

## **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: 02/09/2020 - 12/01/2021**

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**Note: NCIRS prepares a regularly updated summary of deliberations of these NITAGs on policy issues and recommendations that focus on COVID-19 vaccines and their uses. This summary covers deliberations by these NITAGS on topics other than COVID-19, and only lists the COVID-19 related topics without details.**

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## 1 Advisory Committee on Immunization Practices (ACIP), USA

### 1.1 ACIP meeting 28-30 October 2020

- Agenda and live presentation slides of this meeting:  
<https://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2020-10-508.pdf>
- Full minutes of the October 2020 meeting are pending. Therefore, this summary has been developed from the presentation slides and video recordings, available at  
<https://www.cdc.gov/vaccines/acip/meetings/slides-2020-10.html>
- Draft minutes of the October 2020 meeting:  
<https://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/summary-2020-10.pdf>
- Immunisation Schedule: <https://www.cdc.gov/vaccines/schedules/index.html>

### Orthopoxvirus Vaccine

- Update ACIP recommendations to include use of JYNNEOS (new vaccine for orthopoxviruses) to prevent orthopoxviruses in persons at risk for occupational exposure.
  - Policy question (should JYNNEOS be recommended for persons who are at risk of occupational exposure to orthopoxviruses?), systematic review, The Grading of Recommendations Assessment, Development and Evaluation (GRADE), Evidence to recommendation framework (EtR) needed so committee can vote on recommendation
    - presentations planned for February 2020 ACIP meeting
    - vote and clinical guidance to be presented June 2021 ACIP meeting

### Dengue vaccines

- Dengue Vaccines Workgroup Discussions March 2020-October 2020
  - Review of February ACIP Dengue Vaccines session and discussion of possible phased implementation of CYD-TDV in Puerto Rico
  - Sanofi Pasteur CYD-TDV cost effectiveness study (Notre Dame Study)
    - Base scenario: Test Sp-95%, Se-80%; 50% dengue seroprevalence; vaccinating 9 year-olds over 10 years (80% screened)
    - Incremental cost-effective ratio for hospitalisation averted \$16,000 and QALYs \$122,000; 3,415 hospitalisations averted; ratio of 18.6 hospitalisation averted for each additional hospitalisation (due to vaccinating a falsely seropositive child)
  - Acceptability of a CYD-TDV vaccination program for 9-16 year old children to Puerto Rico – paediatricians and school officials, key informant interviews
  - Overview of two economic analyses by CDC ACIP health economist
  - Preliminary results of CDC Phase 1 evaluation of dengue IgG tests
  - Review of initial drafts of EtR for CYD-TDV
  - Anticipated ACIP schedule 2021:
    - February 2021: CDC assessment of lab tests for pre-vaccination screening; Evidence to recommendations framework with draft CYD-TDV recommendations
    - June 2021: ACIP vote on CYT-TDV recommendations

### Pneumococcal vaccines

- New PCV Products on the Horizon
  - Merck: PCV15 (PCV13 serotypes + serotypes 22F and 33F)
    - Licensure anticipated Q3–4 2021
  - Pfizer: PCV20 (PCV13 serotypes + serotypes 8, 10A, 11A, 12F, 15B, 22F, and 33F)

- Licensure anticipated in June 2021
- Pneumococcal Work Group Terms of Reference, 2020–2021: To review considerations for and evidence supporting the use of higher valent pneumococcal conjugate vaccines in 1) the general population of US adults and 2) for adults with certain underlying conditions.
  - Timelines:
    - February 2021 – presentation on epidemiology of US pneumococcal disease; new vaccine products and summary of phase 3 study results; proposed policy questions
    - June 2021 – presentation on cost effective analysis; EtR/GRADE
    - October 2021 – vote (if product licensed).

### **Cholera vaccines**

- In 2017, ACIP recommended the cholera vaccine CVD 103-HgR for adult travellers (aged 18–64 years) from the United States to an area of active cholera transmission. There are plans to review more recent paediatric data to **inform whether ACIP should recommend cholera vaccine for travellers aged 2–17 years**.
  - Work group activities planned: Review available safety and immunogenicity data for CVD 103-HgR among children and adolescents; Develop evidence-based recommendations using the GRADE approach; Update MMWR

### **Zoster vaccines**

- **ZVL (Zostavax)**: effective 1 July 2020, Zostavax no longer sold in the United States
- **RZV (Shingrix)**: 33 million doses distributed from launch through second quarter of 2020
  - Shingrix inventory available to meet demand across all distribution channels
  - European Commission approved an expanded indication on 25 August, 2020; Shingrix now approved in the European Union for prevention of herpes zoster and postherpetic neuralgia in adults  $\geq 50$  years of age, and adults  $\geq 18$  years of age at increased risk of herpes zoster
- Update on post-licensure safety monitoring of RZV: Current as of October 2020, RZV post-licensure safety monitoring findings in VAERS are generally consistent with the safety profile observed in pre-licensure clinical trials.
  - Most reported AEs systemic or at injection site; Serious AEs rare (2.6% of reports, similar to other vaccines administered to same age groups);
  - Number, composition of reported Guillain-Barre Syndrome (GBS) comparable to last update
    - During October 2017–April 2019, 46 reports of GBS
      - 31 met Brighton Level (BL) 1–3 diagnostic certainty (24) or were physician-diagnosed (7)
      - BL 1 (2); BL 2 (17); BL 3 (5)
      - 29 (94%) developed symptoms within 42 days of vaccination
    - During May 2019–October 2020, 44 reports of GBS
      - 27 met Brighton Level 1–3 diagnostic certainty (16) or were physician diagnosed (11)
      - BL 1 (3); BL 2 (9); BL 3 (4)
      - 25 (93%) developed symptoms within 42 days of vaccination
  - No disproportional reporting of any AEs by proportionality reporting ratios (PRR) or empirical Bayesian (EB) data mining – Inappropriate age (19–49.9 years) by EB data mining
- Vaccine Safety Datalink (VSD) update on post-licensure safety monitoring of RZV
  - 647,833 RZV doses were received in VSD, January 2018 - December 2019

