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: 20/01/2022 – 18/05/2022

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

Pneumococcal conjugate vaccines

- ACIP evaluated use of 15vPCV in children (phase 2-3 study results in children), with a recommendation to be made in June 2022.
- In the UK, 13vPCV not recommended for use in adults. A cost-effectiveness model for the adult program considering 23vPPV and high valency PCV has been proposed by JCVI.

HPV vaccines

- WHO SAGE advised that countries may now choose between a one-dose or two-dose schedule for 9-14 year old girls, and young women aged 15-20 years.
- JCVI advised a move to a one dose schedule for nine-valent HPV vaccine for children up to and including the age of 14 years old; aiming for rollout to coincide with new academic year (Sep 2022). A 2 dose schedule is now recommended for all eligible age groups (other than immunocompromised people).

Combination infant vaccine (Vaxelis, DTaP-IPV-Hib-HepB)

- Vaxelis (DTaP-IPV-Hib-HepB) available for use in UK's routine infant schedule as of February 2022. Potentially related schedule changes to other vaccines for age <2 years are under consideration.

Influenza vaccines

- In the USA, GRADE evaluation of enhanced influenza vaccines (high dose, adjuvanted and recombinant) versus standard influenza vaccines concluded evidence favouring enhanced over standard vaccines, but insufficient evidence of superiority of enhanced vaccines types over one another.
- Funded influenza vaccine has been extended to Maori and Pacific peoples aged 55-64 years in New Zealand.
- In the UK,
  - Healthy 50-64 year olds are not included in the 2022/23 season (included in 2021/22).
  - Considering either live attenuated or inactivated influenza vaccine for age <2 years.

Hepatitis A vaccines

- SAGE recommended the use of inactivated hepatitis A vaccines as either a single-dose or 2-dose schedule in countries with endemic disease.

Hepatitis B vaccines

- A 3-antigen hepatitis B vaccine, PreHevbrio, has been recommended as an alternative for adults in the USA and the UK.

Contents

1 Advisory Committee on Immunisation Practices (ACIP), USA

1.1 ACIP meeting 23-24 February 2022

- Meeting agenda: https://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2022-02-23-24-508.pdf
- Presentation slides: https://www.cdc.gov/vaccines/acip/meetings/slides-2022-02-23-24.html
- Immunisation schedule: https://www.cdc.gov/vaccines/schedules/index.html

Tickborne Encephalitis (TBE) Vaccine

- 13 August 2021: FDA approved a TBE vaccine (manufactured by Pfizer as TICOVAC) (no TBE vaccine previously licensed in U.S)
- Proposed TBE vaccine recommendations following TBE Vaccine Work Group consideration and GRADE assessment:
    - Laboratory workers: TBE vaccination is recommended for laboratory workers with a potential for exposure to TBE virus.
    - Persons who travel abroad: TBE vaccine is recommended for persons who are moving abroad or traveling to a TBE-endemic area and will have extensive exposure to ticks based on their planned outdoor activities and itinerary. TBE vaccine might be considered for persons traveling or moving to a TBE-endemic area who might engage in outdoor activities in areas ticks are likely to be found (decision to be based on risk of exposure, access to medical care and tolerance of risk).

Cholera Vaccine

- Lyophilized CVD 103-HgR: a single-dose, oral, live-attenuated bacterial vaccine; only cholera vaccine licensed for use in USA; available beginning 1 May 2022
    - Licensed for use in adults aged 18–64 years
- **Policy question:** Should ACIP recommend CVD 103-HgR for children and adolescents aged 2–17 years traveling to an area with active cholera transmission?
- **Proposed recommendation:** Lyophilized CVD 103-HgR is recommended for children and adolescents aged 2–17 years travelling from the United States to an area with active cholera transmission. This decision is based on:
    - Immunobridging study comparing to adults where there was a ≥4-fold rise in serum vibriocidal antibody titre in the 2-5 year and 6-17 year groups. Seroconversion among 6–17 year and 2–5 year age groups was noninferior to adults 18–45 years from a phase 3 lot consistency study based on prespecified 96.7% confidence interval. No paediatric studies directly assessed vaccine effectiveness. Safety data was generally favourable.
- Uncertainties:
    - No clinical trials have evaluated safety or efficacy of booster doses of CVD 103-HgR in preventing cholera
    - Duration of protection beyond the 3-month period evaluated in adults aged 18–45 years is unknown
    - No data on concomitant administration with other vaccines
    - No data regarding CVD 103-HgR in persons with altered immunocompetence

Influenza Vaccines

- Summary of recent U.S influenza activity (as of week ending 12 February 2022): Cumulative hospitalisation rate (FluSurv-NET) is higher than that for the entire 2020-21 season, but lower

than that observed at this time during the four seasons preceding the COVID-19 pandemic; most specimens that are subtyped are A/H3N2 viruses

- Modelling study to assess how a preferential recommendation for enhanced influenza vaccines (EIVs) (e.g. high-dose, adjuvanted, recombinant) over standard influenza vaccines (SD-IVs) in adults 65+ years impact influenza burden over the course of a season
    - Approach: Dynamic modelling using a baseline age-structured SEIR model
    - Primary outcome: hospitalisations averted in adults aged 65+ years
    - With cost parameters at their best case values (0 week delay, 0% reduction in overall coverage), a new recommendation for EIV always has a positive impact on hospitalisations averted in 65+ years
    - With intermediate and worst case values (3 or 6 week delay, 10 or 20% reduction in overall coverage), negative impacts are introduced, ranging from relatively small to more substantial
    - These outcomes (hospitalisations averted in 65+ years) are most sensitive to the % reduction in overall coverage
    - The chance of having a positive impact on hospitalisations averted can be maximised by having timely/adequate access to EIVs, and promoting SD-IVs when EIVs are not available
- **Influenza Vaccines for Older Adults: GRADE summary**
- **Question:** Do the relative benefits and harms of high dose inactivated influenza vaccines, aTIV, and RIV (referred to collectively as enhanced influenza vaccines, or EIVs) as compared with one another and with standard-dose unadjuvanted inactivated influenza vaccines (SD-IVs) favour the use of any one or more of these vaccines over other age-appropriate influenza vaccines for persons ≥65 years of age.
- Benefits – Prevention of: influenza illnesses, influenza-associated outpatient/ER visits, influenza-associated hospitalisations, influenza-associated deaths
- Harms – Occurrence of: any serious adverse event (SAE), any solicited injection site adverse reaction Grade ≥3, any solicited systemic adverse reaction Grade ≥3, Guillain-Barre Syndrome (GBS)
- Overall Summary: EIVs vs SD-IVs
    - Limited RCT data; high quality evidence favouring TIV-HD over SD-IV from 1 RCT
    - From observational data, overall Moderate certainty favouring each EIV over SD-IVs against influenza-related hospitalisations
        - Limitations of these data include that most are large retrospective cohort studies for which outcomes are defined by diagnostic codes rather than laboratory confirmed influenza
        - The largest quantity of data are available for TIV-HD, less for aTIV, and least (1 study) for RIV (FluBlok)
    - Few differences in safety outcomes overall (and none for critical outcomes):
        - Low certainty of evidence favouring TIV-HD over SD-IV for any SAE
        - Low certainty of evidence favouring SD-IV over aTIV for solicited injection site adverse reaction Grade ≥3
    - Overall, there is evidence of benefits favouring each EIV over SD-IVs
- Overall Summary: EIVs vs One Another
    - Very limited, Very low certainty RCT data

