

ONE SHOT.

One Shot to Prevent Disease and Prepare for Future Pandemics

Identifying the Most Promising Adult Vaccines
and Injectables

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AUTHORS

TAMSIN BERRY
PAUL BLAKELEY
DR HENRY LISHI LI
DR ROMINA MARIANO
DR GABRIEL SEIDMAN

CONTRIBUTORS

DR DAVID AGUS
PROFESSOR SIR JOHN BELL

**The Global Health
Security Consortium**

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Executive Summary

As part of a revolution that began before Covid-19 emerged, vaccine technology had been advancing at speed, with new programmable platforms, including RNA and viral vectors, making it easier to create new vaccines. Meanwhile, the ongoing evolution of adjuvants – ingredients added to vaccines to trigger a stronger immune response – and lipid nanoparticles means the next generation of products will soon be available to tackle many of the world’s major pathogens and chronic diseases. Together, these advances will enable us to prevent many high-burden diseases, including the non-communicable ones that account for 74 per cent of deaths around the world.

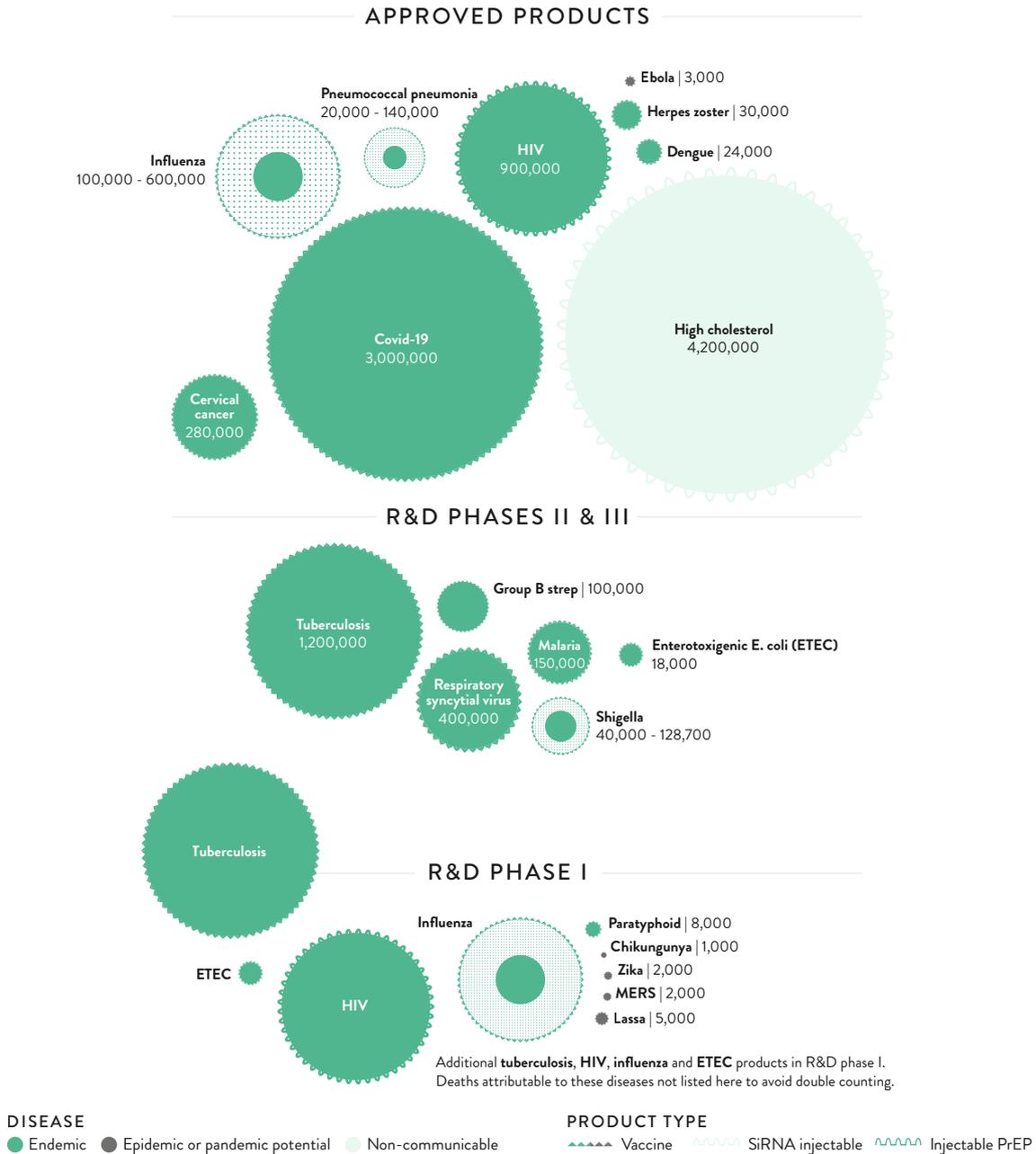
Currently, adult-vaccination efforts are focused on addressing the urgent need for Covid-19 immunisation, particularly among at-risk groups. But in the longer term, this framework should be adapted and evolved to increase access to other vaccines for preventable diseases and to support the rollout of promising new candidates. In a [previous paper](#), the Global Health Security Consortium (GHSC) estimated that at least 10 million deaths per year are attributable to diseases with existing or forthcoming adult vaccines and preventative injectable therapies (see Figure 1).