- A preliminary signal was observed for Bell's Palsy (RR=1.51), but this effect did not persist as more doses accrued (RR = 0.90)
- A preliminary signal was observed for GBS (RR=5.25) based on ICD-9/10 codes, and this effect waned over time (RR=1.24)
  - Chart review was conducted to confirm true GBS case status
  - In the final chart-confirmed analysis, VSD has insufficient evidence to determine if there is an increased risk of GBS; RR = 1.55 (95% CI: 0.17, 18.60)
- No sustained evidence of increased risk of GBS among RZV recipients for any of the pre-specified outcomes
- Subgroup & secondary analyses provide further reassurance (data not shown)
- Risk of Guillain-Barré syndrome following herpes zoster (US, 2010 – 2018)
  - Primary Objective: Evaluate risk of GBS following HZ using a self-controlled case series analysis of healthcare claims data from two large national data sources (IBM MarketScan® Commercial; CMS Medicare)
  - Secondary Objective: Describe characteristics of these GBS cases.
    - Demographics
    - Outcome severity (e.g., duration of GBS hospitalization, ICU admission)
  - Study Exposure Definitions: HZ - Persons with ICD-9 or ICD-10 outpatient claim with primary or secondary diagnostic code for HZ
  - Study Outcome Definitions: GBS - Persons with ICD-9 or ICD-10 inpatient claim for GBS as the principle diagnostic code
  - Study outcome definitions: Negative controls
    - Selected conditions similar to GBS (i.e., acute, frequently result in hospitalization, low rate of reoccurrence) that were not expected to increase after HZ (e.g. Appendicitis, Nephrolithiasis, Cholecystitis, Fractures of upper limb)
    - Defined based on ICD-9 and ICD-10 codes
    - Excluded persons with claims for these conditions in 180 days prior to HZ
  - Conclusions:
    - Increased risk of GBS 1–42 days following HZ compared to primary control window observed across adult age groups in two different administrative data sources (results not shown between 1-42 days because not statistically significant)
    - Negative controls strengthened findings
      - Results clustered around the null effect of RR=1 (range 0.9–1.4)
      - Lower than rate ratios for GBS in both data sources (IBM MarketScan® Commercial; CMS Medicare)
    - Evidence of more severe GBS (e.g., longer duration of hospitalization, higher percentage admitted to the ICU) among those  $\geq 65$  years
- Summary and planned risk-benefit analysis regarding use of RZV in immunocompetent adults
  - HZWG currently reviewing evidence regarding use of RZV in immunocompromised adults
  - Regarding possible risk of GBS, HZWG agree that continued safety monitoring of RZV in VAERS and VSD is warranted
  - A dynamic risk-benefit assessment that incorporates new data on risk of GBS associated with disease and vaccination will inform recommendations on use of RZV in immunocompetent and immunocompromised adults

#### **Tick-borne Encephalitis (TBE) vaccine**

- TBE Vaccine work Group formed September 2020.

- Purpose of vaccine: US adults and children living or visiting TBE endemic areas; laboratory workers
- Possible timeline for licensure of TBE vaccine (Pfizer - FSME-IMMUN)
  - If Pfizer's TBE vaccine receives priority review designation, FDA's intends to review - licensure possible by 3rd quarter of 2021 (October 2021, ACIP to vote on vaccine recommendations and finalise MMWR)
  - Vaccine never previously licensed in US; No existing TBE vaccine ACIP recommendations

### **Rabies vaccine**

- Proposal: Change cut-off from 'complete neutralization at a 1:5 serum dilution' (~0.1-0.3 IU/mL) to 0.5 IU/mL
  - Advantages: Reduces confusion for high stakes infection; Increase in precision and accuracy of rabies virus neutralising antibody (RVNA) results within and between laboratories; Decreased risk in reporting false RVNA positive results; A more robust level that accounts for method variability
  - Disadvantages: Based on previous RVNA antibody monitoring data more people would be recommended to receive a booster vaccination.
- Summary of proposed clinical guidance:
  - Updated table of risk groups
    - Reorganized risk groups for pre-exposure prophylaxis (PrEP) and titles of three risk groups based on changing rabies landscape
    - Included biogeography information for each risk group to make it easier to navigate
    - Provided more examples of occupations for each risk group
  - To ensure long-term immunogenicity, testing for titre introduced as an option for persons in #3 risk group at 2 years post vaccination
  - Minimal antibody titre of 0.5 IU/mL
- Summary of proposed changes:
  - #1 risk group (i.e., laboratorians)
    - Primary immunogenicity: IM [0, 7 days]\*
    - Long-term immunogenicity: Titres every 6 months after primary series
  - #2 risk group (i.e., persons who handle bats or enter high density bat environments)
    - Primary immunogenicity: IM [0, 7 days]\*
    - Long-term immunogenicity: Titres every 2 years after primary series
  - #3 risk group (i.e., veterinarians, vet assistants, animal handlers, vet students, travellers etc.)
    - Primary immunogenicity: IM [0, 7 days]\*
    - Long-term immunogenicity: Titre once at 2 years after primary series OR Booster once no sooner than day 21 and no later than 3 years
- Next steps: Potentially vote on 2 PrEP policy questions in February 2021

## **1.2 Additional ACIP meetings focused on COVID-19 vaccines**

Additional meetings were held on:

- 22 September 2020: <https://www.cdc.gov/vaccines/acip/meetings/slides-2020-09.html>
  - Draft minutes: <https://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/min-2020-09-508.pdf>
- 23 November 2020: <https://www.cdc.gov/vaccines/acip/meetings/slides-2020-11.html>
  - Draft minutes: <https://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/summary-2020-11-508.pdf>

- 1 December 2020: <https://www.cdc.gov/vaccines/acip/meetings/slides-2020-12.html>
  - Draft minutes: <https://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/summary-2020-12.pdf>
- 11-12 December 2020: <https://www.cdc.gov/vaccines/acip/meetings/slides-2020-12-11.html>
- 19-20 December 2020: <https://www.cdc.gov/vaccines/acip/meetings/slides-2020-12-19-20.html>

**Details on the content covered in these meetings are summarised in a separate NITAG summary on COVID-19 related considerations. Briefly, the following topics were covered:**

- Update from Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting
- NVX-CoV2373 Vaccine Candidate; Janssen's SARS-CoV-2 Vaccine Program
- Vaccine implementation planning - including allocations of resources, clinical considerations for populations (Phase 1a; Phase 1b and 1c); Ethical principles for early vaccine allocation; Modelling strategies for the initial allocation of COVID-19 vaccines; clinical considerations for use of mRNA COVID-19 vaccines
- CDC's strategic framework to strengthen vaccine confidence and prevent outbreaks of vaccine-preventable diseases in the United States -Vaccinate with Confidence
- Safety: FDA safety surveillance systems; post authorisation update
- Updates to immunity and epidemiology to inform COVID-19 vaccine policy; Disparities Among COVID-19 Epidemiology
- BNT162b2 Development Program; mRNA-1273 Development Program
- GRADE: Pfizer-BioNTech COVID-19 vaccine; Moderna COVID-19 vaccine
- Evidence to Recommendation Framework: Pfizer-BioNTech COVID-19 vaccine; Moderna COVID-19 vaccine
- Update on COVID-19 vaccines and Anaphylaxis