    - From Observational data, Moderate quality evidence favouring RIV (FluBlok) over TIV-HD and aTIV against hospitalisation; however, this is from one retrospective cohort study conducted over a single season
    - No safety differences among the three EIV comparisons
    - Overall, evidence providing direct comparisons of EIVs with one another does not indicate superiority of one over the others
- Limitations of GRADE assessment include:
    - Few RCT data overall, representing few influenza seasons
    - No data reflecting currently available formulations of high-dose inactivated influenza vaccines and aTIV (which are now quadrivalents—high-dose-QIV and aQIV); Prelicensure studies have generally indicated similar immunogenicity of quadrivalent vaccines and their trivalent counterparts

Hepatitis B Vaccine

- In 2021, ACIP approved universal hepatitis B (HepB) vaccine recommendations for adults ages 19 through 59 years; FDA approval of PreHevbrio, a three-antigen HepB vaccine
- PreHevbrio will be incorporated into the 2023 immunisation schedule
- Policy question: Should PreHevbrio be recommended as an option for adults recommended for hepatitis B (HepB) vaccination?
- Recommendation following GRADE assessment**:** PreHevbrio may be used as a HepB vaccine in persons aged ≥18 years recommended for vaccination against hepatitis B virus (HBV) infection. Decision based on:
    - Evidence suggesting seroprotection conferred by PreHevbrio is noninferior to that conferred by other U.S.-recommended 3-dose HepB vaccines (EngerixB)
    - No difference in safety profile compared with Engerix-B
- Additional considerations: The safety and effectiveness of PreHevbrio have not been established in adults on haemodialysis, pregnant persons and persons who are breastfeeding.

MMR Vaccine Workgroup

- Currently only one licensed measles, mumps, rubella (MMR) vaccine in the U.S. (M-M-R II, Merck)
- ACIP MMR Vaccine Work Group (WG) established in January 2022 to evaluate safety and immunogenicity of Priorix (GSK), compared to M-M-R II
- Five phase III US studies evaluating immunogenicity and safety of PRIORIX compared to M-M-R II (four studies also evaluated co-administration) in 12-15 month, 4-6 years, and ≥7 years age groups
- Priorix safety profile (administered alone or concurrently with other routine vaccines) is acceptable and comparable to that of M-M-R II
- Vaccine can be administered interchangeably to individuals who received a previous vaccination with M-M-R II or ProQUAD
- 22-23 June 2022: WG will present policy options for consideration by ACIP (pending FDA licensure)

Pneumococcal Vaccines

- 15vPCV Licensure anticipated Quarter 1–2 2022; 20vPCV Licensure anticipated Q2 2023
- Policy questions:

    - Should 15vPCV be routinely recommended for U.S. children ≤2 years of age?
    - Should 15vPCV be recommended for U.S. children with underlying medical conditions 2–18 years of age?
- The Work Group is currently not considering any change in recommended pneumococcal vaccination dosing or schedule

- **<u>Epidemiology of pneumococcal disease and impact of pneumococcal vaccine</u>** on invasive pneumococcal disease (IPD), pneumonia in children, and acute otitis media (AOM) in children
    - Among children aged <5 years, overall and 13vPCV-type IPD incidence plateaued since 2013-2014; incidence of invasive disease caused by 15vPCV serotypes has also remained stable
    - In children 5-18 years, rates of IPD are low (1.4 cases per 100,000); 25% had an indication for 13vPCV
    - All-cause and pneumococcal pneumonia in children:
        - Modest declines over time, varied by age group. Analysis of US insurance claims data 2008-9 vs. 2014 showed 17-35% reduction in all-cause pneumonia rates depending on age group; largest reduction among children <2 years old
        - Estimates of rates vary across study. In one study pneumococcal pneumonia among hospitalized children age <5 years (2011-2012) was 6-18 per 100,000
        - Limited data on serotype distribution
    - AOM:
        - Modest declines among younger children, less in older children. Analysis of US insurance claims data 2008 vs 2014 showed 14% reduction in AOM among children aged ≤1 year
        - Burden of AOM in children remains high
        - S. pneumoniae accounted for an estimated 24% of disease in children with clinically diagnosed AOM
    - AOM and IPD data show that the two additional serotypes included in 15vPCV cause 8–17% of remaining pneumococcal disease in children aged <5 years
- **<u>15vPCV Phase 2-3 study results in children</u>**
- In the post-PCV era, serotypes 3, 22F, and 33F are leading causes of IPD in children <5 years of age in the US
- Merck 15-valent PCV (V114) clinical studies in phase-3 Paediatric Program
    - Nine multi-centre, randomized, double blind studies
        - 3 pivotal trials (3+1 or 2+1) in healthy infants; 3 supportive trials (catch-up, interchangeability and safety); and 3 trials in special populations
    - Total Phase 3 paediatric study population: ~8,500 participants, with ~5,300 receiving 15vPCV
    - Infant preterm population: ~290 participants, with ~140 receiving 15vPCV
- From the 3 supportive trials and 3 trials in special populations, vaccination with 15vPCV was well tolerated with a safety profile that is generally comparable to 13vPCV, in:
    - healthy children, 7 months through 17 years of age, receiving catch-up vaccination
    - children with sickle-cell disease (SCD), 5-17 years of age, receiving 1 dose of 15vPCV
    - heathy infants receiving mixed dosing, 13vPCV-15vPCV

    - children living with HIV, 6-17 years of age, receiving 1 dose of 15vPCV followed by 23vPPV
    - Preterm infants
- 15vPCV was immunogenic in all studied populations. From the pivotal 3+1 trial in healthy infants (2, 4, 6, 12-15 months) and 3 supportive trials, 15vPCV induced IgG responses comparable for the shared serotypes and higher for 2 serotypes unique to 15vPCV as compared with 13vPCV
    - responses to shared serotype 3 (ST3) were consistently higher in the 15vPCV group (the single most frequent serotype causing residual disease)
    - 15vPCV is superior to 13vPCV based on the proportion of responders for serotypes 22F (98.6% vs 3.5%) and 33F (87.3% vs 2.1%), which are of high Public Health importance (2 serotypes unique to 15vPCV)
    - 15vPCV is associated with an increase in functional antibodies for all 15 serotypes
    - Mixed dosing elicit comparable responses for the shared serotypes, and higher responses for the unique serotypes in recipients of at least 1 dose of 15vPCV as compared with 13vPCV regimen [GMC of anti-PnP IgG assessed using PnECL assay]
    - Immune response is maintained when 15vPCV is followed by 23vPPV 8 weeks later
    - The pattern of immune responses in preterm infants is consistent with that observed in the overall healthy infant population
- **Conclusion:** 15vPCV has the potential to significantly address the burden of remaining pneumococcal disease due to vaccine-types (including serotype 3) and leading nonvaccine type (serotypes 22F, 33F) in children
- **<u>GRADE assessment: Use of 15-valent Pneumococcal Conjugate Vaccine in Children</u>**
- PICO Question 1: Should 15vPCV be recommended as an option for pneumococcal conjugate vaccination according to currently recommended dosing and schedules, for U.S. children younger than two years of age?
- PICO Question 2: Should 15vPCV be recommended as an option for pneumococcal conjugate vaccination according to currently recommended dosing and schedules, for U.S. children aged 2-18 years with underlying medical conditions?
- Notable considerations included:
    - AOM one of most common reasons for outpatient care in children; pneumococcus one of most common bacterial causes
    - 25% IPD in children aged 6-18 years was in children with immunocompromising conditions
    - Moderate desirable anticipated effects for 15vPCV routine use in children <2 years of age and children with underlying medical conditions 2 - 18 years of age: No 15vPCV studies directly assessed clinical outcomes; anticipated that improved immune response against two additional serotypes translates to clinical effectiveness
    - Minimal undesirable anticipated effects for 15vPCV routine use in children <2 years of age and children with underlying medical conditions 2 - 18 years of age
    - Responses split between “favours intervention” and “favours both”; moderate certainty of evidence for effectiveness and safety in healthy children and low certainty for safety in children with underlying medical conditions
- Equity considerations:

