Policy Document

Vaccinations

Position Statement

AMSA believes that:

1. Vaccination is one of the most effective public health interventions for preventing the contraction and transmission of communicable diseases;
2. Vaccine-preventable diseases (VPDs) continue to pose a significant health threat in both developing and developed countries;
3. Inequitable vaccine access continues to pose a threat to global health, and as such, should be available to every individual who is safe to receive regardless of age, socioeconomic status, country, residency status, race, or gender;
4. Vaccine hesitancy poses a risk to global health and must be addressed in a way that is considerate and cognisant of people's reasons for vaccine hesitancy;
5. Surveillance of vaccine-related adverse effects is essential to ensure vaccine safety and minimise risks associated with vaccination;
6. Further research is needed in developing vaccines for neglected tropical diseases (NTDs), tuberculosis, non-communicable diseases, optimising vaccine access in low resource settings, and creating thermostable vaccines;
7. Product development partnerships (PDPs) are essential in developing vaccines for neglected diseases hindered by expensive costs;
8. First Nations peoples globally experience a disproportionate burden of vaccine preventable diseases.

Policy

AMSA calls upon

1. The World Health Organization to:
    a. Ensure that the Immunization Agenda 2030
        i. Promotes the development of regional and national immunisation programmes, and sets the foundation for disease-specific initiatives;
        ii. Provides equitable and efficient distribution of financial resources and technical assistance to member states to allow them to achieve specific targets;
        iii. Assists member states in improving budgeting processes to sustain procurement of essential vaccination supplies;
    b. Ensure that National Immunisation Technical Advisory Groups:
        i. Expand their capabilities in keeping track of national vaccination programmes;
        ii. Encourage regional and global collaboration between stakeholders, including shared expertise;
    c. Promote exchange of resources, and expertise between nations and partners, and encourage collaboration and integration across all levels;
    d. Promote accountability and transparency of nations, through evidence-based assessments of national targets;
    e. Continue to promote the development of new vaccines for neglected tropical diseases; and

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f. Work with internet and social media companies like Facebook and Google to limit users' access to misinformation about vaccines and ensure they are instead directed to credible information.

2. National Governments (including the Australian Government) to:
    a. Ensure national targets are tailored according to the Immunization Agenda 2030, considering the country's contextual factors;
    b. Assess and utilise local and global information to improve national vaccination programmes;
    c. Introduce or continue implementing nationally funded universal vaccination programs that are accessible for all residents;
    d. Address the barriers that prevent First Nations peoples from accessing vaccinations and the social determinants of health that increase burden of vaccine-preventable diseases amongst First Nations peoples;
    e. Strengthen communication with, and education within, First Nations populations to enhance informed and culturally safe participation in vaccination programs that:
        i. Ensure that First Nations voices are incorporated into their planning and execution;
        ii. Acknowledge the differing expectations between Western Medicine trained healthcare providers and many First Nations communities;
        iii. Geographically target regions in which First Nations peoples comprise a higher percentage of the population;
    f. Support and improve refugee and asylum seeker health by;
        i. Providing free WHO-recommended and locally indicated vaccinations to refugees and asylum seekers;
        ii. Providing vaccinations in refugee camps to prevent infectious disease outbreaks in refugee camps;
        iii. Removing barriers for refugees to access vaccination including by providing culturally inclusive, multi-lingual, and non-discriminatory services;
    g. Work to improve vaccination coverage in rural and remote areas;
    h. Develop new and improve existing public information campaigns about vaccination that:
        i. Address concerns about vaccine safety and efficacy;
        ii. Target populations who have, lower rates of vaccination and/or face a high burden of disease due to VPDs;
        iii. Are culturally appropriate and linguistically accessible;
        iv. Utilise a variety of media including posters, brochures, internet and social media;
        v. Are adjusted based on reviews of their effectiveness;
    i. Consider the implementation of mandatory vaccination as a last resort, and only if:
        i. alternative strategies have failed;
        ii. the mandated vaccines have a proven track record of safety and efficacy;
        iii. sufficient efforts have already been made to address barriers to accessing vaccination such as costs and access to clinical care;
    j. Increase investments into researching neglected tropical diseases; and

k. Promote local research opportunities aligned with the WHO Immunization Agenda 2030.

3. Foreign Aid Organisations to;
    a. Continue to pursue the eradication of polio, and ensure that adequate funds are allocated to do so;
    b. Continue to support the purchase, equitable distribution, and administration of vaccines by low income countries; and
    c. Continue to subsidise vaccination for middle income countries so that purchases remain sustainable with fluctuations in international aid.

4. The Australian Government to:
    a. Expand eligibility for free National Immunisation Program schedule vaccines to all Australian residents, regardless of age;
    b. Continue monitoring vaccine coverage rates through the Australian Immunisation Register, and make efforts to improve the quality of data held in the register;
    c. Provide ongoing funding for vaccination research to:
        i. Monitor causal links between vaccinations and adverse effects;
        ii. Explore opportunities for technology-based strategies to improve vaccination coverage and adverse effects monitoring;
        iii. Monitor and evaluate all new and existing government immunisation policies, including ‘no jab, no pay’ and ‘no jab, no play’, to ensure that they are effective and do not exacerbate inequities;
    d. Introduce a no-fault Vaccine Injury Compensation Program for government recommended vaccines;
    e. Support and fund the expansion of the AusVaxSafety system to cover additional sites and a broader range of vaccines;
    f. Continue working with multilateral organisations to support global vaccination efforts;
    g. Increase the Australian financial commitment to the Global Polio Eradication Initiative;
    h. Continue working with the World Bank to improve vaccination coverage within the Asia-Pacific region;
    i. Continue to support Timor-Leste, Cambodia, Solomon Islands and Papua New Guinea to deliver vaccinations while also supporting their primary healthcare systems;
    j. Appropriately remunerate and support general practitioners to identify and encourage immunisation in accordance with the National Immunisation Program;
    k. Reduce rates of Vaccine Preventable Disease among Aboriginal and Torres Strait Islander Australians by;
        i. Addressing the social determinants of health that create barriers to vaccination for Aboriginal and Torres Strait Islander people;
        ii. Ensuring ongoing equal access to vaccination for Aboriginal and Torres Strait Islander people, particularly during emergencies such as pandemics/epidemics;
        iii. Maintaining and reviewing the specialised vaccine schedule for Aboriginal and Torres Strait Islander people

iv. Improving communication with Aboriginal and Torres Strait Islander people regarding their eligibility for additional free vaccines, particularly seasonal vaccines;
v. Minimising the delay in vaccinating Aboriginal and Torres Strait Islander children under 5-years-old;
vi. Improving frequency of data reporting on vaccine coverage/uptake rates for Aboriginal and Torres Strait Islander people;

l. Continue funding product development partnerships that support research in improved therapies;
m. Use its position on Coalition for Epidemic Preparedness Innovations Investors Council to advocate for an equitable access policy during both the development and distribution of vaccines;
n. Continue working with not-for-profit research organisations to improve access to and the development of tuberculosis vaccinations; and
o. Promote local research opportunities to optimise vaccine development for low-resource settings and ensure they provide protection for local strains.