### **1.3 Newly published or updated recommendations**

#### **1.3.1 Meningococcal vaccines recommendations**

- Meningococcal Vaccination: Recommendations of the Advisory Committee on Immunization Practices, United States, 2020
- Published in MMWR, 25 September 2020: <https://www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm>
- ACIP recommends:
  - routine vaccination with a quadrivalent meningococcal conjugate vaccine (MenACWY) for adolescents aged 11 or 12 years, with a booster dose at age 16 years.
  - routine vaccination with MenACWY for persons aged  $\geq 2$  months at increased risk for meningococcal disease caused by serogroups A, C, W, or Y, including persons who have persistent complement component deficiencies; persons receiving a complement inhibitor (e.g., eculizumab [Soliris] or ravulizumab [Ultomiris]); persons who have anatomic or functional asplenia; persons with HIV; microbiologists routinely exposed to isolates of *Neisseria meningitidis*; persons identified to be at increased risk because of a meningococcal disease outbreak caused by serogroups A, C, W, or Y; persons who travel to or live in areas in which meningococcal disease is hyperendemic or epidemic; unvaccinated or incompletely vaccinated first-year college students living in residence halls; and military recruits. ACIP recommends MenACWY booster doses for previously vaccinated persons who become or remain at increased risk.
    - Age 2 – 9 years: Boosters (if person remains at increased risk)†††

- Aged <7 years: Single dose at 3 years after primary vaccination and every 5 years thereafter
- Aged  $\geq 7$  years: Single dose at 5 years after primary vaccination and every 5 years thereafter
- Age  $\geq 10$  years: Boosters (if person remains at increased risk)†††: Single dose at 5 years after primary vaccination and every 5 years thereafter  
*††† Licensed in the United States only for a single booster dose for persons aged 15–55 years for MenACWY-D and MenACWY-CRM or aged  $\geq 15$  years for MenACWY-TT. Booster doses administered outside of these ages or administration of >1 booster dose are considered off-label.*
- routine use of MenB vaccine series among persons aged  $\geq 10$  years who are at increased risk for serogroup B meningococcal disease, including persons who have persistent complement component deficiencies; persons receiving a complement inhibitor; persons who have anatomic or functional asplenia; microbiologists who are routinely exposed to isolates of *N. meningitidis*; and persons identified to be at increased risk because of a meningococcal disease outbreak caused by serogroup B.
- MenB booster doses for previously vaccinated persons who become or remain at increased risk.
  - Boosters (if person remains at increased risk)§§§: Single dose at 1 year after completion of primary vaccination and every 2–3 years thereafter  
*§§§ Licensed in the United States only for a primary series. Administration of booster doses is considered off-label.*
- ACIP recommends a MenB series for adolescents and young adults aged 16–23 years on the basis of shared clinical decision-making to provide short-term protection against disease caused by most strains of serogroup B *N. meningitidis*.

### 1.3.2 Influenza vaccine recommendations

- Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2020–21 Influenza Season
- Published in MMWR, 21 August 2020: <https://www.cdc.gov/mmwr/volumes/69/rr/rr6908a1.htm>
- ACIP recommends annual influenza for all persons aged  $\geq 6$  months:
  - Inactivated influenza vaccines (IIVs), recombinant influenza vaccine (RIV4), and live attenuated influenza vaccine (LAIV4) are expected to be available.
  - Most influenza vaccines available for the 2020–21 season will be quadrivalent, with the exception of MF59-adjuvanted IIV, which is expected to be available in both quadrivalent and trivalent formulations.
  - Recent licensures of two new influenza vaccines, Fluzone High-Dose Quadrivalent and Flud Quadrivalent. Both new vaccines are licensed for persons aged  $\geq 65$  years.
  - Additional changes include updated discussion of contraindications and precautions to influenza vaccination, updated discussion concerning use of LAIV4 in the setting of influenza antiviral medication use, and updated recommendations concerning vaccination of persons with egg allergy who receive either cell culture–based IIV4 (ccIIV4) or RIV4.

### 1.3.3 Ebola vaccine recommendations

- Use of Ebola Vaccine: Recommendations of the Advisory Committee on Immunization Practices, United States, 2020

- Published in MMWR, 8 January 2021: <https://www.cdc.gov/mmwr/volumes/70/rr/rr7001a1.htm>
  - ACIP recommends:
    - **Pre-exposure vaccination with Ervebo** (rVSVΔG-ZEBOV-GP: live attenuated recombinant vesicular stomatitis virus (VSV) encoding the glycoprotein of Ebola virus species Zaire ebolavirus) **is recommended for adults aged ≥18** years who are at highest risk for potential occupational exposure to EBOV because they are:
      - responding to an outbreak of Ebola virus,
      - health care personnel at Ebola treatment centres in the United States, or
      - laboratorians or other staff at biosafety level 4 facilities in the United States.
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## 2 Immunisation Advisory Centre (IMAC), New Zealand

### 2.1 PTAC Considerations

Meetings were held on:

- 02 September 2020 (Sub-committee meeting) <https://pharmac.govt.nz/assets/2020-09-Immunisation-Subcommittee-Records-published-24-November-2020.pdf>
- 18 September 2020 (no vaccine-specific considerations): <https://pharmac.govt.nz/assets/2020-09-Immunisation-Subcommittee-Records-published-24-November-2020.pdf>
- 20 – 21 August 2020 – <https://pharmac.govt.nz/assets/PTAC-record-2020-08-published-28-October-2020.pdf>; includes consideration of an application for influenza vaccination for people aged ≥65 years (no further details provided)

#### 02 September 2020 / 20 – 21 August 2020:

##### Adjuvanted quadrivalent influenza vaccination for people aged 65 years and over

- The Subcommittee reviewed the application from Seqirus (NZ) Ltd for adjuvanted inactivated quadrivalent influenza vaccine (aQIV) and recommended its use in people aged ≥65 years, if cost neutral to unadjuvanted quadrivalent influenza vaccine (QIV).
  - considered that the evidence of benefit for aQIV over QIV was low but that it is possible that aQIV may provide additional benefit, particularly in more severe influenza seasons when the A/H3 strain dominates and QIV vaccine effectiveness is usually lower. The Subcommittee considered that aQIV was likely to be at least as effective as QIV.

