**Summary of key commentaries, decisions and recommendations of four international immunisation technical advisory groups**

Prepared by the National Centre for Immunisation Research & Surveillance (NCIRS)
Summary: September 2016 to January 2017 as at 31 January 2017

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1 Advisory Committee on Immunization Practices (ACIP), U.S.

1.1 ACIP meeting: 19-20 October 2016

- Agenda, presentation slides, and video recordings of this meeting, and minutes of October 2016: http://www.cdc.gov/vaccines/acip/meetings/meetings-info.html
- Full minutes for the October 2016 meeting are pending; therefore this summary has been developed from the presentation slides and video recordings.

Hepatitis B Vaccines

- Summary and review of existing recommendations for Hepatitis B vaccination
- Changes to the HepB vaccination statement
  - Testing HBsAg-Positive pregnant women for HBV DNA*
  - Post-vaccination serological testing for infants whose mother’s HBsAg status remains unknown indefinitely*
  - Removal of permissive language allowing administration of the birth dose after discharge from hospital, specifying administration of the birth dose within 24 hours of birth and removal of language permitting administration after discharge from hospital.
    - Rationale: serves as a safety net to prevent HepB transmission due to errors in maternal HBsAg testing
    - Current Handbook recommendation is administration of a birth dose “as soon as the baby is medically stable, and preferably within 24 hours of birth. Every effort should be made to administer the vaccine before discharge from the obstetric hospital or delivery unit.”
  - An explicit recommendation for HepB vaccine for persons with HCV infection

* A similar recommendation is currently not explicitly stated in the Handbook.

Pertussis Vaccines

- Modification of guidance on the use of Tdap in pregnancy
  - Epidemiological evidence shows vaccinating at an earlier gestational age within the current recommended time period (between 27 to 36 weeks gestation) may be beneficial, but vaccination too early in pregnancy may not allow for sustained antibodies through the infant’s first vaccine dose
  - Proposed that recommendation be revised to encourage vaccination earlier in the recommended time window\(^1\)
  - WG deliberations:
    1. Expanding window to include earlier Tdap administration (e.g. as early as 22 wks) – no support
    2. Narrowing window (27-32 wks) – minority
    3. No change to current window (27-36), but emphasize earlier administration within window – majority
  - Current: “To maximize the maternal antibody response and passive antibody transfer to the infant, optimal timing for Tdap administration is between 27 and 36 weeks gestation although Tdap may be given at any time during pregnancy. For women not previously vaccinated with Tdap, if Tdap is not administered during pregnancy, Tdap should be administered immediately postpartum”
  - Draft change: “Tdap should be administered between 27 and 36 weeks gestation, although it may be given at any time during pregnancy. Currently available data suggest that vaccinating earlier in the 27 through 36 week window will maximize passive antibody transfer to the infant. ...”

o Recommendation for postpartum vaccination if not vaccinated during pregnancy remains unchanged

- Updated ACIP statement for pertussis, tetanus and diphtheria
  - Includes guidance for use in pregnant women with summary of safety data

**HPV Vaccines**

- Review of evidence for 2-dose schedules for HPV vaccination
  - 9vHPV 2-dose immunogenicity trial
    - Primary analysis was 2-dose 9vHPV in 9-14 year olds (females and males) vs. 3-dose 9vHPV in 16-26 year olds (females only)
    - 2 doses in 9–14 year olds were non-inferior and significantly higher 1 month and 6 months after last dose
    - GMTs by interval between doses in 2-dose (0,6 months) groups support a minimum interval of 5 months for 2-dose schedule
  - Immunogenicity data on 2-dose schedules for 2vHPV and 4vHPV were reviewed
    - In all trials, 2 doses (0,6 months or 0,12 months) in ~9–14 year olds were non-inferior to 3 doses in older age group
    - Follow-up time periods for these trials were 60 months, 36 months and 12 months for 2vHPV, 4vHPV and 9vHPV, respectively
  - No efficacy data from 2- vs. 3-dose RCTs of HPV vaccine on infection or disease endpoints
    - Limited data from a post-hoc analysis (2vHPV) and an observational study (4vHPV) which suggest efficacy of 2-dose schedule
    - Post-licensure evaluations found 2-doses not as effective as 3, but had several limitations (e.g. older population, shorter dose intervals)
  - Modelling and cost-effectiveness study of 2-dose vaccination
    - If efficacy and duration of protection after 2 doses and 3 doses are similar, 2 doses will be cost-saving compared with 3 doses
    - The incremental health benefits and cost-effectiveness of a 3rd dose of HPV vaccine depend most on relative duration of efficacy provided by 2 vs. 3 doses
    - 3-dose vaccination (assuming lifelong protection) is predicted to have high incremental cost per QALY gained (> $118,000) compared to 2 doses, except when 2-dose protection is <20 years (if duration of protection=15 years, ICER=$37,700/QALY [June 2016 ACIP slides])

