Summary of recent issues considered by four national immunisation technical advisory groups (NITAGs) and WHO immunisation-related advisory committees

Prepared by the National Centre for Immunisation Research and Surveillance (NCIRS)

Period of review: 05 May 2021 – 22 August 2021

Contents

1 Advisory Committee on Immunisation Practices (ACIP), USA

1.1 ACIP meeting 23 – 25 June 2021

- Meeting agenda: https://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2021-06-23-508.pdf
- Presentation slides: https://www.cdc.gov/vaccines/acip/meetings/slides-2021-06.html
- Immunisation Schedule: https://www.cdc.gov/vaccines/schedules/index.html
- Full minutes of the June 2021 meeting are pending

Dengue Vaccine

- Dengvaxia timeline: 2019 – FDA licensures; 2021 – ACIP vote on recommendation
- Vaccines for Children (VFC) Program: a child is eligible for federally-funded vaccination if he or she is younger than 19 years of age and is Medicaid eligible; uninsured; under-insured; American Indian or Alaska native. Uninsured and underinsured children are eligible to receive only at Federally Qualified Health Centers or Rural Health Clinics.
    - Mission: To prevent the development of vaccine preventable diseases through strategic implementation and intervention facilitating services in accordance with the vaccine schedule for children, adolescents and adults of Puerto Rico
    - Vision: To maintain a protected population against vaccine preventable diseases thus reducing outbreaks, hospitalizations and deaths.
- Dengue Vaccine in Puerto Rico: Puerto Rico DoH adopts ACIP recommendations for local vaccine schedule-reviewed annually. Significant public health problem in Puerto Rico.
- ACIP recommended 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
- Vaccines for Children (i.e. federally-funded vaccination) Resolution Updates: Dengue Vaccines
    - *Eligible groups*: 9 to 16 years with laboratory confirmation of previous dengue infection and living in endemic areas (i.e., Puerto Rico, American Samoa, US Virgin Islands).
    - *Recommended Vaccination Schedule, Intervals*: Three doses administered 6 months apart at 0, 6, and 12 months

Influenza Vaccines

- FLUCELVAX QUADRIVALENT (cIV): a Phase III Randomized Controlled Trial – Immunogenicity & Safety Results in Young Children (6 through 47 months of age)
    - Background: Flucelvax® Quadrivalent is the only cell-based quadrivalent influenza vaccine (cIV) in the United States; approved for use in persons ≥2 years of age
    - Study design: Phase 3 Randomized Controlled Trial
        - cIV (Flucelvax Quadrivalent) versus a QIV (Afluria Quadrivalent)
        - 2019–2020 Northern Hemisphere Flu Season (influenza B Victoria strain drove early transmission); 47 centres in the United States; included participants aged ≥6 to ≤47 months old.
        - Immunogenicity assessed using hemagglutination inhibition assays for A/H1N1, B/Yamagata, and B/Victoria strains and microneutralization assay for A/H3N2 strain
        - Participants randomized 2:1 (cIV:QIV)
    - Summary
        - cIV met all of the predefined non-inferiority criteria for immunogenicity as compared to QIV; Immunogenicity data consistent against all four strains; cIV well

tolerated, with similar rates of solicited and unsolicited adverse events between the two vaccination groups, consistent with previously reported data in older children

- Work group considerations and Proposed Influenza Vaccine Recommendations, 2021-22
  - 2021–22 ACIP Influenza Statement: core recommendation (unchanged): Annual influenza vaccination is recommended for all persons aged 6 months and older who do not have contraindications.
  - Change in Age Indication for Flucelvax Quadrivalent
    - Cell culture-based inactivated influenza vaccine (cIV).
      - Previously licensed for ages ≥4 years; approved March 2021 for ages ≥2 years.
      - Randomized 1:1 to receive cIV or meningococcal serogroup ACWY conjugate vaccine.
      - Vaccine efficacy 54.6% (95%CI 45.7, 62.1) against RT-PCR or culture) influenza-associated CDC-defined influenza-like illness.
      - Vaccine efficacy 62.7% (95%CI 38.1, 80.8) for matched strains.
  - Co-administration of Influenza Vaccines with COVID-19 Vaccine
    - From the "Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States" - substantial data have now been collected regarding the safety of COVID-19 vaccine...COVID-19 vaccines and other vaccines **may now be administered without regard to timing."**
  - Waning of Protection Following Vaccination - current 2020-21 statement
    - Declines in influenza vaccine effectiveness over the course of the season have been observed in many observational studies.
    - Appears to be more pronounced among older adults; Less evidence for waning among children

Rabies Vaccines

- Anticipated timeline: June 2021 - Present WG interpretation of data about RIG, PEP schedules- Votes on PrEP and children; October 2021 - PEP clinical guidance topics e.g., management of 1) schedule deviations for PrEP and PEP and 2) PEP initiated abroad
- Rabies immune globulin (RIG) - Newly licensed RIG products in U.S (new formulations)
  - Product name: **Kedrab™/ Kedrion** (manufactured by Biopharma and Kamada Ltd)
    - Licensed by FDA in 2017
    - Indicated for: Passive, transient post-exposure prophylaxis; To persons of all ages
    - Clinical study design and trial results similar to previously licensed RIG products
  - Product name: **HyperRab®** (manufactured by Grifols)
    - Licensed by FDA in 2018
    - Indicated for PEP along with rabies vaccine
    - Higher potency formulation of HyperRab™ S/D: Greater concentration of anti-rabies virus antibodies within each mL of volume; Less volume needed to administer recommended amount
    - No FDA post-licensure requirements because considered to be new formulation (not new product)
    - Improved production and manufacturing processes over the years

