Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

CHAPTER

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Vaccines

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Abbreviations

ACIP	advisory committee on immunization practices
AE	Adverse events
AEFI	Adverse events following immunization
AVA	anthrax vaccine adsorbed
BCG	Bacillus Calmette–Guerin vaccine
DTaP	diphtheria + tetanus toxoid + acellular pertussis vaccine
GRADE	grading of recommendations, assessment, development, and evaluation
HAV	hepatitis A vaccine
HBV	hepatitis B vaccine
Hib	*Haemophilus influenzae* type B vaccine
HPV	human papillomavirus vaccine
HPV4	quadrivalent human papillomavirus vaccine
HZ/su	herpes zoster subunit vaccine
HZV	herpes zoster vaccine
IIV	inactivated influenza vaccine
IPV	inactivated poliovirus vaccine
JE	Japanese encephalitis vaccine
JE-CV	Japanese encephalitis chimeric vaccine
LAIV	live attenuated influenza vaccine
MenB	*Neisseria meningitidis* serogroup B vaccine
MenC	*Neisseria meningitidis* serogroup C vaccine
MMR	measles + mumps + rubella vaccine
MMRV	measles + mumps + rubella + varicella vaccine
MMWR	Morbidity and Mortality Weekly Report
OPV	oral poliovirus vaccine
PCV10	10-valent pneumococcal conjugate vaccine
PCV13	13-valent pneumococcal conjugate vaccine
PCV15	15-valent pneumococcal conjugate vaccine
PCV23	23-valent pneumococcal conjugate vaccine
PfSPZ	*Plasmodium falciparum* sporozoite vaccine
PPSV23	23-valent pneumococcal polysaccharide vaccine
QIV	Quadravelent influenz vaccine
RV	rotavirus vaccine
RZV	Recombinant zoster vaccine
SAE	Serious Adverse Events
Tdap	tetanus toxoid + diphtheria toxoid + acellular pertussis vaccine
TIV	Tetravalent Influenza vaccine
VVVL	varicella virus vaccine live
VZV	varicella zoster virus vaccine
WHO	World Health Organization
YF	yellow fever vaccine
ZVL	Zoster vaccine live

VIRAL VACCINES

COVID

After a strong vaccination effort in the U.S., the consensus among public health experts remains that the COVID-19 vaccines will end the pandemic and, most importantly, vaccines will do so safely with minimal AEs. Concerns about the perceived rapid development of the vaccine have resulted in some hesitancy (Nguyen et al., 2021) [S]. Even with the safety profile of vaccines, concerns with AEs associated with all vaccines, not just COVID vaccines, have also increased (Karlsson et al., 2021) [r].

When considering vaccine AEs, it is important to compare with symptomology and risks associated with COVID-19 infection instead of comparing with pre-pandemic health and lack of vaccination. As a risk assessment, COVID-19 morbidity and mortality risk is moderately high; moreover, the long-term morbidity risks of COVID-19 are uncharacterized. Even with absolute risk assessments (Brown, 2021) [MC] and comparing the safety risk of vaccination vs natural infection, the current risk assessment favours vaccination for the vast majority of people.

GENERAL

BioNTech/Pfizer BNT162b2

BioNTech and Pfizer co-developed an RNA-based Covid-19 vaccine candidate, BNT162b2, which is

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approved for emergency use authorization (EUA). The trial demonstrated strong safety and high efficacy (≥92%) across demographic considerations, including "age, sex, race, and ethnicity categories and among persons with underlying medical conditions." Contraindications specific to the Pfizer-BioNTech BNT162b2 vaccine include anaphylactic or immediate allergic reaction to any ingredient in the vaccine, or allergic reaction after getting the first dose of the vaccine (CDC, 2021b) [S].

The Pfizer-BioNTech BNT162b2 vaccine maintains a high safety profile with minimal AEs (rate of reported AEs was ~0.2%) (CDC COVID-19 Response Team; Food and Drug Administration, 2021b [S]; Raw et al., 2021 [S]). Common AEs after administration of BNT162b2 include mild to moderate reactogenicity symptoms within 7 days after vaccination. No adverse events were identified by race, age, underlying medical conditions, ethnicity, or previous SARS-CoV-2 infection (CDC COVID-19 Response Team; Food and Drug Administration, 2021b) [S]. However, women did report higher rates of AEs (78.7%) and those with "Long COVID," reported a slightly higher rate of AEs (Raw et al., 2021) [S].

Janssen Ad.26.COV2.S (J&J)

The Janssen Ad.26.COV2.S vaccine is a replication-incompetent adenovirus type 26 (Ad26) vectored vaccine encoding a stabilized variant of the SARS-CoV-2.S protein (Ad, 2020) [S]. Contraindications specific to the Ad.26.COV2.S vaccine include an anaphylactic or immediate allergic reaction to any ingredient in the vaccine, or a history of thrombosis or thrombocytopenia (Ad, 2020) [S]. Ad.26.COV 2.S vaccine is approved as an emergency use authorization (EUA) based on a randomized, double-blind, placebo-controlled Phase III clinical trial (>40 000 U.S NCT04505722) (Ad, 2020) [S]. The trial demonstrated strong safety and high efficacy across demographic considerations. Different endpoint assessments and study populations makes comparing efficacy and safety against other COVID-19 vaccines problematic (Ad, 2020) [S]. The Ad.26.COV2.S vaccine maintains a high safety profile with minimal AEs (rate similar to placebo group, 0.4% for both groups). Subgroup analysis failed to show meaningful differences in safety or efficacy among subgroups based on sex, race, or ethnic group. Older subgroups (>60) showed "a lower point estimate of vaccine efficacy" (Ad, 2020) [S].

