratory presentations particularly among asylum seekers on arrival to accommodation settings.
  - Preliminary data on anti-toxin levels suggest good broad basic protection across age ranges with some waning seen as expected in older age groups, some of which may be due to lower rates of vaccination in the oldest age groups.
- Meningococcal B (MenB)
  - The UK Health Security Agency (UKHSA) provided an update on meningococcal surveillance data in England; at the end of the 2021/22 academic year the number of cases of invasive meningococcal disease (IMD) remained much lower than pre-pandemic years.
  - Up to the 7th October 2022, 18 cases were reported (15 identified as MenB, one MenW, one MenY, and one ungroupable). These MenB cases were spread across age ranges and geographical regions, only two were associated with higher education settings. No epidemiology links had been found and there was nothing to suggest potential outbreak.
  - It was noted that data collection was changing to capture more consistent data for higher education related cases to address the current difficultly in defining the denominator for a potential cluster.
- Meningococcal ACWY
  - Currently a single dose of MenACWY is given to adolescents at 14 years old. Two doses are recommended for adolescents in the US.
  - JCVI noted that as there are so few cases and transmissions, the risk of contracting IMD is extremely low. There is excellent herd immunity and therefore for the general population the evidence suggests that a booster is not needed.
  - In the June 2022 JCVI meeting, modelling work presented highlighted the potential elimination of meningococcal by 2040.
  - The sub-committee had agreed that the booster should be recommended for those who are travelling to an area with meningococcal outbreaks. It is recommended that travellers should undertake a risk assessment when travelling to high-risk areas and

their likelihood of exposure. The same risk assessment is carried out for subsequent booster doses after five years due to the waning of MenA protection.
    - It was agreed that further clarification should be taken to the travel sub-committee as there are certain travellers for whom this would be recommended, such as healthcare workers and those in close contact with local communities.
- Flu sub-committee update
    - The advice that came from the subcommittee was not a major change from that given last year for the eligible groups, including those aged 65 years and older, at risk 18-64 year olds and children in risk groups.
    - The only change that was advised was an off-label recommendation for the cell-based vaccine QIVc to be the vaccine of choice for children under two years. This was to make the advice consistent for the under twos and those over two years old who cannot have LAIV.
    - The committee had reiterated its previous advice that if the programme was expanded then vaccinating secondary school children should be prioritised over the healthy 50 to 64 year old age group because there was clear evidence of cost-effectiveness in the former.
- Live vaccination after in-utero exposure to infliximab
    - The update from MHRA recommends that after in utero exposure to infliximab (a monoclonal antibody used to treat autoimmune disorders), live vaccines should not be given to infants until 12 months after birth. This update differs from the previous advice for all biological immunosuppressants, which recommends waiting six months. Vaccination may go ahead earlier if a specialist clinician with the correct expertise in the therapy given advises that it can.
    - The recommendation in the Summary of Product Characteristics (SmPC) was not a contraindication but a precaution and if infant serum levels are undetectable or administration was limited to the first trimester of pregnancy then earlier vaccination with live vaccine could be considered if there is a clear benefit for the individual patient.
    - It was noted that neonates have different clearance times from adults, Julsgaard et al. reported the mean infliximab half-life was 3.7 times longer in infants than in adult non-pregnant patients; where paediatric populations are included in indications for infliximab, these do not include neonates and therefore data are sparse.
    - One of the other challenges is the translation of laboratory data to clinical practice; it is not known which serum levels should be considered clinically relevant in infants and neonates. The risk of disseminated BCG as a result of any concentration of monoclonal antibody is likely to be greater than the risk of natural infection with tuberculosis (TB) due to a delay in vaccination.
    - In the UK BCG vaccination is only given to individuals who are at risk of contracting TB. TB cases overall are decreasing in the UK.
- Varicella/shingles sub-committee update
    - The sub-committee discussed some of the outstanding issues relating to the UK Shingrix programme. This includes expansion of the immunosuppressed population eligible down to age 18+ years, vaccination of those who were too old for the Zostavax programme and revaccination of those who had previously received Zostavax.
    - Sub-committee agreed that Shingrix should be made available to stem cell transplant patients as a clinical decision and part of their treatment plan.

- The sub-committee agreed that the role of exogenous boosting is critical to the model and therefore the model should be fitted to the US data before then including UK data. The sub-committee will next meet in 2023.