        - Requires dilution with Dextrose 5% in Water (D5W) rather than normal saline
    - Work Group Conclusions about Kedrab™ and HyperRab®
        - Safety and "efficacy": Similar to previously licensed RIGs
        - "Efficacy", defined as RVNA titer is 0.5 IU/mL or higher on Day 14:
            - Kedrab: 98.2% (n=56/57)
            - HyperRab: 100% (n=59/59)
        - Desirable to have multiple licensed RIG products (shortages have occurred)
        - Products equally "efficacious"; WG opposed to preferential recommendation of a specific RIG
- Rabies post-exposure prophylaxis schedule. PEP vaccine series: Change to the series for healthy and immunocompromised persons
    - Work Group conclusions: more studies are needed before a change can be proposed to the current 4-dose IM series
    - Clinical guidance for immunocompromised persons
        - ACIP currently recommends immunocompromised persons receive 5 dose series and then titres checked with additional doses as needed
        - Not all immunocompromised persons need 5 doses; many will have acceptable titres after 3 doses
- Rabies pre-exposure prophylaxis schedule: GRADE/ Evidence to Recommendations summary
    - Recommendations for June ACIP vote: **recommended**
        - ACIP recommends a 2-dose [0, 7 days] intramuscular rabies vaccine series in immunocompetent persons **<18 years of age** for who rabies vaccine pre-exposure prophylaxis in indicated
        - ACIP recommends an intramuscular booster dose of rabies vaccine, as an alternative to a titre 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.

Zoster Vaccine

- Policy question: Should vaccination with RZV be recommended for immunocompromised adults 19 years of age and older?
    - HZ-Herpes Zoster; ZVL-Zoster Vaccine Live; RZV: Recombinant Zoster Vaccine.
    - Population: immunocompromised adults ≥19 years of age; split into two parts (19–49 years, ≥50 years)
    - Intervention: RZV, 2 doses at least 4 weeks apart
- Current ACIP Recommendations
    - ACIP recommended RZV (Shingrix) in Oct 2017 for use in **immunocompetent** adults age ≥50 years.
    - ACIP recommendations include use of RZV in persons
        - Taking low-dose immunosuppressive therapy
        - Anticipating immunosuppression or who have recovered from an immunocompromising illness

- Burden of HZ in Immunocompromised Adults
  - Immunocompromised Populations under Consideration: 1. Hematopoietic stem cell transplant recipients; 2. Patients with hematologic malignancies; 3. Renal or other solid organ transplant recipients; 4. Patients with solid tumour malignancies; 5. People living with HIV; 6. Immunocompromised populations at increased risk of HZ not covered in groups 1 through 5 **(**primary immunodeficiencies; autoimmune conditions; taking immunosuppressive medications)
- Use of RZV in Immunocompromised Populations
  - Pooled Reactogenicity in Immunocompromised Patients
    - Unsolicited Adverse Events: across 6 studies, the percentage of adults reporting ≥1 unsolicited AE was similar between RZV and placebo groups (sucrose reconstituted with saline; or saline)
    - Serious Adverse Events: the percentage of adults with ≥1 SAE, causally related SAEs, fatal SAEs and potential immune-mediated disease was similar between RZV and placebo and between age groups
    - Safety: Underlying Disease-related Events
      - autologous hematopoietic stem cell transplant; hematologic malignancies: proportion of patients with disease progressions or disease relapse were balanced between RZV and placebo groups.
      - renal transplant: 4 biopsy-confirmed allograft rejections in the RZV group; 7 biopsy-confirmed allograft rejections in the placebo group; No impact on renal-allograft function based on serum creatinine levels.
  - Vaccine Efficacy in Immunocompromised Patients (95% CI)
    - autologous hematopoietic stem cell transplant: 68.2% (55.6–77.5)
      - (RZV: N=870; n=49; HZ Incidence rate=30/1,000 person years)
    - hematologic malignancies: 87.2% (44.3–98.6)
      - (RZV: N=259; n=2; HZ Incidence rate=8.5/1,000 person years)
  - Vaccine Immunogenicity: RZV is immunogenic even considering the impact of age, underlying disease, immunosuppressive treatment and immunisation either before, during or after immunosuppressive treatments
  - **RZV immunogenicity and efficacy and safety data support a favourable benefit-risk profile in immunocompromised adults ≥18 years of age, who are at an increased risk of HZ**
  - Next steps: GRADE analysis of existing evidence of RZV benefits and harms; review knowledge, attitude and practices for RZV in IC populations; cost effectiveness analysis use of RZV in immunocompromised populations.

Pneumococcal Vaccines

- Proposed timeline (2021):
  - June: Cost-effectiveness analysis and public health impact; GRADE/EtR for use of PCV15/20 in older adults.

  - September: Comparison of cost effectiveness analyses; GRADE/EtR for use of PCV15/20 in adults with underlying conditions.
  - October: Vote on recommendations for all newly licensed vaccines
- New Pneumococcal Vaccines
  - **20-valent pneumococcal conjugate vaccine (PCV20), Pfizer**
    - Licensed for use in adults aged ≥18 years on 8 June 2021
  - **15-valent pneumococcal conjugate vaccine (PCV15), Merck**
    - BLA filed to FDA, licensure 30 July 2021
    - FDA: https://www.fda.gov/vaccines-blood-biologics/vaccines/vaxneuvance
- Economic Assessment of PCV15 and PCV20: Evaluate cost effectiveness of using PCV15 or PCV20 in adults (evaluate adding PPSV23 to either of these recommendations)
  - Methods: Interventions – 8 strategies to evaluate
    1. PCV15 at CMC/IC & Age 50
       - PCV15 at diagnosis of immunocompromising (IC) or chronic medical condition (CMC) for adults 19-49 plus PCV15 at age 50 (no PCV revaccination)
    2. PCV20 at CMC/IC & Age 50
    3. PCV15 at CMC/IC & Age 65
    4. PCV20 at CMC/IC & Age 65
    5. PCV15+PPSV at CMC/IC & Age 50
       - As above, but with PPSV at diagnosis of IC or CMC or age 50
    6. PCV20+PPSV at CMC/IC & Age 50
    7. PCV15+PPSV at CMC/IC & Age 65
    8. PCV20+PPSV at CMC/IC & Age 65
  - Compare to current recommendations: PCV13 at diagnosis of IC, PPSV23 eight weeks later, 2nd dose of PPSV23 5 years later if under age 65; PPSV23 at diagnosis of CMC; PCV13 under shared clinical decision making at age 65, PPSV23 one year later
  - Summary of findings on cost effectiveness model:
    - Modelling indicated PCV20 was economically efficient at both ages 50 and 65 under several alternative scenarios
    - PCV15 model findings were mixed even under optimistic assumptions about PCV15 VE vs serotype 3
    - Adding PPSV23 to either PCV15 or PCV20 incurred high costs for minimal health gains in the model
    - PCV20 less likely to be economically efficient under predicted indirect protection from the childhood program over the long term as modelled
- Evidence to Recommendation Framework: Use of 15-valent and 20-valent Pneumococcal Conjugate Vaccines in Adults
  - Summary: Work Group Interpretations
    - Should Merck PCV15 be recommended for persons aged ≥65 years? **The balance between desirable and undesirable consequences is closely balanced or uncertain**