6. Australian hospitals, health professionals and healthcare providers to:
    a. Increase the number of providers participating in the AusVaxSafety program;
    b. Provide adequate counselling and education to vaccine-hesitant patients and carers with appropriate follow up;
    c. Consistently ask all patients if they identify as Aboriginal and/or Torres Strait Islander; and
    d. Educate Aboriginal and Torres Strait Islander patients about their eligibility for additional vaccinations and the benefits of participating in specialised schedules.

7. Health research institutions to:
    a. Increase research in developing vaccines for neglected tropical diseases;
    b. Increase research in developing vaccines for emerging infectious diseases;
    c. Continue working with product development partnerships;
    d. Increase research into optimising vaccines for low-resource settings;
    e. Increase research into developing thermostable vaccines; and
    f. Increase research into developing vaccines targeting non-communicable diseases.

8. The Royal Australian College of General Practitioners and Royal Australian College of Physicians (Paediatrics and Child Health Division) to:
    a. Through their training programs:
        i. Educate general practitioners and paediatricians on the importance of surveillance for vaccine coverage and adverse effects, and encourage reporting of adverse effects to the Therapeutic Goods Association;
        ii. Provide further training to general practitioners and paediatricians about:
            1. The risks, benefits, and efficacy of vaccination and how to relay this information to patients, and

2. How to effectively communicate with vaccine-hesitant patients; and

b. Work with internet and social media companies like Facebook and Google to limit users' access to misinformation about vaccines and ensure they are instead directed to credible information.

9. Medical schools to:
    a. Educate medical students about:
        i. The risks, benefits, and efficacy of vaccination and how to relay this information to patients;
        ii. How to effectively communicate with vaccine-hesitant patients;
        iii. Neglected tropical diseases and importance of developing vaccines to prevent them; and
        iv. The role of product development partnerships in vaccine development.

10. AMSA Med Ed and medical societies to:
    a. Encourage medical students to access resources on how to communicate to patients about vaccines from reputable organisations like 'Sharing Knowledge About Immunisation'.

Background

The Australian Medical Students' Association (AMSA) is the peak representative body of
Australia's 17,000+ medical students. AMSA believes that all communities have the right to the best attainable health and supports initiatives that promote positive health outcomes. Vaccination continues to be a vital tool for global health promotion and disease prevention.

Vaccines are widely acknowledged as one of the most cost-effective means of disease control, preventing an estimated 2-3 million deaths globally each year [1]. Immunity to vaccine-preventable diseases (VPDs) not only protects the vaccinated individual, but also protects the general population by reducing disease transmission. This phenomenon, known as herd immunity, protects sub-populations who cannot receive vaccinations (e.g. young children and immunocompromised individuals) [2, 3]. Vaccination of mothers before or during pregnancy also protects unborn infants, preventing mortality and morbidity from rubella, varicella, pertussis and seasonal influenza [4].

Australia's vaccination system
Australia's immunisation system, services, and policies are internationally recognised for their quality and effectiveness [5]. The current National Immunisation Program (NIP) provides free vaccinations against 17 diseases to Australians who fall within age and medical risk groups outlined in the NIP Schedule [6]. The NIP schedule includes all World Health Organisation-recommended vaccines [7]. In July 2017, the NIP was expanded to provide free catch-up vaccinations for all individuals up to the age of 19 years, and refugees and humanitarian entrants of all ages [6, 8]. Some state and territory health departments also fund free provision of additional vaccines not listed on the NIP schedule.

Australia's current immunisation coverage target is 95% for children aged 1, 2 and 5 years by 2020 [9]. This is in line with the World Health Organisation target for the Western Pacific Region [10]**.** As of March 2020, immunisation coverage was above 90% for all monitored age groups, with 94.37**%** of one-year-olds, 91.46% of 2-year-olds and 94.74% of 5-year-olds fully immunised to schedule [11]. As of 2015, the

main contributors to the burden of VPDs in Australia were influenza, pneumococcal disease, human papillomavirus (HPV), shingles and meningococcal disease [12].

Vaccine coverage in Australia is estimated based on data from the Australian Immunisation Register (AIR), which records vaccinations given under the NIP, through school programs, and privately (e.g. private seasonal influenza and travel vaccinations) [13]. The AIR was introduced in 2016 to replace the Australian Childhood Immunisation Register, making Australia one of the first countries in the world to implement a whole-of-life immunisation register [9].

AIR surveillance is complemented by 5-yearly serosurveys for VPDs, conducted by the NCIRS using randomly sampled residual plasma and serum specimens from diagnostic laboratories throughout Australia [14].

Vaccine Safety

While generally acknowledged to be a safe public health intervention, vaccinations carry a small risk of adverse events [15]. In Australia, adverse events following immunisation are monitored by the Therapeutic Goods Administration (TGA) at a national level, and by state health departments in some states [16]. Adverse event reporting is not mandatory, and the decision to report an adverse effect is based on the vaccine provider's judgment. TGA data on vaccine adverse effects is therefore likely to be limited by underreporting and biased reporting practices [17]. In 2014, in response to this issue, the National Centre for Immune Research and Surveillance (NCIRS) introduced AusVaxSafety, a technology-based surveillance initiative that collects reports of adverse events directly from the public using an automated SMS or email sent in the days after administration of a vaccine. This data is reported to the Department of Health, the TGA and State and Territory governments. As of 2020, AusVaxSafety monitoring will be expanded to cover reports from all vaccines on the NIP schedule [18].

