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: 12/01/2021 - 05/05/2021

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.

Contents

1 Advisory Committee on Immunisation Practices (ACIP), USA

1.1 ACIP meeting 24-25 February 2021

- Meeting agenda: https://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2021-02.pdf
- Presentation slides: https://www.cdc.gov/vaccines/acip/meetings/slides-2021-2-24-25.html
- Immunisation Schedule: https://www.cdc.gov/vaccines/schedules/index.html
- Full minutes of the February 2021 meeting are pending

Rabies Vaccines

- Anticipated timeline: PrEP discussion at this meeting, PEP discussion at June 2021 meeting
- **Policy Question 1**: Should a 2 dose pre-exposure prophylaxis (PrEP) series involving Human diploid cell vaccine (HDCV) or Purified chick embryo cell vaccine (PCECV) IM [0, 7 days] replace the 3 dose series IM [0, 7, 21/28 days] for all those for whom rabies vaccine PrEP is recommended?
- **Policy Question 2**: Should an IM booster dose of rabies vaccine (PCECV or HDCV) be recommended as an alternative to a titer check no sooner than day 21 and no later than 3 years after the two-dose pre-exposure (PrEP) series IM [0, 7 days] for those in the #3 risk category who receive PrEP?
    - Risk category #1: elevated risk of unrecognised and recognised exposures / including unusual high-risk exposures (e.g., aerosol exposure and high concentration exposure)
    - Risk category #2: elevated risk of unrecognised and recognised exposures
    - Risk category #3: elevated risk of recognised exposures
- **WG supported the proposed recommendations for people ≥18 years of age:**

Dengue Vaccine

- Evaluation Of Commercial Dengue Virus IgG Tests For Pre-Vaccination Screening (https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/24-25/Dengue-Medina.pdf)
    - FDA Licensing of first Dengue vaccine (21 May 2019)
        - Dengvaxia is approved for use in individuals 9 through 16 years of age with laboratory-confirmed previous dengue infection and living in endemic areas.
        - Previous dengue infection can be assessed through (a) medical records of a previous laboratory-confirmed dengue infection or **(b) serological testing prior to vaccination.**
    - High IgG test performance is required in areas with moderate endemicity
    - Previous evaluations of DENV IgG tests could have introduced bias by excluding samples → exclusion of DENV IgG positives may result in a reduction of cross-reactive flavivirus specimens
    - Study objective: Perform an independent evaluation of sensitivity and specificity of selected DENV IgG tests for their potential use in pre-vaccination screening, with the following emphasis: Detection of monotypic DENV infections long after exposure;

Cross-reactivity of anti-ZIKV antibodies (study not intended as large-scale evaluation; limited in scope and size).

- Conclusion
  - Commercial tests have potential to be used for pre-vaccination screening
  - Three anti-DENV IgG tests performed with high specificity (97%-98%) and moderate sensitivity (68%-82%) with low Zika cross-reactivity (6%-8%)
  - Half of commercial tests evaluated performed poorly (sensitivity <30%) for the detection of anti-DENV IgG antibodies long after initial exposure (>1 year after infection) despite their demonstrated use to diagnose recent infections.
  - Test sensitivity was higher for multitypic DENV infections than monotypic DENV infections.

- Perspective of the ACIP dengue vaccines workgroup on the evaluation of assays for pre-vaccination screening (https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/24-25/Dengue-Paz-Bailey.pdf)
- Workgroup Perspective
  - CDC evaluation had a small sample size (n=107); generalizability is limited (Goal to address problematic areas for specificity and cross-reactivity)
  - Most tests that work well for acute diagnosis did not perform adequately for pre-vaccination screening
  - One ELISA assay and two versions of a rapid test performed best
  - CDC results may be conservative (i.e., represent minimum performance) as the samples were selected to highlight problematic areas for sensitivity and specificity
  - The test sponsor is planning on conducting a large prospective evaluation of the rapid test in Puerto Rico and the mainland
  - Prioritised assessing that an acceptable test(s) are/will be available for implementation of pre-vaccination screening
  - EtR, draft recommendations **will be presented to ACIP in spring for vote in June**
  - Minimal and optimal performance characteristics (target product profile) **will be included in MMWR with ACIP recommendations**
  - The jurisdiction will have a role in ensuring that recommended test characteristics are met for pre-vaccination screening
  - International target product profile can be adapted for U.S. territories context
    - High levels of flavivirus exposure (Zika virus)
  - Specificity more important than sensitivity to "cause no harm"
  - A sub-group is working on developing a target product profile for dengue vaccines workgroup review
- Questions: Does ACIP concur with including pre-vaccination screening dengue IgG test target product profile in MMWR that accompanies ACIP recommendations?; Are there other considerations the workgroup should address?

Tick-borne Encephalitis (TBE) Vaccine

- Pfizer has submitted a Biologics License Application (BLA) to FDA for their TBE vaccine
  - Licensure possible by 3rd quarter of 2021

  - No TBE vaccine previously licensed in the United States
  - No existing ACIP TBE vaccine recommendations
- Workgroup timeline: TBE epidemiology in Feb, GRADE assessment in June, ACIP vote in Oct
- **Policy question for TBE vaccine GRADE**
  - *Should TBE vaccine be recommended for use in persons aged ≥1 year traveling to or residing in TBE risk areas and in laboratory staff working with TBE virus?*
- Summary of risks and next steps
  - Disease risk: very low numbers of cases among US persons (11 cases in US civilian adult and paediatric travellers, 2000–2020; 9 cases in military personnel, 2006–2020; 4 in US laboratory workers); potentially high morbidity and mortality (case fatality rates 1–20%; sequelae rates 10–80%); transmission mainly aerosol but unknown for substantial proportion of cases
  - Main risk from exposure to ticks when recreating or working in tick habitats. Key risk factors for infection: exposure to ticks (recreational activities including hiking, camping, fishing, cycling, bird-watching, or foraging for mushrooms, berries, or flowers; occupations including forestry workers and military personnel).