- Cost-effectiveness analysis showed some benefits in preventing disease.
- Concerns about losing coverage for 9 serotypes that are included in PPSV23

▪ Should Merck PCV15 be recommended for persons aged ≥65 years in series with PPSV23? **Undesirable consequences probably outweigh desirable consequences in most settings/ The balance between desirable and undesirable consequences is closely balanced or uncertain**

- PCV15-PPSV23 may prevent additional disease but added benefit likely small.
- Potential undesirable consequences related to resource use, feasibility, and equity may outweigh the desirable consequences.
- Some patients currently receive PCV13-PPSV23 series.

▪ Should Pfizer PCV20 be recommended for persons aged ≥50 years/ Should Pfizer PCV20 be recommended for persons aged ≥65 years? **Desirable consequences clearly outweigh undesirable consequences in most settings**

o Next Steps:

▪ Additional cost-effective analyses underway
▪ GRADE and EtR for risk-based recommendation for younger adults not targeted by the age-based recommendation – To be presented at the September ACIP meeting
▪ Refine policy options on age- and risk- based recommendations on PCV15 and PCV20 use in adults for a vote at the October ACIP meeting – PCV15 and PCV20 will be reviewed separately

1.2 Additional ACIP meetings focused on COVID-19 vaccines

Additional meetings were held on:

- 23 – 25 June 2021: https://www.cdc.gov/vaccines/acip/meetings/slides-2021-06.html
- 22 July 2021: https://www.cdc.gov/vaccines/acip/meetings/slides-2021-07-22.html
- 13 August 2021: https://www.cdc.gov/vaccines/acip/meetings/slides-2021-08-13.html

Briefly, the following topics were covered in these meetings:

- Update on COVID-19 vaccine safety, including myocarditis and pericarditis after mRNA vaccines
- COVID-19 mRNA vaccines in adolescents and young adults: benefit-risk discussion
- Guillain-Barré Syndrome (GBS) after Janssen COVID-19 vaccine: findings from Vaccine Adverse Event Reporting System (VAERS); Vaccine Safety Datalink (VSD)
- Vaccine Safety Technical Subgroup (VaST) assessment of GBS after Janssen COVID-19 vaccine
- COVID-19 vaccines: benefits-risk discussion
- Evidence to Recommendations Framework: Additional doses of mRNA COVID-19 vaccines as part of a primary series for immunocompromised
- Clinical considerations for use of an additional doses of mRNA COVID-19 vaccines as part of a primary vaccine series for immunocompromised people
- Update on emerging SARS-CoV-2 variants and COVID-19 vaccines
- Considerations for booster doses of COVID-19 vaccines

1.3 Newly published or updated recommendations

1.3.1 ACIP recommendations:

- These recommendations have been adopted by the CDC Director and will become official once published in MMWR.
- ACIP recommends: by majority vote at 23 – 25 June 2021 meeting
    - ACIP recommends 3-doses of Dengvaxia administered 6 months apart at month 0, 6, and 12, in persons 9-16 years of age with a laboratory confirmation of previous dengue infection and living in endemic areas.
    - ACIP affirms the updated MMWR Recommendations and Reports, "Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunisation Practices—United States, 2021-22 Influenza Season."
    - 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.

2 Immunisation Advisory Centre (IMAC), New Zealand

2.1 PTAC Considerations

Meetings were held on:

- 18 – 19 February 2021 (no vaccine specific considerations): https://pharmac.govt.nz/assets/2021-02-18-PTAC-Record.pdf
- 25 March 2021: https://pharmac.govt.nz/assets/ptac-minutes-2021-03.pdf
- 20 – 21 May 2021 (no vaccine specific considerations): https://pharmac.govt.nz/assets/2021-05-20-PTAC-meeting-record-web-version.pdf

25 March 2021:

Pneumococcal polysaccharide vaccine – Immunisation of people 65 years of age and over

- Recommendation: pneumococcal polysaccharide vaccine (PPV23) for the immunisation of all people 65 years of age and over declined. Considerations included:
    - The possible risks and benefits of funding the PPV23 for Māori; and additionally for Pacific people and others facing health disparities as a result of underlying disadvantage who are also under 65 years of age, and finally for those with comorbidities such as COPD or rheumatic heart disease;
    - The possible risks and benefits of funding the PPV23 for the general population under 65 years of age and whether there were any age groups that would potentially benefit most from immunisation with PPV23;