- Proposed changes to recommendations:
  - Recommended schedule for persons initiating vaccination prior to their 15th birthday: 2 doses of HPV vaccine, with the second dose administered 6-12 months after the first dose (0, 6-12 month schedule)
  - After 15th birthday, a 3-dose schedule is recommended (0, 1-2, 6 month)
  - Persons who received 2 or 3 doses of any HPV vaccine prior to their 15th birthday are considered adequately vaccinated
  - 9vHPV may be used to continue or complete a series started with 4vHPV or 2vHPV
  - Persons vaccinated with 4vHPV or 2vHPV do not need additional vaccination with 9vHPV
  - Minimum intervals:
    - In a 2-dose series, the minimum interval is 5 months between the first and second dose
    - In a 3-dose series, the minimum intervals are 1 month between the first and second dose, 3 months between the second and third dose, and 5 months between the first and third dose
  - Special populations: HPV vaccination is recommended for immunocompromised males and females, MSM and transgender persons through age 26 years
Meningococcal Vaccines

- Impact of MenB-FHbp (Trumenba) on meningococcal carriage among college students in the context of a MenB outbreak
  - Cases were a 19- and 20-year old male undergraduates; rare sequence type ST-9069; attack rate = 44 cases per 100,000 students (national incidence: 0.15)
  - Mass MenB-FHbp vaccination campaign in 2015:
    - February: 3,745 eligible, 94% coverage
    - April: 3,741 eligible, 80% coverage
    - September: 4,087 eligible, 77% coverage
  - Four rounds of oropharyngeal swabs to detect nasopharyngeal carriage: Feb ’15, Apr ’15, Sep ’15, Feb ’16
    - 20-24% meningococcal carriage, 4% serogroup B carriage in each round (higher than recent U.S. estimates of 1-8% among general population)
    - Despite high carriage prevalence, only 1 carrier of outbreak strain identified
  - MenB-FHbp vaccination did not appear to impact carriage
    - Positive association found with class year, males, smoking, and visiting bars, clubs or parties
    - Negative association with recent antibiotic use (≤2 weeks)

- Overall conclusions of three immunogenicity studies of two MenB vaccines in adults (2 studies with MenB-4C and one with MenB-FHbp)
  - One month post dose 2, both vaccines elicited protective bactericidal antibody (titres 1:4) against most strains
  - Some strains are relatively resistant to bactericidal activity despite prediction of susceptibility by sequence analysis and antigen expression
  - After dose 2, titres can decline within 4 to 6 months, especially for strains with low antigen expression

- MenB-FHbp update
  - Changes to the dosage and administration section for MenB-FHbp (Trumenba) – approved by FDA on 14 April 2016
    - Updated 3-dose schedule to allow flexibility in timing of second dose (from 0, 2, 6 month to 0, 1-2, 6 month)
    - Addition of a 2-dose schedule at 0 and 6 months, with the choice of a 2 or 3 dose schedule dependent on the risk of exposure and patient’s susceptibility to MenB

- Considerations for use of 2-and 3-dose schedules of MenB-FHbp
  - Schedules evaluated:
    - 3-dose: 0, 2, 6 months and 0, 1, 6 months
    - 2-dose: 0, 6 months; 0, 4 months; 0, 2 months; 0, 1 months
  - Findings:
    - Among the 2-dose schedules evaluated for MenB-FHbp, the 0, 6 month schedule had the highest % responders and GMTs and is most similar to a 3-dose schedule
    - The proportion of subjects with composite response to the four primary strains is slightly lower with a 2-dose schedule at (0, 6 months) compared to either 3-dose schedule
    - For most strains the GMTs are lower with a 2-dose schedule (0, 6 months) of MenB-FHbp compared to either 3-dose schedule (for some strains 95%CI did not overlap)
    - The percent of subjects with hSBA titers ≥1:4 to the four primary strains is similar for adolescents who received 2-doses (0, 6 months) or 3-doses (0, 2, 6 months)
    - hSBA GMT responses to a single booster dose 4 years following either 2-or 3-doses of MenB-FHbp are similar
    - Safety and tolerability profiles are similar for the 2- and 3-dose schedules of MenB-FHbp