Moderna mRNA-1273

Moderna mRNA-1273 is an mRNA vaccine encoding the stabilized prefusion spike glycoprotein (Oliver et al., 2020) [S]. Contraindications specific to the Moderna mRNA-1273 vaccine include severe allergic reaction (anaphylaxis), an immediate allergic reaction to any ingredient in the vaccine, or after getting the first dose of the vaccine or previous mRNA vaccines (CDC, 2021a) [S]. The Moderna mRNA-1273 vaccine maintains a high safety profile with minimal AEs (rate similar to placebo group). Mild to moderate reactogenicity symptoms during the 7 days after vaccination were common (Oliver et al., 2020) [S]. Systemic AEs were reported with more frequency and severity after the booster (2nd) dose and in adults under 60. Orofacial AEs (peripheral facial paralysis (Bell's palsy), facial swelling, and swelling of the lips, face or tongue associated with anaphylaxis) have been reported (Cirillo, 2021) [A]. Subgroup analysis showed "no specific safety concerns by age, race, ethnicity, underlying medical conditions, or previous SARS-CoV-2 infection" (Oliver et al., 2020) [A].

Oxford Vaxzevria

The Oxford Vaxzevria vaccine is a replication-deficient, simian adenovirus-vectored (ChAdOx1-S) vaccine expressing the full-length SARS-CoV-2 S protein with a tissue plasminogen activator leader sequence (Voysey et al., 2021) [MC]. The vaccine is currently approved for all adults, with clinical trials for adolescents and children underway (Taylor, 2021) [r]. Contraindications specific to the Vaxzevria/Covishield include hypersensitivities to active substance or excipients in the vaccine or a history of thrombosis or thrombocytopenia (COVID-*19, 2021b* [S]; Product Information as Approved by the CHMP on 20 May *2021, Pending Endorsement by the European Commission, 2021* [S]). The trial demonstrated "strong safety and high efficacy across demographic considerations although demographic characteristics of those enrolled varied between countries" (Voysey et al., 2021) [MC]. The most common AEs in the clinical trials were mild or moderate with symptom resolution within a few days. SAEs include "unusual blood clots with low blood platelets, which are estimated to occur in 1 in 100 000 vaccinated people" (Francisco, 2021) [S].

Sinovac CoronaVac

The Sinovac CoronaVac vaccine is a chemically-inactivated (β-propiolactone) vaccine (Butantan Institute, 2021) [MC]. The vaccine is contraindicated for people with hypersensitivities to active substance or excipients in the vaccine, with a history of severe allergic reaction (anaphylaxis), with AEs after getting the first dose of the vaccine, with pregnant or lactating women, with people who have neurological conditions (e.g., transverse myelitis, Guillain-Barre syndrome, demyelinating diseases, etc.), and with people with chronic conditions (Product Information as approved by the CHMP on 20 May *2021, 2021*) [S]. The trial reported no safety concerns (Evidence Assessment, *2021*) [S]. Monitoring of ongoing trials in coming years is warranted. The most-reported AE in the clinical trials were mild or moderate, with symptom resolution within a few days. SAEs include "anaphylaxis, Henoch-Schonlein purpura, laryngeal odema, demyelination, cerebral hemorrhage";

however, all were not above background levels and have not been clinically proven causal to vaccine (Evidence Assessment, 2021) [S].

SUSCEPTIBILITY FACTORS

Age

Moderna mRNA-1273

In a phase 1, dose-escalation trial mRNA-1273 in 40 adults aged 56 and older, the reported AEs were predominantly mild or moderate reactogenicity AEs. These AEs were dose-dependent and more common after second injection. The higher doses did generate higher immunogenicity (Anderson et al., 2020) [c].

Sinovac CoronaVac

Based on evidence from current clinical trials, WHO indicates "low confidence in the quality of evidence that the risk of SAEs following one or two doses of CoronaVac in older adults (≥60 years)" (Evidence Assessment, 2021) [S]. This could change based on future studies.

ORGANS AND SYSTEMS

Hematological

Janssen Ad.26.COV2.S (J&J)

Venous thromboembolic events were observed at a slightly higher frequency than placebo (11 in the vaccine group vs 3 in the control group. In addition, one patient experienced a transverse sinus thrombosis with cerebral haemorrhage. Most of the patients experiencing DVT in the clinical trial had underlying medical conditions that was suggested to have predisposed the patient to AEs (Ad, 2020) [S].

Oxford Vaxzevria

EMA noted that unusual blood clots occurred with patients with low platelet counts. The overall incidence of thromboembolic events and decreased platelets are low (Francisco, 2021) [S].

Immunologic

BioNTech/Pfizer BNT162b2

CDC reports identified the incidence of anaphylaxis or IgE-mediated reactions at 11.1 per million with the BNT162b2 vaccine (CDC COVID-19 Response Team; Food and Drug Administration, 2021b [S]; Marcec & Likic, 2021 [S]). This incidence is 10 times higher than other vaccines; however, anaphylaxis is still considered extremely rare and may be an artefact of reporting (CDC COVID-19 Response Team; Food and Drug Administration, 2021b) [S]. While numerous excipients exist as a cause, a preexisting allergy to Polyethylene glycols (PEG) is a strong candidate as IgE-mediated hypersensitivities to PEG are rare but potentially under-recognized (Marcec & Likic, 2021) [R].

Moderna mRNA-1273

CDC reports identified the incidence of anaphylaxis or IgE-mediated reactions at 2.5 per million with the Modern mRNA1273 vaccine. Preexisting allergies were a highly correlated risk factor (9 out of the 10 reported cases). This incidence is considered extremely rare and may be an artefact of reporting (CDC COVID-19 Response Team; Food and Drug Administration, 2021a) [A]. While numerous excipients exist as a cause, a preexisting allergy to Polyethylene glycols (PEG) is a strong candidate as IgE-mediated hypersensitivities to PEG are rare but potentially under-recognized. Reported cases were commonly seen in women (at least 80%) (CDC COVID-19 Response Team; Food and Drug Administration, 2021a) [A].