Potential candidates include new vaccines for flu, respiratory syncytial virus (RSV), pneumococcal, malaria, human papillomavirus (HPV) in adolescents, tuberculosis (TB) and dengue, as well as long-acting injectables to prevent heart disease through better control of cholesterol and blood pressure, and pre-exposure prophylaxis for HIV. In addition, vaccines against causes of hospital-acquired infections and other bacteria considered to be antimicrobial resistant will be exceedingly important in countries with large numbers of chronically ill patients.

Emerging technologies and established vaccines are an integral part of the infrastructure for the One Shot programme proposed by the GHSC. To facilitate the development of such a global disease-prevention programme for adults, a number of steps will be needed.

Figure 1

SHOWING THE GLOBAL BURDEN OF SELECTED DISEASES THROUGH DEATHS IN THE ADULT POPULATION, AND THE VACCINES AND INJECTABLES THAT COULD PREVENT THEM



Note: a summary schematic of some of the current and promising vaccines that would avert millions of deaths each year. This figure is drawn from estimates based on OWID,¹ IHME Global Burden of Disease metrics for 2019,² systematic reviews^{3,4} and WHO health data.⁵ Deaths are all of adult populations, except for Group B strep where neonatal deaths are measured but vaccination is given to the mother. Herpes zoster, pneumococcal and RSV are estimated for eligible adults (>60 years). Pneumococcal and RSV are representative of an equal split of the total lower-respiratory-tract infections in the >65 age group (roughly 1.2 million), of which they are the most common. Shigella and ETEC deaths are for adults >70 as these were the only available data sets and so are likely to be higher.⁶ Covid-19 deaths represent those that occurred after the first vaccine rollouts began.

Source: GHSC

HOW DO WE TAKE ACTION?

- **Develop a global oversight model led by the World Health Organisation (WHO):** Scientific advisory groups will issue recommendations for the use of adult vaccines and long-acting injectable therapies, based on clinical-trial outcomes and real-world evidence studies.
- **Ensure that such a global oversight model can take timely and efficient decisions.** This is especially crucial in urgent scenarios such as outbreaks and public-health emergencies of international concern.
- **Collect timely, consistent and representative data:** Disease surveillance, which tracks regional disease burden and at-risk groups, will be imperative to efforts by individual countries.
- **Use surveillance data to make evidence-based decisions:** Regional scientific advisory or expert groups will interpret this data and advise policymakers on which of the WHO recommendations are relevant and should be adopted. Cost-benefit analyses can then be carried out for specific vaccines and injectable therapeutics.
- **Adopt a “bundle” approach to adult vaccination:** By viewing adult vaccination in a systematic way and accounting for the needs of particular groups – for example, pregnant women, the elderly and health-care workers – processes and deployment infrastructure can be streamlined and efficient.