  - Whether repeat dosing would be required for an older patient population due to immunosenescence;
  - The relevance of herd immunity to pneumococcal infection;
  - The relevance of the current special groups listed in the Special Authority, and whether these should be revisited.
- The recommendation was based on…
  - Rates of IPD for Māori and Pacific populations in New Zealand is 3.8 and 4.3 times higher than the rate for NZ Europeans, respectively. Of all IPD related mortalities in the Pacific population, 50% occur before the age of 50 years, and for Māori 50% of IPD mortalities occur by 54 years of age. IPD mortality rates for NZ Europeans is 50% by 65 years of age. Māori comprise approximately 16% of the population but contribute to 50% of total deaths from IPD by 64 years of age. This demonstrates that the burden of disease from IPD is higher in a population younger than 65 years, and specifically in Māori and Pacific populations.
  - the evidence for PPV23 against pneumococcal infection in those aged over 65 to be of poor quality and mixed strength, with low-moderate, inconclusive evidence of efficacy against PPV23 serotypes and IPD, and low-quality evidence and imprecise results for the efficacy of PPV23 against non-bacteraemic pneumococcal pneumonia (NBPP).
  - Effectiveness was not demonstrated to be consistent in the general population, and that the meta-analyses reported a wide range of effectiveness estimates. Past advice was that PPV23 is effective against IPD, and that more robust evidence is needed to show efficacy against NBPP. Evidence presented for PPV23 against NBPP is imprecise and of low quality. Noted that although there appears to be limited benefit with PPV23, there would be no additional clinical risk to widening access.
  - It is reasonable to assume that uptake of the PPV23 in people aged 65 years of age and older would unlikely be higher than influenza vaccine, however, due to COVID-19, the uptake of influenza vaccine increased in 2020. The PPV23 vaccine can be administered at the same time as influenza vaccine, and that uptake may be affected if patients receive both at the same visit.
  - Data for IPD incidence and mortality show that the burden of disease from IPD is higher in a population younger than 65 years of age, and specifically in Māori and Pacific populations. Community acquired pneumonia is more common in those over 70 years of age, and not younger than 65 years. Noting the IPD incidence data for the New Zealand population, considered that the patient population that might benefit the most from receiving PPV23 are Māori and Pacific people younger than 65 years of age, who have chronic underlying health conditions.

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 Managing multiple immunisation programmes, Influenza 2021, New Handbook chapter – COVID-19 vaccines – 1 April 2021

- Influenza immunisation program continues but with some changes to recommendations on intervals between influenza and COVID-19 vaccines (2 week interval recommended)
- Asthma eligibility for influenza vaccine
    - PHARMAC confirmed in June 2020 that people with asthma who are prescribed a preventer inhaler meet the eligibility criteria for a funded influenza vaccination regardless of whether or not they routinely collect the inhaler (i.e., whether or not they are adherent with treatment).

2.2.2 Immunisation update – 5 May 2021

- Protecting against measles during the COVID-19 roll-out, especially 15 – 30 years age group.
    - A number of countries are experiencing measles outbreaks, making a large group of unimmunised teenagers and young adults vulnerable as travel restrictions ease.
    - Reduced focus on MMR campaigns in some areas - some DHBs will be reducing their focus on the National Measles Immunisation Campaign between now and October. DHBs will be in touch with providers if anything is changing in their region.
- Updated advice on gap between MMR and COVID-19 vaccines
    - A four-week gap when giving the MMR vaccine **before** the COVID-19 vaccine is preferred where possible.
    - However, the gap only needs to be two weeks when giving the MMR vaccine **after** the second dose of the COVID-19 vaccine.
    - A two-week gap between the COVID-19 vaccine and influenza vaccine, or any other non-live vaccine such as Tdap, where possible, regardless of the order they're given.
    - Why we leave a gap between COVID-19 and MMR/flu vaccines? Having a gap between the different types of vaccinations makes it easier to judge which vaccine may be responsible for any side effects. Note that there are no clinical safety concerns should the gap between vaccines be less than the recommendations above. Do not delay vaccination if such a gap is not possible. It's more important not to delay vaccines than to enforce the gap where it isn't feasible. The MMR and influenza vaccines can be given at the same time.

2.2.3 Immunisation update– 4 June 2021

- Evaluation of the Māori Influenza Vaccination Programme 2020
    - Following the success of last year's Māori Influenza Vaccination Programme (MIVP) in improving Māori influenza vaccination rates, the programme has been extended in 2021 to include the MMR vaccine.

2.2.4 Immunisation update – 8 July 2021

- Meningococcal B vaccine funded for close contacts from 1 June 2021 for:
    - close contacts of meningococcal cases of any meningococcal group (A, C, W, Y, B)

- people who are at higher risk of contracting meningococcal B because they have reduced immune function due to certain health condition

- These high-risk groups can now be offered both the meningococcal B (Bexsero) vaccine and the already-funded MenACWY vaccine (Menactra).
- Note - Only Menactra is funded for adolescents and young adults (13-25 years inclusive) who are, or will be, living in a boarding school hostel or university hall of residence, military barracks or prison.

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

3.1 JCVI meeting: 22 June 2021

- A summary of the JCVI meeting held in June is provided below
- Agenda: https://app.box.com/s/9f24lity6bqso9b6qi7c/file/819801673473
- Draft minutes, 22 June 2020: https://app.box.com/s/iddfb4ppwkmtjusir2tc/file/849032554320

- Infant schedule
    - February 2020: potential changes to the infant schedule had been suggested:
        - hexavalent at 8, 12 and 16 weeks and 12 or 18 months);
        - no change for PCV at 12 weeks and 24 months (NCIRS notes: '24 months' as stated in the published meeting minutes, but is potentially a typo as the current UK schedule is 12 months);
        - no change for MenB at 8, 16 weeks and 12 months and Rotavirus vaccines at 8 and 12 Weeks;
        - MMR 1 staying at 12 months with MMR2 coming down to 18 months which would allow the potential for MMRV (MMR + varicella) if varicella were added to be added to the schedule and,
        - dropping the preschool booster, a TdaP-IPV at 3 years and 4 months
    - Main concerns about the proposed change were whether the primary schedule would provide Hib protection to 18 months. Potentially a better primary response might be obtained using the Hib-OMP hexavalent vaccine (Vaxelis®) and boosting with a Hib tetanus conjugate hexavalent vaccine (Infanrix hexa®). Research or operational data would be required to inform the potential for using the two vaccines in the schedule in a priming boosting combination. Noted - The National Immunisation Schedule Evaluation Consortium (NISEC) had been planning to look at this and that Vaxelis was already being used in some local areas which offered the possibility of a study of the cohorts primed with this vaccine. In the absence of data there was also the potential to make advice based on first principles.
    - MenACWY might be needed for direct protection in infants rather than relying on indirect protection of teenage dose because of W cases occurring in infants. Infants