Oxford Vaxzevria

Anaphylaxis and other hypersensitivities have been noted in patients with previous serious allergies (COVID-19, 2021a) [S].

Neurological

Janssen Ad.26.COV2.S (J&J)

In the trial, a Guillain–Barré syndrome case was identified in 1 vaccine recipient. Evidence is mixed as to the underlying cause (Ad, 2020) [S]. Seizure (4 participants) and tinnitus (6 participants) were observed, but vaccine causality could not be determined and will be tracked post-marketing (Sadoff et al., 2021) [MC].

Oxford Vaxzevria

A case of transverse myelitis was reported and possibly linked to vaccine administration of the second-Vaxzevria dose. An independent neurological committee determined that the probable diagnosis was idiopathic, short-segment, spinal cord demyelination (Voysey et al., 2021) [MC].

DENGUE VACCINE [SEDA-39, 302–303; SEDA-40, 383–384; SEDA-41, 351–352]

Susceptibility factors

Age

In seronegative children who are subsequently vaccinated with CYD-TDV (Dengvaxia), antibody-dependent enhancement (ADE) in 2- to 8-year-old children raises

serious safety concerns. CYD-TDV (Dengvaxia) vaccination increases the risk of severe form of dengue febrile illness (DFI) resulting in increased hospitalization rates (Halstead et al., 2020) [R]. A systematic review of the CYD-TDV vaccine using RCTs showed that in patients 2–17 years of age, the vaccine is "considered safe" and provides partial protection to all serotypes of DENV (note serostatus consideration above) (Rosa et al., 2019) [M].

Serostatus

Dengue outbreaks are of increasing frequency, magnitude, and unpredictability. Dengue morbidity during these outbreaks overwhelms health care systems, and as such, a safe dengue vaccine is an urgent need. A vaccine for dengue for travellers to dengue-endemic areas would be indicated; however, several shortcomings of currently licensed dengue vaccines limit the recommended administration to only seropositive individuals to prevent AEs. The Strategic Advisory Group of Experts (SAGE) on Immunization advised WHO recently to implement a pre-vaccination screening strategy based on an individual's serostatus (Wilder-Smith et al., 2019) [R]." Although CYD-TDV is licensed in many countries, it is not indicated for seronegative individuals for travel due to ADE safety considerations (Wilder-Smith, 2020) [R].

To further this safety research, Sridhar et al. reanalyzed data from three CYD-TDV trials in case-cohort trials. In this analysis, it was determined that seronegative patients at the time of first dose with CYD-TDV (Dengvaxia), have an "excess risk" of severe dengue (Antibody-Dependent Enhancement) according to the analysis of the long-term safety data starting at 30 months post-first-dose, vaccine administration (Sridhar et al., 2018) [MC].

EBOLA VACCINE [SEDA-39, 303–304; SEDA-40, 384–386; SEDA-41, 351]

General

As noted in SEDA 40, WHO prequalified use of rVSV-ZEBOV (Ervebo) in 2018 based on an "urgent public health need" and the safety and efficacy shown in clinical trials. The vaccine is currently recommended for individuals living in at-risk countries in Africa with potential for Ebola exposure (WHO prequalifies Ebola vaccine, paving the way for its use in high-risk countries, *2021*) [S]. Reported safety data on rVSV-ZEBOV has been limited and mixed. Early clinical trials in adults reported some SAE including arthritis and dermatitis (Phase 1 Trials of rVSV Ebola Vaccine in Africa and Europe, *2021*) [C]; however, continued trials show a generally solid safety profile.

Safety monitoring of rVSV-ZEBOV continues. One study with rVSV-ZEBOV in ~2000 front-line workers in Guinea reported AEs including "headache, fatigue, arthralgia, subjective fever, and myalgia." Up to 70% of participants reported AEs, significantly higher rate to placebo group, with symptoms generally resolving within days (Juan-Giner et al., 2019) [c]. The high rates of AEs could be associated with viral exposure, including vaccine administration post-viral exposure, where higher AEs have been observed (Davis et al., 2020) [S].

Second-generation effects

Pregnancy

Pregnant women vaccinated with rVSV-ZEBOV were followed and no AEs were reported. Of the over 2000 vaccinated women, two SAEs related to pregnancy were reported, including a miscarriage and stillbirth. The authors expressed concerns that "we observed that fetal exposure to rVSV led to negative outcome." (Juan-Giner et al., 2019) [c], though larger trials are needed to validate these observations.

Susceptibility factors

Age

In a 600-participant phase II trial of rVSV-ZEBOV in children under 18, AEs were reported at the same rate as placebo, and no vaccine-related SAEs were reported. The study found that the vaccine was well-tolerated (Tapia et al., 2020) [c].

HEPATITIS A VACCINE [SEDA-38, 308; SEDA-39, 304; SEDA-40, 386–387; SEDA-41, 352–352]

Second-generation effects

Pregnancy

Groom et al. conducted a retrospective study of HAV (Havvrix) safety using data in the Vaccine Safety Datalink (VSD) with live births from 2004 through 2015. Although the HAV rate was low, the study showed HAV administration during pregnancy did not increase the risk of AEs. An association was identified with HAV during pregnancy and small-for-gestational-age (SGA) births that warrants "further exploration" (Groom et al., 2019) [C].

In another study of HAV and pregnant women using GSK Worldwide Safety Database, Celzo et al. reported that although AEs with mother and infant were observed, no concerning rates or incidences of pregnancy-related AEs were determined (Celzo et al., 2020) [C].