- Policy options for schedule for MenB-FHbp:
For persons at increased risk and for use during outbreaks: Preference for 3-dose schedule (0, 1-2, 6 months);

Three options for healthy adolescents:
1. Preference for 2-dose schedule (0, 6 months)
2. Option for 2-((0, 6 months) or 3-dose (0, 1-2, 6 months) schedule
3. Preference for 3-dose schedule (0, 1-2, 6 months)

Work Group preference for and proposed to vote on option 1 for healthy adolescents

Herpes Zoster Vaccines

- Update on herpes zoster epidemiology and vaccine coverage
  - Zostavax: licensed by FDA in 2006; recommended by ACIP in 2008 for ≥60 year olds; FDA age expansion to 50-59 year olds in 2011; ACIP reaffirmed recommendation for adults ≥60 year olds due to waning immunity
  - Uptake increasing but still low (~28% in 2014)
    - Reasons for low uptake include price, storage and handling, supply shortages, Medicare Part D reimbursement, lower prioritisation, and general fragmentation of care for older persons
- New vaccines for immunocompromised:
  - V212 (Merck): inactivated formulation of Zostavax: ongoing phase 3 efficacy trials, 4-dose series in persons ≥18 years old
  - HZ/su (GSK): ongoing phase 3 efficacy trials, 2 dose series in persons ≥18 years old
- Update on development of HZ/su vaccine efficacy by GSK
  - Three pivotal phase III efficacy studies:
    - 006 (ZOE-50): RCT adults ≥50 years, n=16,160 – completed
    - 022 (ZOE-70): RCT adults ≥70 years, n=14,816 – completed
    - 022 – adults ≥18 years autologous haematopoietic stem cell transport – ongoing
  - VE outcomes from ZOE-50 (endpoint: HZ cases): ≥50 years – 97.2% (93.7-99.0); 50-59 years – 96.6% (89.6-99.3); 60-69 years – 97.4% (90.1-99.7); ≥70 years – 97.9% (87.9-100); ≥60 years – 97.6% (92.8-99.6)
  - VE outcomes from ZOE-70 (endpoint: HZ cases): ≥70 years – 89.8% (84.2-93.7); 70-79 years – 90.0% (83.5-94.4); ≥80 years – 89.1% (74.6-96.2)
  - Pooled VE from ZOE-50 and ZOE-70; endpoint HZ cases:
    - By age: ≥70 years – 91.3% (86.8-94.5); 70-79 years – 91.3% (86.0-94.9); ≥80 years – 91.4% (80.2-97.0)
    - By year of vaccination: Year 1 – 97.6%; Year 2 – 92.0%; Year 3 – 84.7%; Year 4 – 87.9%
  - Pooled VE from ZOE-50 and ZOE-70; endpoint PHN: ≥70 years – 88.8% (68.7-97.1); ≥50 years – 91.2%; ≥60 years – 89.4%; 70-79 years – 93.0%; ≥80 years – 71.2% (NS)
  - Highly reactogenic:
    - 79% of vaccine recipients report a reaction to the vaccine (placebo= 30%), high frequency of local pain (~70% and ~80% in ZOE-70 and ZOE-50)
    - Most common systemic reactions were fatigue (~45%), myalgia (~45%), shivering (~30%), fever (~20%), and GI symptoms (~20%) [frequencies reported are for ZOE-50; frequencies for ZOE-70 were lower]
    - 12% of vaccine recipients report grade 3 reactions (symptoms that interfere with daily life) (placebo=2%)
  - GSK plans to submit Biologics License Application to CBER before the end of 2016, planned indication is “prevention of herpes zoster in adults greater than 50 years of age”
Yellow Fever Vaccines
- Update from stakeholder discussions initiated in Spring 2016 to address the shortage of yellow fever vaccines:
  - YF-VAX® currently being produced, ordering restrictions to remain in place
  - Contingency plan to import and use YF vaccine licensed outside U.S.
  - Fractional dosing not considered viable option based on limited data and many uncertainties