### 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 Campaign to improve measles immunity (August 2020 – August 2021)

- To reduce the risk of future measles outbreaks, a year-long, district health board (DHB) led immunisation campaign will be launched. The campaign targets 15 to 30-year olds who missed their MMR vaccine as children, particularly Māori and Pacific young people.

#### 2.2.2 National Immunisation Schedule change – 1 October 2020

- New vaccination event scheduled at 12 months will be established, to administer MMR dose one (before 1 October 2020 was scheduled at 15 months) and PCV10 (currently scheduled at 12 months).



- 15 month event will include MMR dose two, Hib and Varicella vaccine, a reduction from four vaccines to three.
- Purpose for this change is to ensure measles control by offering protection as early as possible.
- All children aged under 5 years who are yet to complete PCV10 at age 15 months are MMR dose 2 at age 4 years will be scheduled PCV10 at 12 months and MMR at 12 and 15 months following the schedule change.

### 2.2.3 Childhood immunisation rates

- Updated figures (June – September) published: <https://www.health.govt.nz/our-work/preventative-health-wellness/immunisation/immunisation-coverage/national-and-dhb-immunisation-data>
  - Figures show a reduction in immunisation rates for vaccines that were due last autumn and winter. This varied across different DHB, but disproportionately affected tamariki Māori and babies living in the highest deprivation areas, particularly at the 6 month milestone age.
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## 3 Joint Committee on Vaccination and Immunisation (JCVI), UK Department of Health

### 3.1 JCVI meeting: 27 October 2020

- A summary of the JCVI meeting held on 27 October 2020 is provided below
- Draft minutes, October 2020: <https://app.box.com/s/iddfb4ppwkmjtusir2tc/file/751023891565>
- Additional JCVI Extraordinary Meetings on COVID-19 Immunisation prioritisation were held (these are summarised in a separate summary of NITAG discussions on COVID-19 vaccines):
  - 29 November 2020: <https://app.box.com/s/iddfb4ppwkmjtusir2tc/file/762635288215>
  - 30 November 2020: <https://app.box.com/s/iddfb4ppwkmjtusir2tc/file/762970779302>
  - 01 December 2020: <https://app.box.com/s/iddfb4ppwkmjtusir2tc/file/763385137691>
  - 31 December 2020 (short statement):  
<https://app.box.com/s/iddfb4ppwkmjtusir2tc/file/759357623956>

### Advice on Influenza vaccines 2021/22

JCVI advice on influenza vaccines for the 2021/2022 influenza season is available at:

<https://app.box.com/s/t5ockz9bb6xw6t2mrrzb144njplimfo0/file/737845224649>

- Following changes to vaccines for 2021/22
  - Quadrivalent formulations would be available for the adjuvanted and high dose vaccines licenced for use in the elderly aQIV and QIV-HD.
  - The cell-based vaccine QIVc (Flucelvax tetra®, Seqirus) is now licensed from the age of 2 years (previously it was for age 9 years and above).
  - A new vaccine the quadrivalent recombinant vaccine (Supemtek®, Sanofi Pasteur) (QIVr) licensed for use from age 18 years would also be available. This had received a positive opinion from CHMP in September 2020 with marketing authorisation expected in November 2020.
- Summary of the Committee’s advice on influenza vaccines for 2021/22:
  - For adults aged 65 years and older the following vaccines are suitable in the order of preference: aQIV and QIV HD (equally suitable), followed by QIVc or QIVr. (JCVI remarked that the level of uncertainty in the available evidence is considered too great to allow for a preferential recommendation between the aQIV and QIV HD.)

- For at risk adults aged under 65 years (including pregnant women) the following vaccines are suitable in the order of preference: QIVc or QIVr, then QIVe. (JCVI remarked that QIVc has been used more extensively than QIVr in the UK and there is more real-world effectiveness data in support of this vaccine compared with QIVr.)
- For Children aged two to 18 years old for whom LAIV is not suitable: QIVc is preferred then QIVe.
- For Children aged less than two years: QIVe (the only licensed vaccine).

#### Addendum

- JCVI undertook a further review of the available data on neuraminidase. While there was some evidence of a role in protection after infection, JCVI did not find strong supporting evidence for the role of neuraminidase in vaccine protection. Whilst there may be a theoretical advantage for an influenza vaccine that contains neuraminidase there is uncertainty about the quantity of neuraminidase or the presence of antigenic epitopes contained in current products. JCVI considered that QIVc and QIVr should be considered acceptable alternatives to aQIV and QIV-HD.

#### **COVID-19 Horizon scanning**

- Details on this discussion can be found in a summary of NITAG discussions on COVID-19 vaccines
- Briefly, JCVI discussed the following:
  - Immune responses to SARS-CoV-2
  - Vaccines in development, with some results from clinical trials
  - Outstanding questions around safety, immunogenicity and efficacy of any vaccine, especially in older adults, those with underlying conditions and children
  - Acceptability of any COVID-19 vaccine and the need for communication
  - The need for data on co-administration of SARS-CoV-2 vaccines with influenza and pneumococcal vaccines
  - Vaccination in women who are pregnant and breastfeeding
  - Indirect protection in health and social care workers
  - Phase III data from Pfizer BioNTech (safety, efficacy, storage, distribution)
  - Vaccine prioritisations
  - Reducing complexity of the vaccination program (particularly overcomplicating risk groups)
  - Single dose or delayed second dose schedules
  - Use and supply of vaccines

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## **4 National Advisory Committee on Immunization (NACI), Canada**

### **4.1 NACI Meetings**

The most recent meeting was conducted virtually on 7 January 2021; 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:

- 07 January 2021
- 04 December 2020; 07 December 2020; 14 December 2020; 17 December 2020
- 25 November 2020