Organs and systems

Hematological

HAV is recommended for patients with haemophilia; however, intramuscular (IM) injections pose a potential safety concern. A study of subcutaneous HAV showed both long-term efficacy and improved safety over IM injections (Nakasone et al., 2020) [c].

Susceptibility factors

Age

Maritsi et al. conducted a prospective study of 28 children with periodic fever, aphthous stomatitis, pharyngitis, and adenitis (PFAPA). HAVs are well-tolerated and effective in children with PFAPA (Maritsi et al., 2019) [R].

Disease: Systemic lupus erythematosus

A trial of patients with childhood-onset systemic lupus erythematosus (SLE) showed the vaccine efficacious and safe (Mertoglu et al., 2019) [c].

HEPATITIS B VACCINE [SED-16, 255–293, 696–706; SEDA-38, 307–308; SEDA-39, 306–307; SEDA-40, 387]

Second-generation effects

Pregnancy

In an analysis of the GSK Worldwide Safety Database for AEs following immunization of pregnant women with the Havrix (Hep A), Engerix-B (Hep B), or Twinrix (Hep A & B), it was determined that AEs are uncommon and no identified safety signals related to adverse pregnancy outcomes during pregnancy were determined (Celzo et al., 2020) [C].

Susceptibility factors

Disease: Diabetes, type 2

A clinical trial (NCT02117934) reports that a two-dose HBsAg/CpG 1018 provides higher effectiveness and a similar safety profile in adults aged 60–70 years with type 2 diabetes (Hyer & Janssen, 2019) [c].

HUMAN PAPILLOMAVIRUS VACCINE [SED-16, 255–293; SEDA-38, 308–309; SEDA-39, 306–307; SEDA-40, 387–388; SEDA-41, 353–354]

General

Shimabukuro et al. performed an analysis of the safety of the 9vHPV vaccine. 9vHPV vaccine generated 7244 AE reports in VAERS based on the ~28 million 9vHPV vaccines administrated. The analysis showed that the 9vHPV vaccine is safe and remains consistent with the safety profiles of 9vHPV vaccine prelicensure trials and the safety profile of the quadrivalent human papillomavirus vaccine (Shimabukuro et al., 2019) [MC].

An additional near real-time analysis of the safety of the 9vHPV vaccine by Donahue et al. identified four potential signals for AEs, including "appendicitis among boys 9 to 17 years old after dose 3; pancreatitis among men 18 to 26 years old; and allergic reactions among girls 9 to 17 years old and women 18 to 26 years old after dose 2" (Donahue et al., 2019) [MC]. Further analysis of the potential signal failed to confirm the association of any of the identified AE with the 9vHPV vaccine (Donahue et al., 2019) [MC].

Organs and systems

Neurological

Hviid et al. researched the association of 4vHPV vaccination and syndromes of autonomic dysfunction (869 patients of the 1 375 737 Danish-born, female participants aged 10–44 years during 2007–16) (Hviid et al., 2020) [c]. The study failed to support a causal link between quadrivalent human papillomavirus vaccination and selected syndromes of autonomic dysfunction including "chronic fatigue syndrome, complex regional pain syndrome, or postural orthostatic tachycardia syndrome." However, up to a 32% increased risk cannot be excluded, and further study is warranted (Hviid et al., 2020) [c].

Reproductive system

An analysis of VAERS detected that premature ovarian insufficiency (POI) and 4vHPV vaccination were associated (Gong et al., 2020) [MC]. In addition, the study indicated that 4vHPV vaccination was associated with "amenorrhea, FSH increased, menstrual irregularities and premature menopause," and HPV9 was associated with irregular menstruation. However, the authors noted "our results only represent statistical association between HPV vaccine and POI related events, causal relationship needs further investigation" (Gong et al., 2020) [MC].

Susceptibility factors

AGE

The Ministry of Health, Labour and Welfare of Japan (MHLW) suspended their recommendation of the HPV vaccine in 2013 due to perceived SAE, primarily by the evidence presented by Shuichi Ikeda and team (Bodily et al., 2020 [r]; Ueda et al., 2020 [R]). This suspension resulted in sharp declines in HPV vaccination (rate 14.3%) in Japan (Nakagawa et al., 2020) [R]. While HPV has been shown effective and safe (minimal SAE and AE)

(Murata et al., 2020), Japan has not changed its official position (Bodily et al., 2020 [r]; Ueda et al., 2020 [R]).

IMMUNOCOMPROMISED PATIENT

Boey et al. conducted a phase III trial by administering 9VHPV vaccines to 100 persons living with HIV (PLIH) and 171 SOT recipients. Minor reactogenicity AEs and no SAEs were reported. The vaccine is well tolerated and safe in both groups, while efficacy is high for persons living with HIV and suboptimal in SOT patients (Boey et al., 2020) [C]. A meta-analysis by Zhan et al. shows that HPV vaccines are safe and efficacious for PLIH (Zhan et al., 2019) [M].

DISEASE: AUTOIMMUNITY

Corinne et al. performed a meta-analysis to identify any HPV vaccination post-licensure AEs related to autoimmunity (Willame et al., 2020) [M]. Diseases in the included analysis were type 1 diabetes mellitus, immune thrombocytopenic purpura, and thyroiditis diseases. The study showed no association with HPV vaccines and autoimmune diseases (Willame et al., 2020) [M].

DISEASE: SYSTEMIC LUPUS ERYTHEMATOSUS

In a small trial, researchers enrolled ~256 children (9–20 y/o) diagnosed with systemic lupus (cSLE) to study the safety and efficacy of 4vHPV vaccination. No SAEs were associated with 4vHPV vaccination. The vaccines demonstrated immunogenicity and safety and were thus recommend for cSLE patients (Rotstein Grein et al., 2020) [c].