- IPD rates in Native American children decreased after 13vPCV use, but remain 4x higher compared to children of all races in 2018; Alaskan Native infant OM-associated outpatient visit rate 1.6-fold higher than general U.S. infant population
- These populations experience cyclical outbreaks due to serotype 12F which is not included in 13vPCV, but is included in 23vPPV
- WG split in responses re impact of 15vPCV for health equity in US children likely due to uncertainty regarding whether 15vPCV use will improve healthy equity compared to 13vPCV use – considered "probably increased"

- Next steps: June 2022 – EtR part 2 and cost-effectiveness; vote on recommendations (if product has been licensed for use)

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 Zoster Vaccine Recommendations

- MMWR; 21 January 2022: https://www.cdc.gov/mmwr/volumes/71/wr/mm7103a2.htm
- ACIP recommends: Two recombinant zoster vaccine (RZV) doses for prevention of herpes zoster and related complications in immunodeficient or immunosuppressed adults aged ≥19 years.
- Primary updates:
  - Immunodeficient or immunosuppressed people who would benefit from a shorter vaccination schedule, the second dose can be administered 1–2 months after the first. Minimum interval between doses is 4 weeks.
  - RZV can be administered concomitantly, at different anatomic sites, with other adult vaccines, including COVID-19 vaccines.
  - Immunocompromised persons with evidence of immunity to varicella should receive two doses of RZV. For immunocompromised adults with no documented history of varicella, varicella vaccination, or herpes zoster, providers should refer to the ACIP varicella vaccine recommendations for further guidance, including post-exposure prophylaxis guidance.
  - Currently no ACIP recommendation for RZV use in pregnancy, therefore providers should consider delaying RZV until after pregnancy.

1.2.2 Pneumococcal Vaccine Recommendations

- MMWR; 28 January 2022: https://www.cdc.gov/mmwr/volumes/71/wr/mm7104a1.htm
- Updates reflect changes to recommendations agreed to at 20 October 2021 meeting
- Primary updates:
  - The recommended interval between administration of 15vPCV and 23vPPV is ≥1 year. A minimum interval of 8 weeks can be considered for adults with an immunocompromising condition, cochlear implant, or cerebrospinal fluid leak to minimize the risk for IPD caused by serotypes unique to 23vPPV in these vulnerable groups.

- Adults who have only received 23vPPV may receive a PCV (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.
- The incremental public health benefits of providing 15vPCV or 20vPCV to adults who have received 13vPCV only or both 13vPCV and 23vPPV have not been evaluated. These adults should complete the previously recommended 23vPPV series.
- 15vPCV, 20vPCV, or 23vPPV has been demonstrated to be immunogenic and safe when coadministered with aQIV in an adult immunisation program. Currently, no data are available on coadministration with other vaccines.

1.2.3 Ebola Vaccine Recommendations – ERVEBO vaccine

- MMWR; 25 February 2022: https://www.cdc.gov/mmwr/volumes/71/wr/mm7108a2.htm
- ACIP recommends: Preexposure vaccination with ERVEBO for adults aged ≥18 years in the U.S. population who are at high risk for potential occupational exposure to Ebola virus:
  - Health care personnel involved in the care and transport of patients with suspected or confirmed EVD at SPTCs, or
  - Laboratorians and support staff members at LRN facilities that handle specimens that might contain replication-competent Ebola virus (species *Zaire ebolavirus*)

1.2.4 Hepatitis B Vaccine Recommendations

- MMWR; 1 April 2022: https://www.cdc.gov/mmwr/volumes/71/wr/mm7113a1.htm
- ACIP recommends Hepatitis B (HepB) vaccination for adults aged 19–59 years and adults aged ≥60 years with risk factors for hepatitis B. Adults aged ≥60 years without known risk factors for hepatitis B may also receive HepB vaccines. Infants and all other persons aged <19 years are already recommended to receive HepB vaccines.
  - Primary updates:
    HepB vaccination is now universally recommended for adults aged 19-59 years. Anyone aged 60 years or older who does not meet risk-based recommendations may still receive Hepatitis B vaccination.
  - Providers should vaccinate pregnant women needing HepB vaccination with Engerix-B, Recombivax HB, or Twinrix (safety data on PreHevbrio is insufficient).

2 Immunisation Advisory Centre (IMAC), New Zealand

2.1 PTAC Considerations

Meetings were held on:

- 18 – 19 November 2021 (no vaccine specific considerations): https://pharmac.govt.nz/assets/2021-11-PTAC-meeting-record.pdf
- 17 – 18 February 2022: Minutes are not available yet. No vaccine specific applications were listed for review. https://pharmac.govt.nz/about/expert-advice/pharmacology-and-therapeutics-advisory-committee-ptac/

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 – 13 December 2021

- Focus on MMR campaign restart – aim to ensure that children receive MMR vaccines on time, and closing the immunity gap in those born between 1989 and 2004, who may have missed out on MMR vaccinations. Improving MMR data collection, proactive checking of MMR vaccination status, and ability to concomitantly administer MMR vaccine with COVID-19 vaccine provide opportunities to increase MMR uptake.

2.2.2 Immunisation Update – 21 February 2022

- COVID-19 vaccine rollout for children aged 5 to 11 years – eight week interval between doses; reduced dosing interval can be used if clinically indicated or if best approach for psychosocial circumstances – minimum interval of 3 weeks.
    - Updated guidance: https://covid.immune.org.nz/sites/default/files/2022-02/8%20week%20interval%20for%205%20to%2011y%20old%20vaccination.pdf
    - COVID-19 Immunisation Clinical Toolkit – February 2022: https://covid.immune.org.nz/sites/default/files/2022-02/IMAC_C19_Clinical_Toolkit_FEBRUARY.pdf
- COVID-19 boosters encouraged from 3 months after completion of primary course, including for pregnant women who had 3 doses as a primary course.
    - Pfizer COVID-19 vaccine is the preferred booster
    - Astra-Zeneca COVID-19 vaccine is available off-label as a booster for those unable to have Pfizer or who prefer it.
- Influenza immunisation programme to begin on 1 April 2022 – prioritising people at high risk of serious illness if they catch influenza, including people over 65, those who are pregnant and those with certain chronic health conditions.
- Other updates on MMR campaign restarting, working to develop a local education model for renewal of yellow fever vaccinator authorisation, reopening of Provisional Vaccinator Course (run by IMAC).

2.2.3 Immunisation Update – 31 March 2022

- Pharmac announced access to nationally-funded influenza vaccine from 1 April 2022 has been widened to include Māori and Pacific peoples who are 55-64 years of age.
- Novavax COVID-19 vaccine available for adults 18 years and older – prescription is required for anyone receiving Novavax as a second dose, if their first dose was a COVID-19 vaccine other than Novavax. Not approved as a booster vaccine.
- COVID-19 vaccination in children –
    - If a child has had COVID-19 they have a 3 month gap before their next COVID vaccination dose, regardless of whether it is dose one or two.
    - Those who started on the paediatric dosing schedule should continue on it even if they have since turned 12.
- Other updates on catch-up of other vaccine preventable diseases (e.g. MMR campaign), enrolled nurses as full vaccinators.