- 13 August 2020

## 4.2 Newly published or updated statement/recommendations

### 4.2.1 Guidance on the use of influenza vaccine in the presence of COVID-19

Published 29 September 2020

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

- Delivery and administration of influenza vaccine during COVID-19 pandemic
  - Public health measures (e.g., physical distancing) to be considered in the vaccination setting to reduce the spread of SARS-CoV-2
  - Consider modifications to immunisation practices and processes (e.g., scheduling appointments)
  - Consider alternate vaccine delivery models (e.g., outdoor clinics)
  - Appropriate use of personal protective equipment (PPE) by staff and volunteers required, and use of non-medical masks or face coverings by vaccine recipients
  - Outreach strategies to administer influenza vaccine to vulnerable persons
- To reduce the risk of severe illness, individuals who fall into the following groups are also particularly recommended to receive the influenza vaccine:
  - People at high risk of severe COVID-19 related illness (e.g. adults 65 years of age and older, individuals with chronic health conditions)
  - People capable of transmitting influenza to those at high risk of severe and critical illness related to COVID-19
- Seasonal influenza vaccine safety and adverse events - Potential for interference between influenza vaccine and COVID-19 disease
  - The possibility of influenza vaccine to increase the risk of infection with coronavirus or other non-influenza respiratory diseases was presented in a recent study from the United States by Wolff et al. published in January 2020.
  - Study was conducted using data from the 2017-2018 influenza season (before the COVID-19 pandemic). It found the odds of seasonal coronavirus infection (the study did not assess SARS-CoV-2) were higher in individuals vaccinated with influenza vaccine compared to those who were not.
  - Canadian study by Skowronski et al. conducted in response to the Wolff et al. study, provided a test-negative design analysis of 7 years of data from the Canadian Sentinel Practitioner Surveillance Network. This study showed no evidence that influenza vaccine increased the risk of infections from seasonal coronaviruses. This study also did not assess SARS-CoV2.
  - Literature review conducted by the Public Health Agency of Canada (PHAC) to identify studies examining the question of influenza vaccine and risk of COVID-19 infection found few results (2 studies specific to COVID-19) that were of low quality. The studies that were identified which looked at other coronaviruses were also of low quality and had conflicting findings.
  - Taken together, the hypothesis that influenza vaccine increases the risk of SARS-CoV-2 infection is **not** supported by the current evidence base. The influenza vaccine has a longstanding safety record and is a critical tool to protect against influenza-related disease

and to reduce the influenza-associated burden on the Canadian health care system, which is even more important for this influenza season, in the context of COVID-19.

- Therefore, influenza vaccine should continue to be offered to everyone 6 months of age and older who does not have contraindications to the vaccine.
- PHAC will continue to monitor evidence for this phenomenon and will issue new guidance as needed.

#### 4.2.2 Recommendations on the use of COVID-19 vaccines

Published 12 January 2021

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

- Currently authorised vaccines (Pfizer BioNTech COVID-19, Moderna COVID-19 vaccine)
  - Authorised for use for individuals 16 years of age and older (Pfizer-BioNTech COVID-19 vaccine) or 18 years of age and older (Moderna COVID-19 vaccine).
- **All published recommendations, prioritisation statements and COVID-19 related guidance are documented in the COVID-19 Deliberations Summary.**

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## 5 Immunisation updates from the World Health Organization (WHO)

### 5.1 Strategic Advisory Group of Experts (SAGE) on Immunization, WHO: 5 – 7 October 2020

- Full report: <https://apps.who.int/iris/bitstream/handle/10665/337100/WER9548-eng-fre.pdf?ua=1>
- Background documents: [https://www.who.int/immunization/sage/meetings/2020/october/presentations\\_background\\_docs/en/](https://www.who.int/immunization/sage/meetings/2020/october/presentations_background_docs/en/)

#### Report from Gavi, the Vaccine Alliance

- June 2020 Global Vaccine Summit (hosted by UK) - showed a strong commitment to equitable immunisation coverage and global health security in the face of the COVID-19 pandemic
- Gavi resources for 2021–2025, more than US\$10.5 billion.
- Gavi 5.0 priorities:
  - (1) Continuity of immunisation; (2) Reaching “zero-dose” children; (3) Pacing breadth of protection; (4) Safeguarding domestic financing; and (5) COVID-19 vaccine access and delivery.
  - Gavi’s support for innovation is articulated in The Vaccine Innovation Prioritisation Strategy as well as in Maintaining, Restoring & Strengthening Immunisation: GAVI Innovation Catalogue, which describes health system innovations that have been successfully tested in selected countries.

#### Reports from the WHO Regional Offices

- The WHO Regional Office for Africa reported >1.4 million cases and >35,000 deaths due to COVID-19 as of 30 September 2020, with a peak in cases in July 2020.
  - ~1 million children missed their first doses of measles-containing-vaccine (MCV1) in the first 7 months of 2020 compared to the same period in 2019; 50 vaccination campaigns for various vaccines were postponed in 2020; marked decline in VPD surveillance was observed

- due to staff being diverted to COVID-19 surveillance activities, travel restrictions, and delays in specimen shipments, laboratory accreditation processes and data sharing.
- Countries are now progressively resuming immunisation activities, particularly to address the circulating vaccine derived poliovirus (cVDPV) outbreaks occurring in many parts of sub-Saharan Africa.
  - Regional focus is currently directed at continued tracking of COVID-19 impact on immunisation programmes; supporting countries to plan the resumption of services and catch-up activities.
- The WHO Regional Office for the Americas reported that the COVID-19 pandemic had exacerbated some pre-existing problems in immunisation programmes.
    - May – June 2020: demand for services dropped significantly, mainly due to limited public transport and the reluctance of people to leave their homes; resulted in remarkable declines in the administered doses of MMR vaccine (by 25%) and of DTP3 (by as much as 40% in selected countries).
    - Supply chains were significantly disrupted; surveillance capacities were reduced due to personnel being diverted to COVID-19 response activities and staff becoming infected.
  - The WHO Eastern Mediterranean Regional Office immunisation activities were disrupted during March – May 2020 due to COVID-19 lock down related movement restrictions, supply-chain disruptions, and fear of COVID-19 among communities and health workers. June 2020 onwards, services gradually resumed.
    - Challenges included providing catch-up vaccinations and the investigation and notification of VPD cases.
    - During the past 9 months, VPD outbreaks had been reported from Yemen (cVDPV, diphtheria and measles) and Sudan (cVDPV and diphtheria). Several planned supplementary immunisation activities (SIAs) were either postponed or delayed due to the pandemic in Lebanon, Tunisia, Yemen, and elsewhere.
    - Countries worked to mitigate the impact of the pandemic by adopting different strategies such as enhancement and expansion of outreach services.
  - The WHO European Regional Office: The Region was the epicentre of the COVID-19 pandemic by mid-March 2020 and, by the end of April, deaths accounted for 63% of global COVID-19 mortality.
    - 6 countries reported nation-wide interruptions of routine immunisation services in early April 2020.
    - By early June 2020, all countries where immunisation services had been interrupted had resumed services. Countries were innovative, employing drive-through vaccination and making use of webinars to train health workers on infection prevention and control (IPC) and adapt to new realities on the ground. There is concern regarding the decrease in immunisation coverage and the risk of VPD emergence.
  - The WHO South-East Asia Regional Office: Prior to the COVID-19 pandemic, the Region had made extensive progress in achieving the goals of the Global Vaccine Action Plan and the Regional Vaccine Action Plan.
    - Following the COVID-19 pandemic, actions were taken to assess and minimise its impact on immunisation and surveillance in the Region, including development of a regional dashboard (quantitative and qualitative), involvement of NITAGs to assess impact and provide guidance on overcoming challenges and mitigating risks, and SIAs. Immunization activities, stopped or interrupted in 8 of 11 countries, have since resumed and are currently functioning in all countries.