Ebola Vaccine

- Recap from February 2020: ACIP recommended pre-exposure vaccination with Ervebo® for adults aged ≥18 years in the U.S. population who are at highest risk for potential occupational exposure to Ebola virus species Zaire ebolavirus because they are:
  - Responding to an outbreak of Ebola Virus Disease (EVD), or
  - work as health care personnel at federally designated Ebola treatment centers in the United States, or
  - work as laboratorians or other staff at biosafety level 4 facilities in the United States.
- rVSVΔG-ZEBOV-GP Vaccine Acceptability Survey
  - Surveys conducted at State Designated Ebola Treatment Centers and Laboratory Response Network (LRN)
  - 81-86% expressed interest in receiving vaccine when EVD cases were reported in US/their state; decreased to 54%-59% when there were no active Ebola outbreaks globally
  - Main concerns: low risk of exposure, transmission of vaccine virus and adverse events
- Ebola vaccination policy issue for consideration Feb 2021 meeting
  - ***Should pre-exposure vaccination with rVSVΔG-ZEBOV-GP be recommended for adults aged ≥18 years in the U.S. population who are at potential risk for occupational exposure to EBOV because they are working as:***
    - ***HCP1 at state-designated Ebola Treatment Centers in the United States, or:***
    - ***Staff in LRN facilities that receive, process, and perform diagnostic testing on suspect cases of EVD?***
  - Considerations are ongoing, but preliminary discussions suggest the Work Group favours recommending with shared clinical decision making

Hepatitis Vaccine

- Proposed Policy Question: ***Should all unvaccinated adults receive hepatitis B vaccination?***
    - Alternative PICO for ACIP Committee consideration: ***Should all unvaccinated adults age 59 years and under receive hepatitis B vaccination?***
    - Major achievements with incremental HepB vaccine policy over the past 4 decades, but recent trends in HBV incidence demonstrate limits of current risk-based HepB recommendations
        - Surveillance shows risk factor identified in merely 25% of acute HBV cases
        - Evidence of inefficiency in performing HBV risk-factor assessment in clinical settings
    - Universal adult vaccination policy could overcome challenges in ascertaining important risk factors, reduce stigma in clinical settings, increase adult HepB vaccine coverage and thus could advance towards hepatitis B elimination in the US by 2030
- Economic Evaluation of Universal Hepatitis B Vaccination Among Adults: Evaluate cost-effectiveness of a universal hepatitis B vaccination recommendation of all adults ≥19 years
    - Base Case Assumptions: 50% vaccination initiation among general population; no additional vaccination among high-risk persons.
    - 3-dose strategy: Incremental cost-effectiveness ratio (ICER) =$152,722; 100% increase in # of doses; avert 24% of incident acute HBV infections
    - 2-dose strategy: ICER=$155,429; 76% increase in # of doses; avert 24% of incident acute HBV infections
    - Increased (20%) vaccination in high-risk persons yields greater benefits - ICERs ≈ $135,000; avert ~31% of acute HBV infections

Pneumococcal Vaccines

- Anticipated Timeline for Licensure of Higher-Valent Pneumococcal Conjugate Vaccines
    - Pfizer (PCV20): Licensure anticipated June 2021
    - Merck (PCV15): Licensure anticipated July 2021
    - Licensure for children anticipated in Q2–Q3 2022 (PCV15) or mid-2023 (PCV20)
- Proposed Timeline of ACIP Presentations
    - June 2021 ACIP: Cost-effectiveness analysis and public health impact; EtR/GRADE
    - October 2021 ACIP: vote (if licensed)
- Epidemiology of Invasive Disease
    - Children and adults, overall and PCV13-type IPD incidence plateaued since 2013-2014
    - Incidence of invasive disease caused by PCV15 and PCV20 serotypes - remained stable
    - Opportunities to prevent additional 30% IPD burden among adults through new PCV use
- Epidemiology of Pneumococcal Pneumonia
    - All-cause pneumonia after paediatric PCV13 introduction (in 2010): modest declines among adults; less impact among older adults
    - Pneumococcal Pneumonia declined in adults after introduction of PCV13 (largest impact through indirect effects; direct effects through adult PCV13 use not documented)

    - Reductions in vaccine-type pneumococcal pneumonia documented through PCV13 direct effects among adults – ST3 most common remaining PCV13-type pneumonia
    - Burden estimates of all-cause, pneumococcal, and VT pneumococcal pneumonia vary across studies
    - Opportunities to prevent additional disease burden among adults through new PCV use
- Coverage of pneumococcal vaccines
    - Among adults age 65 years and older: PPSV23 coverage has been relatively stable; PCV13 coverage has increased to around 50%, since 2014 recommendation for adults 65 or older
    - Pneumococcal vaccine coverage has been low (<25%) among adults 19-64 years with underlying conditions, despite long-standing recommendation for PPSV23 use and 2012 PCV13 recommendation for adults with immunocompromising conditions
- 20 -valent Pneumococcal Conjugate Vaccine (PCV20) Phase 3 in Adults
    - PCV20 contains PCV13 components + 7 additional serotypes to broaden disease coverage for IPD and pneumonia in adults (20 Serotypes)
    - PCV20 is immunogenic across all ages, including in those with chronic medical conditions and regardless of prior pneumococcal vaccination
    - FDA granted Breakthrough Designation for PCV20 recognizing the benefit of conjugate technology in long term protection and importance for prevention of pneumonia
    - PCV20 is well tolerated and has a safety profile similar to PCV13 regardless of prior pneumococcal vaccination, and across subgroups of age, sex, and race
    - PCV20 is currently under review by the FDA for the prevention of IPD and pneumonia in adult 18 years of age and older with target action date of June 8, 2021
- V114: An Investigational 15-Valent Pneumococcal Polysaccharide Conjugate Vaccine (PCV)
    - Conclusions of the adult V114 clinical development program in adults ≥18 years:
        - V114 is well tolerated with a safety profile that is consistent with licensed PCVs
        - V114 induces robust immune responses to 12 serotypes shared with PCV13 without significant loss of immunogenicity
        - V114 is superior to PCV13 for shared serotype 3
        - V114 is superior to PCV13 for epidemiologically important serotypes 22F and 33F (currently not in PCV13)
        - V114 can be followed sequentially by PPSV23 and administered concomitantly with influenza vaccine
- Overarching Policy Questions for Use of PCV15 and PCV20 in U.S. Adults – should PCV15 or PCV20 be recommended:
    - ***For older adults aged ≥50 or ≥65 years?***
    - ***For younger adults with underlying medical conditions?***
    - ***Alone or in series with PPSV23?***

Zoster Vaccine

- Risk of Guillain-Barré syndrome (GBS) following Recombinant Zoster Vaccine (RZV)
    - Summary – Self-Controlled Analysis: Interim results of the FDA SCCS analysis of post-vaccination GBS rate in the vaccinated RZV population between the selected risk and

control periods indicate: An elevated unadjusted rate ratio **= 4.30 (95% CI 1.76, 10.53), p=0.001**

- RZV-GBS Medical Record Review
  - Records for all GBS cases following RZV or ZVL vaccination were requested from providers (36 total)
  - Brighton Collaboration's GBS Case Definition applied to data from records
  - Additional layer of adjudication performed by subject matter expert neurologists
- None of the pre-planned sensitivity analyses led to a different conclusion