- Polio
  - JCVI issued a statement of advice that in addition to the ongoing work to vaccinate those who are unvaccinated or under vaccinated, an inactivated polio vaccine (IPV) booster campaign should be commenced for children aged 1 – 9 years in London**.**
  - Polio cases in UK could be travel related**.** There is likely to have been movement between the UK, US and Israel because of this religious holiday. Data from Israel will further confirm this.
- Routine Infant Schedule
  - In November 2022, the JCVI published a statement outlining the advised changes to the routine childhood immunisation schedule. This advised that:
    - A Hib containing DTP vaccine should be given at 12 or 18 months
    - The second dose of MMR vaccine should be brought forwards from the pre-school visits (3 years 4 months) to 18 months
    - A meningococcal C containing vaccine was no longer required in infancy due to the protection offered by the MenACWY given to adolescents.
  - The Committee agreed that the overall priority remains to ensure that a maternal pertussis campaign is in place as the programme continues to save lives. If a non-IPV containing pertussis vaccine with a UK marketing authorisation can be secured at a cost-effective price, it would be preferable to switch at the next contract opportunity, otherwise to maintain the programme as is.
  - In a scenario with the absence of disease transmission, it would be reasonable to put the additional Hib containing dose at either 12 or 18 months. The main purpose of the programme is to achieve herd protection within the population.
  - If there were circulating Hib disease there may be some individual benefit in choosing administration at 12 months, however in the absence of disease, giving the dose at 18 months is just as beneficial. Scheduling the vaccine at 18 months would leave space and flexibility in the schedule to consider adding other vaccinations such as varicella which is planned to be reviewed once modelling work has been completed. These changes are currently planned to commence nationally in 2025 once the existing stocks of Hib/MenC have been used.
  - Uptake of all childhood vaccines remains to be important to maintain herd immunity. The JCVI agreed that as recommended in the interim statement the second dose of MMR should be given at 18 months. In the UK school starts earlier than some other countries, it is beneficial overall to have an opportunity to catch up any missed vaccine doses prior to starting school.
- High Consequence Infectious Disease
  - Previously the decision had been taken by the JCVI and New and Emerging Respiratory Virus Threats Advisory Group (NERVTAG) not to replace pre-pandemic stockpile of H5N1 vaccine as it was considered unlikely that the vaccine would have much impact as the variant of H5N1 in the vaccine had disappeared. The decision was made to move from having a pre-pandemic stock to having a sleeping contract with vaccine manufacturers.

- Respiratory Syncytial Virus Modelling
  - The Committee noted that a license for a new RSV monoclonal product Nirsevimab by Sanofi was expected very soon. The expectation was that MHRA licensure would then follow via the reliance procedure which theoretically meant it could be licenced soon after the EMA approval and potentially by the end of the year.
  - Nirsevimab could replace palivizumab if the programme remains the same(and Nirsevimab was acceptably priced);
  - For large-scale programmes, the seasonal programme was most likely to be cost-effective, but this would depend on yet to-be-confirmed factors:
    - price (to be confirmed);
    - efficacy (age-specific efficacies to be confirmed), and
    - duration of protection (end-point was 150 days but this could be longer)
  - Future work planned includes:
    - looking at the cost-effectiveness of augmenting the risk-specific intervention programmes against RSV using Nirsevimab, and
    - a static model/simpler dynamic transmission model
  - It was noted that the dosage was determined by the earlier studies on slightly premature babies but for ethical reasons it was not possible to study the high-risk infants with a placebo therefore a head-to-head study with palivizumab was required.
- Yellow fever vaccine
  - Children who have had cardiac surgery, if there is a record that thymic tissue has been left, this is a caution rather than a contraindication for Yellow Fever vaccination and vaccination could be offered following travel risk assessment. If there is no record, it should be assumed that the thymus was removed and vaccination is therefore contraindicated.
  - For adults who had cardiac surgery more than 20 years ago, Yellow Fever vaccination is contraindicated as thymic fat was routinely removed.
  - In all cases if there is no record of thymic tissue remaining, it should be assumed that it was removed and Yellow Fever vaccination is contraindicated.
- Ebola vaccination
  - There was an ongoing Ebola outbreak in Uganda however; risk to UK residents within these areas was considered low and the overall risk to the UK public very low.
  - Two vaccines one from Merck (rVSV-ZEBOV, Ervebo) and one from Janssen (Ad26.ZEBOV and MVA-BN-Fil) have been licensed by the European Medicines Agency (EMA) but only the Merck vaccine is licensed in the UK.
  - Ebola expert WG recommended that
    - Vaccination against Ebola should be offered to healthcare workers in High consequence infectious diseases (HCID) units
    - There was a preference for the Janssen vaccine because of potential priming against the Sudan strain and for Marburg and Tai Forest virus.
    - Offering vaccination would also mitigate against future outbreaks of Ebola and both available vaccines are licensed for protection against the Zaire strain. There was the likelihood for outbreaks of this virus to contend with in the future.
    - There was also the potential benefit that the MVA viral vector of Mvabea might be a substitute for the first or second dose of the MVA smallpox vaccine though the