The Foundations for a Disease-Prevention Programme Exist

Beyond those developed for Covid-19, the World Health Organisation (WHO) has a recommended list of routine vaccines for adults.¹ In high-income countries, including the United States and the United Kingdom, guidelines for their use exist^{2,3} but there is no global consensus on access to these interventions yet, with coverage remaining generally limited, especially in low- and middle-income countries (LMICs).⁴

Our ability to prevent disease with injectable therapies is increasing quickly, for instance, the recent approval of an injectable to reduce cholesterol (Inclisiran, which reduces low-density lipoprotein (LDL) cholesterol by 50 per cent through a small-interfering RNA therapy),⁵ or the approval of both a long-acting injectable pre-exposure prophylaxis and an injectable treatment for HIV. Such developments have the power to transform health care, with evidence also suggesting that long-acting injectable therapies improve both adherence to treatment regimens and the retention of patients.⁶

A combination of vaccines and injectables will be critical in the management of epidemics, pandemics and, crucially, chronic diseases. High-burden chronic diseases not only make populations more vulnerable in the face of a pandemic, but are the leading driver of annual health-care costs as well as loss of productivity and poor quality of life. The ability to repurpose treatments in times of acute need – most recently, the use of the smallpox vaccine Imvanex for monkeypox – should also not be underestimated.

CONTINUITY FROM CHILDHOOD THROUGH TO ADULTHOOD

Childhood-vaccination programmes are cited as one of the most cost-effective and successful public-health interventions globally.⁷ The recommendations and guidelines for childhood vaccinations are evidence based and outcome driven. We argue the same concept should be applied

to adolescents and adults, with a programme targeting different age groups and cohorts (such as health-care workers and pregnant women) at integrated points of delivery. This aligns with the fourth strategic priority of the WHO's Immunisation Agenda 2030 – “life course integration” – which states that all people benefit from recommended immunisations throughout the course of their lives.⁸ While the programme would include routine vaccinations, preventative injectables (either primary or secondary), catch-ups and boosters, it must be robustly designed to avoid drawing on resources for childhood vaccinations but instead provide continuity into adolescence and adulthood.

A programme that addresses disease prevention would seek to make use of these products routine, especially within primary care. Supported by the right digital-health infrastructure, health systems would ensure that eligible cohorts are identified, contacted and made aware of what products are available to them. This deployment infrastructure for vaccines and long-acting injectables could also be used to support the administration of other products, including during outbreaks.

Further details on available candidates can be found in Figure 2 below and in the Technical Deep Dive 1: Candidates and Eligible Populations chapter of our GHSC report *A Global Opportunity to Combat Preventable Disease*.

Figure 2

APPROVED PRODUCTS THAT COULD BE IMMEDIATELY INCORPORATED INTO A DISEASE-PREVENTION PROGRAMME FOR ADULTS

VACCINES		
Established evidence and guidelines		
Disease prevented	Populations/conditions that may benefit	Recent updates
Covid-19	May require annual boosters, especially for at-risk groups	Bivalent boosters, including for Omicron, expected to be available later this year ^{1,2}
Influenza	All adults	New and improved flu-vaccine trials are ongoing: ³ e.g., mRNA-1010, Moderna (phase III), qNIV, Novavax (phase III) ⁴
Human papillomavirus (HPV)	All adolescents	Single-dose HPV schedule determined to be as effective as two or three doses ⁵
Herpes zoster	Adults 60 to 65 years of age or younger if at risk	Shingrix (GSK) approved in July 2021 for use in immunocompromised adults ⁶
Dependent on country and individual risk profile (e.g., demographics, occupation), outbreaks or further evidence for regular use in adults		
<ul style="list-style-type: none"> • Pneumococcal conjugate vaccine (Pfizer)⁷ (recently approved by the FDA for use in adults aged over 65; however, the public-health impact is unclear when compared with vaccinating children and protecting adults by herd immunity) • Typhoid (in highly endemic areas, studies show cost effectiveness up to 40 years of age) • Cholera (may be used in outbreaks) • Ebola • Yellow fever • Rabies • Diphtheria, tetanus and pertussis (DTaP) (an adolescent booster together with HPV may be considered) • Varicella (may be considered in adolescents in specific settings) • Meningococcal B (may be used in outbreaks) • Meningococcal ACWY (may be used in outbreaks) • Measles/mumps/rubella (MMR) (boosters may be appropriate for adults not previously vaccinated or health-care workers) • Hepatitis B (boosters may be required in health-care workers) 		
LONG-ACTING INJECTABLES		
Significant impact on high-burden conditions that could be incorporated into One Shot		
Cardiovascular disease and stroke	High cholesterol	Inclisiran (Leqvio, Novartis) lowers LDL cholesterol by >50% and requires only twice-yearly dosing; ⁸ VICTORION-SPIRIT study is underway to assess implementation in primary care ⁹
HIV	HIV-negative but at risk	Cabotegravir (Apretude, ViiV) injectable pre-exposure prophylaxis (PrEP) is 69% more effective than oral PrEP for all adults and 92% more effective in women ¹⁰
One Shot infrastructure could be linked with other services where long-acting injectables are used and support deployment		
Morbidity and mortality associated with schizophrenia	Schizophrenia	Paliperidone palmitate (Janssen, Invega Hafyera) is the first and only twice-yearly treatment for schizophrenia; >92% of study participants were relapse-free at 12 months ¹¹
Contraception	Women of child-bearing age who request contraception	The effectiveness of long-acting reversible injectable contraception is shown to be superior to other methods (20-fold lower incidence of pregnancy) ¹²