- Projected Risks and Health Benefits of Vaccination against Herpes Zoster and Related Complications: Interim Results
  - Objective: To evaluate the trade-offs between benefits of averted cases of herpes zoster and complications and risks of potential adverse events, specifically Guillain-Barré syndrome (GBS)
  - Estimated probability of GBS associated with RZV
  - VSD analysis, unpublished data (Nelson et al., presented ACIP, 10/2020)
    - Risk of GBS following RZV estimated using historical Zostavax (ZVL) comparator [3 cases in ZVL group: 1 unconfirmed)
    - Compared adverse event risks among 50-65 years old RZV recipients (2018-2019) with 60-65 years old ZVL vaccinees (2013-2017); N = 647,307 doses.
    - Incremental risk difference (pooled single-dose risk) per million doses
      - If limited to 2 confirmed cases ZVL (comparator): 1.65 (-5.02, 8.33)
      - Including all 3 cases (incl. 1 unconfirmed) ZVL (comparator): 0.16 (-7.12, 7.45)
  - FDA safety study, unpublished data
    - Risk of GBS following RZV estimated using self-controlled case series approach; Medicare data
    - Extended Study Period/Positive Predictive Value-Adjusted attributable risk (10/2017-2/2020)
    - N = 1,318,004 doses
    - Attributable risk (pooled single-dose risk) per million doses: 3.13 (0.62, 5.64)
  - New input parameters for GBS|HZ
    - New health state added to model to estimate GBS following HZ
    - Probability of GBS following HZ (unadjusted attributable risk estimates calculated using data from Anderson et al, under review)
      - 18-64 years: 8.6 (1.3-33.9) per million HZ episodes - IBM MarketScan® data Anderson et al., under review
      - 65+ years: 12.8 (3.7 31.9) per million HZ episodes - CMS Medicare data Anderson et al., under review
  - Summary -
    - Evaluated trade-offs between benefits of averted cases of HZ and complications and risks of rare adverse events
    - Estimated outcomes per 1,000,000 vaccinated individuals

        - Averted cases of Herpes zoster, Postherpetic neuralgia, other complications (e.g., GBS), and deaths
        - Rare adverse events (e.g., GBS)
    - Projected cases of GBS are sensitive to parameter uncertainty
    - Estimates of averted cases of HZ, complications, and deaths rely on published data and less sensitive to changes in parameter inputs
- Summary: Herpes Zoster Work Group Interpretation - Recombinant Zoster Vaccine Safety Data
    - Clinical trials, observational studies, and the risk-benefit analysis confirm the considerable benefits of RZV vaccination in preventing HZ, severe disease, and complications
    - GBS is rare, and data on the risk of GBS following HZ and vaccination are limited
    - Based on available data, there was consensus among the work group that:
        - No change to current zoster vaccination recommendation is warranted
        - Continued safety monitoring of RZV in VAERS and VSD is warranted
- Introduction of the Evidence to Recommendations Framework for Use of Recombinant Zoster Vaccine in Immunocompromised Adults
    - Plan to split the policy question into two parts - should vaccination with RZV be recommended for immunocompromised adults 19 years of age and older? → 19–49 years and 50+ years

Influenza Vaccines

- Influenza Activity Summary
    - U.S. Influenza Activity for the 2020-21 season is low
        - % of influenza specimens testing positive reported by public health labs is unusually low
        - Influenza-like illness activity below national and region-specific baselines
        - Cumulative hospitalization rate 0.6/100,000 (lowest since 2005; lower than 2011-12 season)
    - Low activity likely multifactorial, related to COVID-19 mitigation strategies (masks, social distancing, school closures, less/restricted travel)
- Influenza Vaccine Effectiveness for 2020-21
    - Due to low influenza activity, no interim VE estimates available
- 2020-21 ACIP Influenza Statement:
    - Discussion took place around timing of vaccination, in particular as relates to current guidance recommending interval of 14 days between COVID-19 vaccines and other vaccines
    - No new language proposed for this meeting

Cholera Vaccine

- Policy topic under consideration by work group: ***Should ACIP cholera vaccine recommendations be expanded to include children and adolescents 2–17 years old?***
    - ACIP currently recommends CVD 103-HgR for adult travellers (18–64 years old) from the United States to an area of active cholera transmission

    - CVD 103-HgR (Vaxchora): Single-dose, live, attenuated serogroup O1 oral vaccine
- Vaxchora in Children and Adolescents
    - Vibriocidal antibody seroconversion rates in children and adolescents 2 to 17 years of age immunized with Vaxchora were non-inferior to seroconversion rates in adults
    - Vaxchora was well-tolerated in the paediatric population, with no vaccine related serious adverse events
    - In an immunogenicity subset of Vaxchora recipients 12-17 years of age, serum vibriocidal antibody GMTs remained elevated 2 years post-vaccination
    - Vibriocidal antibody seroconversion occurred in most children who received only partial doses of the vaccine
- Conclusion
    - Vaxchora is a single-dose vaccine with demonstrated safety and efficacy
    - Vaxchora may be used for the prevention of cholera in travellers 2-17 years of age visiting high risk areas
- Anticipated work group timeline: June 2021 – GRADE/EtR; October 2021 – ACIP vote

Orthopoxvirus Vaccines

- Work group update: Use of Vaccinia Virus Vaccine in Persons at Risk for Occupational Exposure to Orthopoxviruses:
    - Reason for Work Group Update: ACIP recommendations to include use of JYNNEOS® to prevent orthopoxviruses in persons at risk for occupational exposure
- JYNNEOS (Bavarian Nordic A/S) is a live smallpox and monkeypox vaccine produced from the strain Modified Vaccinia Ankara-Bavarian Nordic (MVA-BN), an attenuated, non-replicating orthopoxvirus
- Considerations for Orthopoxvirus Response and Healthcare Teams
    - Working group recognizes the benefit of having cadres of vaccinated public health and healthcare personnel available to respond and care for orthopoxvirus infected individuals
        - The recent increase in monkeypox cases in Africa and importation into other countries (UK, Israel, and Singapore) suggests the risk of monkeypox exportation is increasing
    - Desire to avoid being overly prescriptive in defining who and how many such persons be vaccinated as assessments of the threat level of these pathogens changes over time
    - Empower appropriate local, state, and federal public health and antiterrorism authorities to make decisions
- **Proposed policy question #1** Should persons who are at occupational risk for orthopoxviruses be offered JYNNEOS® as a vaccination option
- **Proposed policy question #2** Should persons who are at continued risk for occupational exposure (i.e. laboratorians at CDC, research labs and state health departments working with smallpox or monkeypox) to more virulent orthopoxviruses such as smallpox or monkeypox receive a booster dose of JYNNEOS® two years after the primary JYNNEOS series?