Due to the inherent risks of vaccinations, some adverse effects occur through no fault of the manufacturer, regulator or health care system [15]. For this reason, most individuals who suffer serious adverse effects following vaccination cannot access compensation through the legal system, as they cannot demonstrate that any individual or organisation is legally liable for the injury [19]. In recognition of this issue, 25 countries have implemented no-fault Vaccine Injury Compensation Programmes (VICPs). Under a VICP, the government directly compensates individuals who are harmed by vaccines without the need for litigation [20]. At present, Australia does not have a Vaccine Injury Compensation Program.

<u>Mandatory Vaccination Policies</u>

On January 1st 2016, the Australian government implemented 'No Jab, No Pay' legislation, removing this form of objection as a valid way for parents to remain eligible for Family Tax Benefit (FTB) Part A or child care fee assistance. To supplement this scheme, the 'No Jab No Play' policy was introduced at the state level. This policy requires children to be fully immunised, or to be on an approved catch-up schedule, when enrolling in early childhood education and care services to minimise the risk to other children. However, this is currently not a national standard, as this policy is not in place in Australian Capital Territory, Northern Territory, and Tasmania [21].

Although some research shows mandatory vaccinations increases vaccination uptake, it was also suggested that it can lead to unintended consequences [22, 23, 24, 25]. For example, many migrant children who were immunised overseas have incomplete immunisation records, and information about past vaccinations is often unavailable. Those with this information were reported to encounter delays when entering their previous immunisation record into AIR. With the implementation of the "No Jab No Pay" policy, these logistical difficulties caused disruption in Centrelink payments for large numbers of migrant families. [22] Similarly, the state level "No jab

no play" policy raises concern over damaging children's education and social connections because of their parents' beliefs [26].

Most parents of incompletely vaccinated children in Australia do not object to immunisation, but they have been unable to overcome a range of logistic and access barriers [27]. Vaccine refusal is in fact the least important of the three factors (refusal, hesitancy and barriers to access) that contribute to lower vaccine coverage. Greater success is likely to come from first improving accessibility and minimising logistic barriers to vaccination [23]. More research and evaluation are needed to look into all aspects of mandatory vaccination, including its effectiveness, impact on public opinion, justice and equity, and what alternatives could be used to improve vaccination coverage [24].

Aboriginal and Torres Strait Islander Peoples

In Australia, addressing the health disparities between Indigenous and non-Indigenous Australians is an ongoing priority for governments and health providers. Aboriginal and Torres Strait Islander people experience a significantly higher burden of VPDs than non-Indigenous Australians. Despite making up only 3.3% of the population, they account for 10% of the national burden of VPDs in 2015, experiencing a preventable burden 4.1 times that of non-Indigenous Australians [12].

This disparity has been attributed to lower standards of living, higher burden of chronic diseases, poorer access to clean water, housing and health care, and social determinants of health such as low education outcomes and intergenerational trauma [16]. Aboriginal and Torres Strait Islander people are also more likely to experience barriers to accessing healthcare and vaccination, including transport, cost, communication difficulties, distrust in government programs, concerns about vaccine effectiveness and safety and, notably, a failure of health practitioners to identify Indigenous status within a primary healthcare setting [28, 29]. These determinants and barriers are discussed further in the AMSA Aboriginal and Torres Strait Islander Health Policy (2019).

For these reasons, Aboriginal and Torres Strait Islander people have been identified within the National Immunisation Program as a group for whom full immunisation coverage is of particular importance [9]. Under the NIP, Aboriginal and Torres Strait Islander people of all ages are eligible for various free and "catch-up" vaccinations, and for children under five years old, there is a tailored immunisation schedule that includes additional vaccines such as Meningococcal B, Pneumococcal, Hepatitis A and Influenza [30].

These vaccination schedules have reduced the incidence of many VPDs such as diphtheria, hepatitis A and B, measles, mumps and rubella amongst Aboriginal and Torres Strait Islander people [31]. *Haemophilus influenza*e Type B (Hib) notification rates have decreased by more than 95% since 1993, and hepatitis A notification rates have been lower than for non-Indigenous people since 2007, following the introduction of specialised programs for Aboriginal and Torres Strait Islander children [24]. Notably, Aboriginal and Torres Strait Islander children were the first to reach the 95% immunisation coverage target nationwide, and by March 2020 the national coverage rate for Aboriginal and Torres Strait Islander 5 year-olds was 96.86% [9, 32].

Although most Aboriginal and Torres Strait Islander children eventually complete the appropriate vaccination schedule, many do not do so in the recommended time frame. In March 2020, only 92.92% of 1-year-olds and 89.70% of 2-year-olds were fully vaccinated, compared to 94.37% and 91.46% of non-Indigenous children respectively [11, 32]. This delay is significant due to the lower median age of onset for certain VPDs amongst Aboriginal and Torres Strait Islander children compared with non-Indigenous children. For example the median age of onset for Hib is 9.4 months versus 17.7 months in non-Indigenous children [31].

Further, despite improvements brought about by the NIPS, Aboriginal and Torres Strait Islander adults still experience a disproportionate burden of disease and poorer overall vaccine coverage rates compared to non-Indigenous Australians . The majority of this burden can be attributed to HPV. Although HPV vaccination uptake rates are comparable between populations, Aboriginal and Torres Strait Islander women experience much higher rates of morbidity and mortality from cervical cancer [12]. Similarly, despite similar (albeit low) rates of vaccination for influenza across both populations, influenza hospitalisation rates were 2.4 times higher amongst Aboriginal and Torres Strait Islander peoples of all age groups compared with non-Indigenous Australians between 2011-2015 [33]. These disparities highlight the need for more effective, targeted communication with Aboriginal and Torres Strait Islander people regarding the importance of, and their eligibility for, free seasonal influenza vaccinations [28].

Improving timeliness and rates of vaccination coverage and lowering the burden of VPDs amongst the Indigenous population will require enhanced collection and utilisation of data and improved efforts to reduce barriers to vaccination for Aboriginal and Torres Strait Islander people. Currently, national vaccination coverage data for Indigenous adults is only reviewed in four-year periods and publication of this data can be delayed. Reviews are needed more regularly to more effectively monitor and target program delivery efforts. A failure of health practitioners to correctly identify Indigenous patients also significantly impedes accurate data collection and delivery of appropriate healthcare [34].