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

3.1 JCVI meeting: 15 December 2021

- A summary of the JCVI meeting held in December is provided below
- Agenda: https://app.box.com/s/9f24lity6bqso9b6qi7c/file/895680334752
- Endorsed minutes, 15 December 2021: https://app.box.com/s/iddfb4ppwkmtjusir2tc/file/917206905793

- Infant schedule
  - February 2022: Vaxelis (DTaP-IPV-Hib-HepB) will be available for use as well as Infanrix Hexa in the routine schedule
  - Oxford Vaccine Group 6 in 1 (DTaP-IPV-Hib-HepB) study
  - RCT comparing the immunogenicity, reactogenicity and safety of the two hexavalent vaccines (Vaxelis and Infanrix Hexa). Vaccines were given in line with the current routine immunisation schedule (three visits).
    - Study immunisation schedule: Infanrix Hexa or Vaxelis with MenB and Rotavirus (2 months); Infanrix Hexa or Vaxelis with Rotavirus and 13vPCV (3 months); Infanrix Hexa or Vaxelis with MenB (4 months); Infanrix Hexa or Vaxelis with Hib-MenC and 13vPCV and MMR and MenB (12 months).
    - Local reactogenicity results showed little difference and no consistent pattern between the two vaccines across the three visits. There were slightly higher rates of severe erythema, swelling, and moderate fever with Vaxelis. The Committee noted that prophylactic paracetamol use is recommended for visit one and three due to co-administration with the MenB vaccine.
    - Vaxelis immunogenicity against Hib met non-inferiority criteria against Infanrix Hexa. There were differences in the response to pertussis as both vaccines contain different pertussis components. Antibody response for diphtheria and pneumococcus at 5 months was higher with Infanrix Hexa, but this trend was not evident at 13 months. Vaxelis had a higher response to the tetanus toxoid, while Infanrix Hexa was higher for HepB response.
  - It was noted that slightly lower levels for diphtheria and others seen with Vaxelis were probably not important with plans for an additional dose in a potential new schedule, the higher antibodies for Hib at 5 months persisting was reassuring that Hib could be delayed if needed; the impact on the immunogenicity was likely to be nil or favourable on the concomitant routine infant vaccinations.
  - A concern raised was the recent pneumococcal schedule change in 2020 (1+1 at 12 weeks and 12-13 months; replaced 2+1) was in place which relies on enduring high levels of antibody for pneumococcal disease to create prolonged carriage effects and that a switch to using only Vaxelis would reduce the antibodies to ~8 serotypes; the effect on additional serotypes in a higher valency pneumococcal vaccine is currently not known.
    - From Oxford Group study: At 5 months trends for higher IgG GMC for Infanrix Hexa coadministered with 13vPCV than for Vaxelis coadministered with 13vPCV across multiple serotypes. At 13 months (following the second dose) this trend is not as evident.

- Potential schedule change: single dose of MenACWY at 12 months and an additional dose of Hib containing vaccine (DTaP-IPV-Hib-HepB) at 18 months.
    - Considerations: The schedule change would require an additional visit, however second dose of MMR (currently scheduled at 3 years and 4 months) could be brought forward to 18 months – would likely improve MMR uptake due to accessibility. A three-dose accelerated schedule for DTaP-IPV-Hib-HepB (3+1) would be better for operational delivery and achieving high coverage. The Hib boost at 18 months should be similar with either vaccine.
    - Concerns: Concern around the resilience of the programme supply if switching completely to a single brand of DTaP-IPV-Hib-HepB; additional studies examining use of Vaxelis/Infanrix specifically for priming or boosting would be beneficial.
- Potential schedule change: addition of MenACWY at 12 months (currently scheduled at around 14 years of age). JCVI concluded that further information is needed on the persistence of the indirect benefit from the teenage MenACWY vaccine with normal social mixing patterns post pandemic.
- It was noted that higher valency PCV vaccines may become available for the infant schedule in the future, and therefore the current schedule for PCV (1+1) may need to be reconsidered. There is a pneumococcal sub-committee planned for 2022.

- HPV
    - JCVI agreed that there was enough evidence to advise a move to a one dose schedule for the nine-valent HPV vaccine (9vHPV) in the adolescent programme for children up to and including the age of 14 years old.
    - Data considered included more than 10 years of data on efficacy with both the bivalent and quadrivalent vaccine, robust shorter term efficacy data for the nine-valent vaccine and sustained and consistent immunogenicity data that allowed immunobridging from the quadrivalent to the nine-valent vaccine.
        - JCVI Interim advice: https://www.gov.uk/government/publications/single-dose-of-hpv-vaccine-jcvi-interim-advice/jcvi-interim-advice-on-a-one-dose-schedule-for-the-routine-hpv-immunisation-programme
    - Implementation of one dose schedule is undergoing consultation, currently no set timeline for switch to single dose, but aim to rollout with the start of the academic year (September 2022). Effect of shift to single dose on coverage is unknown due to decreased opportunities for catch up but increased capacity/resources for follow up.
    - Additional HPV vaccine updates (not discussed at this specific JCVI meeting):
        - Updated recommendations for adult MSM aged ≥15 years: from 1 April 2022, adult gay and bisexual men and MSM can received 2 doses of HPV vaccine (instead of 3 doses) 6 months apart to be fully vaccinated. Press release: https://www.gov.uk/government/news/gay-and-bisexual-men-and-those-aged-15-and-over-to-receive-2-doses-of-hpv-vaccine
        - Updates to the Green Book HPV chapter (31 March 2022) made to reflect switch to a 2-dose schedule (0, 6-24 months) for all ages and HPV vaccines (3 dose recommendation for immunocompromised remains). Note, updates to reflect interim recommendation on single dose schedule not made yet.

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1065283/HPV-greenbook-chapter-18a.pdf

- MHRA Yellow Card report
  - The number of Yellow Card reports have remained relatively stable, however a decrease in reports for schools-based immunisations was noted which mirrors the decrease in coverage/uptake due to the pandemic/lockdowns. Overall, there were small numbers of reports with fatal outcomes, these cases have been reviewed and were found to be unrelated to the vaccines. No new safety concerns have been identified.
- Influenza
  - The influenza programme for the 2021/22 season had been extended for children up to Year 11 in secondary schools and in adults to include otherwise healthy 50-64 year olds. If funding and supply is limited, the most vulnerable cohorts should be prioritised over the otherwise healthy 50-64 year olds and given the most effective vaccines available: first QIVr or QIVc; while QIVe should be reserved for otherwise healthy 50-64 year olds.
  - Current influenza activity this season: less than 1% of laboratory tests were positive for influenza; of those subtyped most were predominantly influenza A (H3N2) and a good match to vaccine strain. Influenza B Yamagata lineage may be disappearing. The programme was performing well in terms of vaccine uptake and higher than at this stage last year for those aged 65 and older and for at-risk groups aged 6 months to under 65 years.
  - Future considerations:
    - a routine programme for otherwise healthy children aged 6 months to two years old;
    - what the appropriate mortality assessment was to use in impact and cost-effectiveness analyses for influenza and,
    - the impact of successive seasonal vaccination, which has been recently reviewed by WHO SAGE.
  - Final decision: While otherwise healthy 50-64 year olds were eligible in the 2021/2022 season, they were not included in the program for the 2022/2023 season. (National flu immunisation programme 2022 to 2023 letter: https://www.gov.uk/government/publications/national-flu-immunisation-programme-plan/national-flu-immunisation-programme-2022-to-2023-letter)
- Monkey Pox and other business
  - JCVI received a request for advice supporting the option of having the MVA smallpox vaccine to protect against monkeypox for those working in high consequence infectious disease (HCID) units. It was noted that the MVA smallpox vaccine was only licensed against smallpox not monkeypox so this would be off label advice. JCVI agreed with the advice to offer the MVA Smallpox vaccination to healthcare workers in HCID settings.
  - Need to consider varicella vaccination as part of the considerations around changes to the routine childhood schedule and that shingles vaccination with the Shingrix vaccine also needed further consideration on the issues of catch-up and for those aged over 80 years.