- **Proposed policy question #3** Should persons who are at continued risk for occupational exposure to replication competent orthopoxviruses like vaccinia or cowpox receive a booster dose of JYNNEOS® after the primary JYNNEOS series?
- **Proposed policy question #4** Should persons who are at continued risk for occupational exposure to orthopoxviruses, **and who received an ACAM2000 (Smallpox [Vaccinia] vaccine) primary vaccination**, receive a booster dose of JYNNEOS® as an option to a booster dose of ACAM2000?
- Evidence to be reviewed at June 2021 meeting

1.2 ACIP meeting 5 May 2021

- Meeting agenda: https://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2021-05-05-508.pdf
- Presentation slides: https://www.cdc.gov/vaccines/acip/meetings/slides-2021-05-05.html

Rabies Vaccines

- Anticipated timeline: June 2021 - Votes on PrEP and children; Present WG interpretation of data about RIG, PEP schedules (GRADE and EtR if WG prefers change); Clinical guidance, e.g., for PrEP and PEP schedule deviations
- Rabies Pre-exposure Prophylaxis and Children
    - PrEP and children from Yellow Book* and 2008 ACIP recommendations - "Children should receive the same vaccine dose (i.e., vaccine volume) as recommended for adults"
    - Primary immunogenicity: no difference between primary immunogenicity in children compared to adults (including for young children) for any given schedule
        - One observation study showed 190 (100%) children aged 5-13 mounting titers over 0.5 IU/mL cut-off after primary series
    - Long-term immunogenicity: titers in children may stay higher for longer; since boostability is not a concern for adults, it should not be a concern for children
- **Proposed recommendations for June ACIP vote**
    - ACIP recommends a 2-dose [0, 7 days] intramuscular rabies vaccine series in immunocompetent persons <18 years of age for whom rabies vaccine pre-exposure prophylaxis (PrEP) is indicated
    - ACIP recommends an intramuscular booster dose of rabies vaccine, as an alternative to a titer check, for immunocompetent persons **< 18 years of age** who have sustained and elevated risk for only recognized rabies exposures (i.e., those in risk category #3 of rabies PrEP recommendations table). The booster dose should be administered no sooner than day 21 but no later than 3 years after the 2-dose PrEP series
- Tentative agenda for June ACIP meeting:
    - Summary of PrEP about children, GRADE and EtR
    - Vote on 2 PrEP recommendations for children
    - Continue PEP presentations: RIG; Number of vaccine doses

Dengue Vaccine

- ACIP Schedule 2021: May - EtR and draft WG recommendations (NO VOTE); June - ACIP vote CYD TDV recommendations
- Policy Question: Should 3- doses of Dengvaxia be administered routinely to persons 9-16 years of age with **laboratory confirmed previous dengue infection** and living in endemic areas?
    - Draft recommendation: ACIP recommends policy question stated above.

1.3 Additional ACIP meetings focused on COVID-19 vaccines

Additional meetings were held on:

- 27 January 2021: https://www.cdc.gov/vaccines/acip/meetings/slides-2021-1-27-21.html
    - Summary Minutes: https://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/summary-2021-01.pdf
- 28 February – 1 March 2021: https://www.cdc.gov/vaccines/acip/meetings/slides-2021-02-28-03-01.html
    - Summary Minutes: https://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/summary-2021-02.pdf
- 14 April 2021: https://www.cdc.gov/vaccines/acip/meetings/slides-2021-04.html
- 23 April 2021: https://www.cdc.gov/vaccines/acip/meetings/slides-2021-04-23.html
- 12 May 2021: https://www.cdc.gov/vaccines/acip/meetings/slides-2021-05-12.html

Briefly, the following topics were covered in these meetings:

- AstraZeneca COVID-19 vaccine (AZD1222)
- COVID-19 Epidemiology among Children
- Paediatric COVID-19 Clinical Trials
- COVID-19 Vaccine Safety Update; Vaccine Safety Technical Subgroup (VaST) assessment of safety data
- COVID-19 Vaccine Administration and implementation considerations
- COVID-19 Vaccine Effectiveness Studies
- Updates on thromboembolic events and COVID-19 vaccines safety surveillance
- GRADE assessment of Janssen's single dose COVID-19 vaccine, Ad26.COV2.S; Updated recommendations for use; Thrombosis with thrombocytopenia syndrome (TTS) following Janssen COVID-19 vaccine; Overview of safety with Janssen's COVID-19 vaccine (Ad26.COV2.S); Update on Janssen COVID-19 vaccine (recommendations for use)
- Clinical Considerations for use of COVID-19 vaccines
- Emerging SARS-CoV-2 Variants; vaccine considerations
- Pfizer COVID-19 Vaccine for 12-15 years; Safety, immunogenicity and efficacy of BNT162b2 in persons aged 12-15 years; Evidence to Recommendation Framework: Pfizer-BioNTech COVID-19 vaccine in adolescents aged 12-15 years
- Clinical considerations for Pfizer-BioNTech COVID-19 vaccination in adolescents
- GRADE: Pfizer-BioNTech COVID-19 vaccine
- VaST updates; VaST assessment
- COVID-19 Vaccine Effectiveness studies

- Pathogenesis and Management of Thrombosis with Thrombocytopenia Syndrome (TTS)
- Thrombosis with thrombocytopenic syndrome (TTS) after COVID-19 vaccines: Applying the Evidence to Recommendation Framework

1.4 Newly published or updated recommendations

1.4.1 DTaP/IPV/Hib/HepB ACIP Vaccine Recommendations

- DTaP/IPV/Hib/HepB ACIP Vaccine Recommendations: Licensure of a Diphtheria and Tetanus Toxoids and Acellular Pertussis, Inactivated Poliovirus, Haemophilus influenzae Type b Conjugate, and Hepatitis B Vaccine, and Guidance for Use in Infants
- Published in MMWR, 7 February 2020: https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/dtap-ipv-hib-hepb.html
- ACIP recommends:
    - Combination vaccines merge equivalent component vaccines into a single product to prevent multiple diseases, which can reduce the number of injections administered and improve vaccination coverage.
    - A new hexavalent vaccine (VAXELIS) was approved by the FDA to prevent diphtheria, tetanus, pertussis, polio, *Haemophilus influenzae* type b, and hepatitis B (DTaP-IPV-Hib-HepB).
        - In late 2018, a new hexavalent combination vaccine (DTaP-IPV-Hib-HepB) from the MCM Vaccine Company, a joint venture between Merck and Sanofi Pasteur, received FDA approval.
        - The manufacturer has stated that vaccine will not be commercially available in the United States before 2021.
    - ACIP members voted unanimously to include this vaccine in the federal Vaccines for Children program.
    - The vaccine is **licensed for use in children aged 6 weeks through 4 years** and is indicated for the **primary vaccination series in infants at ages 2, 4 and 6 months**.