The Promise of the Vaccines and Injectables Pipeline

Looking ahead, several vaccines and long-acting injectables are in the pipeline that will save lives, prevent chronic and high-burden diseases, enable healthy ageing and even tackle complex cancers.⁹ Furthermore, vaccinations against bacteria or viruses, which are often inappropriately treated with antibiotics at present,¹⁰ will assist in the fight against antimicrobial resistance.

The products listed in Figure 3 on the next page are not an exhaustive list, but they do show the types of conditions that could be combatted in the very near future. One regularly updated tool is the WHO Global Observatory's "[Health products in the pipeline](#)" reference tool, which summarises the AdisInsight database from academic publisher *Springer Nature*.

While identifying the potential vaccine candidates that could form part of One Shot is crucial, so too is understanding the established processes for drug discovery and development that would inform such planning. Figure 4 shows the typical timelines and processes that can be expected for vaccine candidates to reach the market.

There are also approaches underway to develop vaccines that confer broader immunity against multiple pathogens or strains. These products could confer significant population-level health benefits.¹¹ For instance, a phase I clinical trial of a novel universal flu vaccine, conducted by the National Institutes of Health (NIH), has begun recruitment. The trial will test candidate BPL-1357, which is a whole-virus vaccine made up of four strains of non-infectious, chemically inactivated, low-pathogenic avian flu. Animal studies have shown that mice receiving two doses of BPL-1357 survived later exposure to lethal doses of each of the six different influenza virus strains.¹²

Figure 3

EXAMPLES OF PIPELINE PRODUCTS THAT GOVERNMENTS AND GLOBAL-HEALTH ORGANISATIONS SHOULD BE PREPARED TO DEPLOY WHEN THEY REACH THE MARKET

	Disease prevented	Indication	Product	Manufacturing platform	Most recent efficacy data	Population that may benefit
VACCINES						
Phase I	HIV	At-risk adults	BG505 MD39.3 mRNA, BG505 MD39.3 gp151 mRNA, BG505 MD39.3 gp151 CD4KO mRNA <i>NIH, Gates, Moderna</i> ¹	mRNA	Results pending	All at-risk adults; between 2016 and 2021, >400 million HIV tests were conducted in PEPFAR* countries alone; 1.5 million new cases globally per year
			HIVconsvX <i>University of Oxford</i>	Mosaic adenovirus		
Phase III	RSV	All adults aged over 60 or younger but at risk; pregnant women	AReSVi 006 GSK	Recombinant subunit + adjuvant (RSVPreF3/AS01) ²	Phase III efficacy data imminent; Phase II trials have proven safety and immunogenicity	1 billion over-60s in 2020 (2.1 billion by 2050) ³ 213 million pregnancies each year ⁴
			mRNA-1345 <i>Moderna</i>	mRNA		
			Ad26.RSV.preF <i>Janssen</i>	Adenovirus		
			PF-06928316 <i>Pfizer</i>	Protein-based		
Phase III	TB	Adults in endemic areas	M72/AS01 <i>Gates</i>	Recombinant fusion protein + adjuvant (M72/AS01E)	>50% protection against progression to active TB in Phase II Safety and immunogenicity proven in Phase II	1.7 billion with latent TB globally; >2 billion adults living in high-risk areas
			GamTBvac <i>Gamaleya</i>	Recombinant subunit		
	Dengue	Adults in or travelling to endemic areas	TAK-003 <i>Takeda</i> ⁵	Live, attenuated	84.1% efficacy against hospitalisation; 61.2% efficacy against illness ⁶	4 billion people live in dengue-endemic areas ⁷
	Malaria	Currently being tested on children but with potential for adults	R21/Matrix-M <i>Oxford University</i>	Recombinant protein + adjuvant (R21/Matrix-M)	77% efficacy (first to exceed WHO benchmark of 75%) ⁸	More than half the world's population is at risk (241 million cases in 2020) ⁹
LONG-ACTING INJECTABLES						
Phase I	Cardiovascular disease and stroke	High blood pressure	Zilebesiran (Kardia) <i>Alynlyam</i>	RNAi	Safe and well-tolerated	1.28 billion people currently living with hypertension (700 million currently untreated) ¹⁰