Zika Virus Vaccines
- Overview of epidemiology of cases of Zika virus in the USA
  - 3,892 travel-associated cases and 128 locally acquired cases in 2015-2016 (as of 12 Oct 2016) in US States; 84 and 25,871, respectively, in US Territories (98% of local cases in Puerto Rico)
  - Majority of cases in summer months (June-August)
  - Regions where cases were acquired: Caribbean (62%); Central America (20%); South America (7%); North America (7%); Other (4%)
  - Sporadic locally acquired cases identified in multiple counties in south Florida
    - Resulted in recommendations for pregnant women to avoid travel to those areas
    - As of Oct 17th, there were 160 locally acquired cases reported by Florida DOH
    - No evidence of ongoing active local transmission in one of the three areas after aerial spraying and other mosquito control efforts
- Zika virus vaccine development and clinical trials
  - Many vaccine candidates in preclinical development
  - Four vaccines in phase 1 clinical trials by end of 2016
  - Phase 2 studies scheduled to begin in 2017

Pneumococcal Vaccines
- Update on direct and indirect impact of PCV13 use on IPD among adults and children in the USA
  - In 2010-2015, PCV13 use in children has prevented an estimated 280,000 IPD cases and 20,000 deaths among all ages
  - Significant reductions in PCV13-type IPD following the 5 years of PCV13 use; reductions driven by types 19A and 7F
    - Proportion of PCV13 type cases decreased from 43% in 2007-08 to 22% in 2014-15 in adults ≥65 years
  - Significant decreases in overall IPD among children and adults
  - No significant changes in non-PCV13 types among children and adults
- PCV13 impact among adults with chronic medical conditions with and without indications for PCV13 use
  - PCV13 introduction among children in the USA reduced IPD incidence among healthy adults and those with underlying conditions; benefits observed appear to be largely due to indirect PCV13 effects
    - Decline in IPD from 48% in 2007-08 to 24% in 2014-15 in adults without indication for PCV13 use
  - Changes in overall IPD post-PCV13 introduction (in 2013-14 vs. 2007-08):
    - In healthy adults (indirect effects only): -47% (-52, -42)
    - PPV23-only indications (indirect effects only): -19% (-24, 13)
    - PCV13 indications (indirect+direct effects): -24% (-35, -10)
  - Adults with PCV13 and PPV23 indications continue to experience higher IPD rates compared to healthy adults in the post-PCV13 period
  - PCV13 type 16–28% of overall IPD burden; PPV23 unique and non-vaccine type account for 71–84% of overall IPD burden
Outline of research agenda to inform potential policy reconsideration in 2018 for PCV13 use in adults
  - PCV13 effectiveness evaluation in adults ≥65 years (case control study)
  - Assessing the impact of PCV13 on all-cause pneumonia hospitalizations (CDC)
  - Population-based surveillance for non-invasive pneumococcal pneumonia (CDC)
  - Population-based surveillance for PCV13-type pneumococcal pneumonia (University of Louisville, Pfizer)
  - Adult pneumococcal colonisation study in adults ≥65 years

**Influenza Vaccines**

- Influenza surveillance update: Global laboratory data continue to indicate that most currently circulating viruses are antigenically similar to the vaccine viruses included in the 2016-17 U.S. vaccines
- Afluria Quadrivalent: FDA approved on 24 August 2016
  - Phase III, randomised double-blind multicentre safety and immunogenicity study in healthy adults (18+ years); comparator was a US-licensed 2014-15 TIV (IIV3-YAM and IIV3-VIC)
  - Afluria met non-inferiority criteria for all immunogenicity endpoints in all age groups and superiority criteria for unmatched B strain included in QIV; acceptable safety profile (comparable to both TIV) [immunogenicity endpoints shown graphically only]

**Respiratory Syncytial Virus**

- Burden of RSV disease in older adults – summary of disease burden in the USA and some international studies
  - Key summary rates: infection – 2-6 per 100; medical attendance – 0.5-4 per 100; hospitalisation – 1-1.5 per 1,000; death – 0.4-7 per 10,000; rate of secondary complications is unknown
- Update on Novavax RSV vaccine development programs – slides unavailable