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2 Immunisation Advisory Centre (IMAC), New Zealand

2.1 PTAC Considerations

No new meetings to date in 2021.

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 Influenza 2021, Measles Immunisation Campaign, Boostrix at ages 45 and 65, Authorised Vaccinators, Handbook corrections - 4 February 2021

- Influenza Immunisation Programme 2021 (vaccine supply and distribution)
    - A significant review of the process identified key areas of improvement for vaccine distribution. Distribution will be more effectively planned and closely monitored.

Programme start date will be finalised soon based on shipping and delivery schedules of the vaccine.

- Coordinating immunisation programmes
    - Development of vaccination plans with providers that take into account the current recommended spacing of **at least two weeks** between receiving COVID-19 and influenza vaccines.
- COVID-19 programme – workforce planning
    - Planning for an extra 2000 to 3000 full-time (or equivalent) vaccinators to be trained and available throughout New Zealand
- Guardians of the Future - Measles Immunisation Campaign for 15-30-year olds
    - Window of opportunity before the influenza programme starts and the COVID-19 vaccination rollout gets underway to focus hard on improving measles immunity in our 15-30-year olds. **It is important to rapidly pick up the momentum during the early part of this year to make up for lost time following impacts of COVID-19.**
- Clarification of scheduled Boostrix at ages 45 and 65
    - PHARMAC has amended the wording of the Pharmaceutical Schedule to clarify that people are eligible for scheduled Boostrix immunisation *from* ages 45 and 65, and can receive this due vaccine even if they are older than the recommended age.

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

3.1 JCVI meetings:

- There were no considerations made (other than on COVID-19 vaccines) during this time.
- Additional JCVI Extraordinary Meetings on COVID-19 Immunisation prioritisation were held (select content of these meetings are summarised in a separate summary of NITAG discussions on COVID-19 vaccines):
    - 29 December 2020: https://app.box.com/s/iddfb4ppwkmtjusir2tc/file/774777545981
    - 22 December 2020: https://app.box.com/s/iddfb4ppwkmtjusir2tc/file/771979108388
    - 16 February 2021: https://app.box.com/s/iddfb4ppwkmtjusir2tc/file/801843118120

COVID-19 Horizon scanning

- Briefly, JCVI discussed the following:
    - Discussions on AstraZeneca vaccine; Phase III data on the AstraZeneca vaccine
    - Vaccine choice (clinical differences; operational considerations; risk groups and clinically extremely vulnerable; health and social care workers; pregnancy and breastfeeding; immunocompromised; children)
    - Single dose and extended schedules (discussions around modelling; AstraZeneca vaccine; Pfizer-BioNTech vaccines; considerations)

- Tier 4 measures (Some areas of the UK had been placed in tier 4 measures due to high and increasing levels of infection - was agreed that no specific focus on vaccination should be placed on tier 4 areas)
- Vaccination in women who are pregnant and breastfeeding
- Discussion on allergies (note regarding anaphylaxis)
- Discussion about vaccination of Immunosuppressed individuals (AstraZeneca)
- Dose interval; Vaccine schedules
- Occupational exposure and risk
- Modelling and advice of Phase 2 vaccination program rollout
- OpenSAFELY data - a new secure analytics platform for electronic health records in the NHS, created to deliver urgent results during the global COVID-19 emergency.

4 National Advisory Committee on Immunisation (NACI), Canada

4.1 NACI Meetings

The most recent meeting was conducted virtually on 13 April 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:

- 1 April 2021; 6 April 2021; 13 April 2021; 20 April 2021
- 10 March 2021; 16 March 2021; 24-25 March 2021
- 5 February 2021; 8 February 2021; 18 February 2021; 24-25 February 2021
- 19 January 2021; 28 January 2021

4.2 Newly published or updated statement/recommendations

4.2.1 Recommendations on the use of COVID-19 vaccines

Current vaccine statement: Published 16 March 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, AstraZeneca COVID-19 vaccine)
- Summary of updated NACI vaccine statement (3 May 2021): https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines/summary-updated-statement-may-3-2021.html
    - NACI has updated its Recommendations on the use of COVID-19 vaccines on 3rd May 2021 to include advice on the use of the Janssen COVID-19 vaccine. NACI has also reaffirmed its recommendation on COVID-19 vaccination during pregnancy.
    - NACI recommends the Janssen COVID-19 vaccine may be offered to individuals 30 years of age and older without contraindications, if the individual does not wish to wait for an mRNA vaccine and if the benefits outweigh the risk for the individual.

- NACI continues to preferentially recommend authorized mRNA COVID-19 vaccines due to the excellent protection they provide and the absence of safety signals of concern.
- NACI recommends that a complete vaccine series, preferably with an mRNA COVID-19 vaccine, may be offered during pregnancy, if the benefits outweigh the risks for the individual and the foetus. An mRNA vaccine is preferred due to recently published data indicating the safety of mRNA vaccines during pregnancy, and concerns about the treatment of Vaccine-Induced Immune Thrombotic Thrombocytopenia (VITT) during pregnancy, should it occur following the administration of a viral vector vaccine.
- NACI also reaffirms that, until further evidence emerges, those previously infected with SARS-CoV-2 be offered a complete series with a COVID-19 vaccine.
- Public health measures remain the foundation of the pandemic response while vaccines continue to roll out across the country. It is important that everyone, regardless of vaccination status, continue to follow recommended public health measures.

5 Immunisation updates from the World Health Organization (WHO)

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

- Last meeting: 23 – 25 March 2021: https://www.who.int/news-room/events/detail/2021/03/22/default-calendar/sage_meeting_march_2021
- **Full report: to be published 4 June 2021**
- Highlight report: https://cdn.who.int/media/docs/default-source/immunization/sage/2021/march/highlights-march-2021-sage-meeting-31march2021.pdf?sfvrsn=8c927c28_7
- Background documents: https://terrance.who.int/mediacentre/data/sage/SAGE_eYB_Mar2021.pdf

Points from Highlight Report:

Ebola Vaccines

- Two Ebola vaccines have been licensed – one is WHO prequalified (rVSVΔG-ZEBOVGP vaccine) and the other is under review (Ad26.ZEBOV and MVA-BN-Filo Ebola vaccines administered as a heterologous prime boost 8 weeks apart).
- In the context of an Ebola Vaccine Disease (EVD) outbreak response, SAGE made a recommendation for off-label use of the two Ebola vaccines to include infants and children from birth to 17 years of age, as well as pregnant and lactating women.
- SAGE reconfirmed previous recommendation to use a ring vaccination strategy for EVD outbreak response.
- Due to vaccine supply constraints and the unknown duration of protection, widespread preventive use of Ebola vaccines in the absence of an outbreak is currently not recommended.