content of virus in the former was 10^8 infectious units compared with 5 X 10^7 infectious units for Imvanex.

- Timelines for when the vaccine might be available would depend on the procurement process, supply, availability and the required regulatory process. Therefore, the vaccine might not be available until the New Year.

3 National Advisory Committee on Immunisation (NACI), Canada

3.1 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

3.1.1 NACI meeting held on 6 September 2022

Summary of Discussion – 6 September 2022:

- Update to NACI Imvamune guidance and Monkeypox vaccination: Overview of the data on the current status of the monkeypox outbreak in Canada and globally, along with additional evidence included in published scientific literature and from the manufacturer, regarding the safety, immunogenicity and protection offered by Imvamune.
- Modelling information on the impact of dose sparing strategies when vaccine supply is limited.
- Updates: In the context of an active monkeypox outbreak, NACI recommends that the Imvamune vaccine should be offered as pre-exposure vaccination to individuals with highest risk of monkeypox. See section 4.2 below for details.

3.1.2 NACI meeting held on 12-13 September 2022

Summary of Discussion – 12-13 September 2022:

- Pneumococcal 15vPCV and 20vPCV for Adults: proposed recommendations on the use of 15- or 20-valent pneumococcal conjugate vaccines in scenarios including or compared to a 23-valent pneumococcal polysaccharide vaccine in adults. *Interim statement and recommendations for 15vPCV are not yet available.*

3.1.3 NACI meeting held on 3-4 October 2022

Summary of Discussion – 3-4 October 2022:

- Summary of the supporting clinical evidence for expanded paediatric indications for two seasonal influenza vaccines (Flucelvax Quad and Influvac Tetra) and updated recommendations on their use. Previously recommended for use in people aged 2 years of age and older, now recommended for use in people aged 6 months of age and older.
- Overview of the evidence and considerations reviewed by the Pneumococcal Working Group (PWG) on the use of the recently authorised 15vPCV in paediatric populations and its interchangeability with the 13vPCV currently used in paediatric programs. Proposed interim recommendations on the use of the 15vPCV in paediatric populations. *Interim statement and recommendations for 15vPCV are not yet available.*
- Provided an overview of the Influenza Working Group's proposed approach, key considerations and discussions to date for the review of safety and effectiveness of influenza vaccine in pregnancy.
- Provided a status update to the committee on the NACI 2022-2024 workplan.

3.1.4 NACI meeting held on 13 December 2022

- Summary of Discussion for the 13 December 2022 meeting not yet released.

3.2 Newly published or updated statement/recommendations

Current vaccine statements:

- Published 23 September 2022: Updated interim guidance on Imvamune in the context of ongoing monkeypox outbreaks

https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/rapid-response-updated-interim-guidance-imvamune-monkeypox-outbreaks.html

  - Summary: https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/rapid-response-updated-interim-guidance-imvamune-monkeypox-outbreaks/summary-september-23-2022.html
  - Updates to the recommendations:
  - In the context of an active monkeypox outbreak, NACI recommends that the Imvamune vaccine should be offered as pre-exposure vaccination to individuals with highest risk of monkeypox. After considering the current and projected outbreak epidemiology, NACI recommends the following individuals be considered for pre-exposure vaccination *(Strong NACI Recommendation)*:
    - Men who have sex with men (MSM), and individuals who have sex with MSM (who have two or more sexual partners or who are in a relationship where at least one of the partners has other sexual partners, have had a confirmed sexually transmitted infection in the past year, or engage in sexual contact in sex-on-premises venues);
    - Individuals who self-identify as sex workers, regardless of self-identified sex/ gender;
    - Staff or volunteers in sex-on-premises venues where workers may have contact with objects or materials that may be contaminated with the monkeypox virus without the use of personal protective equipment.
    - Those with a history of monkeypox infection do not need to be vaccinated.
  - In the context of the ongoing monkeypox outbreaks and limited vaccine supply, dose sparing strategies, including extended dosing intervals and fractional dosing, should be considered to maximise vaccine coverage for those at highest risk of exposure to the monkeypox virus. *(Strong NACI Recommendation)*
  - When vaccine supply is adequate, NACI recommends that Imvamune pre-exposure vaccination should be offered as a two-dose primary series, with at least 28 days between doses, to individuals at highest risk of monkeypox. *(Strong NACI Recommendation)*
  - NACI continues to recommend the use of Imvamune as post-exposure vaccination for individuals who have had a high risk exposure to a probable or confirmed case of monkeypox, or within a setting where transmission is happening.