**2017 Immunisation Schedule for Children 0-18 years**

- Introduction of Figure 3 – High-risk figure
- Hepatitis B: birth dose schedule updated (as above)
- Hib: Update on use of Hiberix
- Pneumococcal: Updates to use of PCV13
  - Single supplemental dose of PCV13 in children 14-59 months of age who have received an age-appropriate series of PCV7
  - Completion of pneumococcal vaccine course with PCV13 in children with incomplete vaccination
- Influenza: LAIV not recommended and contraindications updated
- Meningococcal: Updated schedule for MenB-FHbp; use of MenACWY for children with HIV
- HPV: Recommendations changed to align with policy changes detailed above (dosing schedule)

**2017 Immunisation Schedule for Adults aged 19 years or older**

- Influenza:
  - LAIV should not be used during the 2016–2017 influenza season
  - Adults with history of egg allergy other than hives may receive age-appropriate IIV or RIV
- Td/Tdap: Revised guidance for use during pregnancy
- Varicella: Updated special populations (evidence for immunity in healthcare workers, adults with a malignant condition/systemic immunosuppressive therapy and adults with HIV infection with CD4+ count <200 should not receive varicella vaccine; adults with HIV infection with CD4+ count ≥200 may consider 2-dose varicella vaccination)
• Zoster: Updated special populations – adults with a malignant condition and adults with HIV infection with CD4+ count <200 should not receive zoster vaccine; adults with HIV infection with CD4+ count ≥200 have no zoster recommendation (no evidence for or against vaccination)
• HPV: Recommendations changed to align with policy changes detailed above (dosing schedule)
• Hepatitis B: Updated at risk populations (inclusion of persons with hepatitis C virus infection)
• Meningococcal: Updated schedule for MenB-FHbp; use of MenACWY for adults with HIV

1.2 Newly published or updated recommendations

1.2.1 Recommendations for Use of Meningococcal Conjugate Vaccines in HIV-Infected Persons — Advisory Committee on Immunization Practices, 2016
• Published MMWR 4 November 2016 – https://www.cdc.gov/mmwr/volumes/65/wr/mm6543a3.htm
• Estimate of meningococcal disease burden among HIV-infected:
  o USA data: 62 cases of meningococcal disease among HIV-infected persons during 1995-2014 captured in Active Bacterial Core surveillance (2% of 3,951 meningococcal cases reported); MenB – 13 (21%), MenC – 23 (37%), MenW – 3 (5%), MenY – 17 (27%), other/unknown serogroups – 6 (10%); majority were in adults aged 20-59 years
  o Studies from South Africa, USA and UK show incidence in HIV-infected persons to range from 3.4 to 6.6 per 100,000 (relative risk = 5–13 compared with HIV-uninfected persons)
• Provides guidance on the use of meningococcal vaccination in HIV-infected persons. Key recommendations:
  o <2 years: 4 doses of MenACWY-CRM (Menveo) at ages 2, 4, 6, and 12–15 months, OR 2 doses of MenACWY-D (Menactra) at age 9–23 months, 12 weeks apart
  o ≥2 years: 2 doses of MenACWY-D or MenACWY-CRM, 8–12 weeks apart
  o Booster dose:
    ▪ <7 years at previous dose: Additional dose of MenACWY-D or MenACWY-CRM 3 years after primary series; boosters should be repeated every 5 years thereafter
    ▪ ≥7 years at previous dose: Additional dose of MenACWY-D or MenACWY-CRM 5 years after primary series; boosters should be repeated every 5 years thereafter
• Consistency with Australian Handbook recommendation: HIV-infection regardless of disease stage or CD4+ count is listed as a high risk condition for meningococcal; vaccination recommendations are similar to ACIP recommendations
  o For aged 7-23 months, Handbook recommends 2 doses 12 weeks apart whereas ACIP recommends 2 doses from 9-23 months
  o For infants 2-6 months, 12 month dose timing recommendation is 12-18 months in Handbook and 12-15 months by ACIP

1.2.2 Use of a 2-Dose Schedule for Human Papillomavirus Vaccination — Updated Recommendations of the Advisory Committee on Immunization Practices
• Published MMWR 16 December 2016 - https://www.cdc.gov/mmwr/volumes/65/wr/mm6549a5.htm
• Updates dosage schedule for young adolescents who initiate vaccination at ages 9 through 14 years; these are detailed above
2 Immunisation Advisory Centre (IMAC), New Zealand