The Global Response

Although vaccination is a major element of primary healthcare and global health security, there have been challenges in obtaining universal immunisation coverage [35]. While 85% of children were vaccinated for diphtheria, tetanus and pertussis (DTP-3) globally in 2019, 19.7 million children have been left unprotected, with half of this population in the African region. Of these, 14 million infants are completely unvaccinated due to lack of access to vaccination services. Despite increasing coverage, only 15% of girls globally are currently vaccinated for HPV, with only one in five high-income countries and lower middle-income countries obtaining 80% final HPV vaccination coverage [36]. Globally, girls aged 9 to 14 years are primarily targeted and males are secondarily targeted if it is feasible and cost-effective [37]. However in Australia, both genders are currently targeted for the HPV vaccine, with the 75.9% of males aged 15 years completing all 3 doses of the HPV vaccine in 2017 [38].

<u>The Global Vaccine Action Plan (GVAP) 2011-2020</u>

GVAP was executed by the World Health Organization (WHO) from 2011 – 2020, with the vision of eradicating VPDs [39]. The plan aimed to reach a minimum of 90% national immunisation coverage and its six strategic objectives to achieve the goals [40].

Since 2011, more than 470 new vaccines have been introduced in low- and middle-income countries, and global child mortality has rapidly decreased by 25% since 2010 [39]. Much progress has been made through GVAP, and global donor support for vaccination exceeded US$1 billion in 2018 [39]. The GVAP also encourages implementation of regional and National Immunization Technical Advisory Groups (NITAG), to guide national health policies based on the local context and evidence-based advice [41]. However, the GVAP has been criticised as difficult, with overly ambitious goals, limited accountability from countries and lacking a formal organisational structure [39]. While its strategic objectives of increasing vaccine coverage, addressing inequities and researching new vaccine technologies are equally relevant today, many countries could not fully commit to achieving all aspects of GVAP and had set regional targets that were less ambitious than those in GVAP [42]. There is also uncertainty about whether middle-income nations can financially support vaccines using domestic budgets once they become ineligible for funding

from The Vaccine Alliance (Gavi). Gavi is an alliance that aims to ensure that low- and middle-income countries can access affordable vaccines [39, 43, 44].

The Immunization Agenda 2030

The WHO has introduced The Immunization Agenda 2030 (IA2030), setting an overarching global vision and strategies for vaccination for 2021-2030. Its vision is "A world where everyone, everywhere, at every age, fully benefits from vaccines for good health and well-being." [45]. The IA2030 has also been structured to fit into 14 of the 17 Sustainable Development Goals (SDG), as shown in the table below [45]:

Table 1: The relevance of immunisation to SDG, according to IA2030

No poverty	Vaccination helps in eliminating poverty, through decreasing treatment costs and increasing long-term productivity.
Zero Hunger	There is a higher chance of malnourished individuals, especially children, dying from infectious diseases.
Good Health and Well-being	Immunisation is cost-beneficial in saving lives and supporting good health and well-being.
Quality Education	Children who are vaccinated usually undergo more years of schooling, and score higher in cognitive tests than those who are unvaccinated.
Gender Equality	Removing gender- related barriers to immunisation promotes gender equality and increases equity for women in accessing healthcare services.
Clean Water and Sanitization	Immunisation enhances clean water and sanitization, and prevents diarrhoeal diseases in low-income countries.
Affordable and clean energy	New vaccination technologies involve using more sustainable methods through renewable sources of energy.
Decent work and economic growth	Vaccination results in a healthy and efficient workforce that boosts the economy.
Industry innovation and infrastructure	Vaccine production supports infrastructure in low- and middle- income countries.
Reduced Inequalities	Vaccines prevent diseases that affect disadvantaged peoples, including remote rural communities and displaced peoples.
Sustainable cities and communities	Vaccination protects public health and aids disease control.
Climate action	Vaccination increases immunity to disease outbreaks related to climate change, including yellow fever and malaria.
Peace, justice, and strong institutions	Immunisation promotes efficient, safe, people-centred health systems within the population, thus promoting peace, justice and strong institutions.
Partnerships for the goals	Vaccination programmes promote partnerships and collaborations between civil society and the public sector in achieving goals.

Through the lessons learnt from GVAP, IA2030 aims to strengthen current partnerships and build new relations at a country level under the guidance of national programmes. It has also formulated disease-specific goals, including polio eradication and the elimination of major VPDs - neonatal tetanus, measles and rubella, yellow fever epidemics and meningitis epidemics [45]. This is accompanied by goals for the reduction of cases and deaths, control of cholera and vector-borne diseases, and reduction of seasonal influenza burden and zero deaths from dog-mediated rabies [45].

The new platform for IA2030 has been set by the changing global context. For example, in 2018 70% of unvaccinated children were from middle income countries [36]. The IA2030 aims to address subnational inequity, cross-border movements and respond to global demographic shifts by ensuring immunisation for every person of all

ages. This would be done through a bottom up approach by collaborating with countries, and tailoring the agenda to a national context [45]. The overarching strategy of IA 2030 is to ensure that vaccination programmes are a key part of primary health care to achieve universal health coverage. The other strategic priorities have been summarised in the table in the appendix [45].

Groups at High Risk

Forcibly displaced people

At the end of 2019, there were 79.5 million forcibly displaced people worldwide [46]. People from refugee backgrounds are at risk of being under- or unimmunised [47]. They often originate from countries with different immunisation schedules, or have had their routine immunisations interrupted by conflict and other social or political factors [47]. Forcibly displaced people may also have been exposed to conditions associated with exacerbating disease transmission, such as stress and trauma, malnutrition, poor sanitation, and overcrowding during transit and resettlement [48]. There have been more than 300 infectious disease outbreaks in refugee camps around the world since 2009, highlighting the importance of infectious disease prevention for this group [49]. For host countries, low vaccination coverage rates in existing populations and inadequate immunisation services for migrants creates the risk of importing pathogens from endemic areas [48].