- Published 23 September 2022: Guidance on the use of influenza vaccine in the presence of COVID-19

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

- The influenza vaccine should continue to be offered to anyone 6 months of age and older who does not have contraindications to the vaccine.
- Individuals with COVID-19 or asymptomatic SARS-CoV-2 infection should not leave isolation solely to be vaccinated against influenza.
- Individuals with symptoms of acute respiratory infection can be vaccinated against influenza. However, in the outpatient setting, vaccination should be deferred until the resolution of symptoms, given the possibility of unknowingly transmitting COVID-19 or other respiratory infections to others, including healthcare providers.
- Individuals in quarantine for COVID-19 or asymptomatic SARS-CoV-2 infection can be vaccinated against influenza but should not leave quarantine solely to do so.
- For people 5 years of age and older, all seasonal influenza vaccines, including live-attenuated influenza vaccine (LAIV), may be given at the same time as, or at any time before or after, administration of other vaccines, including COVID-19 vaccines.
- At this time, it is not recommended that children aged 6 months to 5 years of age routinely receive the COVID-19 vaccine at the same time as the influenza vaccine. NACI currently recommends that children 6 months to 5 years of age wait at least 14 days between COVID-19 vaccines and non-COVID-19 vaccines, including the influenza vaccine.

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

4 Immunisation Advisory Centre (IMAC), New Zealand

4.1 PTAC Considerations

Meetings were held on:

- 18 – 19 August 2022; Minutes (published 9 November 2022): https://pharmac.govt.nz/assets/2022-08-combined-PTAC-meeting-record.pdf
  - No vaccine specific considerations were discussed.
- 17 – 18 November 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.

4.2 Other updates

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

- There have been no immunisation updates since 11 August 2022.

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5 Immunisation updates from the World Health Organization (WHO)

5.1 WHO Position Papers

- **Hepatitis A vaccines: WHO position paper – 7 October 2022**

https://www.who.int/publications/i/item/who-wer9740-493-512

- WHO recommends that vaccination against hepatitis A virus be introduced into national immunisation schedules for individuals aged ≥12 months, if indicated on the basis of: i) an increasing trend over time of acute hepatitis A disease, including severe disease, among older children, adolescents or adults; ii) changes in the endemicity from high to intermediate; and iii) considerations of cost–effectiveness.
- For children, inactivated hepatitis A vaccines can be given as a single- or two-dose (off-label) schedule, and administered intramuscularly. With a two-dose schedule, the first dose should be given starting from age ≥12 months. The interval between doses is flexible, from 6 months up to 4–5 years or more, but is usually 6–18 months.
- For adults aged >40 years, vaccination with inactivated vaccines using the two-dose schedule is preferred since there is insufficient evidence on the immunogenicity and long-term protection from a single dose in this age group.
- Live attenuated vaccines are licensed for individuals aged ≥18 months and are administered as a single subcutaneous dose.
- In highly endemic countries, most individuals are asymptomatically infected with HAV in childhood, which prevents clinical hepatitis A in adolescence and adulthood. In these countries, large-scale hepatitis A vaccination programmes are not routinely recommended, because they carry a risk of a paradoxical increase in disease incidence in unvaccinated people.
- Countries with improving socioeconomic status may rapidly move from high to intermediate hepatitis A endemicity, rendering a larger proportion of the adolescent and/or young adult population susceptible to HAV infection. In such countries, large-scale hepatitis A vaccination in early childhood is likely to be cost–effective and is therefore recommended.
- Targeted vaccination of high-risk groups should be considered in low and very low endemicity settings to provide individual health benefits.
- In outbreak situations, single-dose hepatitis A vaccination is recommended, taking into account the epidemiology and feasibility of rapidly implementing a well-targeted vaccination programme.