Interactions

DRUG-DRUG INTERACTIONS

A meta-analysis of HPV vaccines (2vHPV, 4vHPV, and 9vHPV) administered concomitant and nonconcomitant with other vaccines was performed. The analysis shows that concomitant administration of other vaccines with HPV vaccination is safe and effective. With the HPV (2vHPV) vaccine, the risks of AEs, both local and systemic, were minimal. The non-bivalent HPV (4vHPV and 9vHPV) vaccines showed a slightly higher risk of local AEs, and higher risk of systemic AE. While some risks were noted, the authors concluded the safety risk was minimal and acceptable, and increased vaccine schedule adherence justified concomitant vaccination for HPV (Li et al., 2020) [M].

INFLUENZA VACCINE [SED-16, 98–106; SEDA-38, 309; SEDA-39, 307–313; SEDA-40, 388–390; SEDA-41, 354–355]

General

In a retrospective cohort study of the Royal College of General Practitioners (RCGP) Research and Surveillance Centre (RSC) sentinel network database from 2010 to 2018 ($N = 848\,375$), AEs were analysed within 7 days of immunization. Seasonal AEs were identified in the analysis including higher incidence of rash and musculoskeletal conditions in the 2014/15 season and respiratory conditions in 2016/17. Pregnant women had elevated relative incidence of AEs at 1.78 (95% CI, 1.62–1.95), as did children under 5 at 1.76 (95% CI, 1.56–1.99). It was noted that vaccine manufacturer, QIV vs TIV, route of administration, and manufacturing methodology affected the incidence of AEs (Cross et al., 2020) [MC].

Second-generation effects

PREGNANCY

In a randomized phase IV study with TIV and QIV vaccines in pregnant women, rates of AEs in mothers and newborns between TIV and QIV vaccines were the same (Vesikari et al., 2019) [C].

Susceptibility factors

AGE

Several studies reported a strong safety profile for high-dose TIV and QIV vaccines for adults aged 65 and older (Chang et al., 2019 [c]; Moro et al., 2020 [MC]; Pillsbury et al., 2020 [MC]). An MF59-adjuvanted TIV study of both young children and older children showed an acceptable safety profile. Revaccination did show an increase in AE (Patel et al., 2019) [MC]. Other studies support the safety profile of MF59-adjuvanted TIV in children (Lindert et al., 2019 [MC]; Patel et al., 2019 [MC]).

DISEASE: MULTIPLE SCLEROSIS

A prospective, multicenter, non-randomized observational study including 108 patients affected with Multiple Sclerosis receiving a trivalent seasonal influenza vaccination, was conducted. No severe AEs were reported, and the vaccine led to good immunogenicity (Metze et al., 2019) [MC].

DISEASE: ASTHMA

In a trial of 4771 children with asthma given QIV, it was determined that LAIV is safe in children age 2–17 years with asthma (Nordin et al., 2019) [MC].

SEX

A systematic review of influenza vaccine clinical trials III/IV from January 1990 to June 2018 showed higher rates of AEs in females. More study is warranted to validate and further characterize this data (Tadount et al., 2020) [R].

Interactions

DRUG-DRUG INTERACTIONS

In a small (24 patients) trial, cancer patients receiving checkpoint inhibitors were analysed for efficacy and

safety of the influenza vaccine. AEs included rash, hypothyroidism, myalgia, and colitis. SAEs (grade 3 nephritis and grade 4 diabetes) were seen in two patients. While further study is necessary, influenza vaccination appears safe and effective (both vaccine and anti-cancer therapy) to administer to cancer patients treated with immune checkpoint inhibitors (Gwynn et al., 2020) [c].

An additional study with cancer patients receiving Pembrolizumab also showed strong safety and efficacy (Failing et al., 2020) [c].

JAPANESE ENCEPHALITIS VACCINE [SED-16, 393–396; SEDA-38, 319; SEDA-39, 313; SEDA-40, 390–391; SEDA-41, 355]

General

In MMWR, the ACIP updated guidance for travellers' states vaccination is only for people at high risk or taking residence in JE-endemic areas. This was based on an analysis using the ACIP GRADE system evaluating the JE-VC data. Low-risk and short-term travelling is not recommended based on the AE profile of the vaccine (Hills, Walter, Atmar, & Fischer, 2019) [S].

Ma et al. analysed the Taiwan Food and Drug Administration's ADR Reporting System for AE following JE-CV. Thirty patients reported 51 AEs for a rate of 4.7 AEs per 100 000 doses distributed. Four of the AEs were serious, including acute renal failure, viral respiratory tract infection, febrile seizure, and injection site cellulitis, with none being diagnosed causally related to JE-CV vaccination. In addition, the safety profile for JE-CV was confirmed (Ma et al., 2020) [MC].

In a clinical trial of 181 subjects, IC51 (Ixiaro®, Jespect, Jeval) safety and efficacy was analysed. AEs were comparable to background, and no SAEs were determined to be related to vaccine (Taucher et al., 2019) [MC]. A systemic review also confirmed the safety but noted that additional RCTs are needed in special risk groups (Kling et al., 2020) [M].

Second-generation effects

PREGNANCY

A retrospective study of pregnant, U.S. active-duty women (2003–2014) reported first dose JE-VC vaccination was associated with a 1.87 (95% CI: 1.12–3.13) times increased risk of low birth weight. However, this finding was not observed in the larger main analyses. The study supported the safety profile of JE-VC in pregnant women (Khodr et al., 2020) [C].