2.1 PTAC Considerations
- Meeting held on 11\textsuperscript{th} & 12\textsuperscript{th} August 2016 - https://www.pharmac.govt.nz/assets/ptac-minutes-2016-08.pdf

2.1.1 Pneumococcal vaccine for people with chronic autoimmune and rheumatic conditions on treatment with biologic disease modifying agents
- A submission from the New Zealand Rheumatology Association for the funding of PPV23 for people with autoimmune and rheumatic conditions in treatment with DMARDs was considered
- The Committee recommended that the application to fund PPV23 for this population be declined on the basis of unclear benefit, cost effectiveness (potentially increased cost given that PCV vaccine would be given at least 8 weeks prior to PPV23), and similar or higher needs of other special risk populations

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

3.1 JCVI meeting: 5\textsuperscript{th} October 2016
Agenda / draft minutes: https://www.gov.uk/government/groups/joint-committee-on-vaccination-and-immunisation#minutes
This summary was based on the draft minutes only

Meningococcal Disease and Vaccine Updates
- MenW epidemiology
  - A new sub-lineage 2013 strain of MenW (that initially emerged in the UK in 2009) was driving a rapid expansion in MenW case numbers from <10 in 2012/13 to almost 100 in 2015/16
  - The increase in cases was across most age groups but most pronounced in 20—24 year olds; presentation was more severe with high levels of GI or upper respiratory tract symptoms and a higher case fatality rate than the original strain (12% vs. 8%)
  - No cases have been seen in vaccinated adolescents, and the number of cases in the 2015 school leavers’ cohort (vaccine-eligible) was significantly lower; in England a 60% reduction in disease in vaccine eligible cohorts was observed
  - A presentation on the cost-effectiveness of the continuation of the routine MenACWY adolescent program beyond 2018/19 will be provided at the Feb 2017 meeting
- Preliminary effectiveness of Bexsero (4CMenB)
  - Preliminary analysis of the Bexsero program based on enhanced surveillance data
  - Coverage for infants was high: 95.5\% for 1 dose and 88.6\% for 2 doses by 6 months of age
  - 2-dose VE was 82.9\% (95\%CI: 24.1-95.2\%) against all MenB cases, equivalent to a VE of 94.2\% against the highest predicted MenB strain coverage of 88\%
  - By June 2016, a 50\% reduction (IRR, 0.50; 95\%CI, 0.36-0.71; p<0.0001) was observed in the vaccine-eligible cohort for all MenB invasive disease when compared to the four pre-vaccine years
- Meningococcal Carriage Study update
  - Two thirds of the isolates from the UKMENCAR4 study had been characterised, with full results expected in February 2017
  - Data from the isolates characterised indicated a prevalence lower than expected for serogroup B
Hepatitis B vaccination schedule for infants born to HepB positive mothers

- Current recommendation for infants born to HepB positive mothers: monovalent dose at birth (and HBIG if indicated), followed by additional monovalent vaccine doses at 1 month, 2 months and 12 months, with an additional pre-school booster advised at 3 years and 4 months. A serology test (to detect infection) is also done at 12 months.

- The Committee considered the following vaccination schedule options for this population given historical suboptimal delivery of the existing program:
  - monovalent hepatitis B vaccine at 0 and 1 month of age, followed by pentavalent vaccine at 2, then 3 and 4 months in lieu of hexavalent vaccine;
  - monovalent hepatitis B vaccine at 0 months and hexavalent at 2, 3, 4 months;
  - monovalent hepatitis B vaccine at 0 and 1 month with hexavalent at 2, 3, 4 months;
  - hexavalent vaccine only at 2, 3, 4 months;
  - the implications of inclusion or removal of the 12 month and pre-school booster doses.

- The Committee advised that the schedule for the selective infant programme should be monovalent doses at 0 and 1 month; with hexavalent doses at 2, 3 and 4 months, with a monovalent booster at 12 months of age, pending further information
  - Further information requested on:
    - Evaluation of the 12 month booster dose
    - Immunogenicity and clinical impact of the one month dose

- This decision was based on:
  - Unacceptability of removal of the birth dose given the increased risk of infant infection
  - Concern over logistical problems with the use of pentavalent vaccine

Removal of existing pre-school booster requirement based on lack of evidence to support it

Pertussis vaccination of healthcare workers

- JCVI previously advised that healthcare workers with close contact to children under 3 months old should receive pertussis-containing vaccine; however supply constraints limited coverage
- There were 77 HCW incidents reported to, or identified by PHE since January 2015, and that there was at least one documented transmission between a healthcare worker and an infant
- JCVI agreed that their extant advice should remain. However further work should be undertaken to identify a more defined cohort of healthcare workers to be vaccinated, and for PHE to consider the development of guidance on this issue. Ongoing supply constraints were noted and will be considered further.