In some countries, refugees and asylum-seekers may be vaccinated during their visa application process or in immigration detention centres. After they settle into communities, there are inconsistencies in immunisation policies in different regions directed towards this group. Some countries provide free access to vaccination, while others only provide selected vaccines and limited booster shots. A lack of clear planning was seen in Europe, where only 11 of the 42 WHO Member States included recommendations for vaccinations for refugees and migrants in their National Immunisation Programs. Forcibly displaced people can face barriers that limit their access to vaccinations in the country they move into. These include social determinants like lack of access to health care, inability to pay, cultural differences, and discrimination. Navigating the health system can also be challenging due to limited health literacy and language barriers. For undocumented migrants, it is even more difficult to access vaccination, since they are often ineligible to receive free vaccines. In addition, undocumented migrants may feel fearful to visit a healthcare provider to receive vaccination, due to concerns about their legal status and possible immigration consequences. [48]

Rural and Remote communities

People living in rural or remote areas may be affected by many barriers to healthcare, such as lower income, education levels, and reduced availability of health services [50]. As a result, residents of remote regions around the world experience lower life expectancy and poorer health outcomes [51]. In many developing countries, major challenges for receiving vaccinations in remote areas are transportation, storage, and lack of healthcare resources [52, 53]. In some regions, vaccine providers need to cross geographical barriers like jungles or mountains to deliver their service [52, 53]. Many remote areas do not have reliable power supply, therefore, the cold-chain condition that maintains vaccine effectiveness cannot be achieved [54].

Disparities in vaccination coverage between rural and urban communities are also present in high-income countries. A 2018 report in Australia showed that children living in very remote areas have a lower rate of complete immunisation compared to their metropolitan counterparts (88% compared to 92%) [55]. Residents of remote and very remote areas also had the highest rate of hospitalisations due to VPDs in 2015 to 2016 (3.1 and 9.0 per 1000 population, compared to 1.4 in inner regional areas) [56].

People of Low Socioeconomic Status

Socioeconomic status is often measured as a combination of education, income, and occupation [57]. Barriers to receiving vaccinations, especially childhood immunisations, include poor access to healthcare systems, lack of parent education, low income, and unsocial work hours [58, 59]. Effective health policies and public campaigns aim to address and remove these barriers. However, some government policies maintain a punitive approach, which can further marginalise already disadvantaged people. For example, the Australian government's "no jab no pay" policy mandates that the children of parents who claim Family Tax Benefit (FTB) Part A or child care fee assistance must be fully vaccinated, or be on a catch-up schedule [60]. Families with low income are more likely to be eligible for, and be receiving these payments [61, 62]. If children of these families are unvaccinated due to socioeconomic factors, rather than objections to vaccination, policies that enforce financial penalties can result in further hardship and inequities [63]. A more nuanced approach is needed in public health policies, rather than a blanket rule with the underlying assumption that everyone with unvaccinated children are vaccine-hesitant.

Humanitarian crises

Humanitarian crises include man-made conflicts, natural disasters, and pandemics [64]. Regardless of type and cause, humanitarian crises are linked to risk factors for VPDs, which may lead to sudden changes in the burden of these diseases [65]. Humanitarian crises can disrupt the delivery of routine health services, including vaccination programmes, due to more challenging security, ethical, and logistical issues [65]. This has been seen during the COVID-19 pandemic, where preliminary data on vaccine administration published in July 2020 shows significant declines as a result of suspension of outreach programs and fears of SARS-CoV 2 transmission in healthcare facilities [36].

The WHO has developed a decision-making framework that outlines vaccination options in crises. In an emergency, vaccines can be procured through purchase (directly from manufacturer, through response mechanisms of organisations, and from stockpiles) and by donations. Various mechanisms are in place to ensure the availability of affordable and effective vaccines. However, the challenges associated with the timely distribution of vaccines, monitoring their uptake and reaching populations with low health literacy, are all factors that can complicate administering vaccines in regions affected by crises Ethical considerations like consent, political factors like tension between local authorities and international stakeholders, and availability of public health personnel can also add to the existing challenges [65]. Some other key considerations for obtaining a suitable vaccine for an emergency are:

- Efficacy of vaccine at less than full course or with a fractional vaccine dose;
- Groups that cannot be vaccinated due to health concerns;
- Feasibility of vaccination schedule in a humanitarian crisis;
- Availability of vaccine;
- If the vaccine can withstand ambient temperature outside of labelled storage conditions;
- If cold-chain equipment for storage is present, or can be installed. [65]

First Nations People Globally

Historically, many First Nations peoples have been devastated by introduced infectious diseases and continue to experience a higher morbidity and mortality of VPDs compared with the general population of their countries [66].

High-income countries

In high income countries, Indigenous people experience much higher rates of VPDs than non-Indigenous people. In Canada, Indigenous people have much higher HPV infection rates, and worse cervical cancer outcomes, than non-Indigenous women. Barriers to vaccination for these people include historical mistrust in healthcare

systems, infrastructure gaps, and community sensitivity surrounding sexual health [67].

In the absence of structured, funded vaccination programs, the highest rates of other diseases such as invasive *Haemophilus influenzae* type B (Hib) , hepatitis B and hepatitis A are amongst Indigenous populations in the U.S, Canada, Australia and New Zealand. Notably, in Canada, the Inuit people had a carriage rate for hepatitis B twenty times higher than the non-Indigenous population before vaccines were routine [66].

However, when introduced, funded vaccination programs have been shown to be the most effective way of reducing VPD incidence within First Nations populations, particularly those that target viral diseases with little strain variation and high herd immunity. Introduction of Hib vaccine programs for First Nations children under five in the U.S. and New Zealand resulted in decreases in disease incidence of 98% and 92% respectively [66]. Geographically targeting high-incidence regions and First Nations peoples in regions where they constitute a larger portion of the population has also historically been successful in reducing disparities between Indigenous and non-Indigenous people for diseases such as hepatitis A (in the U.S) and influenza (in some North American regions). However, programs that target only Indigenous people in urban areas are the least effective as they rely on correct identification of Indigenous people, which can be difficult [66, 67].

Unfortunately, targeted programs for First Nations peoples are not always effective due to: cost, low disease rates in non-indigenous populations, delayed vaccination, and higher prevalence of risk factors. Innovative solutions, such as tailoring vaccine composition and schedule, have had positive impacts, but continued improvement is needed [66].

Low-income Countries

For the same reasons as above, First Nations people in low-income countries also experience a significant burden of VPD, and additional barriers including geographical access, sociocultural differences, and religious factors. In South America, infectious diseases are one of the main reported causes of death amongst Indigenous people. Despite availability of mobile vaccination teams, vaccine coverage rates remain low and vaccine refusal is high [68].