EARLY-STAGE TRIALS

- Group B strep: Early-stage clinical trials are underway by Novartis, Pfizer and MinervaX to develop a vaccine for group B strep, which the WHO has made a priority for administering to pregnant women.¹¹ Although predominantly used to prevent infant mortality, it is administered to adults and has the dual effect of preventing excess maternal morbidity.
- Zika, Lassa, Middle East Respiratory Syndrome (MERS) and chikungunya:¹² The Coalition for Epidemic Preparedness Innovations (CEPI) has announced funding for early-stage studies of vaccines for these diseases.
- Staphylococcus aureus: Pfizer has entered phase II trials and GSK into phase I trials for a new candidate vaccine.¹³
- Shigella: A new vaccine has entered clinical trials.¹⁴
- Enterotoxigenic Escherichia coli: Phase I candidates are being investigated.¹⁵
- BioNTech has announced that clinical trials for its mRNA tuberculosis vaccine are due to begin soon.^{16,17}
- Early-stage trials for paratyphoid.¹⁸

*Countries in the US President's Emergency Plan for AIDS Relief

Highly pathogenic viral strains that circulate in animals but have not yet acquired the ability to transmit between humans remain a looming threat. Should they acquire human-transmission capacity, they could result in rapid and devastating future pandemics. Providing populations with pre-emptive exposure to highly pathogenic influenza antigens is a novel concept, but worth exploring as part of a whole new approach to managing future pandemic risks. Wellcome Leap and the Coalition for Epidemic Preparedness Innovations (CEPI) recently announced their support for the “all-in-one vaccine for SARS-like betacoronaviruses” project run at the California Institute of Technology.¹³

Figure 4

**THE ROUTE TO MARKET FOR NEW VACCINES AND INJECTABLES,
INCLUDING CLINICAL-TRIAL PHASES AND TIMELINES**



*Number of participants in each phase

Source: GHSC

A future pandemic may one day literally be prevented by this approach.

Finally, with significant developments in needle-free technologies, there may be alternative methods of administering these life-saving candidates for those circumstances in which needle injection is not suitable. This may even increase our ability to distribute life-saving candidates and only increase the impact of such a programme.¹⁴

Get Ready to Act

The global health system needs a mechanism to identify future vaccine and injectables candidates, informed by demand across different regions.

We set out below the preliminary actions required to enable candidate selection and prioritisation.

Develop global recommendations. A global oversight model is required to develop policy recommendations for adult vaccines and long-acting injectable therapies, based on clinical-trial outcomes and real-world evidence studies. We recommend the WHO leads, deploying a strategy to encompass both types of therapeutics, with the model similar to the existing Strategic Advisory Group of Experts on Immunization (SAGE).

Maintain the momentum for action from the delivery of Covid-19 vaccines.

It is essential that the promptness and rigour with which recommendations have been considered and issued for Covid-19 be reflected in any new oversight model for adult vaccines and long-acting injectables. This will ensure that implementation can take place as soon as new products are available.

Put surveillance of diseases, based on representative, timely and consistent data collection, at the centre of disease-prevention and control efforts.

To achieve effective epidemiological surveillance, there needs to be political will, best-practice data collection (including quality control at clinical-microbiology laboratories for testing) and a regional or local scientific committee that can interpret data and advise policymakers.