- SAGE requested the development of a learning agenda to more broadly examine the potential preventive role of Ebola vaccines and to provide more clarity on vaccine use and vaccine demand in the longer term.
- SAGE urged manufacturers to increase production capacity to meet the expected vaccine demand resulting from the recommendations.

Polio

- SAGE noted a significant drop in wild poliovirus detections in the endemic areas during the past 6 months. SAGE expressed concern about the inability of the program to effectively control outbreaks of circulating vaccine-derived poliovirus type 2 (cVDPV2) in Africa and Asia. SAGE noted that the first cVDPV2 outbreak response campaign with novel oral polio vaccine type 2 (nOPV2) was conducted in Nigeria in March 2021.
- SAGE recommended that WHO prequalified Sabin-based IPV may be used interchangeably with the traditional Salk-based IPV.
- SAGE agreed with the Global Polio Eradication Initiative plan for transition from initial to wider nOPV2 use for response to cVDPV2 outbreaks, contingent on safety and genetic stability reviews.
- SAGE recommended that vigorous efforts be made to improve IPV coverage in locations at risk of cVDPV2 outbreaks to reduce the number of susceptible children before transmission or outbreaks can occur.
- SAGE urged all countries at risk of cVDPV2 outbreaks to prepare to meet the criteria for use of nOPV2 and to complete a readiness assessment.
- SAGE emphasized the priority for countries experiencing cVDPV2 outbreaks is to conduct high quality outbreak responses without delay, with whichever oral polio vaccine is available.

Measles Rubella

- SAGE recognized that measles control and elimination efforts need significant improvement. Current measles and rubella policies are appropriate, there are major issues related to policy implementation and sub-national heterogeneity. Given the ongoing risk of measles outbreaks, SAGE supported urgent implementation of the Measles Outbreaks Strategic Response Plan.
- SAGE strongly advised WHO and partners to maintain resources for measles and rubella efforts and to restore those that have been redeployed to the COVID-19 response, given the growing immunity gaps and increasing risk of measles outbreaks.
- SAGE strongly advocated more research and innovation on measles and rubella, including faster progress on subnational data science and the development of measles rubella microarray patch vaccines and Rapid Diagnostic Tests as potential game-changers.
- SAGE recommends measles rubella and COVID-19 vaccine co-administration studies be planned and executed to facilitate health worker immunisation and eventually measles rubella vaccination catch-up as COVID-19 vaccination roll out extends to younger age groups.

Vaccine Acceptance and Uptake

- SAGE was presented with an update on the field of work in relation to acceptance and uptake of vaccination, and a summary of work currently underway to develop tools and guidance to measure and address behavioural and social drivers of vaccination.

- The latest evidence and knowledge have enabled development of a framework to illustrate that uptake is affected by what people think and feel, social influences, motivation, and practical/logistical factors.
- Current context (given the challenges and opportunities for both routine immunisation and for COVID-19 vaccination) highlights the importance of supporting programmes to gather and use behavioural and social data to determine how different factors contribute to under-vaccination, and to identify evidence-based interventions that are prioritised and adapted locally.

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

21 January 2021:

- Presentations: https://www.who.int/news-room/events/detail/2021/01/21/default-calendar/extraordinary-meeting-of-the-strategic-advisory-group-of-experts-on-immunization-(sage)---21-january-2021
- Agenda: https://cdn.who.int/media/docs/default-source/immunization/sage/2021/january/sage_agenda_21january2021_virtual.pdf?sfvrsn=e9e34dae_20
    - Session objective setting, update on regulatory decisions and overview of Working Group deliverables → Purpose: Update on vaccine pipeline, registration, vaccine introduction status, COVAX and virus variants
    - Vaccine safety and efficacy data emerging from Moderna mRNA COVID-19 vaccine clinical trials (phase 1-3 trial results). Risk management plans; other considerations.
    - Assessment of Evidence (SAGE working group).

8 February 2021:

- Presentations: https://www.who.int/news-room/events/detail/2021/02/08/default-calendar/extraordinary-meeting-of-the-strategic-advisory-group-of-experts-on-immunization-(sage)---8-february-2021
- Agenda: https://cdn.who.int/media/docs/default-source/immunization/sage/2021/february/sage_agenda_8february2021_virtual.pdf?sfvrsn=8aac09f9_26
    - Update on recent developments including on COVAX → Purpose: Update on vaccine registration, vaccine introduction status and COVAX.
    - Vaccine safety and efficacy data emerging on AstraZeneca's COVID-19 vaccine, also known as AZD1222, clinical trials (phase 1-3 trial results). Risk management plans and other implementation considerations.
    - Assessment of the critical evidence, including data and draft recommendations related to vaccine use in older adults → For recommendation - Presentation of the assessment of the SAGE working group on the available evidences and the strength of evidences on the questions of the evidence to decision tables. Specific focus is given to the discussion on vaccine use in older adults.

- Emerging data on the use of AZD1222 in the context of new virus variants.
- Presentation of draft recommendations on the use of AZD1222 vaccine against COVID-19.

15 March 2021:

- Presentations: https://www.who.int/news-room/events/detail/2021/03/15/default-calendar/extraordinary-meeting-of-the-strategic-advisory-group-of-experts-on-immunization-(sage)---15-march-2021
- Agenda: https://cdn.who.int/media/docs/default-source/immunization/sage/2021/march/sage_agenda_15march2021_virtual.pdf?sfvrsn=ab6c43c3_5
    - Update on recent developments including on COVAX → Purpose: Update on vaccine registration, vaccine introduction status and COVAX.
    - Vaccine safety and efficacy data emerging on Janssen's Ad26.COV2.S COVID-19 vaccine clinical trials (phase 1-3 trial results). Risk management plans and other implementation considerations.
    - Presentation of clinical data on Ad26.COV2.S vaccine from phase 1, 2 and 3 studies on safety, immunogenicity and efficacy. Outline of ongoing and planned studies.
    - Presentation of draft recommendations on the use of Ad26.COV2.S vaccine against COVID-19.