- VPD surveillance, including acute flaccid paralysis surveillance and measles rubella (MR) surveillance, was partially affected in 9 countries. Sub-national analysis of immunization coverage and VPD surveillance performance were initiated.
- Key priority actions in the Region include: (a) ensuring continuity of immunisation services under safe conditions; (b) tailoring strategies, including policy adjustments, for catch-up vaccination of children who missed vaccination during recent months; (c) monitoring programme performance to take corrective actions; (d) active positive messaging to reinforce the importance of immunisation; (e) using innovative strategies for VPD surveillance; (f) enhanced engagement of NITAGs to advise on immunisation and VPD surveillance performance improvement; and (g) mitigation planning to keep all control and elimination targets on track.
- The WHO Regional Office for the Western Pacific: national and provincial immunisation staff and WHO staff at country offices and Regional Office were re-assigned to COVID-19 response activities
  - Performance of regular immunisation programme work was affected by this shift as well as by travel restrictions and reductions in vaccine stocks at all levels.
  - Vaccination coverage in 2020 compared to same time period in 2019 decreased in 6 countries. Delayed outbreak response, e.g., to cVDPVs in Malaysia and the Philippines.
  - The immunisation service disruptions caused by the COVID-19 pandemic are likely creating conditions for new measles outbreaks in 2021–2022, especially in the Philippines.
  - To counteract and prevent resurgence, combined MR and bivalent oral poliovirus vaccine (bOPV) SIAs are planned in the Philippines for late 2020 and early 2021 to catch-up on vaccinations missed during the first half of 2020.

#### Evidence on COVID-19 co-morbidity and benefit of vaccination in relation to influenza and pneumococcus

- Currently limited data on COVID-19 co-morbidity with influenza or pneumococcal disease, or on the benefits of influenza or pneumococcal vaccination in the COVID-19 context.
- In the context of the COVID-19 pandemic, SAGE reconsidered the prioritization of risk groups for influenza vaccination. SAGE recommended the highest priority groups for influenza vaccination are health workers and older adults. In no particular order, additional groups are pregnant women, individuals with underlying health conditions, and children who are 6–59 months of age.
- SAGE noted that evidence was insufficient to support a recommendation to introduce an adult pneumococcal vaccination programme in response to the COVID-19 pandemic. In countries with existing adult pneumococcal vaccination programmes, improving vaccine coverage and thereby reducing pneumococcal disease may be expected to alleviate the related burden on health systems.

#### Rotavirus vaccines

- SAGE last reviewed rotavirus vaccines in April 2012, additional safety and effectiveness data have accrued for Rotarix™5 and RotaTeq™ and, in 2018, WHO prequalified 2 more rotavirus vaccines, Rotavac™ and Rotasiil™.
- Globally, 112 or 58% of countries have introduced rotavirus vaccines into their national immunization programmes. The global impact of rotavirus vaccine is evident from the 40% reduction in rotavirus prevalence following the introduction of vaccine during 2008–2016. Rotavirus vaccination has consistently been found to be cost-effective and cost-saving in most low- and middle-income countries (LMICs) when compared to no vaccination.
- Prior reviews by GACVS of Rotarix™ and RotaTeq™ in 2011, 2013, and 2017 emphasized that the benefit of these vaccines is greater than the small risk of intussusception. During the December 2019 GACVS Meeting, a review of data on RotaTeq™ in sub-Saharan Africa and RotaVac™ in India did not indicate a significantly higher risk of intussusception during the post-vaccination risk periods

than in the reference period. GACVS recommended monitoring risk for intussusception when new rotavirus vaccines are introduced into new populations.

- Based on the Cochrane review, the GACVS reports, and other available information, SAGE concluded that Rotavac™ and Rotasiil™ are safe and effective. SAGE recommends all 4 oral rotavirus vaccines (Rotarix™, RotaTeq™, Rotavac™, and Rotasiil™) for use.
- For these 4 prequalified rotavirus vaccines, SAGE re-affirmed recommendations made in the 2013 WHO position paper on rotavirus vaccines.
- If a child was not vaccinated on time, SAGE noted that the considerable rotavirus disease burden during the second year of life supports catch-up vaccination, particularly in high-mortality and crisis contexts. Because of the typical age distribution of rotavirus gastroenteritis (RVGE), rotavirus vaccination of children >24 months of age is not recommended.

#### Poliomyelitis

- 25 August 2020, the African Regional Certification Commission certified the WHO African Region as wild polio virus (WPV)-free after 4 years without detection of any WPV cases.
- increased circulation of WPV type 1 (WPV1) in Afghanistan and Pakistan with expansion into previously polio-free areas in these countries as well as the inability of the programme to effectively control cVDPV outbreaks in Africa.
- 1 January and 30 September 2020, there were 119 WPV1 cases and 425 cVDPV cases reported globally, compared to 85 WPV1 and 86 cVDPV cases in the same period in 2019. SAGE noted that new cVDPV type 2 (cVDPV2) outbreaks have emerged and older ones are continuing in Central Africa, the Horn of Africa, West Africa, and most recently, in Egypt as well as in Afghanistan and Pakistan. A cVDPV1 outbreak was reported in Yemen. Malaysia and Philippines have not detected any new cVDPV2 cases in the past 6 months.
- All polio campaigns were suspended in March 2020 due to the COVID-19 pandemic. Since July 2020, polio campaigns have gradually resumed, using COVID-19 IPC measures.
- SAGE reviewed data from clinical studies on the immunogenicity of routine immunisation schedules with 2 IPV doses in conjunction with bOPV. SAGE noted that 2 doses of IPV provide higher immunogenicity against type 2 poliovirus than one dose; that the older the age at first dose and the longer the interval between doses, the higher the immunogenicity; and that 2 fractional doses provide similar immunogenicity as 2 full doses of IPV but only when age at first dose is at  $\geq 14$  weeks of age and the time interval between the 2 doses is  $\geq 16$  weeks.
- SAGE recommended that a second IPV dose be introduced by all countries that currently administer one IPV dose and bOPV in their routine immunization schedule. The preferred schedule is to administer the first IPV dose at 14 weeks of age (with DTP3/Penta3), and to administer the second IPV dose at least 4 months later (possibly coinciding with other vaccines administered at 9 months of age). This schedule may be carried out using full dose IPV or fractional intradermal IPV (fIPV) without loss of immunogenicity. Countries may consider alternative schedules based on local epidemiology, programmatic implications and feasibility of delivery. As an alternative to the preferred schedule, countries may choose an early IPV schedule starting with the first dose at 6 weeks of age (with DTP1/Penta1) and the second dose at 14 weeks (with DTP3/Penta3). This alternative schedule offers the advantage of providing early-in-life protection; however, there is a lower total immunogenicity achieved. If this schedule is chosen, full dose IPV should be used rather than fIPV due to lower immunogenicity of fIPV at early ages. Regardless of the 2 dose IPV schedule used, introduction of the second IPV dose would not reduce the number of bOPV doses used in the routine immunization schedule.