- **Human papillomavirus (HPV) vaccines: WHO position paper – 16 December 2022**

https://www.who.int/publications/i/item/who-wer9750

- HPV vaccines should be included in all national immunisation programmes and should reach 90% of all girls by age 15 by 2030. Prevention of cervical cancer is best achieved through the immunisation of girls before they become sexually active. Achieving over 80% coverage in girls also reduces the risk of HPV infection for boys.
- *Two*-dose *schedule*: The current evidence supports the recommendation that a 2-dose schedule be used in the primary target group from 9 years of age and for all older age groups for which HPV vaccines are licensed. The minimum interval between first and second dose is 6 months. A 12-month schedule results in higher geometric mean titres (GMTs) and is suggested for programmatic and efficiency reasons. There is no maximum recommended interval between doses and longer intervals – up to 3 or 5 years – can be considered if useful from a programme perspective.

- Alternative *single-dose schedule*: As an off-label option, a single-dose schedule can be used in girls and boys aged 9–20 years.
- Current evidence suggests that a single dose has comparable efficacy and duration of protection as a 2-dose schedule and may offer programme advantages, be more efficient and affordable, and contribute to improved coverage. From a public health perspective, the use of a single dose schedule can offer substantial benefits that outweigh the potential risk of a lower level of protection if efficacy wanes over time, although there is no current evidence of this.
- *Schedule for Immunocompromised persons*: Individuals known to be immunocompromised or HIV-infected (regardless of age or antiretroviral therapy status) should receive at least two HPV vaccine doses (minimum 6 months interval) and, where possible, three doses.

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: 3 – 6 October 2022

- Meeting details: https://www.who.int/news-room/events/detail/2022/10/03/default-calendar/sage_meeting_october_2022
- Agenda: https://cdn.who.int/media/docs/default-source/immunization/sage/2022/october/draft_sage_agenda_3-6_oct2022.pdf?sfvrsn=e4216a26_11
- Highlights: https://cdn.who.int/media/docs/default-source/immunization/sage/2022/october/highlights_sage_oct_2022.pdf?sfvrsn=69f947c4_5

- Global reports
  - *Report from the department of Immunization, Vaccines, and Biologicals*: The decline in vaccination coverage has led to large disruptive outbreaks of measles and circulating vaccine derived polio viruses mainly affecting low- and low-middle-income countries, while outbreaks of Monkeypox has newly affected high-income countries in the Americas and Europe. COVID-19 vaccination targets were not achieved, including among priority-use groups.
  - *Report from Gavi, the Vaccine Alliance*: The Alliance will focus on the relaunch of human papilloma virus (HPV) vaccination, long-term support for COVID-19 vaccination and regional vaccine manufacturing, support for polio eradication, launch malaria vaccination in the Malaria Vaccine Implementation Plan (MVIP) countries, expand the use of Zaire ebolavirus vaccines held in a stockpile to prevent vaccines passing their expiry dates.
- Immunization Agenda 2030 (IA2030) and Regional reports
  - Several factors that impede the achievement of the IA2030 goals and targets cut across the regions and country income levels and include: inadequate and overstretched health workforce, exacerbated through the COVID-19 response; insecurity and population