22-25 March 2021:

- Presentations (yet to be published): https://www.who.int/news-room/events/detail/2021/03/22/default-calendar/sage_meeting_march_2021
- Agenda: https://cdn.who.int/media/docs/default-source/immunization/sage/2021/march/sage-agenda-22-25march2021-final.pdf?sfvrsn=baedcc7c_5
- Highlights document: https://cdn.who.int/media/docs/default-source/immunization/sage/2021/march/highlights-march-2021-sage-meeting-31march2021.pdf?sfvrsn=8c927c28_7
    - COVID-19 Vaccines:
        - Review of interim data on Sinopharm and Sinovac COVID-19 vaccine products
        - Review of case definitions and clinical endpoints used in trials for COVID-19 vaccines
    - COVID-19 Variants; COVID-19 Vaccination and Early Learning; COVID-19 Vaccine safety

29 April 2021

- Presentations: https://www.who.int/news-room/events/detail/2021/04/29/default-calendar/extraordinary-meeting-of-the-strategic-advisory-group-of-experts-on-immunization-(sage)-29-april-2021

- Agenda: https://cdn.who.int/media/docs/default-source/immunization/sage/2021/april/sage_agenda_29april2021_virtual_final.pdf?sfvrsn=e6906937_5
    - Vaccine safety and efficacy data emerging on Sinopharm's COVID-19 vaccine clinical trials (phase 1-3 trial results). Risk management plans and other implementation considerations.
    - Presentation of clinical data on BIBP-CoV vaccine from phase 1, 2 and 3 studies on safety, immunogenicity and efficacy. Outline of ongoing and planned studies.
    - Presentation of the assessment of the SAGE working group on the available evidences and the strength of evidences on the questions of the evidence to decision tables.
    - Based on the presented evidences, presentation of draft recommendations on the use of BIBP-CoV vaccine against COVID- 19.
    - Vaccine safety and efficacy data emerging on Sinovac's COVID-19 vaccine clinical trials (phase 1-3 trial results). Risk management plans and other implementation considerations.
    - Presentation of clinical data on CoronaVac vaccine from phase 1, 2 and 3 studies on safety, immunogenicity and efficacy. Outline of ongoing and planned studies.
    - Presentation of the assessment of the SAGE working group on the available evidences and the strength of evidences on the questions of the evidence to decision tables.

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

- A meeting was held on 1-3 December 2020 - Weekly epidemiological record, 22 January 2021, vol. 96, 3 (full issue).
- Meeting report is now available: https://www.who.int/publications/m/item/WER-2021-vol.-96-3

Report of the Meeting of the WHO Global Advisory Committee on Vaccine Safety (GACVS), 1–3 December 2020

Session on pharmacovigilance of COVID-19 vaccines

- The COVID-19 vaccine safety surveillance manual was endorsed by GACVS; purpose is to guide the processes for collecting, analysing and sharing safety data and information on COVID-19 vaccines within and across countries.
- GACVS recommended the development of a specific module for surveillance of COVID-19 vaccine safety in pregnant and lactating women.
- Synopsis for active surveillance of AESI associated with COVID-19 vaccines:
    - a cohort event monitoring protocol that can be quickly implemented to monitor the groups that are first vaccinated (e.g. health care workers, high risk groups) for generation and validation of AESI signals
    - a sentinel surveillance protocol that can be used to recognize and evaluate signals of rare adverse events.
- GACVS agreed that a subcommittee be established to review, evaluate and interpret post-introduction data on COVID19 vaccine safety, as these become available from different sources, to: advise WHO on the safety of the different COVID19 vaccines; provide recommendations on

safety studies, to investigate and/or validate emerging safety signals; guide the development of COVID19 vaccines safety advisories and communiques on vaccine safety for Member States.

Safety in pregnancy: the Global Vaccine Safety Multi-country Collaboration Project

- Global efforts to develop new vaccines targeted specifically for use in pregnant women in low- and middle-income countries (LMIC).
- Global Alignment of Immunisation Safety Assessment in Pregnancy (GAIA) project was launched in 2015, managed by the Brighton Collaboration, was to improve data to facilitate comparability and interpretation among surveillance systems, ultimately leading to strengthened programmes of immunisation in pregnancy.
- A global network of hospital-based sentinel sites was established in 4 the WHO regions, including in LMIC, to assess the applicability of GAIA case definition for selected neonatal outcomes.
- >84,000 births were recorded over 1 year, and detailed information was recorded on over 8000 outcomes of interest to assess the applicability of GAIA case definitions.
- Results: the case definitions for preterm birth, low birth weight, neonatal death, bloodstream infections and respiratory infections were applicable at all study sites. But limited applicability for stillbirth, congenital microcephaly, neonatal meningitis and small for gestational age.
- The vaccination status of 26% of the recruited mothers was unknown, and only 2 sites were able to classify the immunisation status of most mothers to level 1 (Multiple "levels of diagnostic certainty" are recognized in each case definition, so that the definitions are globally applicable for all immunisation safety purposes and in settings with different diagnostic capacity).
- GACVS noted the inconsistencies between case definitions (e.g., different gestational age and birth weight requirements for some definitions) identified by the study team.
- The project contributed to the development of expertise in participating hospitals and countries and built collaboration among maternal and child health programmes, immunisation programmes and national regulatory agencies.
- The next steps will include publication of the results and identification of relevant projects to further support the sites in preparing for the introduction of new vaccines.

Vaccine safety indicator for the immunisation agenda 2030

- At its meeting in December 2014, GACVS proposed that the ratio of 10 reports of AEFI per 100,000 surviving infants per year be a benchmark for determining whether a country has a functional AEFI surveillance system.
- Changes to the existing indicator are being proposed
    - It is proposed to introduce a new indicator of the rate of case-based serious AEFI (date of onset in January–December of the previous year) reported per 1 000 000 total population of a country or subnational area in a year.
    - It is proposed that serious AEFI be documented on a reporting form or listed in a line-list with basic information on the patient, reporter, vaccine and event, and that the initial target be at least 1 serious case report per 1 000 000 individuals per year.

        - This benchmark is based on current reporting rates by Member States in different WHO regions and the feasibility of transitioning to the new indicator during the next decade, with goal to achieve new benchmarks over time (5 serious AEFI cases per 1,000,000 by 2026 and 10 serious AEFI cases per 1,000,000 by 2030).
    - Monitoring the proportion of countries per WHO region that report individual serious AEFI into Vigibase (the WHO global database of individual case safety reports) every year, according to the date of onset of the AEFI, would help to determine whether data are harmonized and shared between the national regulatory agency (NRA) and the national Expanded Programme on Immunisation (EPI).
- GACVS agreed that case-based reporting rate is a good indicator to aspire for but expressed concern that some LMIC would have difficulty in achieving it, especially initially.
- GACVS proposed that the new indicator be pilot-tested for feasibility and that the previous practice, of collecting aggregated data, be continued until all countries can report on the new indicator.