MEASLES–MUMPS–RUBELLA AND MEASLES–MUMPS–RUBELLA-VARICELLA VACCINE [SED-15, 3555, 3566, 3567, 3569; SEDA-35, 575; SEDA-36, 473; SEDA-37, 391; SEDA-40, 391]

General

The Italian Ministry of Health in 2012 recommended improved surveillance of AEs to MMRV. As a result, an analysis of the post-marketing active surveillance program for AEFI tor MMWR was performed analysing 2540 children in the Puglia region of Italy. No safety signals associated with seizures were detected (Stefanizzi et al., 2019) [c].

POLIOVIRUS VACCINE [SED-16, 257, 847–853; SEDA-38, 320; SEDA-39, 315–316; SEDA-40, 391–392; SEDA-41, 356]

General

Tian et al. describe a case report where a child presented with acute flaccid paralysis possibly associated with poliovirus vaccination. Vaccine-associated paralytic poliomyelitis (VAPP) and other neurological disorders have been hypothesized to be linked to vaccination; however, no direct evidence suggests that polio vaccination increases the risk of GBS and anti-NMDARe (Tian et al., 2019) [A].

ROTAVIRUS VACCINE [SED-16, 252–256; SEDA-36, 473; SEDA-37, 391; SEDA-39, 316; SEDA-40, 392–393; SEDA-41, 356]

General

Using disproportionality analysis and Reporting Odds Ratio (ROR) analysis of VAERS from 2007 to 2017 of the two licensed rotavirus vaccine, Rotarix (GlaxoSmithKline) and the pentavalent (RV5) RotaTeq (Merk and Co., Inc), and looked at the AEs of those vaccines, it was determined that diarrhoea, vomiting, and intussusception rates remained consistent with trial rates, confirming vigilance in monitoring for AEs. In addition, several additional SAEs showed signals worthy of further analysis including fontanelle bulging, hypotonic-hyporesponsive episode, livedo reticularis, and opisthotonos. Even with additional safety considerations, the analysis confirmed a favourable safety profile (Bonaldo et al., 2020) [M].

In a Cochrane review analysing 55 RCTs in children (216 480 participants), vaccination with Rotarix (RV1), RotaTeq(RV5), and Rotavac had no increased risk of SAEs and prevented rotavirus-associated diarrhoea (Soares-Weiser et al., 2019) [M].

In a systemic review of the literature (four trials and studies) and RV associated with Kawasaki disease, it was determined that there is a low incidence of developing Kawasaki disease and no association with this SAE (Mellone et al., 2019) [M].

Organs and systems

Gastrointestinal

Intussusception is an SAE associated with all Rotavirus vaccines. ACIP and AAP released new guidance judging that the small risk of intussusception ~40 to 120 infants for all administered Rotavirus vaccines coupled with available, non-surgical interventions justified continued vaccination (Meissner, 2019) [r]. New approaches to monitoring exist that may improve identification and treatment to reduce intussusception risk (Tate & Parashar, 2019) [r].

Drug administration

Drug dosage regimines

In an RCT from June 2017 through June 2018 in Bangladesh, comparing standard dose or double dose of oral Rotarix (GlaxoSmithKline) in 220 infants (110 per group), significant increase in immunogenicity was reported (RV-IgA) with no significant AEs (Lee et al., 2020) [R].

Drug formulations

Porcine circovirus type-1 (PCV-1) was discovered in Rotrix in 2010. GSK began a Phase III RCT for PCV-free HRV in infants ages 6–12 weeks to assess the safety and efficacy of the PCV-free HRV vaccine. In this trial, the incidences of SAE and AE as well as efficacy were similar for PCV-free HRV and HRV groups (de Salamanca la Cueva et al., 2020) [MC].

VARICELLA/HERPES ZOSTER VACCINE [SED-16, 260–365; SEDA-37, 391; SEDA-40, 393–394; SEDA-41, 357]

General

A meta-analysis comparing RZV and ZVL vaccines demonstrated higher efficacy with RZV with significantly more rates of minor reactogenicity AEs but no differences in rates of SAEs (McGirr et al., 2019) [M].

Susceptibility factors

AGE

Woodward et al. reviewed the VVVL (Varivax) study reports and the literature for safety. Common AEs including varicella, rash, and pyrexia are consistent with previous reports. SAEs are also consistent and occur at 0.8 per million doses. The study confirmed the safety profile of the vaccine (Woodward et al., 2019) [MC]. Trials of adults older than 70 y/o and older comparing RZV to placebo showed higher reactogenicity AE rates and similar SAE rates between the two groups (Cunningham et al., 2016 [c]; Schmader et al., 2019 [MC]).

Organs and systems

Immunologic

In a short-term study, 195 HIV-unexposed children and 64 HIV-exposed uninfected (HEU) children were vaccinated with VVVL and hepatitis-A vaccines. Minor, short-term, local AEs were reported, and no short-term SAEs were reported in either group (Mutsaerts et al., 2020) [c].

Neurological

A case study reported a 52-year-old patient with a history of childhood varicella who developed a disseminated VZV infection progressing to Horner's Syndrome following Varivax Vaccination. (Henry et al., 2020) [A].

Drug administration

Drug-drug interactions

In a phase 3, two-arm, randomized, double-blind, placebo-controlled, multicenter trial done in 5300 immunocompromised patients with malignancy, VZV safety and efficacy was determined to be well tolerated in immunocompromised patients receiving chemotherapy for cancer. In addition, the vaccine was efficacious for patients with solid tumour malignancies but was not efficacious in haematological malignancies (Mullane et al., 2019) [MC].

YELLOW FEVER VACCINE [SED-16, 537–540; SEDA-38, 321; SEDA-39, 318–319; SEDA-40, 394–395; SEDA-41, 358]

General

A case reported AEFI for YF vaccine detailed a case of a 45-year-old man after YF vaccination developed invasive aspergillosis (IA) leading to YEL-AVD. The patient recovered after treatment (Breda et al., 2020) [A]. IA may be causative or opportunistic and warrants further investigation.