displacement; competing priorities and diversion of resources from routine service delivery; and inadequate financing.
    - The Measles & Rubella Initiative (M&RI) will join the IA2030 partnership structure to promote alignment in efforts to use measles as a tracer to identify service delivery gaps and take coordinated measures to strengthen immunisation systems.
- Monkeypox – now known as Mpox
    - Based on the available, limited data, SAGE recommended primary preventive (preexposure) vaccination (PPV) for groups at high risk for exposure to monkeypox. The group at highest risk of exposure in the current outbreak is gay, bisexual, or other MSM with multiple sexual partners. Others at risk include individuals with multiple casual sexual partners; sex workers; health workers at repeated risk of exposure; laboratory personnel working with orthopoxviruses; clinical laboratory and health care personnel performing diagnostic testing for monkeypox; and outbreak response staff. The level of risk of infection may be used for prioritisation in case of limited vaccine supply.
    - Post-exposure vaccination (PEPV) is recommended for close contacts of cases, ideally within 4 days of first exposure and up to 14 days in the absence of symptoms.
    - For healthy adults, any of the three currently available vaccines is appropriate. For individuals for whom replicating or minimally replicating vaccines are contraindicated, non-replicating vaccines should be used.
    - Updated interim recommendations and guidance on monkeypox vaccination were published (with associated annexes and background document).
- Respiratory Syncytial Virus (RSV)
    - The burden of acute lower respiratory tract infections (ALRTI) remains high with an estimated more than 100 000 deaths attributed to RSV in children under 5 years; 97% of deaths occur in low-income (LICs) and lower middle-income countries (LMICs) and 45% occur in infants < 6 months.
    - Market authorisation of a long-acting monoclonal antibody by a stringent regulatory authority (SRA) is imminent (Q4 2022); also, a maternal vaccine in phase 3 development is expected to have an interim efficacy readout by end of 2022 with possible licensure in 2023 by a SRA.
    - A pre-fusion F protein vaccine when administered to pregnant women showed 85% efficacy against medically attended RSV ALRTI and 91% against severe RSV ALRTI in infants in a phase 2b clinical trial; a phase 3 trial is underway with results from an interim analysis expected in mid-2023.
- COVID-19 vaccines
    - *Variant containing vaccines*: reviewed the safety and immunogenicity of the bivalent vaccines containing the mRNA of the original strain and of the Omicron sub lineages when given as a booster dose in adults. Booster vaccination 4-6 months after the last dose provides improved protection against currently circulating SARS-CoV-2. Either the monovalent ancestral virus vaccines or bivalent variant-containing vaccines can be used as boosters. The bulk of the benefit is from the provision of a booster dose, irrespective of whether it is a monovalent or bivalent vaccine.
    - *Product specific recommendations – Corbevax - Biological E*: Reviewed clinical trial results from the protein subunit vaccine. Will issue recommendations once the product is listed by WHO for emergency use (EUL).

- Polio vaccination
    - Concern about renewed wild poliovirus 1 (WPV1) circulation in Pakistan; and about continuing detections of WPV1 in South-eastern Africa. SAGE noted the ongoing transmission of vaccine-derived poliovirus type 2 (VDPV2), particularly in the African region and in Yemen, as well as detections in New York, London, and Jerusalem.
    - SAGE endorsed the option for the timely initial use of IPV to respond to outbreaks, in countries that use only IPV for routine childhood immunisation. This option is recommended if the poliovirus transmission is confined to a well-defined population group or geographical area and with high levels of sanitation; preparation for a response with oral polio vaccines (OPVs) should begin in parallel should transmission continue following the response with IPV.
    - The outbreak response campaigns should primarily target children less than 5 years, though wider age range response may be considered when there is evidence of immunity gaps in older age groups or low historical vaccination coverage rates.
    - Ensure that zero dose children identified by the polio eradication programme are included in routine immunisation micro plans for all recommended paediatric vaccines. SAGE also recognised the importance of accelerated efforts to develop and authorize novel OPVs against type 1 and 3 virus.
    - Recommended that all countries have outbreak response plans to be prepared for timely response against VDPV or WPV1 outbreak.
- Ebola (Sudan ebolavirus outbreak update)
    - The outbreak of Sudan ebolavirus was declared in Uganda on the 20th of September 2022, with the index case detected on the 11th of September 2022. As of October 6, there are 44 confirmed cases, 20 suspected cases and 10 deaths reported from 5 districts in Uganda.
    - Vaccines against the Zaire ebolavirus do not offer cross-protection against the Sudan ebolavirus. There are 6 candidate vaccines under development against the Sudan ebolavirus, 3 of which have undergone phase 1 or 2 clinical trials.
    - The opportunity of a vaccination response will be used to evaluate the efficacy of one of the candidate vaccines using a ring vaccination approach. Only contacts will be offered vaccination to optimise the use of the limited doses of vaccine.

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.

There have been no meetings since the 11 August 2022 Extraordinary meeting of SAGE (reported in last summary).

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

There have been no meetings since the 14-16 June 2022 combined Advisory Committee on Safety of Medicinal Products (ACSoMP) and the Global Advisory Committee on Vaccine Safety (GACVS) meeting (reported in last summary).

5.4 WHO Regional Committee for the Western Pacific meeting

- Regional Committee meeting page: https://www.who.int/westernpacific/about/governance/regional-committee
- **24 – 28 October 2022, 73rd session (Manila, Philippines):** https://www.who.int/westernpacific/about/governance/regional-committee/session-73
- Agenda: https://www.who.int/docs/default-source/wpro---documents/regional-committee/session-73/wpr-rc73-1-provisional-agenda.pdf?sfvrsn=c652c79a_1
- Documents from the 73rd session: https://www.who.int/westernpacific/about/governance/regional-committee/session-73/documents
- Summary report from the Chairperson: https://www.who.int/docs/default-source/wpro---documents/regional-committee/session-73/rc73-report-of-the-chairperson.pdf?sfvrsn=da7b1a59_1
    - Topics covered: cervical cancer, mental health, non-communicable disease prevention and control, primary health care, climate change and environmental health.
- The Final report of the Regional Committee is not yet available.