<u>Safety of RTS,S malaria vaccine</u>

- 2016 - WHO recommended pilot introduction of the RTS,S/AS01 malaria vaccine to answer outstanding questions, including the feasibility of reaching children with the recommended 4-dose schedule, the impact and safety signals observed in a phase-III trial for which causality has not been established, including higher relative risks for meningitis (10 times), cerebral malaria (2 times) and female deaths (2 times). The results will inform WHO recommendations on introducing the vaccine for routine use. Three countries, Ghana, Kenya and Malawi, were selected for pilot implementation of a 4-dose schedule.
- A policy decision on broader use of RTS,S/AS01 will be undertaken in April 2021. The pilot tests will continue until 2023 to determine the added incremental benefit of the 4th dose. A final decision on full use of the RTS,S/AS01 vaccine will be made in 2023.
- GSK updated the GACVS on the activities described above. No safety signals have been identified among the 53,459 study participants in the three countries.
- WHO will request an interim analysis of data to inform the policy decision in 2021. Further analysis is planned in September 2023 and the final analysis in April 2026.
- An update on routine surveillance of RTS,S /AS01 by the NRAs and the EPI in the three countries showed that AEFI reporting has improved in all countries since vaccination was implemented, for both RTS,S/AS01 and other vaccines. The data presented to the Committee did not reveal any unusual AEFIs or AESIs. It was observed, however, that AESI reporting had not kept pace with AEFI reporting.
- GACVS observed no unusual or unexpected signals had been reported after use of RTS,S/AS01 vaccine for over 1 year.

5.4 WHO Regional Committee for the Western Pacific meeting

- No meetings held after 6-9 October 2020

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

5.5 Global immunisation news and other items and resources

- Latest news available here: https://www.who.int/immunization/gin/en/
- Immunisation Agenda 2030: A Global Strategy to Leave No One Behind (1 April 2020) - a strategy to address challenges in immunisation over the next decade, to be endorsed by the World Health Assembly. IA 2030 envisions a world where everyone, everywhere, at every age, fully benefits from vaccines to improve health and well-being. 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
- Acceptance of available traditional vaccine supply with reduced shelf life – 1 March 2021: https://www.who.int/publications/i/item/acceptance-of-available-traditional-vaccine-supply-with-reduced-shelf-life
- Evaluation of COVID-19 vaccine effectiveness – 17 March 2021: https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccine_effectiveness-measurement-2021.1
- Sample size calculator for evaluation of COVID-19 vaccine effectiveness (Excel) – 17 March 2021: https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccine_effectiveness-measurement_tool-2021.1
- INN for Variant COVID-19 Vaccine Active Substances – 19 April 2021: https://www.who.int/publications/i/item/inn-21-520
- Interim recommendations for use of the ChAdOx1-S [recombinant] vaccine against COVID-19 (AstraZeneca COVID-19 vaccine AZD1222, SII Covishield, SK Bioscience) – 21 April 2021 https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-AZD1222-2021.1
- Disability considerations for COVID-19 vaccination: WHO and UNICEF policy brief, 19 April 2021 – 26 April 2021: https://www.who.int/publications/i/item/who-2019-ncov-vaccination-and-disability-policy-brief-2021.1
- The COVID-19 candidate vaccine landscape – 27 April 2021: https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines

- COVID-19 Weekly Epidemiological Update: https://www.who.int/emergencies/diseases/novel-coronavirus-2019/situation-reports

6 Other items

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

6.1.1 Public summary documents

- Vaxigrip Tetra (Sanofi-Aventis Australia Pty Ltd) - influenza virus haemagglutinin (split virion, quadrivalent, inactivated)
    - Approved on 18 March 2021, entry on ARTG on 23 March 2021
    - For prevention of influenza disease caused by the two influenza A virus subtypes and the two influenza B virus types contained in the vaccine for passive protection of infant(s) from birth to <6 months of age following vaccination of pregnant women
    - Australian Public Assessment Report for Inactivated Quadrivalent Influenza Vaccine (split virion) https://www.tga.gov.au/sites/default/files/auspar-inactivated-quadrivalent-influenza-vaccine-split-virion-191219.pdf
- Comirnaty (Pfizer)
- AstraZeneca ChAdOx1-S COVID-19 vaccine

6.1.2 TGA media releases

- Media releases and statements landing page: https://www.tga.gov.au/media-releases-statements
- COVID-19 vaccines undergoing evaluation (page updated 26 February 2021) https://www.tga.gov.au/covid-19-vaccines-undergoing-evaluation
- Updates related to COVID-19 vaccines can be found here: https://www.tga.gov.au/covid-19-vaccine-news-and-updates
- 2021 seasonal influenza vaccines – information for consumers and health professionals (13 April 2021): https://www.tga.gov.au/alert/2021-seasonal-influenza-vaccines
- Statement by Acting Australian Government Chief Medical Officer, Professor Michael Kidd and Head of the Therapeutic Goods Administration Adjunct Professor John Skerritt (2 April 2021) - Australia's vaccine safety and regulatory process is world class and people can be confident that vaccines approved for use are safe and effective: https://www.tga.gov.au/media-release/statement-acting-australian-government-chief-medical-officer-professor-michael-kidd-and-head-therapeutic-goods-administration-adjunct-professor-john-skerritt
- AusPAR: Meningococcal Polysaccharide Tetanus Toxoid Conjugate Vaccine – Australian Public Assessment Report (23 March 2021): https://www.tga.gov.au/auspar/auspar-meningococcal-polysaccharide-tetanus-toxoid-conjugate-vaccine
- TGA is one of only five non-European regulators invited to participate on European committees on COVID-19 vaccines and therapeutics (8 February 2021) - Australia, through the TGA, is one of only five non-European Union regulators formally invited to participate by the European Medicines Agency (EMA): https://www.tga.gov.au/media-release/tga-one-only-five-non-

european-regulators-invited-participate-european-committees-covid-19-vaccines-and-therapeutics

7 Upcoming meetings and agendas

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

- 2021: 23 April; 5 May; 23-24 June; 20-21 October;
- 2022: 23-24 February; 22-23 June; 19-20 October

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

- 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)

- 28 April 2021 - virtual meeting
- 26 May 2021 - virtual meeting

SAGE WHO (http://www.who.int/immunization/sage/future_meetings/en/)

- 5 – 7 October 2021

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

- 2-3 June 2021
- 1 – 2 December 2021

WPRO

- Future meeting dates pending

ACV

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