Amongst the Warao people of Venezuela, only 25% of children are fully immunised, two to three times less than the percentage of children immunised in the general population [68]. This has been attributed to a preference for traditional medicine, religious objections, misconceptions surrounding causes of disease and methods of transmission, differing expectations between healthcare providers and these communities, and particularly, a fear of side effects [68, 69, 70].

When successfully implemented and accepted, vaccine programs for Indigenous people in low-income countries have been shown to be successful. Notably, Hib vaccine coverage of less than 70% amongst the Firsts Nations people of The Gambia was successful in eliminating Hib [71]. However, even for the Indigenous populations receptive to vaccination and Western medicine, concerns about adverse effects remain one of the greatest barriers to full immunisation coverage [68, 70]. Strengthening communication and education will enhance informed and willing participation in vaccination programmes amongst these peoples.

Vaccine Hesitancy

The WHO lists vaccine hesitancy as one of the top 10 health threats facing humanity [72]. The WHO Strategic Advisory Group of Experts (SAGE) Working Group on Vaccine Hesitancy has determined that vaccine hesitancy refers to ‘delay in acceptance or refusal of vaccination despite availability of vaccination services.’ Even relatively low levels of vaccine delay or refusal can have profound impacts, as some essential vaccines require coverage rates of at least 95% for herd immunity,

emphasising the danger vaccine hesitancy poses to public health [73]. In Australia, conscientious objection to vaccination as recorded in the Australian Immunisation Register (AIR) increased from 0.23% of all children in 1999 to 1.34% in 2015, which is the last year of data, as conscientious objection was removed as a reason for refusal [74].

The three Cs model of *complacency, convenience* and *confidence* categorises vaccine hesitancy based on its main causative factor and these vary based on context and even the specific vaccine in question. *Complacency* refers to when perceived risks of VPDs are low and therefore vaccination is not considered as necessary. *Confidence* encompasses trust in the efficacy and safety of vaccines, the reliability of the health system (including health professionals) who deliver them, and the motivations of policymakers who determine needed vaccines. Vaccine hesitancy due to lower confidence encompasses a broad array of people from those who may have questions about the risks and benefits of vaccinations to those who are completely against vaccination [73, 75]. *Convenience* refers to the physical and geographical availability and affordability of vaccines as well as the ability to understand service providers [75].

Regardless of a nation's economic status, 'scientific risks versus benefits' is one of the top three reported reasons for vaccine hesitancy. However, other top three reasons appear to follow trends according to economic status. Low- and middle-income countries often report 'religion/culture/gender/socioeconomic factors' and 'knowledge and awareness' as their other top three reasons for vaccine hesitancy. On the other hand, high-income countries report 'beliefs and attitudes about health and prevention' as well as 'perceived risks versus benefits (non-scientific)' as their other top three reasons [76]. This data highlights that no single strategy can effectively address vaccine hesitancy around the world, and similar strategies will have different outcomes in different countries, particularly in countries of differing economic status. It is also important to be cognisant of within-country variation as data from Australia (a high-income country) shows that children from both the highest and lowest quintiles of socioeconomic status have lower vaccination rates compared to their age-matched peers. This indicates that even in developed countries, higher socioeconomic status is not necessarily a protective factor and diverse strategies are needed to target both groups [77].

Strategies to Address Vaccine Hesitancy

Strategies to address vaccine hesitancy need to address both the community context and the three Cs model [75, 78]. Where there is a lack of accessible services (*convenience*), it is important to prioritise resources to solve this before attempting to address other parts of vaccine hesitancy [73]. SAGE have suggested the following strategies:

- Engagement of religious or other influential leaders to promote vaccination in the community;
- Social mobilisation;
- Mass media;
- Improving convenience and access to vaccination;
- Mandating vaccinations / sanctions for non-vaccination;
- Employing reminder and follow-up;
- Communications training for healthcare workers;
- Non-financial incentives;
- Aim to increase knowledge and awareness about vaccination. [78]

<u>Mandatory vaccination</u>

Mandatory vaccination presents an ethical challenge and in practice, the success of mandatory vaccination schemes compared to other strategies is equivocal, though often results in an immediate and long term increase in coverage for that region [79,

25, 80, 81]. However, some countries with mandatory vaccination have lower vaccination rates than some countries that do not, for example, Italy and France have some mandatory vaccines but have lower rates of DPT3 and measles vaccine coverage than other European countries such as Cyprus, Sweden and Spain where vaccination is voluntary [82, 83]. Where mandatory vaccination has been implemented there are often many exemptions including for personal objections, or lax enforcement. This approach avoids physically forcing vaccination, but also makes it difficult to compare the success of mandated vaccination programs [79, 81, 84]. Where exemptions have been limited, there frequently was already extremely high support for vaccination which enabled such laws to be acceptable to those populations [85]. The WHO does not have an official policy on mandatory vaccination, leaving the choice to member states, but prefers that "high community demand and acceptance make compulsory vaccination programs unnecessary" [79].

Mandatory vaccination creates an ethical issue, generates considerable media attention, can increase mistrust causing vaccine-refusers to more strongly commit to their refusal, and can detract from the core messages that vaccines are safe and effective [86, 87, 88]. Any implementation of mandatory vaccination must be carefully considered, and alternative approaches may be more effective at reducing disease transmission to acceptable levels. Common alternative strategies where voluntary uptake of vaccinations has not been sufficient include only making vaccination compulsory for those with a high risk of exposure or transmission, such as health care workers; campaigns targeting the most vulnerable groups; and campaigns to target vaccination efforts to areas experiencing or close to an outbreak, where there is an increased individual incentive to seek vaccination [87, 89].

Access to misinformation

Confidence is significantly impacted by the spread of misinformation through the internet and social media sites. Misinformation can significantly influence people's decision making through conflicting evidence on the risks and benefits of vaccination, especially when people deem such resources as trustworthy [73]. Reducing access to misinformation is therefore essential to maintain confidence in vaccines. Organisations like the American Academy of Paediatrics, have requested partnerships with social media and internet organisations like Google, Facebook, and Pinterest ensure their platform's users only view credible, science-based information. Since then, Facebook has announced that groups and pages that share anti-vaccine misinformation would be removed from its recommendation algorithm. Preventing the spread of vaccine misinformation depends on such partnerships [73].