5.5 Global immunisation news (GIN) and other items and resources

- GIN landing page: https://www.who.int/teams/immunization-vaccines-and-biologicals/about/newsletter
- Recommended composition of influenza virus vaccines for use in the 2023 southern hemisphere influenza season (23 Sep 2022): https://www.who.int/publications/m/item/recommended-composition-of-influenza-virus-vaccines-for-use-in-the-2023-southern-hemisphere-influenza-season
- WHO Vaccine Prioritization Working Group: Summary of the evaluations and recommendations on the three Sudan ebolavirus vaccines that are candidates for inclusion in the planned ring vaccination trial in Uganda (16 Nov 2022): https://www.who.int/publications/m/item/who-vaccine-prioritization-working-group.--summary-of-the-evaluations-and-recommendations-on-the-three-sudan-ebolavirus-vaccines-that-are-candidates-for-inclusion-in-the-planned-ring-vaccination-trial-in-uganda-(-tokomeza-ebola)
- Monkeypox observational studies on vaccine effectiveness (22 Nov 2022): https://www.who.int/publications/m/item/monkeypox-observational-studies-on-vaccine-effectiveness
- Mpx situation report #14 (14 Dec 2022): https://www.who.int/publications/m/item/multi-country-outbreak-of-mpox--external-situation-report-12--14-december-2022

5.6 Other items of relevance to vaccine preventable diseases

- Immunisation and Vaccine related Implementation Research Advisory Committee (IVIR-AC) (12-14 September 2022): https://www.who.int/groups/immunization-and-vaccines-related-implementation-research-advisory-committee

https://terrance.who.int/mediacentre/data/sage/220912-IVIR-AC-Pink--Book-Sept-2022.pdf

  - Final minutes and publication in the Weekly Epidemiological Record are not available yet.
  - Topics discussed: COVID-19 vaccine impact modelling, influenza vaccine assessment, Influenza Vaccine Global Demand Forecasting tool, Pneumococcal Conjugate Vaccine use in humanitarian crises, Measles Case Fatality Ratio estimation, TB Full Value of Vaccine Assessment (FVVA), MR-MAP initial Full Value of Vaccine Assessment (MR-MAP iFVVA), IA2030 vaccine impact estimates, Vaccine Impact Modelling Consortium (VIMC).

- Thirty-third meeting of the International Health Regulations (2005) (IHR) Emergency Committee on the international spread of poliovirus (1 November 2022): https://www.who.int/news/item/01-11-2022-statement-of-the-thirty-third-polio-ihr-emergency-committee
  - Reviewed the data on wild poliovirus (WPV1) and circulating vaccine derived polioviruses (cVDPV) in the context of global eradication of WPV and cessation of outbreaks of cVDPV2 by end of 2023.
  - Technical updates were received about the situation in the following countries and territories: Afghanistan, Algeria, Malawi, Mozambique, Pakistan, the United Kingdom of Great Britain and Northern Ireland, the United States of America and Yemen.
  - Temporary recommendations:
  - States infected with WPV1, cVDPV1 or cVDPV3 with potential risk of international spread should:
    - Ensure that all residents and long-term visitors (> four weeks) of all ages, receive a dose of bivalent oral poliovirus vaccine (bOPV) or inactivated poliovirus vaccine (IPV) between four weeks and 12 months prior to international travel.
    - Ensure that those undertaking urgent travel (within four weeks), who have not received a dose of bOPV or IPV in the previous four weeks to 12 months, receive a dose of polio vaccine at least by the time of departure.
    - Ensure that such travellers are provided with an International Certificate of Vaccination or Prophylaxis in the form specified in Annex 6 of the IHR to record their polio vaccination and serve as proof of vaccination.
    - Restrict at the point of departure the international travel of any resident lacking documentation of appropriate polio vaccination.
  - States infected with cVDPV2, with or without evidence of local transmission should:
    - Consider requesting vaccines from the global mOPV2 stockpile based on the recommendations of the Advisory Group on mOPV2.
    - Those with local transmission should encourage residents and long-term visitors to receive a dose of IPV four weeks to 12 months prior to international travel.
  - States no longer infected by WPV1 or cVDPV, but which remain vulnerable to re-infection by WPV or cVDPV should: urgently strengthen routine immunisation to boost population immunity; enhance surveillance quality to reduce the risk of undetected WPV1 and cVDPV transmission.