Pneumococcal Vaccines – PCV modelling

- Updates on modelling work to estimate the cost effectiveness of PCV13 were presented, comparing an individual based model of pneumococcal transmission with three serotype groupings: PCV7 type IPD, PCV13-7 type IPD and non-vaccine type IPD
- JCVI agreed the PCV13 program had a greater impact than that predicted by the model, with serotype replacement below that assumed by the model

Anthrax vaccination

- The Green Book chapter on anthrax vaccination was revised, see minutes for details

Maternal Group B Streptococcal (GBS) vaccination

- Initial results from a cost effectiveness model were presented, and indicate a maternal immunisation program that prevented early and late-onset GBS disease was likely to be cost-effective
- Further research was needed to further define the efficacy/effectiveness and impact of a GBS vaccine
3.2 Newly published or updated statement/recommendations

No new or updated statements or recommendations have been published since August 2016.

4 National Advisory Committee on Immunization (NACI), Canada

A meeting was conducted on 5-6 October 2016 in Ottawa Ontario, however the summary of discussions have not been released. The latest available summary was for their February 2016 meeting, which is available at http://www.phac-aspc.gc.ca/naci-ccni/meetings-reunions-eng.php.

4.1 Newly published or updated statement/recommendations

4.1.1 Update on Measles-Mumps-Rubella-Varicella Vaccine and Febrile Seizures

- Issue addressed: Evidence has accumulated of an increased risk of febrile seizures after the first dose of MMRV given up to 47 months of age, as compared to MMR and varicella given separately (approximately additional febrile seizure for every 2,300 to 2,800 doses of MMRV vaccine)
- NACI recommendations:
  - For the first dose up to 47 months of age, MMRV or MMR+V may be given with the following considerations: parental acceptability of the increased risk of febrile seizure, potential impact on the perception of safety and vaccination coverage, as well as the need for an additional injection
  - Children at higher risk for seizures as a result of underlying medical conditions including a history of febrile seizures, seizure disorder or other neurologic conditions may receive MMRV

4.1.2 Update on the use of 13-valent pneumococcal conjugate vaccine (PNEU-C-13) in addition to 23-valent pneumococcal polysaccharide vaccine (PNEU-P-23) in immunocompetent adults 65 years of age and older – Interim Recommendation

- Objective of this statement: to provide evidence and interim recommendations for the use of PVC13 in immunocompetent adults over 65 years of age
- Recommendations:
  - There is good evidence, on an individual basis, to recommend in immunocompetent adults aged 65 years and older not previously immunised against pneumococcal disease, the use of PCV13 vaccine followed by PPV23 for the prevention of CAP and IPD. The minimum dose interval between doses is 8 weeks, with the purpose of PPV23 being to expand the breadth of serotypes to which the individual has protection. Concomitant administration of PCV13 and PPV23 is not recommended. Additional vaccine doses are not recommended.
  - Based on circulating serotypes, there is fair evidence to recommend the use of PPV23 in routine immunisation programs for adults aged 65 years and older.
- NACI will be developing a recommendation that considers the impact of the PCV13 childhood vaccination program on adult disease and strain replacement

4.1.3 Statement on Rotavirus Vaccines and Intussusception

- Published online in September 2016 (date of publication: April 2016) – http://www.healthycanadians.gc.ca/publications/healthy-living-vie-saine/statement-rotavirus-vaccines-
Objective of this statement: to summarise key information for immunisation providers on the increased risk of intussusception following vaccination with rotavirus vaccines (1-7 cases per 100,000 doses)

Recommendations:
- Rotavirus vaccines continue to be recommended for infants starting at 6 weeks to less than 15 weeks of age. Parents should be informed and counselled in regards to this risk.
- Based on expert opinion, NACI recommends against vaccination of children with a history of intussusception as a precaution, based on the theoretical risk of recurrence.