3.2 JCVI meeting: 9 March 2022

- A summary of the JCVI meeting held in March is provided below
- Agenda: https://app.box.com/s/9f24lity6bqso9b6qi7c/file/926758815629
- Draft minutes, 9 March 2022: https://app.box.com/s/iddfb4ppwkmtjusir2tc/file/947702344531

- Influenza
  - Vaccine effectiveness of repeat influenza vaccination: JCVI agreed the evidence still supported annual vaccination. There were evidence gaps around whether having a year off from annual vaccination might be beneficial but there was not enough evidence to support that approach.
    - Initially raised whether repeat vaccination might attenuate vaccine effectiveness as some studies had indicated such an effect. WHO SAGE presentation included a systematic review and meta-analysis summarising the findings of repeat vaccination on vaccine effectiveness of influenza vaccine; GRADE assessment concluded low evidence to support a change in policy. Further work needed to characterise the conditions under which A(H3N2) VE is compromised and whether it is consistent with existing hypotheses (e.g. antigenic distance).
  - Scoping of influenza vaccination in children under two years old:
    - good quality evidence for efficacy of flu vaccines in under-2s was lacking but the evidence was stronger for live attenuated influenza vaccine (LAIV) than inactivated influenza vaccine (IIV);
    - LAIV does cause transient wheezing in some under-2s but does not seem to be associated with subsequent diagnosis of asthma; the immune response to LAIV is distinct from the response to IIV in particular the induction of cell-mediated immune responses and mucosal IgA responses, both of which may be protective;
    - priming with IIV inhibits LAIV strain shedding less effectively than LAIV priming – but both vaccine types may have indirect protective effects, and
    - LAIV may influence transmission dynamics of upper respiratory bacteria but any such effects are likely to be outweighed by its effects on influenza.
  - Conclusions: JCVI agreed the issues of vaccinating the under twos and modelling of mortality merited further consideration and that the influenza subcommittee should meet to review these issues. JCVI agreed it would be helpful to explore the feasibility of a study to generate safety data on LAIV in the 12 month to 2 year old age group.
- Update from pneumococcal sub-committee
  - The EMA and FDA have recently approved 20vPCV for the prevention of IPD and pneumonia in adults. In 2015, 23vPPV was retained as part of the UK adult programme; 13vPCV was not considered cost effective due to the indirect effects of 13vPCV from the infant schedule. However, data from the UK show that 23vPPV vaccine effectiveness wanes rapidly, and therefore administering at age 65 years may not achieve optimal protection.
    - Recent increase in IPD cases in those under 15-years of age; reached a nadir in February 2021, when they accounted for 8% of the pre-pandemic 3-year average for February. Since then, cases have increased gradually and by June2021, they were only 25% lower than the pre-pandemic 3-year average for June (Ref Amin-Chowdhury et al. *The Lancet* 2021. https://doi.org/10.1016/S2213-2600(21)00538-5).
  - There is a difficulty in assessing the January 2020 infant PCV schedule change from 2+1 to 1+1 due to the impact on transmission from lockdowns and other restrictions. It is therefore important to follow the data for a longer period of time before considering a change in product due to the reliance on indirect protection.

- The sub-committee proposed that a cost-effectiveness model for the adult programme should be done with options including 23vPPV and high valency PCV vaccines, and to consider the age of vaccination in older adults. A recent WHO study suggested only a modest difference in cost effectiveness between 23vPPV and 13vPCV in adults.

- Hepatitis B
  - Dossier received from VBI vaccines for their three-antigen hepatitis B vaccine (PreHevbrio). The vaccine is derived from mammalian cells rather than yeast cells used for other products. The vaccine had higher reactogenicity compared to other products; however had an acceptable safety and reactogenicity profile. There was no data provided on interchangeability with other products.
  - It was noted that this vaccine may be useful in groups where sero-conversion tends to be low (e.g. haemodialysis and chronic kidney disease), however there was not enough information on the analysis methods to determine the extent of any advantage. There were concerns around supply which may be problematic if a preferential recommendation was made for this specific product.
  - JCVI agreed that the VBI hepatitis B vaccine could be included in the Green Book; however there was not enough information to make a preferential recommendation. Further information on methods, results in special sub-populations, data on interchangeability with other hepatitis B vaccines, and data on concomitant administration with other vaccines should be sought from VBI Vaccines.
- Hepatitis A epidemiology
  - It was noted that the WHO SAGE working group on hepatitis A is to recommend that countries with a high endemicity of hepatitis A universally offer a single dose of hepatitis A vaccine. Currently the UK offers a selective targeted programme aiming to give two doses of hepatitis A containing vaccine to those at high risk of exposure to the virus or of complications from the disease.
  - Overall low incidence of hepatitis A in the UK; when outbreaks occur they tend to be in clusters (including an outbreak among MSM). There tend to be fewer diagnoses in children however this is likely to be due to lower exposure and an increased likelihood of being asymptomatic. Seroprevalence increases with age reaching more than 70% in those aged over 60 years.
  - The JCVI agreed from the data seen there was nothing to suggest that there should be changes to the current programme however noted that it would be helpful to see updated serology when available in the coming years.
- Emergency Preparedness Countermeasures: Vaccines
  - UK Government work specifically considering vaccine stockpiles (no specific vaccine mentioned) for pandemic vaccination, pre-pandemic vaccination and pre-exposure prophylaxis and how vaccines may be deployed in a pre-pandemic setting. This will consider currently licensed vaccines and may also consider vaccines in development.

4 National Advisory Committee on Immunisation (NACI), Canada

4.1 NACI Meetings

The most recent meeting was conducted virtually on 10 May 2022; however, the summary of discussions has not yet been released.
https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/meetings.html

Meeting dates since previous NITAG summary:

- 2022:
    - 25 January
    - 1 February; 15 February
    - 1 March; 22 March
    - 12 April; 26 April
    - 10 May

4.2 Newly published or updated statement/recommendations

There were no new or updated recommendations from NACI other than a number of updates and recommendations for COVID-19 vaccines.

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

- Malaria vaccine: WHO position paper – 4 March 2022:
  https://www.who.int/publications/i/item/WER9709
    - Includes updated recommendations on the wider use of the RTS,S/AS01 vaccine for the reduction of malaria morbidity and mortality in children living in areas of moderate to high malaria transmission. It also incorporates findings from the evaluation of the WHO-coordinated Malaria Vaccine Implementation Programme (MVIP), and from additional studies since 2015. Does not include findings on vaccine efficacy in infants first vaccinated at 6–12 weeks of age.
    - The RTS,S/AS01 malaria vaccine should be used for the prevention of P. falciparum malaria in children living in regions with moderate to high malaria transmission (as defined by WHO), from 5 months of age.
    - Schedule: 3-dose primary schedule with the first dose of vaccine administered from 5 months of age with a minimum interval of 4 weeks between doses. The booster (fourth) dose should be approximately 12–18 months after the third dose. Can be a 5-dose schedule in areas with highly seasonal malaria, or with perennial malaria transmission.
    - Other considerations: The RTS,S/AS01 vaccine may be administered simultaneously with other vaccines of the childhood immunisation programme. Malnourished or HIV-positive infants may be vaccinated with the RTS,S/AS01 vaccine using a standard schedule. The vaccine should be provided to infants and young children aged 5–17 months who relocate to an area of moderate to high transmission, including during emergency situations.