- 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.

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/resources/article

Note: only key updates are provided in this summary

- No new updates since the last summary.

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

7 Upcoming meetings and agendas

ACIP, USA (https://www.cdc.gov/vaccines/acip/meetings/index.html)

- 2023: 22-23 February; 21-22 June; 25-26 October
- 2024: 28-29 February; 26-27 June; 23-24 October

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

- 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)

- 2023: 6-7 February; 27-28 April; 5-6 June; 11-12 September; 15-16 November

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

- 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

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

ACV (https://www.tga.gov.au/committee/advisory-committee-vaccines-acv)

- The dates for the 2023 ACV meetings have not yet been announced.

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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

Novavax NVX-CoV2373 vaccine against COVID-19

- Interim recommendations for use of the Novavax NVX-CoV2373 vaccine against COVID-19 (updated 27 September 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-novavax-nvx-cov2373
    - Annexes to the interim recommendations for use of the Novavax NVX-CoV2373 vaccine against COVID-19 (updated 27 September 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-Novavax-NVX-CoV2373-annexes

Variant-containing COVID-19 vaccines

- Good practice statement on the use of variant-containing COVID-19 vaccines (17 October 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccines-SAGE-Variants-2022.1

COVID-19 Vaccine Effectiveness

- Evaluation of COVID-19 vaccine effectiveness in a changing landscape of COVID-19 epidemiology and vaccination (3 October 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccine_effectiveness-VE_evaluations-2022.1

General COVID-19 vaccination

- WHO policy brief: Reaching COVID-19 vaccination targets (14 September 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-Policy_Brief-Vaccination-2022.1

8.2 Additional ACIP meetings focused on COVID-19 vaccines

Additional meetings were held on:

- 19-20 October 2022 [as a subsection]: https://www.cdc.gov/vaccines/acip/meetings/slides-2022-10-19-20.html

Briefly, the following topics were covered in these meetings:

- Epidemiology of COVID-19 and COVID-19 vaccine coverage in pregnant women
- mRNA vaccine safety in pregnancy
- mRNA vaccine effectiveness of maternal vaccination

- Epidemiology of COVID-19 and COVID-19 vaccine coverage in infants aged 0-5 months

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

- Canadian Immunization Guide COVID-19 chapter (last updated 31 October 2022): https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-26-covid-19-vaccine.html
- Current vaccine statements:
    - Published 7 October 2022: Updated guidance on COVID-19 vaccine booster doses in Canada

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

        - Summary: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/guidance-covid-19-vaccine-booster-doses/summary-october-7-2022.html
    - Published 21 October 2022: Recommendations on the use of Pfizer-BioNTech Comirnaty (3 mcg) COVID-19 vaccine in children 6 months to 4 years of age

https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-pfizer-biontech-comirnaty-3-mcg-covid-19-vaccine-children-6-months-4-years.html

        - Summary: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-pfizer-biontech-comirnaty-3-mcg-covid-19-vaccine-children-6-months-4-years/summary-october-21-2022.html
    - Published 3 November 2022: Recommendations on the use of Moderna Spikevax BA.4/5 bivalent mRNA (50 mcg) COVID-19 booster vaccine in adults

https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/summary-national-advisory-committee-immunization-november-3-2022-recommendations-use-moderna-spikevax-bivalent-mrna-50-mcg-covid-19-booster-vaccine-adults.html

    - Published 9 December 2022: Updated recommendations on the use of COVID-19 vaccine booster doses in children 5 to 11 years of age and concurrent vaccine administration

https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/updated-recommendations-use-covid-19-vaccine-booster-doses-children-5-11-years-concurrent-administration.html

        - Summary: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/updated-recommendations-use-covid-19-vaccine-booster-doses-children-5-11-years-concurrent-administration/summary-december-9-2022.html

8.4 COVID-19 related TGA media releases

- Updates related to COVID-19 vaccines can be found here: https://www.tga.gov.au/products/covid-19/covid-19-vaccines
- COVID-19 vaccines undergoing evaluation (page updated 13 December 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