Role of Health Professionals

Health professionals play a very important role in influencing vaccine hesitant people as they are able to address all parts of the 3Cs model [73, 90]. General practitioners (GPs), being the primary and most common point of contact between people and the health system makes them most suitable for both providing and advocating for the timely delivery of immunisations, thereby helping address convenience [9, 91, 92]. Being more familiar with their patients and generally enjoying a high degree of trust, GPs are best able to identify at-risk groups and educate patients about vaccines, decreasing complacency [9, 90, 92]. This familiarity also makes them more effective at addressing the medical concerns of vaccine hesitant people such as medically necessary alterations to the vaccination schedule to suit individual needs, improving confidence [9, 92]. In recognition of this key role, GPs and other vaccine providers in Australia receive a $12 incentive payment for identifying overdue children to the AIR and delivering catch-up immunisation [n93]. Similarly to GPs, paediatricians play an important role in addressing vaccine hesitancy through educating and communicating with parents and caregivers about infant and childhood vaccinations [A94]. Technology-based strategies may also aid health professionals to increase vaccine coverage. For instance, in Australia, the AIR can provide information to the My Health Record system, which may allow individuals and healthcare providers to keep track of vaccines received and overdue [9].

When considering the role health professionals play, it is also important that all health professionals (including students) engage in training on how to effectively communicate with vaccine hesitant people [73]. Organisations such as Sharing Knowledge About Immunisation (SKAI) provide resources and training modules for health professionals for this purpose [95]. A poor interaction or conflicting advice can significantly impact on trust of the health system and practitioners are encouraged to set aside sufficient time (such as at a follow-up appointment) to discuss relevant issues if a patient or carer is vaccine hesitant. This is particularly important for child health workers [73].

Public Information Campaigns

Addressing complacency and confidence on a broader scale involves public education programs about the benefits of vaccinations and dispelling common pieces of misinformation. In 2017, the Australian Government launched the 'Get the facts about immunisation' campaign, targeted at Australian parents and carers (including pregnant women and partners, Aboriginal and Torres Strait Islander people, and people from Culturally and Linguistically Diverse (CALD) backgrounds) primarily through online and social media. The evaluation report on the 8-week long third phase of the campaign, published in February 2020, showed an increase in parents being 'familiar' or 'very familiar' with the vaccinations children required from 78% to 84%. Of parents or carers exposed to campaign material, 82% took some action, while 52% took specific actions like checking if their children's vaccinations were up to date, or booking an appointment with a general practitioner to discuss immunisation. However, the report also noted a lower percentage of parents and carers who were 'very likely' to vaccinate their children before 5 years of age (83% to 78%), as well as an increase in 'strong agreement' to the statement "I oppose vaccination for children" (2% to 7%) [96]. While these results show some positive outcomes, they also highlight the need for information campaigns to be monitored and evaluated for their effectiveness and altered where indicated.

Australian Foreign Aid for Vaccination

Australia's foreign aid contribution towards vaccination operates across three levels: providing funding for global multilateral organisations such as the WHO, funding support for regional development partners, and direct funding and support to four nations within our region [97]. This three-tiered approach provides Australia with a framework for being directly and practically involved at the local level, while providing financial support that can be directed as needed by globally operating organisations, without direct political involvement from Australia.

At the global level, Australia's contributions are primarily through multilateral organisations who provide locally targeted health and vaccination campaigns, and support vaccine development. Many of the organisations have broader objectives related to health and development, and vaccination is offered alongside primary health care and infrastructure development [98]. Gavi, The Vaccine Alliance, seeks to ensure that low and middle income countries that are becoming less reliant on foreign aid funding are still able to access vaccines at prices they can afford, allowing for a sustainable transition to self-funded vaccination programs [99]. Gavi prioritises the most common causes of childhood illness and death including measles, pneumonia and diarrhoea and has a clear focus and strong track record of improving vaccination rates in target countries while improving their capacity self-funding [100]. Australia also contributes to the Global Polio Eradication Initiative which seeks to entirely eradicate polio, primarily through widespread vaccination [101]. While it was projected that polio would be eradicated by 2023, regional instability and the COVID-19 pandemic have interfered with progress and increased funding will likely be needed [102, 103]. Although Australia remains a substantial contributor to the initiative, in recent funding rounds both the proportion of total funding contributed by Australia and the annual value of our contributions has decreased from the previous levels [104]. Australia also makes a biennial core contribution to the World Health Organisation [105].

In addition to global partners, Australia contributes to the World Bank Multi-Donor Trust Fund for Integrating Donor Financed Health Programs, and Window 2 of this program is specific to immunisation. This program operates within Cambodia, Lao PDR, Indonesia, Papua New Guinea, Myanmar, Vietnam and the Philippines and seeks to sustainably finance routine immunisation and the systems that support vaccination [105].

Australia's largest foreign aid contribution is made at the level of individual countries, providing substantial funding to Papua New Guinea, Timor-Leste, Solomon Islands and Cambodia [97]. Funding is used to support national health plans, primary care, and development of health related infrastructure. Vaccination is often offered alongside programs rather than as the sole initiative [107, 108, 109, 110, 111, 112, 113, 114]. In Papua New Guinea, Australia provides funding to support their Government's *National Health Plan: 2010-2020,* which seeks to improve access to primary health care. Childhood nutrition and immunisation is supported across 14 provinces through this initiative [107]. Health funding provided to Timor-Leste is targeted towards infrastructure improvements, and also includes training of general practitioners to improve access to primary healthcare [109, 110]. Australia's contributions to Solomon Islands have a strong focus on maternal and child health which incorporates vaccination, as well as access to clean water and sanitation [111]. In Cambodia, ensuring high vaccination coverage rates is a strong priority for the local healthcare system [113]. Australia's funding is primarily directed towards ensuring free healthcare access for the poorest 20% of the country's population [114].

The prioritisation and deployment of foreign aid funding is a complex and multi-faceted policy space, with much of its objectives and drivers beyond the scope of this policy; however, it is reasonable to expect that any investment in vaccine programs abroad should culminate in practical, local outcomes. Australia's three-tiered approach can clearly be seen to drive accountability at local levels, even when programmes have faced setbacks or delays. Continued investment should align with global best practices and ensure that visibility to local outcomes is maintained.