- SAGE was updated on nOPV2 vaccine development and noted that the interim recommendation for Emergency Utilization Listing (EUL) was under consideration by the WHO ad hoc Product Evaluation Committee (PEC) in accordance with the draft WHO Roadmap for assessment of nOPV2 manufactured by PT Biofarma under the EUL procedure.
- SAGE endorsed the prioritization framework for type 2 vaccines for cVDPV2 outbreak response and agreed with the phases of the framework. SAGE recommended that an independent nOPV2 safety monitoring group be established and that criteria for assessment of nOPV2 safety be developed and then reviewed by SAGE. SAGE will review the decision criteria used to transition between phases of nOPV2 use based on findings from the initial use period.
- SAGE recommended that IPV should not be used for outbreak response because evidence demonstrates that IPV campaigns are unlikely to reach children not reached with OPV campaigns, have limited impact on stopping transmission and have a high programmatic cost.

#### Measles Rubella Strategic Framework

- Global annual number of measles cases of 872 872 in 2019 was the highest in 15 years.
- SAGE was presented with the Measles and Rubella Strategic Framework (MRSF), 2021–2030, a document developed by the Measles & Rubella Initiative (M&RI)
- A 2019 report on the Feasibility Assessment of Measles and Rubella Eradication recommended that a time-bound measles and rubella eradication goal should be set only when accelerated progress has been made, benchmarks establishing conditions for a successful endgame to achieve eradication have been achieved, and there is evidence of a clear trajectory toward the goal. The purpose of the MRSF is to create the conditions for that trajectory through pivots in strategy delivered in a unified approach that strengthens routine immunization.
- Measles Outbreak Strategic Response Plan (MOSRP) described its goal to help WHO, countries and partners to better prevent, prepare for, respond to, and recover from measles outbreaks and the aim to assist countries to improve surveillance and use outbreaks as entry points to uncover systems gaps and strengthen routine immunization programmes.
- Immunization Agenda 2030 (IA2030) – Development of the IA2030 Monitoring, Evaluation and Action (ME&A) Framework and Ownership and Accountability (O&A) Mechanism - The IA2030 M&E Task Force and the IA2030 Core Team of Partners presented SAGE with updates on progress in developing the IA2030 ME&A Framework and emerging options for the IA2030 O&A Mechanism.
- Pneumococcal vaccines - advice to countries on use of pneumococcal vaccines in national programmes to vaccinate older adults
- Pneumococcal meningitis outbreaks and strategies for prevention and response
  - periodically reported outbreaks generally occur in sub-Saharan Africa.
  - Based on modelled data from a pneumococcal meningitis outbreak in Ghana, reactive vaccination does not appear to be an efficient approach to reduce the impact of outbreaks. Thus, from the perspective of impact, there is currently insufficient evidence to recommend reactive campaigns.
- Vaccine innovation prioritization strategy (VIPS) a 3-year collaboration between the Gavi Secretariat, WHO, the Bill & Melinda Gates Foundation, UNICEF and PATH – to develop a single integrated framework to evaluate and prioritize vaccine product innovations.



- In May 2020, VIPS prioritized 3 vaccine product innovations: microarray patches (MAPs); heat stable formulations including Controlled Temperature Chain qualified vaccines; and barcodes on primary packaging.
- SAGE endorsed the following principles as a basis for VIPS strategic planning:
  - Innovations in vaccine product attributes and approaches are needed to achieve coverage and equity goals; this implies future procurement and implementation of differentiated products and approaches.
  - Co-ordinated and integrated end-to end strategies are needed to advance the priority innovations and prepare for country uptake, taking into consideration lessons from previous experience, e.g. Uniject.
  - Ideally, innovative vaccine products should be procurement cost neutral; if procurement cost is incrementally greater than the existing vaccine, evidence of cost savings in programmatic delivery and economic impact is needed to rationalize procurement.
- SAGE recommended that VIPS should continue to assess the product innovation landscape to identify opportunities in the context of COVID-19 vaccines. Beyond advancing development and use of “supply-side” product innovations, SAGE advised that VIPS should explore “demand-side” innovations which are needed to reach the unreached.

## **5.2 Extraordinary meeting of the Strategic Advisory Group of Experts (SAGE) on Immunization, WHO: 5 January 2021**

- Meeting to propose recommendations to WHO on the use of COVID-19 vaccine(s) - [https://www.who.int/news-room/events/detail/2021/01/05/default-calendar/extraordinary-meeting-of-the-strategic-advisory-group-of-experts-on-immunization-\(sage\)--5-january-2021](https://www.who.int/news-room/events/detail/2021/01/05/default-calendar/extraordinary-meeting-of-the-strategic-advisory-group-of-experts-on-immunization-(sage)--5-january-2021)
- Agenda: [https://www.who.int/docs/default-source/immunization/sage/2021/january/sage\\_agenda\\_5january2021\\_virtual\\_20210104.pdf?sfvrsn=60e645c6\\_7](https://www.who.int/docs/default-source/immunization/sage/2021/january/sage_agenda_5january2021_virtual_20210104.pdf?sfvrsn=60e645c6_7)

### **Recommendation on the first mRNA vaccine BNT162b2**

- Interim recommendations for use of the Pfizer– BioNTech COVID-19 vaccine, BNT162b2, under Emergency Use Listing Interim guidance 8 January 2021 [https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE\\_recommendation-BNT162b2-2021.1](https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1)
- This framework is intended to offer guidance for considering data emerging from clinical trials in support of issuing vaccine-specific evidence-based recommendations.