Susceptibility factors

Age

YF vaccine is a live vaccine that has two associated SAEs- yellow-fever-vaccine-associated neurologic disease

(YEL-AND) and yellow-fever-vaccine-associated viscerotropic disease (YEL-AVD). While the standardization in manufacturing, has improved the safety of the YF vaccine in regards to these SAEs, case reports with YEL-AND and YEL-AVD still occur and are reported (Volkov et al., 2020). These SAE are reported in all age groups, but the rate for both YEL-AND and YEL-AVD increases in persons aged 60 years and above (Domingo et al., 2020 [A]; Fletcher et al., 2020 [r]). New guidance from the Medicines and Healthcare products Regulatory Agency (MHRA), Public Health England (PHE), National Travel Health Network and Centre (NaTHNaC), Health Protection Scotland (HPS) emphasize stronger precautions against YF vaccination in adults over 60 and people with weakened immunity (Lecomte et al., 2020) [M]. Another scoping review contends that more education and guidance are needed to reduce YF infections and AEFIs to the YF vaccine (Wilder-Smith, 2019) [R].

Immunologic

A series of case reports recount that children with egg allergies tolerate YF vaccination well with no SAEs reported (Sharma et al., 2020) [c]. Another series of case reports by Gerhardt et al. confirmed this finding. In addition, the authors found that performing an intradermal test is recommended to identify individuals with a higher risk of AEFIs (Gerhardt et al., 2020) [c].

In a retrospective study of 63 YF-vaccinated patients with psoriasis in Brazil, AEs were reported as mild and rare with no SAEs. Psoriasis treatments were also unaffected, regardless of treatment regimens (with or without immunosuppressive drugs) (de Barros et al., 2019) [c].

Drug administration

Drug dosage regimines

A review of fractional-dose YF vaccination shows no improvement in SAEs over standard doses with encouraging but not confirmatory efficacy results (Roukens & Visser, 2019) [c].

BACTERIAL VACCINES

Anthrax vaccine [SED-16, 270, 527; SEDA-39, 319–320; SEDA-40, 395; SEDA-41, 358]

General

In 2019, ACIP updated recommendations on Anthrax vaccine (Bower et al., 2019) [S]. The recommendations were focused on emergency use of Anthrax vaccine; however, it was reported that SC administration had two AEs that were more common over IM injection; limitation of arm motion and generalized myalgia. It was noted that IM injection (either primary or subsequent doses) could increase adherence to vaccination and the timing of vaccination (Bower et al., 2019) [S].

Based on the ACIP report, Ian Cook performed a meta-analysis of 58 studies, including RCT and observational studies. The analysis confirmed the ACIP recommendation of IM administration to reduce reactogenicity AEs (Cook, 2021) [S].

Susceptibility factors

AGE

BioThrax (anthrax vaccine adsorbed) and NuThrax AV7909 (anthrax vaccine adsorbed with a CpG adjuvant) were assessed in adults 66 years of age and older. Results showed similar AEs to previously published studies (Wolfe et al., 2020) [MC].

Organ systems

DERMATOLOGICAL

A case report detailing injection site nodules of years duration related to the anthrax vaccine has been reported. Biopsy showed granule-containing histiocytes that contained aluminium which is a component of the vaccine (May Franklin et al., 2020) [A].

NEUROLOGICAL

BioThrax induces a protective antigen (PA63) that has been implicated in neuronal dysfunction and/or apoptosis in neuronal cells. This is being investigated as a potential contributor to symptomatology associated with Gulf War Illness (GWI) (Tsilibary et al., 2020) [E].

Drug administration

DRUG-DRUG INTERACTION

Raxibacumab is a monoclonal antibody treatment to the Anthrax toxin. A post-approval trial of 573 was performed to assess the efficacy and safety of AVA after raxibacumab treatment. AVA and raxibacumab co-administration does not decrease AVA immunogenicity, and no AEs were reported (Skoura et al., 2020) [MC].

Bacillus Calmette–Guerin vaccines [SED-16, 267, 797–806; SEDA-40, 395–397; SEDA-41, 358]

Organs and systems

IMMUNOLOGICAL

Lymphadenitis in 8 infants after BCG vaccination was evaluated in India, and the mean time-to-onset was 5.12 months after vaccination (Pendharkar et al., 2019) [c].

NEUROLOGICAL

BCG strain meningitis and ventriculitis were seen involving a 16-month-old boy after being vaccinated at 7 months old (Furuichi et al., 2020) [A].

Meningococcal vaccines [SEDA-38, 322; SEDA-39, 322; SEDA-40, 397–399; SEDA-41, 359–361]

Age

In a small U.K. trial, 133 pre-mature infants received 4CMenB alongside their routine immunizations. The trial concluded that in hospitalized, premature infants, immunization with 4CMenB does not increase the risk of SAEs (Kent et al., 2019) [MC].

Organ systems

Skin

A case report of a 22-year-old male developed reactive pericarditis 5 days post vaccination (Meningococcal groups A, C, W-135, and Y conjugate vaccine). After testing for other causes of pericarditis, vaccine-induced pericarditis was diagnosed (Al-Ebrahim et al., 2020) [A].

Drug administration

Drug-drug interactions

In three RCTs of 5026 healthy infants in Europe, 4CMenB was co-administered with routine vaccines. The rate and risk of AEs is reduced with co-administration of 4CMenB and routine infant vaccines (Zafack et al., 2019) [MC].