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

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

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

Meeting date: 4 – 7 April 2022

- Meeting details: https://www.who.int/news-room/events/detail/2022/04/04/default-calendar/sage_meeting_april_2022
- Agenda: https://cdn.who.int/media/docs/default-source/immunization/sage/2022/april/draft-sage_agenda_04-07_apr2022_v1april.pdf?sfvrsn=77187eee_6
- Highlights: https://cdn.who.int/media/docs/default-source/immunization/sage/sage-pages/sage_april2022meetinghighlights_11apr2022_final.pdf?sfvrsn=c2bd9f68_1

- Hepatitis A vaccination
  - SAGE recommended the use of inactivated hepatitis A vaccines in childhood immunisation programmes either as a single-dose or two-dose schedule, updating the previous recommendation favouring a 2-dose schedule.
  - New evidence on long-term protection indicates that single- and two-dose schedules of inactivated vaccine are equally effective in preventing the disease and in providing durable sero-protection.
- COVID-19 vaccines
  - SAGE reviewed data on the CanSino COVID-19 vaccine but did not issue any recommendations until such time as the product is listed by WHO for emergency use.
- Typhoid conjugate vaccination
  - New data that demonstrated high efficacy and effectiveness of a single dose of Typhoid conjugate vaccine (TCV) across diverse settings (overall efficacy between 79-88%). There is no indication of waning immunity over 2 years. Seroconversion following a single dose of Typbar-TCV® in adults >45 to 65 years was high and comparable to younger adults 18-45 years of age for whom the vaccine is currently licensed.
  - More data are expected in the next 1-2 years on outstanding questions about the duration of protection and the potential need for booster doses of TCV and an age indication for adults >45 years
- Human Papillomavirus vaccination
  - SAGE advised that countries may now choose between a one- or two-dose schedule for 9–14-year-old girls and young women aged 15–20 years. This off-label single-dose option for routine and multi-age cohort catch-up vaccination was considered because it provides comparable and high levels of individual protection, fewer doses per cancer case prevented, less resource-intensive, and is easier to implement than a two-dose schedule.
  - Two doses with a 6-month interval should be used for females older than 21 years.
  - Boys and older males can follow the same dose schedule as females.
  - Immunocompromised persons aged 9 years and older should be prioritised and receive at least two doses, though three doses would be considered optimal
  - Given the high incidence of HPV-related cancers in immunocompromised persons, those living with HIV, and girls who face sexual abuse, SAGE recommends that they be

considered for vaccination against HPV both within and outside of standard eligibility age-range.
    - Concerns over the 13% decline in global HPV vaccine coverage in 2020 due to COVID-19 related disruptions and limited supply were noted
- Poliovirus vaccines
    - Data presented on the safety and genetic stability data of novel OPV2 (nOPV2) confirming a good safety profile and genetic stability of the vaccine. The establishment of an "Oral Polio Vaccine (OPV) Cessation Team" was endorsed to enable efficient planning and implementation of the withdrawal of OPV from routine immunisation programs one year after certification of wild poliovirus eradication.
- Global updates
    - SAGE noted the unprecedented speed at which COVID-19 vaccines have been rolled out, yet coverage in 21 countries remains below 10% and coverage of high priority groups remains insufficient in some regions. COVAX has sufficient supply to achieve the WHO 70% coverage target by June 2022.
    - Disruptions to routine immunisation persist, including delays of campaigns in 37 countries as of January 2022; large outbreaks of measles have occurred in at least 19 countries in the past 12 months
    - SAGE noted that the ongoing COVID-19 vaccination presents opportunities to strengthen immunisation programs and enhance their resilience, with specific areas identified including health worker vaccination, immunisation logistics and registries, surveillance, data and communications
    - The document "Guiding Principles for recovering, building resiliency, and strengthening of immunization in 2022 and beyond" was endorsed *[document not yet available publically]*

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

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

Meeting date: 16 December 2021

- Meeting details: https://www.who.int/news-room/events/detail/2021/12/16/default-calendar/extraordinary-meeting-of-the-strategic-advisory-group-of-experts-on-immunization-(sage)-16-december-2021
- Agenda: https://cdn.who.int/media/docs/default-source/immunization/sage/2021/december/sage-agenda-16dect2021-virtual-final.pdf?sfvrsn=2b4d396f_5
- Minutes: https://www.gov.uk/government/publications/sage-99-minutes-coronavirus-covid-19-response-16-december-2021
- Topics covered: Novavax NVX-CoV2373 COVID-19 vaccine.

Meeting date: 19 January 2022

- Meeting details: https://www.who.int/news-room/events/detail/2022/01/19/default-calendar/extraordinary-meeting-of-the-strategic-advisory-group-of-experts-on-immunization-(sage)-19-january-2022

- Agenda: https://cdn.who.int/media/docs/default-source/immunization/sage/2022/january/sage_agenda_19_jan_2022_version_17_jan.pdf?sfvrsn=82a9ba61_9
- No meeting minutes are available yet.
- Topics covered: COVID-19 Omicron global update, COVID-19 vaccine booster doses, paediatric COVID-19 vaccination, updated recommendations on Pfizer-BioNTech COVID-19 vaccine.

5.3.1 Other meetings of SAGE where only COVID-19 and COVID-19 vaccines were discussed:

16 December 2021: https://www.gov.uk/government/publications/sage-99-minutes-coronavirus-covid-19-response-16-december-2021

20 December 2021: https://www.gov.uk/government/publications/sage-100-minutes-coronavirus-covid-19-response-20-december-2021

23 December 2021: https://www.gov.uk/government/publications/sage-101-minutes-coronavirus-covid-19-response-23-december-2021

7 January 2022: https://www.gov.uk/government/publications/sage-102-minutes-coronavirus-covid-19-response-7-january-2022

13 January 2022: https://www.gov.uk/government/publications/sage-103-minutes-coronavirus-covid-19-response-13-january-2022

28 January 2022: https://www.gov.uk/government/publications/sage-104-minutes-coronavirus-covid-19-response-28-january-2022

10 February 2022: https://www.gov.uk/government/publications/sage-105-minutes-coronavirus-covid-19-response-10-february-2022

5.4 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
- **45th GACVS meeting on 15 December 2021 (held online):**
- Full report (published 28 March 2022, pages 8-11): https://www.who.int/publications/i/item/who-wer9710-81-96
    - COVID topics covered: Reviewed the work achieved on the safety of COVID-19 vaccines, and the latest evidence on case management for thrombosis with thrombocytopenia syndrome (TTS); general protocol for studying maternal, perinatal, neonatal and postpartum outcomes in women who have COVID-19 disease during pregnancy expanded to include the study of the same outcomes in women who have received at least one dose of a COVID-19 vaccine.
    - Non-COVID topics covered:
        - Reviewed the guidance on vaccine-associated enhanced disease (VAED) as an adverse event of special interest (AESI) and the evaluation criteria 2.0 for Vaccine Safety Net (VSN);

- Vigibase (the global pharmacovigilance database) contains about 28 million reports of adverse events following immunisation (AEFIs), with nearly 2 million related to COVID-19 vaccines received in 2021. Most of the reports are from higher income countries (HICs), but as COVID-19 vaccines are being rolled-out in more low-middle-income countries (LMICs) it will be important that the pharmacovigilance systems are in place to enable them to collect AEFI data from the ground level and transmit them to the global level. To improve the data flow, an app, VigiMobile, is being developed.
- Three activities for maternal immunisation and safety monitoring funded by Bill and Melinda Gates Foundation: identify optimal data models and data elements to implement these in a pilot test in selected countries to assess changes in recording and reporting; landscape analysis of pregnancy exposure registries in LMICs in collaboration with PATH; to monitor the safety of COVID-19 vaccines during pregnancy for adverse maternal and perinatal outcomes, as an amendment to the existing study protocol.