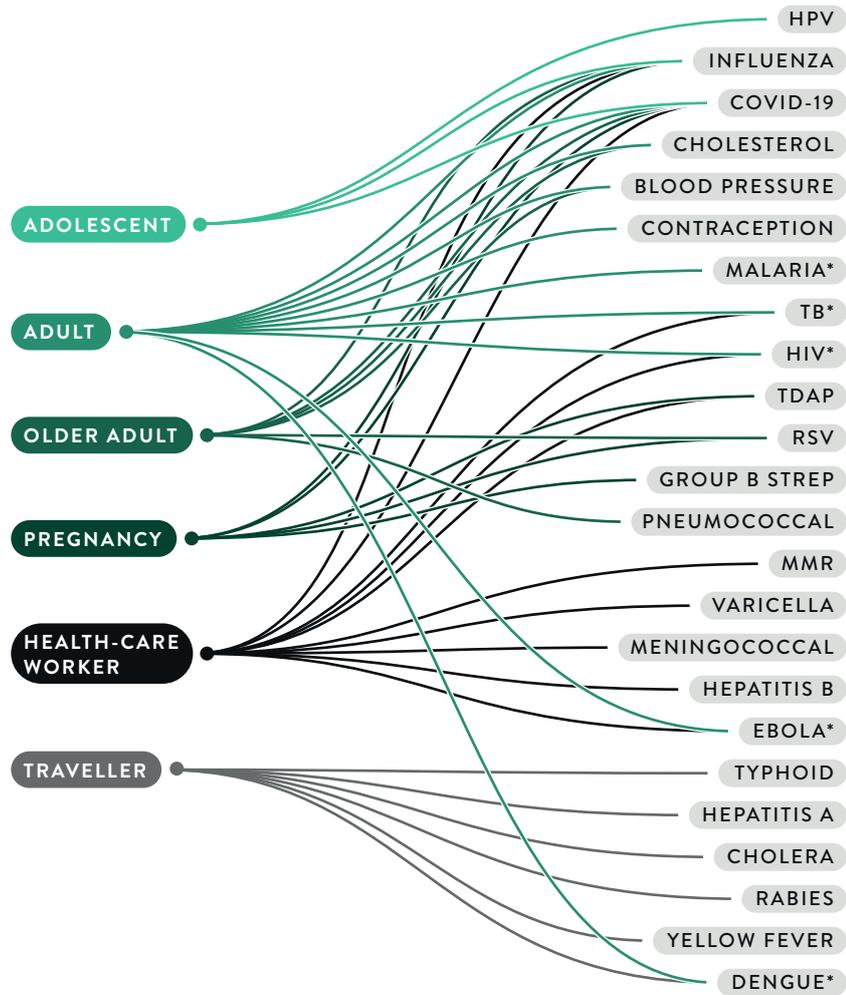
Use surveillance data to forecast local demand and make evidence-based decisions. The successful deployment of vaccines and long-acting injectables will depend in part on a mechanism to clearly forecast and communicate global health risks. Based on WHO recommendations, governments in individual countries will need to be prepared to decide whether to approve vaccines and long-acting injectables for national use – and to develop policies around their issuance. Disease-burden data will be essential to

governments in understanding the impact of these products on their populations and so that they can carry out an informed cost-benefit analysis for specific cases and uses. Additionally, initiatives such as those being driven by the National Immunisation Technical and Advisory Group Support Hub (NiSH), which provides evidence-informed decision-making support to countries in the WHO Africa region, and Ready2Respond, a global collaboration of partners from the public, private and non-profit sectors committed to augmenting LMICs' readiness to respond to influenza and emerging respiratory viral pandemics, will continue to strengthen local capabilities. As digital-health infrastructure is central to these efforts, we will provide details on the digital toolbox needed to deliver One Shot in a forthcoming paper.

Adopt a “bundle” approach. Since adults may require more than one vaccination or long-acting injectable, demand may extend to a bundle of vaccines for each individual. Within the One Shot framework, regional needs, and additional requirements for pregnant women, high-risk individuals, frequent travellers and those with high-levels of occupational risk should be accommodated. Figure 5 demonstrates how different vaccines and injectables could be bundled for different populations.

Figure 5

AN EXAMPLE OF WHAT VACCINE BUNDLES COULD LOOK LIKE DEPENDING ON AGE AND NEEDS



*Based on regional risk and/or outbreak

Source: GHSC

Conclusion

Scientific developments are leading to a robust pipeline of adult vaccines and preventative injectables, with the power to transform the management of chronic diseases, epidemics and pandemics. We need to be ready to deploy these existing and upcoming products to bring about significant health benefits and help reduce inequalities across the globe. To achieve a permanent disease-prevention programme that enables the routine use of vaccines and injectable therapies for adults, the WHO could oversee global recommendations through an oversight model, with country-specific recommendations then made by regional scientific advisory or expert groups, informed by epidemiological surveillance.

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One Shot to Prevent Disease and Prepare for Future Pandemics:

Identifying the Most Promising Adult Vaccines and Injectables

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