might require two doses of MenACWY. There was also the question of whether a single dose in infancy was better than a toddler dose.
    - Operational perspective: need to consult as to whether it would be better to have one big change or a series of changes. Frequent changes could be harder to manage and have a knock-on effect on uptake. The additional visit at 18 months would be the major change. Giving four vaccinations at 12 months is also a challenge for both the service and parents.
- RSV
    - Horizon scanning: indicated several products were in the pipeline from manufacturers which would require considering in the near term via an RSV subcommittee.
    - Loosening of lockdown there was a potential resurgence in RSV happening with a recent rise in cases seen in the North West (England). Western Australia had also had an unseasonal outbreak in RSV with a substantial wave 26 weeks later or earlier than usual which lasted 8 weeks. A small signal in lab reports and admissions in infants had also been detected.
    - JCVI agreed to the policy to widen the eligible cohort to receive Palivizumab. Noted that there was almost no RSV detected during 2020/21; Palivizumab policy was stopped in March 2021.
    - Noted that a long-lasting monoclonal product, Nirsevimab, which was currently unlicensed, looked promising and only required a single dose for the RSV season. Possibility for some early supply being made available and the potential to factor this into clinical advice for 2021/22 season.
    - Agreed that all efforts should be made to explore the potential use of the new monoclonal for the coming winter. Potential target groups for this might be larger than the current Palivizumab population. Would need to consider what would be the most logical extended group/cohorts to offer this to, and what was deployable (might be all children born prematurely aged less than six months of age and older children at risk about to leave neonatal units). Modelling could help identify what might be the best strategy. Monitoring for potential escape mutants would be important as this was a single monoclonal antibody.
    - Consideration for future seasons: look at using the new monoclonal product in babies at birth born from June onwards to be protected until the end of the following RSV season, or to cover babies who will be aged up to six months of age by the end of the season. The exact window would depend on the cost effectiveness estimates.
- Influenza
    - Planning for the 2021/22 season noted that:
        - All 50-64 years olds would again be offered flu vaccination
        - The children's program was extended into year 7 in secondary schools
        - All children in secondary school up to year 11 will be offered LAIV - funded for one season only (COVID-19 pandemic - expectation that flu would rebound in 2021/22 in the absence of social distancing); policy were looking to make roll out routine

- For 2020/21 Influenza vaccine uptake across the UK population was the highest ever: 81% in ≥65 years, 53% in at-risk groups <65 years, 77% in healthcare workers, 43.6% in pregnant women, 62.5% for children up to Year 6, 56.2% for children in Year 7.

- Shingles
  - Recap of recent advice on shingles program and issues that still required advice:
    - Zostavax® was to be replaced with a two dose schedule of Shingrix® (once available), offered routinely at the age of 60 years;
    - Program implemented in stages, starting with vaccination at ages 65 and 70 years until vaccine had been offered to all those aged 65 to 70 years of age and so on. Vaccination should then be routinely offered at age 60;
    - Those >70 years who were contraindicated to receive the live vaccine Zostavax® should also receive Shingrix® once stocks were available;
    - Shingrix® should be offered to immunocompromised individuals aged 50 and over, and that an expert working group be formed to consider the definition of immunocompromised for vaccination;
    - Outstanding issues for advice: offer of Shingrix® to those in the 70-86 years age group who had been offered Zostavax® under the existing program.
  - Presentation from PHE noting that:
    - A program in place to commence in September 2021 to offer Shingrix® to those contraindicated for Zostavax® for the routine programme with a catch up within the first year for those who remaining eligible up to 80 years old;
    - The program was projected to move to routinely offer Shingrix® to the clinical risk groups for whom Zostavax® is contraindicated from 2022/23;
    - Additional JCVIs advice: recommendation to offer Shingrix® to immunocompromised in age groups outside routine programme; shown to be cost effective for any age from 50 to 90 years old;
    - Outstanding questions remaining included whether individuals aged 87 years and older who have not previously been eligible for Zostavax and those aged 70-87 eligible for Zostavax®, should be offered Shingrix® (as they have been in the US). In the latter a large proportion remain unvaccinated whilst the question of revaccination required additional modelling.
    - Real world effectiveness data was now available from the US showing a VE against herpes zoster of 56.9% (95% CI, 55.0-58.8) and 70.1% (95% CI, 68.6-71.5) for one and two doses respectively and 76.0% (95% CI, 68.4-81.8) against PHN for two doses among 70 – 80 year olds. VE was not significantly lower in those aged 80+ years or for longer intervals between doses. Two dose VE in immunocompromised individuals was 64.1% (95% CI, 57.2–69.8);
    - Clinical trials: shown Shingrix® to be quite a reactogenic vaccine but with no specific safety concerns for the immunocompromised. VAERS monitoring system had not raised anything unexpected and was in line with the trial data

with no specific safety concerns. Signals of Bell's palsy and GBS were detected from an alternative safety data source (US vaccine safety datalink) which provides rapid real time analysis. Further analyses showed no sustained evidence of an increased risk for these two adverse events but this was being kept under review by the FDA.

  - Real world VE data was lower than that seen in the clinical trials, however, estimates were not directly comparable due to differences in the groups studied and the case definitions used. The Committee noted that high efficacy and lack of waning were important components in the original modelling work.