4.1.4 Updated recommendations for the use of varicella zoster immune globulin (VarIg) for the prevention of varicella in at-risk patients

Objective of this statement: to provide guidance to providers on the use of VarIg to prevent or mitigate varicella disease following exposure

Recommendations:
- VarIg should be administered as soon as possible following exposure, and ideally within 96 hours after first exposure.
- If more than 96 hours but less than 10 days have elapsed since the last exposure, VarIg may be administered to individuals for whom it is indicated.
- The benefit of administering VarIg after 96 hours is uncertain.

5 Strategic Advisory Group of Experts (SAGE) on Immunization, WHO

5.1 SAGE meeting: 18-20 October 2016

- Agenda, meeting background documents and presentations, and summary report: http://www.who.int/immunization/sage/meetings/2016/october/SAGE_October_2016_Meeting_Web_summary.pdf?ua=1
  Full report: http://apps.who.int/iris/bitstream/10665/251810/1/WER9148.pdf?ua=1
- Yellow fever:
  - Establishment of a new global strategy to Eliminate Yellow Fever Epidemics (EYE strategy) globally by 2026; key activities are: 1) continued access to affordable vaccines through a sustainable vaccine market, 2) political commitment at global, regional and country levels, 3) robust governance and strong partnerships, and 4) research to support better tools and practices
  - An update on the experience of the fractional dose campaign in Kinshasa in August 2016 was provided; it was shown to be logistically and operationally feasible. SAGE reaffirmed that a fractional dose can be used as part of an exceptional response in a time when there is a large outbreak and a shortage of vaccine.
- Measles and rubella elimination:
  - SAGE recommended that a routine second dose of measles containing vaccine (MCV) should be added to national immunisation schedules in all countries regardless of MCV1 coverage
- Maternal and neonatal tetanus elimination and broader tetanus prevention
  - Global elimination by 2015 was not achieved; achievement by 2020 was considered feasible
  - All immunisation programs should review and adjust their routine immunisation schedules to ensure tetanus protection over the life course (3 priming doses in infancy and 3 booster doses in childhood/adolescence). The 3 booster doses schedule is intended to achieve protection throughout adulthood (reproductive age for women), and probably providing lifelong protection. These booster
doses should preferably be given during the second year of life, between 4-7 years of age, and between 9-15 years of age.

- **Hepatitis B vaccination**
  - Countries were urged to introduce universal birth dose vaccination (preferably within 24 hours of birth)
  - If within 24 hours is not possible, SAGE recommends that all infants receive the birth dose during the first contact with health facilities any time up to the time of the first primary dose

- **HPV immunisation schedules and strategies**
  - SAGE recommends prompt introduction of HPV vaccination for adolescent girls aged 9-14 years, with the age range expanded up to 18 years where resources are available

5.2 **Newly published news or documents**

There were no new position papers published since July 2016.

5.2.1 **Global Immunization News**

Available here: http://www.who.int/immunization/gin/en/

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6 **Other items**

6.1 **Updates from TGA**

- Changes to TGA Advisory Committees:
  - As part of the response to the Expert Review of Medicines and Medical Devices Regulation (the MMDR), the Government agreed to a more streamlined structure for TGA’s advisory committees. The number of committees was reduced from 11 to 7. ACSON has been replaced by the Advisory Committee on Vaccines (ACV) which will have a broader role.
- AusPAR for 9vHPV

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7 **Upcoming meetings and agendas**

**ACIP, USA** (http://www.cdc.gov/vaccines/acip/meetings/upcoming-dates.html)
- 22-23 February 2017
- 22-23 June 2017

**PTAC, New Zealand** (https://www.pharmac.govt.nz/about/committees/ptac/)
- 9-10 February 2017
- 4-5 May 2017

**JCVI, UK** (https://www.gov.uk/government/policy-advisory-groups/joint-committee-on-vaccination-and-immunisation)
- Future meeting dates pending, but usually the 1st Wednesday of February, June and October

**NACI, Canada** (http://www.phac-aspc.gc.ca/naci-ccni/meetings-reunions-eng.php)
- 8-9 February 2017
- 7-9 June 2017

**SAGE WHO** (http://www.who.int/immunization/sage/future_meetings/en/)
- 25-27 April 2017
- 19 October 2017