5.5 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

- Previous Session: Session 72; 25 – 29 October 2021: https://www.who.int/westernpacific/about/governance/regional-committee/session-72
- 25 – 29 October 2021 Agenda: https://www.who.int/docs/default-source/wpro---documents/regional-committee/session-72/wpr-rc72-01_provisional_agenda.pdf/
- Working documents which were not available in the last horizon scanning are available now: https://www.who.int/westernpacific/about/governance/regional-committee/session-72/documents
- Summary report from the Chairperson: https://www.who.int/docs/default-source/wpro---documents/regional-committee/session-72/rc72-final-report.pdf?Status=Master&sfvrsn=5fce9a4d_17
    - No vaccine specific considerations covered.
    - Topics covered: school health, traditional and complementary medicine, tuberculosis.

5.6 Global immunisation news and other items and resources

- Latest news: https://www.who.int/news-room/fact-sheets/detail/immunization-coverage
- GIN Aug-Sept 2021: https://cdn.who.int/media/docs/default-source/immunization/gin/gin_august-september2021.pdf?sfvrsn=69774694_1&download=true
- GIN Oct 2021 – Nov 2021: https://cdn.who.int/media/docs/default-source/immunization/gin/gin_october-november2021.pdf?sfvrsn=ba37eee1_1&download=true
- GIN December 2021-January 2022: https://www.who.int/publications/m/item/gin-december-2021---january-2022
- PATH summary on updates and current consideration to HPV vaccination including evidence supporting single dose schedule, April 2022: https://www.path.org/resources/single-dose-hpv-vaccination-current-evidence/

- Press release for WHO's recommendation of single dose HPV vaccination: https://www.who.int/news/item/11-04-2022-one-dose-human-papillomavirus-(hpv)-vaccine-offers-solid-protection-against-cervical-cancer

5.7 COVID-19 related reports, guidelines and publications

- Recent 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
- Disease Outbreak News (DONs): https://www.who.int/emergencies/disease-outbreak-news

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

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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

- 2022 Seasonal Influenza Vaccines: Information for consumers and health professionals (25 March 2022): https://www.tga.gov.au/media-release/2022-seasonal-influenza-vaccines
- Zostavax: Safety advisory - careful assessment and screening for immunocompromise essential before administration of Zostavax (17 February 2022): https://www.tga.gov.au/alert/zostavax

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: 22-23 June; 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: 19–20 May; 18–19 August; 17–18 November

JCVI, UK (https://www.gov.uk/government/policy-advisory-groups/joint-committee-on-vaccination-and-immunisation)

- Future meeting dates pending, but usually the 1st Wednesday of 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: 24 May; 7 June; 21 June

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

- 2022: 4-6 October
- 2023: 21-23 March; 26-28 September
- 2024: 19-21 March; 24-26 September

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

The first joint WHO Global Advisory Committee on Vaccine Safety (GACVS) and WHO Advisory Committee on Safety of Medicinal Products (ACSoMP) meeting will be held on: 14-16 June 2022

WPRO

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

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

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

8 Appendix

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

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

Moderna mRNA-1273 vaccine against COVID-19

- Interim recommendations for use of the Moderna mRNA-1273 vaccine against COVID-19: interim guidance (updated 23 February 2022): https://apps.who.int/iris/handle/10665/352124
    - Annexes to the recommendations for use of the Moderna mRNA-1273 vaccine against COVID-19 (23 February 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-mrna-1273-GRADE-ETR-annexes
- Background document on the mRNA-1273 vaccine (Moderna) against COVID-19 (3 February 2022): https://www.who.int/publications/i/item/background-document-on-the-mrna-1273-vaccine-(moderna)-against-covid-19

ChAdOx1-S [recombinant] vaccine against COVID-19 (AstraZeneca COVID-19 vaccine AZD1222 Vaxzevria™, SII COVISHIELD™)

- Interim recommendations for use of the ChAdOx1-S [recombinant] vaccine against COVID-19 (AstraZeneca COVID-19 vaccine AZD1222 Vaxzevria™, SII COVISHIELD™)

(updated 15 March 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-AZD1222-2021.1

- Annexes to the interim recommendations for use of theChAdOx1-S [recombinant] vaccine against COVID-19 (AstraZeneca COVID-19 vaccine AZD1222 Vaxzevria™, SII COVISHIELD™) (updated 15 March 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-AZD1222-GRADE-ETR-2021.1

- Background document on the AZD1222 vaccine against COVID-19 developed by Oxford University and AstraZeneca (5 March 2022): https://www.who.int/publications/i/item/background-document-on-the-azd1222-vaccine-against-covid-19-developed-by-oxford-university-and-astrazeneca

Novavax NVX-CoV2373 COVID-19 vaccine

- Vaccine explainer: NVX-CoV2373 recombinant, adjuvanted COVID-19 vaccine (9 February 2022): https://www.who.int/publications/m/item/nvx-cov2373-recombinant-adjuvanted-covid-19-vaccine

CoronaVac, developed by Sinovac

- Interim recommendations for use of the inactivated COVID-19 vaccine, CoronaVac, developed by Sinovac (updated 15 March 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-Sinovac-CoronaVac-2021.1
  - Annexes to the recommendations for use of the Sinovac-CoronaVac vaccine against COVID-19: Grading of evidence, Evidence to recommendation tables (updated 15 March 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-Sinovac-CoronaVac-annexes-2021.1

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

- Interim recommendations for use of the inactivated COVID-19 vaccine BIBP developed by China National Biotec Group (CNBG), Sinopharm (updated 15 March 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-BIBP

Bharat Biotech BBV152 COVAXIN® vaccine

- Interim recommendations for use of the Bharat Biotech BBV152 COVAXIN® vaccine against COVID-19 (updated 15 March 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-bbv152-covaxin
  - Annexes to the interim recommendations for use of the Bharat Biotech BBV152 COVAXIN® vaccine against COVID-19 (updated 15 March 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-bbv152-covaxin-annexes

Variants

- Contact tracing and quarantine in the context of the Omicron SARS-CoV-2 variant: interim guidance (17 February 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-Contact-tracing-and-quarantine-Omicron-variant-2022.1

Technical Documents

- Infection prevention and control in the context of coronavirus disease (COVID-19): A living guideline (7 March 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-ipc-guideline-2022.1
- Use of SARS-CoV-2 antigen-detection rapid diagnostic tests for COVID-19 self-testing (9 March 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-Ag-RDTs-Self_testing-2022.1
- Accelerating COVID-19 Vaccine Deployment (20 April 2022): https://www.who.int/publications/m/item/accelerating-covid-19-vaccine-deployment
- Infection prevention and control in the context of coronavirus disease (COVID-19): a living guideline, 25 April 2022: updated chapter: mask use, part 1: health care settings (25 April 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-ipc-guideline-2022.2