- HPV
  - JCVI would be able to advise a one dose schedule for the bivalent and quadrivalent (4vHPV) vaccines but needed to see more data for the 9-valent vaccine (9vHPV). Currently there were no short term persistence antibody data for one dose of 9vHPV, but this was expected at the end of this year from ongoing trials. The Committee wanted to see shorter term efficacy data on one dose of 9vHPV for all nine HPV types.
  - Noted that 9vHPV was expected to replace 4vHPV) in the UK in coming academic year 2021/22 and that during this transition some would receive a mixed schedule of 4v and 9vHPV. No concerns about the interchangeability of the two vaccines.
  - Agreed with the HPV Subcommittees advice last year to move from two to three doses in those aged over fifteen years of age. Outstanding issue: whether to include those with HIV or who were immunocompromised in this change. Given the absence of data in this group, the schedule would stay at three doses.
  - Noted that in the MSM program run in HIV and genitourinary medicine (GUM) clinics adherence to a two-dose schedule might be challenging and that a move to two doses might mean the second dose is missed compared with someone receiving the first two doses (at 0 and 1 month) of the three dose schedule.
  - Need: study to investigate a rapid two dose schedule for MSM in the HIV population.
- Pneumococcal
  - Higher valent pneumococcal conjugated vaccines (PCV15; PCV 20) currently undergoing clinical trials; not far off from potential licensure in elderly and infants.
  - Since the introduction of the 1+1 infant schedule it has not been possible to evaluate the impact of this as the pandemic has had a substantial impact on pneumococcal transmission due to social distancing measures.
- Vaccine strategy
  - Phase 1: cover the progress achieved to date and what could be drawn from the success of the COVID-19 and enhanced influenza programmes. Set out ambitions for COVID-19 and influenza this winter and operational considerations.
  - Phase 2: focus planning in the longer term, to be published in 2022.

4 National Advisory Committee on Immunisation (NACI), Canada

4.1 NACI Meetings

The most recent meeting was conducted virtually on 31 August 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:

- 26 April 2021.
- 4 May 2021; 13 May 2021; 18 May 2021; 26 May 2021.
- 1 June 2021; 9 June 2021; 15 June 2021; 21 June 2021; 22 June 2021; 24 June 2021; 29 June 2021; 30 June 2021.
- 8 July 2021; 9 July 2021; 13 July 2021; 20 July 2021; 27 July 2021.
- 3 August 2021; 10 August 2021; 17 August 2021; 24 August 2021; 31 August 2021.

4.2 Newly published or updated statement/recommendations

4.2.1 Recommendations on the use of COVID-19 vaccines

- Current vaccine statement: Published 22 July 2021
  https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines.html
    - Summary of NACI updates of 22 July 2021: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines/summary-updates-july-22-2021.html
    - Table of updates: Recommendations on the use of COVID-19 vaccines: https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/recommendations-use-covid-19-vaccines/table-updates.html
- Currently authorised vaccines*:* Pfizer BioNTech COVID-19 vaccine, Moderna COVID-19 vaccine, AstraZeneca COVID-19 vaccine, Janssen COVID-19 vaccine

4.2.2 Canadian Immunisation Guide Chapter on influenza and statement on seasonal influenza vaccine for 2021–2022

- Published 31 May 2021: https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/canadian-immunization-guide-statement-seasonal-influenza-vaccine-2021-2022.html
    - Update to age indication for Flucelvax® Quad (Seqirus): is now authorised for use in persons ≥2 years of age.

4.2.3 Use of Measles-Mumps-Rubella (MMR) Vaccine for the Management of Mumps Outbreaks in Canada:

- Published 27 July 2021: https://www.canada.ca/en/public-health/services/publications/vaccines-immunization/use-measles-mumps-rubella-vaccine-management-outbreaks-canada.html
    - Recommendation 1: NACI recommends that an outbreak dose of MMR vaccine may be considered in an outbreak setting. (Discretionary Recommendation)

        - NACI concludes there is fair evidence to recommend MMR vaccine use (including catch-up vaccination with or without MMR3) during outbreaks (Grade B Evidence)
    - Recommendation 2: NACI recommends that providing MMR vaccine up to a third dose to close contacts following exposure to a case of mumps may be considered in an outbreak setting (Discretionary Recommendation)
        - NACI concludes there is insufficient evidence for or against recommending a dose of mumps-containing vaccine to close contacts following exposure to a case of mumps (Grade I Evidence).

5 Immunisation updates from the World Health Organization (WHO)

5.1 WHO Position Papers

- No updates

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

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

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

Meeting date: 29 April 2021

- Meeting details: 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

Meeting date: 27 May 2021

- Meeting details: https://www.who.int/news-room/events/detail/2021/05/27/default-calendar/extraordinary-meeting-of-the-strategic-advisory-group-of-experts-on-immunization-(sage)-27-may-2021

Meeting date: 29 June 2021

- Meeting details: https://www.who.int/news-room/events/detail/2021/06/29/default-calendar/extraordinary-meeting-of-the-strategic-advisory-group-of-experts-on-immunization-sage-29-june-2021

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

A number of meetings of SAGE occurred where the use of COVID-19 vaccines was discussed; only key updates are included in this summary. There were no discussions related to the use of other vaccines.

31 March 2021:

- Minutes: https://www.gov.uk/government/publications/eighty-fifth-sage-meeting-on-covid-19-31-march-2021

8 April 2021:

- Minutes: https://www.gov.uk/government/publications/sage-86-minutes-coronavirus-covid-19-response-8-april-2021
    - Data from before the pandemic shows that for adults, the majority of contacts are associated with work (for children, the majority are associated with school). Epidemic trajectory over the coming months is therefore likely to depend to a large extent on the scale of increase in workplace contacts (high confidence).
    - While wild-type SARS-CoV-2 appears unable to infect rats and mice, laboratory studies suggest that the N501Y spike protein mutation (found in several variants of concern) increases binding to rat and mouse ACE2 leading to viral replication. SARS-CoV-2 infection in wild rodents has not however been detected. While rodents are a possible animal reservoir, the likelihood currently of a variant of concern emerging as a result of adaptation in rodents is low.