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

- A meeting was held on 1-3 December 2020; however details of the discussion at this meeting are not yet available

## **5.4 WHO Regional Committee for the Western Pacific meeting**

- No meetings held after 6-9 October 2020

## **5.5 Global immunisation news and other items and resources**

- Latest news available here: <https://www.who.int/immunization/gin/en/>

- Immunization Agenda 2030: A Global Strategy to Leave No One Behind – a strategy to address challenges in immunisation over the next decade, to be endorsed by the World Health Assembly [https://www.who.int/immunization/immunization\\_agenda\\_2030/en/](https://www.who.int/immunization/immunization_agenda_2030/en/)

## 5.6 COVID-19 related reports, guidelines and publications

- Recent COVID-19 publications published by WPRO: <https://iris.wpro.who.int/handle/10665.1/14505>
- Resources for providing routine immunisation services in the context of COVID-19:
  - Framework for decision-making: implementation of mass vaccination campaigns in the context of COVID-19, May 2020 <https://www.who.int/publications/i/item/framework-for-decision-making-implementation-of-mass-vaccination-campaigns-in-the-context-of-covid-19>
  - Immunisation in the context of COVID-19 pandemic: FAQs, 16 April 2020 [https://apps.who.int/iris/bitstream/handle/10665/331818/WHO-2019-nCoV-immunization\\_services-FAQ-2020.1-eng.pdf?sequence=1&isAllowed=y](https://apps.who.int/iris/bitstream/handle/10665/331818/WHO-2019-nCoV-immunization_services-FAQ-2020.1-eng.pdf?sequence=1&isAllowed=y)
- Rational use of personal protective equipment for coronavirus disease (COVID-19) and considerations during severe shortages – 23 December 2020: [https://www.who.int/publications/i/item/rational-use-of-personal-protective-equipment-for-coronavirus-disease-\(covid-19\)-and-considerations-during-severe-shortages](https://www.who.int/publications/i/item/rational-use-of-personal-protective-equipment-for-coronavirus-disease-(covid-19)-and-considerations-during-severe-shortages)
- Considerations for implementing a risk-based approach to international travel in the context of COVID-19 – 16 December 2020: <https://www.who.int/publications/i/item/WHO-2019-nCoV-Risk-based-international-travel-2020.1>
- COVID-19 Weekly Epidemiological Update: <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports>
- The COVID-19 candidate vaccine landscape: <https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines>
- COVID-19 diagnostic testing in the context of international travel 16 December 2020: [https://www.who.int/publications/i/item/WHO-2019-nCoV-Sci\\_Brief-international\\_travel\\_testing-2020.1](https://www.who.int/publications/i/item/WHO-2019-nCoV-Sci_Brief-international_travel_testing-2020.1)
- Log of major changes and errata in WHO daily aggregate case and death count data: <https://www.who.int/publications/m/item/log-of-major-changes-and-errata-in-who-daily-aggregate-case-and-death-count-data>
- Interim recommendations for use of the Pfizer–BioNTech COVID-19 vaccine, BNT162b2, under Emergency Use Listing: [https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE\\_recommendation-BNT162b2-2021.1](https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1)
- mRNA-1273 vaccine (Moderna) against COVID-19 Background document (draft): [https://www.who.int/publications/i/item/mrna-1273-vaccine-\(moderna\)-against-covid-19-background-document-\(draft\)](https://www.who.int/publications/i/item/mrna-1273-vaccine-(moderna)-against-covid-19-background-document-(draft))

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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

- Fluzone Quadrivalent High Dose (Sanofi) –quadrivalent high dose influenza vaccine

- Approved on 30 July 2020, entry on ARTG on 31 July 2020
- Registered for use in persons 65 years of age and older.
- Australian Public Assessment Report for Inactivated quadrivalent influenza vaccine (split virion) influenza virus haemagglutinin - <https://www.tga.gov.au/sites/default/files/auspar-inactivated-quadrivalent-influenza-vaccine-virus-haemagglutinin-201127.pdf>
- Flucelvax Quad (Seqirus) – quadrivalent influenza vaccine (surface antigen, inactivated)
  - Approved on 14 August 2020, entry on ARTG on 1 September 2020
  - For the prevention of influenza caused by Influenza Virus, Types A and B contained in the vaccine. Indicated for use in adults and children aged 9 years and older
  - <https://www.tga.gov.au/apm-summary/flucelvax-quad>
  - Australian Public Assessment Report for Quadrivalent Influenza Vaccine - <https://www.tga.gov.au/sites/default/files/auspar-quad-quadrivalent-influenza-vaccine-201217.pdf>

### 6.1.2 TGA media releases

- Updates related to COVID-19 vaccines can be found here: <https://www.tga.gov.au/covid-19-vaccine-news-and-updates>
  - As of 2 December 2020, the TGA has received applications and preliminary data for 3 COVID-19 vaccines using the provisional pathway and rolling review procedures <https://www.tga.gov.au/covid-19-vaccines-undergoing-evaluation>
  - **Media release (11 August 2020):** <https://www.tga.gov.au/alert/study-affirms-safety-human-papillomavirus-hpv-vaccine>
  - Safety advisory - risk of infection with the vaccine virus Zostavax Vaccine– 16 July 2020 <https://www.tga.gov.au/alert/zostavax-vaccine-1>
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## 7 Upcoming meetings and agendas

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

- 27 January 2021
- 24–25 February 2021
- 23-24 June 2021
- 20-21 October 2021
- 23-24 February 2022
- 22-23 June 2022
- 19-20 October 2022

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

- 18 – 19 February 2021
- 20 – 21 May 2021
- 19 – 20 August 2021
- 11 – 12 November 2021

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

Future meeting dates pending, but usually the 1st Wednesday of June and October

**NACI, Canada (<https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/meetings.html>)**

- 7 January 2021 – virtual meeting
- 28 January 2021 – virtual meeting
- 24-25 February 2021 – virtual meeting
- 24 March 2021 - virtual meeting
- 28 April 2021 - virtual meeting
- 26 May 2021 - virtual meeting

**SAGE WHO ([http://www.who.int/immunization/sage/future\\_meetings/en/](http://www.who.int/immunization/sage/future_meetings/en/))**

- 23–25 March 2021
- 5 – 7 October 2021

**WHO-GACVS ([https://www.who.int/vaccine\\_safety/committee/en/](https://www.who.int/vaccine_safety/committee/en/))**

- 2-3 June 2021
- 1 – 2 December 2021

**WPRO**

- 6-9 October 2020

**ACV**

- 3 February 2021
- 7 April 2021
- 2 June 2021
- 4 August 2021
- 29 September 2021
- 1 December 2021