Surveillance

- Public health surveillance for COVID-19: interim guidance (14 February 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-SurveillanceGuidance-2022.1
- Acknowledgements: The Unity Studies for sero-epidemiological investigation of COVID-19 (24 March 2022): https://www.who.int/publications/m/item/acknowledgements-the-unity-studies-for-sero-epidemiological-investigation-of-covid-19
- Environmental surveillance for SARS-COV-2 to complement public health surveillance – Interim Guidance (14 April 2022): https://www.who.int/publications/i/item/WHO-HEP-ECH-WSH-2022.1

COVID-19 Vaccines

- Injection safety in the context of coronavirus disease (COVID-19) vaccination: Addendum to policy brief, 5 April 2022 (5 April 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-Policy_brief-Vaccination-Injection_safety-Addendum-2022.1

COVAX

- Annex for Phase 2 of COVAX Allocation Framework (14 April 2022): https://www.who.int/publications/m/item/annex-for-phase-2-of-covax-allocation-framework
- Explainer for COVAX Allocation Phase 2 (14 April 2022): https://www.who.int/publications/m/item/explainer-for-covax-allocation-phase-2

Toolkits

- WHO COVID-19 Essential Supplies Forecasting Tool (COVID-ESFT) v4.1 (15 February 2022): https://www.who.int/publications/i/item/WHO-2019-nCoV-Tools-Essential_forecasting-2022.1
- COVID-19 Vaccine Introduction and deployment Costing tool (CVIC tool) (21 April 2022): https://www.who.int/publications/i/item/who-2019-ncov-vaccine_deployment_tool-2021.1

8.2 Additional ACIP meetings focused on COVID-19 vaccines

Additional meetings were held on:

- 4 February 2022: https://www.cdc.gov/vaccines/acip/meetings/slides-2022-02-04.html
- 20 April 2022: https://www.cdc.gov/vaccines/acip/meetings/slides-2022-04-20.html

Briefly, the following topics were covered in these meetings:

- Biologics License Application (BLA): Moderna mRNA-1273 updated safety and efficacy data;
- Myocarditis and pericarditis: updates following Moderna mRNA-1273 vaccination; surveillance data; MOVING outreach program for adolescents and clinicians; VSD Moderna and Pfizer-BioNTech COVID-19 vaccine; intervals; international data and policies
- Vaccine Safety Technical (VaST) assessment; VaST summary
- GRADE: Moderna mRNA-1273 vaccine; EtR framework: Moderna mRNA-1273 primary series in adults
- Clarification of guidance for people who are moderately to severely immunocompromised
- Updates to recommendations: passive antibody products intervals; second booster doses
- Extended intervals: primary series mRNA vaccines; Canadian primary series data; international data and policies for myocarditis;
- Booster doses
    - Vaccine effectiveness for Omicron infections, hospitalisations
    - Safety; rapid cycle analysis for boosters
    - EtR framework: booster doses in adults ≥50 years of age and immunocompromised individuals
- Second booster dose; up to date definitions; individuals who may receive second booster as soon as possible; individuals who may consider waiting
- Framework for future doses: key considerations and data; defining goals of COVID-19 vaccination; waning effectiveness; implementation considerations

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

- Current vaccine statements:
    - Published 12 April 2022: Updated guidance on a first booster dose of COVID-19 vaccines in Canada

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

        - Summary: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/guidance-first-booster-dose-covid-19-vaccines/summary-april-12-2022.html
    - Published 5 April 2022: Initial guidance on a second booster dose of COVID-19 vaccines in Canada

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

        - Summary: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/guidance-second-booster-dose-covid-19-vaccines/summary-april-5-2022.html
    - Published 17 March 2022: Recommendations on the use of Moderna Spikevax COVID-19 vaccine in children 6 to 11 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-6-11-years-age.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-6-11-years-age/summary-march-17-2022.html

- Published 11 March 2022: Recommendations on the use of Medicago COVID-19 vaccine (Covifenz)

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

- Summary: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-medicago-covid-19-vaccine/summary-march-11-2022.html

- Published 17 February 2022: Recommendations on the use of Novavax Nuvaxovid COVID-19 vaccine

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

- Summary: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-novavax-nuvaxovid-covid-19-vaccine/summary-february-17-2022.html

- Published 4 February 2022: NACI rapid response: Updated guidance on COVID-19 vaccination timing for individuals previously infected with SARS-CoV-2

https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/rapid-response-guidance-covid-19-vaccination-timing-individuals-previously-infected-sars-cov-2.html

- Summary: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/rapid-response-guidance-covid-19-vaccination-timing-individuals-previously-infected-sars-cov-2/summary.html

- Published 28 January 2022: NACI rapid response: Guidance on the use of booster COVID-19 vaccine doses in adolescents 12 to 17 years of age

https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/rapid-response-guidance-use-booster-covid-19-vaccine-doses-adolescents-12-17-years-age.html

- Summary: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/rapid-response-guidance-use-booster-covid-19-vaccine-doses-adolescents-12-17-years-age/summary.html

Table of updates: Recommendations on the use of COVID-19 vaccines:
https://www.canada.ca/en/public-health/services/canadian-immunization-guide/updates.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 8 April 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/periodic/covid-19-vaccine-weekly-safety-report

- TGA grants provisional determination for the Moderna bivalent COVID-19 vaccine "SPIKEVAX Bivalent Zero/Omicron" (28 April 2022): https://www.tga.gov.au/media-release/tga-grants-provisional-determination-moderna-bivalent-covid-19-vaccine-spikevax-bivalent-zeroomicron
- TGA provisionally approves Pfizer's COVID-19 vaccine (COMIRNATY), for use as a booster for individual aged 12–15 years old (8 April 2022): https://www.tga.gov.au/media-release/tga-provisionally-approves-pfizers-covid-19-vaccine-comirnaty-use-booster-individual-aged-12-15-years-old
- TGA approves provisional determination for Biocelect Pty Ltd for COVID-19 vaccine, Nuvaxovid (10 March 2022): https://www.tga.gov.au/media-release/tga-approves-provisional-determination-biocelect-pty-ltd-covid-19-vaccine-nuvaxovid
- TGA provisionally approves AstraZeneca's combination therapy (tixagevimab and cilgavimab, EVUSHELD) - for pre-exposure prevention (prophylaxis) of COVID-19 (25 February 2022): https://www.tga.gov.au/media-release/tga-provisionally-approves-astrazenecas-combination-therapy-tixagevimab-and-cilgavimab-evusheld-pre-exposure-prevention-prophylaxis-covid-19
- Moderna's COVID-19 vaccine (SPIKEVAX) provisionally approved for use in individuals 6 years and older (17 February 2022): https://www.tga.gov.au/media-release/modernas-covid-19-vaccine-spikevax-provisionally-approved-use-individuals-6-years-and-older
- TGA provisionally approves AstraZeneca's COVID-19 vaccine as booster dose (9 February 2022): https://www.tga.gov.au/media-release/tga-provisionally-approves-astrazenecas-covid-19-vaccine-booster-dose
- Pfizer's COVID-19 vaccine (COMIRNATY) provisionally approved for use as a booster in individuals aged 16-17 years old (28 January 2022): https://www.tga.gov.au/media-release/pfizers-covid-19-vaccine-comirnaty-provisionally-approved-use-booster-individuals-aged-16-17-years-old