Drug administration

Drug-drug interactions

A systematic literature search was completed to assess the safety and efficacy of infants co-administered rotavirus and meningococcal vaccines. The study determined that co-administration of the two vaccines is efficacious and safe, although further study is warranted due to limited data (Pereira et al., 2020) [R].

Pertussis vaccines (including diphtheria–tetanus–acellular/whole-cell pertussis-containing vaccines) [SEDA-38, 325; SEDA-39, 323–325; SEDA-40, 400; SEDA-41, 361–363]

Organ and systems

GASTROINTESTINAL

An analysis of 17 studies looking at vaccines with an acellular pertussis component found an increase in GI symptoms, specifically nausea and vomiting; otherwise, adverse effects were similar or safer than placebo or other vaccines without the acellular pertussis component (Xu et al., 2019) [M].

NEUROLOGICAL

Acellular pertussis vaccines have essentially supplanted the previous whole-cell pertussis vaccines due to their improved safety profile, specifically neurological sequelae. However, the use of acellular pertussis vaccines do not eliminate the risk of AEs. Case reports of seizures, transverse myelitis in infants have been reported (Mukund et al., 2019 [A]; Nergiz et al., 2020) [A].

Another case involved a 13-year-old girl who developed ocular accommodation spasm after receiving the tetanus-diphtheria vaccine (Td) (Batur et al., 2020) [A].

A 50-year-old woman developed the Miller Fisher variant of GBS after vaccination with Tdap. She was found to have high serum anti-GQ1b IgG levels. She did completely recover with treatment (Garg & Moudgil, 2019) [A].

Susceptibility factors

Age

A VAERS review of Tdap AEs in adults over 65 years old did not show any significant differences from those reported in previous studies of younger patients (Haber et al., 2020) [MC].

Pneumococcal vaccines [SEDA-38, 327; SEDA-39, 325–326; SEDA-40, 400–404; SEDA-41, 363–364]

General

Numerous studies have looked at the immunogenicity and safety of pneumococcal vaccines of both polysaccharide and conjugate formulations in specific populations. Generally, the adverse effects were similar to the general population. A Phase 1 trial of a 20-valent pneumococcal conjugate vaccine was studied in 66 healthy adults. It included the same strains as the PCV13 plus seven additional strains. Immunogenicity was achieved, and adverse events were similar to those reported for PCV13 (Thompson et al., 2019) [c].

ASP3772 is a novel 24-Valent pneumococcal polysaccharide vaccine. Safety and efficacy were evaluated in a trial with 93 patients. There were a few mild to moderate in severity AEs reported (Chichili et al., 2020) [c].

Susceptibility factors

AGE

The safety of the PCV in preterm infants was limited. A study out of Spain found that the safety profile and efficacy of PCV administration in low birth weight and preterm infants was similar to term infants (López-Sanguos et al., 2019) [M]. A similar study was done with healthy

infants given the PCV20, and similar adverse effects to the PCV13 were noted (Senders et al., 2020) [MC].

NEPHROTIC SYNDROME

A systemic review found that pneumococcal vaccination was efficacious and safe, with no SAEs reported for children with nephrotic syndrome. An alternative timing administration was suggested to optimize the efficacy of the vaccine (Goonewardene et al., 2019) [M].

IMMUNOLOGIC

Pneumococcal diseases have significantly more morbidity in people living with HIV (PLHIV). PCV is a potential solution. A study of people living with HIV with high and low CD4+ T cells counts, were vaccinated with PCV13. The study found the PCV13 was well tolerated but had inferior immunogenicity with the PLHIV showing lower CD4 T-cell counts <350 cells/μL. (Song et al., 2020) [s].

Rheumatoid arthritis (RA) patients have more comorbid infections impacting quality of life. A study of PCV23 vaccination in patients with RA was conducted evaluating RA patients over a 5-year period. The PCV23 vaccination was well tolerated, did not exacerbate the RA or other autoimmunity, and prevented pneumococcal pneumonia (Bukhanova et al., 2019) [c].

RENAL TRANSPLANTATION

A trial of 133 kidney transplant candidates was conducted where one group received PCV13 and the other group received PPV23 to assess immunogenicity and safety of PCV13. The trial concluded that PCV13 was safe and efficacious in dialysis patients (Eriksson et al., 2020) [S].

Drug administration

DRUG-DRUG INTERACTIONS

A study of 106 rheumatoid patients on baricitinib, a Janus kinase (JAK) 1/Jak2 inhibitor, with or without methotrexate, was done to see the immunogenicity of PCV13 and TTV (tetanus toxoid vaccine). Approximately 68% of patients had a satisfactory humoral response at 5 weeks. AEs were reported in 30 patients (28.3%), with one patient having moderate pain and seven patients reporting injection-site reactions (Winthrop et al., 2019) [c].

A prospective controlled trial of patients with inflammatory bowel disease (IBD) who were administered PCV13, influenza, HBV, and PPSV23 vaccines and treated with vedolizumab or other non-immunosuppressive therapies was conducted. The trial found that all vaccines were well-tolerated and efficacious, and IBD treatment options were unaltered (Harrington et al., 2020) [c].

PARASITIC VACCINES

Malaria vaccine [SED-16, 733–734; SEDA-39, 326–327; SEDA-40, 404–406; SEDA-41, 364–365]

Second generation

PREGNANCY

A malaria vaccine safe and effective for pregnant women is of high priority due to high maternal, perinatal, and infant mortality rates. Malaria vaccine trials in pregnant women have been limited. A pregnancy registry for PfSPZ safety and efficacy evaluation has been initiated to fill that need (Healy et al., 2019). Another vaccine candidate (Differentially Adjuvanted PAMVAC) is in trials with pregnant women and has been well tolerated with indications of efficacy (Mordmüller et al., 2019) [MC].

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