Research & development

Neglected tropical diseases (NTDs) are a group of bacterial, viral, parasitic, and fungal diseases that primarily affect impoverished, low-resource populations in tropical countries [115]. The WHO currently focuses on 20 NTDs that are estimated to impact approximately 1.5 billion people annually, including 830 million children in the developing world [115, 116]. Not only do NTDs exacerbate poverty through their adverse health effects, but many are chronic conditions with long-term effects on childhood development, education, and work productivity [117]. The UN has highlighted the importance of addressing NTDs as one of the Sustainable Development Goals targets, specifically 3.3, which aims to, "by 2030, end the epidemics of… neglected tropical diseases…" [118]. However, few vaccines exist for these diseases. Currently, vaccines are only available for dengue, rabies, and in addition, the tuberculosis Bacillus Calmette–Guérin (BCG) vaccine is only used for leprosy in certain instances [115]. There are a limited number of medicines available, many of which are old, resulting in increased rates of resistance and drug toxicity side effects [115]. A key research and development priority outlined by the WHO is the development of vaccines for Leishmaniasis, and the Buruli ulcer [119, 120]. Although there have been recent investments in vaccines targeting viruses and emerging diseases with pandemic potential, there has been limited investment to combat NTDs through vaccination development [121].

Translating research to new feasible biotechnologies, such as vaccines, depends on addressing both scientific and financial elements [121]. The profitability and financial realisation of a potential vaccine are critical in incentivising investments both before and after development. Product development partnerships (PDPs) were established to help fund the development of products that pharmaceutical and biotechnology companies were unable to invest in due to financial risk [121]. PDPs are international non-profit organisations that combine public, private, academic, and philanthropic

donors to drive the development of new products, such as vaccines, for neglected diseases hindered by expensive upfront costs, and potentially low market return for shareholders [122]. The Australian Department of Foreign Affairs and Trade (DFAT) has been a key contributor to several PDPs, including the TB alliance, Foundation for Innovative New Diagnostics (FIND), Innovative Vector Control Consortium (IVCC), Medicines for Malaria Venture (MMV), and Coalition for Epidemic Preparedness Innovations (CEPI) [122]. A recent evaluation by DFAT, examining investments in FIND, MMV, and the TB alliance reaffirmed that PDPs represent financially viable and cost-effective ventures [123].

Among the PDPs supported by DFAT, CEPI develops vaccines against emerging infectious diseases that impact individuals in lower and middle-income countries, particularly in the Indo-Pacific region [124]. Although Australia's $4.5 million contribution is relatively minor compared to the $750 million USD contributed from other donors, Australia still has a position on the Investors Council [124].

Among non-profit organisations supporting vaccine development, Australia has partnered with the Bill and Melinda Gates Foundation, whose Medical Research Institute focuses on developing vaccines for TB [123]. The current BCG vaccine is over 85 years old and yet provides limited protection in newborns and children, and no protection for pulmonary TB in adults [123]. The End TB Strategy by the WHO advocates for the development of a vaccine that is effective pre- and post-exposure, in order to prevent disease latency, allowing for the global elimination of TB [125].

Rotavirus commonly causes gastrointestinal infections in children [126]. Within Australia, two rotavirus vaccines are available, Rotarix, and RotaTeq. While the differences in the vaccines' effectiveness against specific genotypes remains unclear, rotavirus vaccines have been shown as less effective in poorly resourced settings [126]. Although some explanations such as the prevalence of other gastrointestinal pathogens, interference from breast milk, and higher maternal antibody levels have been suggested, further research is needed [126]. A core principle underlying The WHO's Immunization Agenda 2030 is "country-owned", whereby countries should be able to identify and develop vaccines according to their priorities using both local and global innovations [45]. As many vaccines are designed overseas and used locally, there is an opportunity to research optimising rotavirus vaccines specific to resource poor settings.

Vulnerable to heat, light, radiation, and changes in environment, vaccines need to be stable during storage, transport, and handling to be effective [127]. The issue of vaccine instability limits their use in many remote regions and developing countries lacking sufficient storage capabilities [128]. While there are several different types of vaccines, each with their own stability issues that must individually be addressed, the cost of infrastructure designed for thermostability accounts for approximately 80% the cost of vaccination programs [128]. Consequently, developing stable vaccines will not only reduce the economic burden but improve the accessibility of vaccines to low-resource regions globally [128].

Non-communicable diseases (NCDs) are a group of chronic diseases that disproportionately affect low- and middle-income countries, killing 41 million people annually [129]. The rising burden of NCDs not only exacerbates poverty through reduced productivity but also by the economic burden on national health care budgets [130]. Vaccines targeting hepatitis B and HPV have helped reduce the global burden of liver and cervical cancer respectively [131]. The 9vHPV is expected to prevent up to 90% of cervical and 96% of anal cancers [132]. In addition to targeting infectious diseases causing cancer, research exploring vaccinations for hypertension, diabetes, obesity, asthma, multiple sclerosis, and other NCDs are in development [133].

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Policy Details

Name: Vaccinations

Category: G – Global Health

History: Reviewed, Council 3, 2020
Adam Lapidus, Yufei Xu, Hannah Bates, Tegan Cosgrove, Ashraf Docrat, Dayna Duncan, Aye Mya Khine, Guy Jeffery (Global Health Policy Officer)
Adopted, Council 1, 2016

Appendix

Table 2: Strategic priorities of IA2030

Commitment and demand	Stressing political and financial commitment for vaccination at all levels. Ensuring that every person actively searches for vaccination services.
Coverage and equity	Sustaining and achieving high and equitable vaccination coverage across countries. Expand vaccination programmes to reach under-vaccinated children and communities.
Life-course and integration	Strengthening vaccination policies and services throughout life-course. Reinforcing integration between vaccination and other public health interventions for different age groups.
Outbreaks and emergencies	Ensuring adequate preparation for a fast and exceptional response to vaccine-preventable disease outbreaks. Establish timely vaccination services during emergencies and in areas with humanitarian crisis, conflict and disaster.
Supply and sustainability	Providing adequate financial resources for vaccination programmes in all countries. Increasing vaccination expenses from domestic resources in aid-dependent countries and maintaining government funding when transitioning away from aid. Developing healthy global markets across all vaccine antigens.
Research and Innovation	Developing new technologies and improving existing vaccination programmes, by locating priorities for innovation at all levels. Expanding and managing innovations as appropriate.