22 April 2021:

- Minutes: https://www.gov.uk/government/publications/sage-87-minutes-coronavirus-covid-19-response-22-april-2021
    - Variants other than Alpha make up around 2% of sequenced genomes in the UK where the variant can be determined.
    - Ongoing baseline measures and sustained long-term behavioural change will be required to control a resurgence in infections. Three main ways in which baseline measures can reduce transmission (from most to least effective):
        - Reducing the likelihood that people who are infectious mix with others.
        - For those potentially infectious people who are not isolated, reducing the likelihood that they enter higher risk settings or situations.
        - Decreasing the transmission risk from a potentially infectious person in any given environment.

5 May 2021:

- Minutes: https://www.gov.uk/government/publications/sage-88-minutes-coronavirus-covid-19-response-5-may-2021

13 May 2021:

- Minutes: https://www.gov.uk/government/publications/sage-89-minutes-coronavirus-covid-19-response-13-may-2021
    - Transmission of this variant is currently faster than that of the Alpha variant most prevalent in the UK (high confidence). Observed doubling times are around a week or shorter for some of the largest clusters but slower in others.

27 May 2021:

- Minutes: https://www.gov.uk/government/publications/sage-90-minutes-coronavirus-covid-19-response-27-may-2021
    - PHE analysis also indicates some decrease in vaccine effectiveness against Delta compared to effectiveness against Alpha. Effectiveness against symptomatic infection after a first dose drops from around 50% to 33%, and after two doses from 88% to 81%.

3 June 2021:

- Minutes: https://www.gov.uk/government/publications/sage-91-minutes-coronavirus-covid-19-response-3-june-2021
    - The delta variant has a significant growth advantage over the Alpha variant (high confidence) and in local areas with higher proportions of S-gene positive (a proxy for delta variant) cases, the number of infections is increasing more rapidly.

9 June 2021:

- Minutes: https://www.gov.uk/government/publications/sage-92-minutes-coronavirus-covid-19-response-9-june-2021
    - R is now estimated to be 40–80% higher for delta than for Alpha.

7 July 2021:

- Minutes: https://www.gov.uk/government/publications/sage-93-minutes-coronavirus-covid-19-response-7-july-2021
    - COVID-19 Clinical Information Network (CO-CIN) analysis shows reductions in morbidity and mortality in hospital patients, due to the lower average age of patients and the impact of vaccination.

22 July 2021:

- Minutes: https://www.gov.uk/government/publications/sage-94-minutes-coronavirus-covid-19-response-22-july-2020
    - Data suggest that those who have been vaccinated who become infected with the delta variant may still have a high viral load (medium confidence).

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

- A meeting was held on 13 and 20 July 2021
- Statement of the WHO Global Advisory Committee on Vaccine Safety (GACVS) COVID-19 subcommittee on reports of Guillain-Barré Syndrome (GBS) following adenovirus vector COVID-19 vaccines: https://www.who.int/news/item/26-07-2021-statement-of-the-who-gacvs-covid-19-subcommittee-on-gbs

  GACVS subcommittee conclusions and recommendations:
    - Rare cases of GBS have been reported following vaccinations with adenovirus vector COVID-19 vaccines; Increased reports of GBS have not been observed following mRNA COVID-19 vaccines.
    - More rigorous studies using alternative data sources and robust study designs, and comparison of vaccinated and unvaccinated populations would be needed, to fully assess the significance of these events.

- Healthcare professionals should monitor for and report all adverse events including GBS. Countries should continue to collate detailed data on cases. Ideally, data should be gathered through active surveillance within hospitals to provide a more thorough understanding of this safety issue.
- Individuals receiving Janssen or AstraZeneca COVID-19 vaccines should be alert to signs and symptoms of GBS and should seek immediate medical attention if they develop weakness/tingling and paralysis in the extremities that may progress to other parts of the body including the chest and face. Most people fully recover from GBS.
- Conclusion: potential benefits of Janssen and AstraZeneca COVID-19 vaccines continue to outweigh any potential risk of GBS, particularly given the increase in the Delta variant.

5.5 WHO Regional Committee for the Western Pacific meeting

- No meetings held after 6-9 October 2020
- The next meeting is scheduled for 25-29 October 2021
- Regional Committee meeting page: https://www.who.int/westernpacific/about/governance/regional-committee

5.6 Global immunisation news and other items and resources

- Latest news available here: https://www.who.int/news-room/fact-sheets/detail/immunization-coverage
- 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/
  Includes a framework for action to implement IA2030, with a monitoring and evaluation framework https://www.who.int/publications/m/item/implementing-the-immunization-agenda-2030

5.7 COVID-19 related reports, guidelines and publications

- Recent COVID-19 publications published by WPRO: https://iris.wpro.who.int/handle/10665.1/14505
- Disease Outbreak News (DONs): https://www.who.int/emergencies/disease-outbreak-news

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

6 Other items

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

6.1.1 Public summary documents

Provisional Registrations: https://www.tga.gov.au/covid-19-vaccine-provisional-registrations

6.1.2 TGA media releases

- Media releases and statements landing page: https://www.tga.gov.au/media-releases-statements
  Note: only key updates are provided in this summary
- Updates related to COVID-19 vaccines can be found here: https://www.tga.gov.au/covid-19-vaccine-news-and-updates
- Provisional determination granted to Pfizer in relation to COVID 19 vaccine, COMIRNATY - for use in individuals 12 years of age and older (12 May 2021): https://www.tga.gov.au/provisional-determination-granted-pfizer-relation-covid-19-vaccine-comirnaty-use-individuals-12-years-age-and-older
- TGA grants provisional determination for the Moderna COVID-19 vaccine, Elasomeran (24 June 2021): https://www.tga.gov.au/media-release/tga-grants-provisional-determination-moderna-covid-19-vaccine-elasomeran
- COVID-19 vaccine: Janssen (25 June 2021): https://www.tga.gov.au/covid-19-vaccine-janssen
- TGA Provisional Approval of Pfizer-BioNTech COVID-19 vaccine to include 12-15 years age group (23 July 2021): https://www.tga.gov.au/tga-provisional-approval-pfizer-biontech-covid-19-vaccine-include-12-15-years-age-group
- COVID-19 vaccines undergoing evaluation (page updated 9 August 2021) https://www.tga.gov.au/covid-19-vaccines-undergoing-evaluation
- COVID-19 vaccine weekly safety reports (weekly)
  - 19 August 2021: https://www.tga.gov.au/periodic/covid-19-vaccine-weekly-safety-report-19-08-2021

7 Upcoming meetings and agendas

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

- 2021: 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/)

- 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)

All meetings will be conducted virtually.

- 27 July 2021
- 3 August 2021; 10 August 2021; 17 August 2021; 24 August 2021; 31 August 2021
- 7 September 2021; 14 September 2021; 21 September 2021; 28 September 2021

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

- 5 – 7 October 2021

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

- 15 - 16 December 2021

WPRO

- Future meeting dates pending

ACV

- 29 September 2021
- 1 December 2021

8 Appendix

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

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

Pfizer BioNTech COVID-19 Vaccine COMIRNATY

- Interim recommendations for use of the Pfizer–BioNTech COVID-19 vaccine, BNT162b2, under Emergency Use Listing (15 June 2021): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BNT162b2-2021.1
- Training on handling, storing and transporting Pfizer BioNTech COVID-19 Vaccine COMIRNATY® (Tozinameran), 4 August 2021 - https://www.who.int/publications/m/item/training-on-handling-storing-and-transporting-pfizer-biontech-covid-19-vaccine-comirnaty-(tozinameran)

COVID-19 (AstraZeneca COVID-19 vaccine Vaxzevria)

- AstraZeneca ChAdOx1-S/nCoV-19 [recombinant], 10 May 2021 - https://www.who.int/publications/m/item/chadox1-s-recombinant-covid-19-vaccine
- Interim recommendations for use of the ChAdOx1-S [recombinant] vaccine against COVID-19 (AstraZeneca COVID-19 vaccine AZD1222 Vaxzevria™, SII COVISHIELD™), Interim guidance, 30 July 2021 - https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-AZD1222-2021.1

- Annexes: https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-AZD1222-GRADE-ETR-2021.1

Moderna mRNA-1273 vaccine against COVID-19

- Interim recommendations for use of the Moderna mRNA-1273 vaccine against COVID-19, 15 June 2021 - https://www.who.int/publications/i/item/interim-recommendations-for-use-of-the-moderna-mrna-1273-vaccine-against-covid-19

Janssen Ad26.COV2.S (COVID-19) vaccine

- Interim recommendations for the use of the Janssen Ad26.COV2.S (COVID-19) vaccine, 15 June 2021 - https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-Ad26.COV2.S-2021.1
    - Annexes: https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-Ad26.COV2.S-GRADE-ETR-annexes

CoronaVac, developed by Sinovac

- Interim recommendations for use of the inactivated COVID-19 vaccine BIBP developed by China National Biotec Group (CNBG), Sinopharm, Interim Guidance (7 May 2021): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BIBP-2021.1
    - Annexes to WHO interim recommendations for use of the COVID-19 vaccine BIBP: GRADE and Evidence to Recommendations tables (7 May 2021): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-COVID-19-vaccine-BIBP-GRADE-ETR-annexes
    - Background document on the inactivated COVID-19 vaccine BIBP developed by China National Biotec Group (CNBG) (6 May 2021): https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-COVID-19-vaccine-BIBP-background
- Interim recommendations for use of the inactivated COVID-19 vaccine, CoronaVac, developed by Sinovac, 1 June 2021 - https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-Sinovac-CoronaVac-2021.1
    - Annexes: https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-Sinovac-CoronaVac-annexes-2021.1
    - Background document: https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-Sinovac-CoronaVac-background-2021.1

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

- Interim recommendations for use of the inactivated COVID-19 vaccine BIBP developed by China National Biotec Group (CNBG), Sinopharm, Interim guidance, 7 May 2021 - https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BIBP-2021.1
    - Annexes: https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BIBP-annexes-2021.1

- Background document: https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE_recommendation-BIBP-background-2021.1
- Annexes to WHO interim recommendations for use of the COVID-19 vaccine BIBP: GRADE and Evidence to Recommendations tables - https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccines-SAGE-recommendation-COVID-19-vaccine-BIBP-GRADE-ETR-annexes

Vaccine effectiveness evaluations

- Guidance on conducting vaccine effectiveness evaluations in the setting of new SARS-CoV-2 variants: Interim guidance, 22 July 2021. Addendum to Evaluation of COVID-19 vaccine effectiveness - https://www.who.int/publications/i/item/WHO-2019-nCoV-vaccine_effectiveness-variants-2021.1

Surveillance

- Guidance for surveillance of SARS-CoV-2 variants: Interim guidance, 9 August 2021 - https://www.who.int/publications/i/item/WHO_2019-nCoV_surveillance_variants

Pregnancy

- Update on WHO Interim recommendations on COVID-19 vaccination of pregnant and lactating women, 10 June 2021 - https://www.who.int/publications/m/item/update-on-who-interim-recommendations-on-covid-19-vaccination-of-pregnant-and-lactating-women

Vaccine prioritisation

- WHO Global COVID-19 Vaccination Strategy: July 2021 Update (draft document): https://cdn.who.int/media/docs/default-source/immunization/sage/draft_global_covid19_vaxstrategy20210625b52f92d0-1cab-465f-a9cb-93fc282dbc8c.pdf?sfvrsn=a997952f_1
- **Interim WHO recommendations:** WHO SAGE Roadmap For Prioritizing Uses Of COVID-19 Vaccines In The Context Of Limited Supply - 16 July 2021: https://www.who.int/publications/i/item/who-sage-roadmap-for-prioritizing-uses-of-covid-19-vaccines-in-the-context-of-limited-supply