ONE SHOT.

A Vision for Global Health: The Digital Toolbox Needed to Deliver One Shot

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Executive Summary

Huge progress has been made globally in building digital-health infrastructure, including the use of technology and digital systems to support the delivery of health-care services. The World Health Organisation began formally advising countries to develop digitally enabled health systems in 2005, a process that was then accelerated by the Covid-19 pandemic and the rollout of vaccination programmes around the world. This has helped to further realise the potential of digitalised health systems, such as improving the quality of health care, increasing process efficiencies, expanding the accessibility of health services, and enhancing data-driven analytics and evidence-based medicine.[1] We highlight throughout this paper examples of the use of digital-health tools and analytics that advanced population health goals, including in response to the pandemic.

Despite the advances made during the pandemic in the development of more effective digital-health tools including vaccine infrastructure, challenges emerged with regard to engaging and reaching different patient populations, securing supply chains and training the clinical workforce at scale. In some ways, the challenges in engaging the entire population for preventative medicine should have been foreseen. Two-thirds of global health funding to low- and middle-income countries (LMICs) before the pandemic was focused on HIV, tuberculosis (TB) and malaria, together with maternity, neonatal and child health care.[2] While addressing these patient populations and disease areas is crucial, those programmes primarily focus on a minority of the total population of LMICs, meaning that an effort to comprehensively reach the adult population with Covid vaccines could not rely exclusively on infrastructure already developed through investments in global health.[3]

The Global Health Security Consortium's One Shot campaign is an initiative that seeks to develop a permanent and preventative global public-health programme with life-course vaccinations and prophylactic injectables at its core. Unlike previous global health efforts, One Shot is designed to focus

on the global adult population so that comprehensive disease-prevention infrastructure is in place and "always on" – both to manage routine care and to reach patients in response to future outbreaks or pandemics.

This type of population-level programme will require countries to take a far more ambitious and coordinated approach to storing, using and sharing electronic health information. That means a new digital toolbox that includes expanded immunisation registries, appointment registration, patient communication, clinical-trial enrolment, integration with diagnostics and labs, clinical-decision support, population targeting and collection of real-world evidence to support products.

These tools will require the ability to store, integrate and access vast amounts of data on platforms that can securely handle sensitive patient information and link to other sources of data such as viral genomic sequences (to track viral epidemiology) and patient records. While cloud-based technology has significant benefits in terms of cost, security and scalability, many governments have concerns about dependency on offshore data storage.

Potential data-storage solutions must also take into account the needs of different countries and contexts, including in settings where resources are limited. For example, telecom and mobile networks can offer viable and practical solutions where internet access is otherwise limited. When possible, LMICs should seek to leapfrog straight to state-of-the-art digital infrastructure and capitalise on the fact that they start with fewer legacy systems and investments than found in many developed economies.

The creation of this digital ecosystem can also be a first step towards a wider and deeper transformation of digital health globally. Longitudinal records that can be developed from immunisation registries and a master patient index would contribute to the One Shot programme and would be foundational for a wide range of health-care use cases.

HOW DO WE TAKE ACTION?

- **Ministries of health** should take a holistic view of their digital-health strategy, allowing for both primary data uses (those guiding individual care) and secondary data uses (those that go beyond individual care) by a range of stakeholders, and invest in secure, cloud-based technology when appropriate and consistent with existing laws and regulations. They should specifically invest in adult-immunisation registries and build on digital tools launched or scaled during the pandemic. They should prioritise

the digitisation of existing paper-based systems and also invest in the digital infrastructure needed to conduct epidemiological research and surveillance to inform life-course immunisation programmes.

- **Regulators**, including ministries of health, should create a regulatory environment that can mandate the collection and sharing of relevant data, with the necessary privacy protections and security in place. They should specifically ensure regulations create life-course immunisation registries, allow for the creation of longitudinal patient records that are built off or link to these registries, and foster innovations in patient- and population-health management (including for novel products such as adult vaccines). Regulators should also develop tailored strategies to harness the power of cloud-based technologies while upholding national data-sovereignty laws.

- **Industry** should develop new digital tools and business models and, more broadly, use its technical expertise to support governments and regulatory bodies with standards development and product implementation. Industry should further capitalise on the momentum created by Covid-19 adult-vaccination initiatives to build new use cases and support governments in overcoming regulatory and technical challenges.

- **Global and regional health organisations, together with their partners and donors,** should commit to investing in national digital-health strategies, integrated health-system strengthening, the creation of globally available digital-health products and the sharing of information among peers.

These efforts must build on the valuable lessons, challenges and successful experience in applying digital tools in response to Covid-19 at the global, regional and country levels. Gavi, the Vaccine Alliance has notably developed a "Digital Health Information Strategy Technical Brief Series" related to vaccine delivery for Covid-19 and routine immunisations, including for children. Throughout this paper, we highlight examples of where Gavi's recommendations accord with recommendations for strengthening digital-health infrastructure for adult vaccinations.[4]

Overview of Digital Health

In this section, we lay out some of the fundamentals of digital health to inform how it can be applied to adult vaccinations and prophylactic injectables.

DIGITAL-HEALTH TOOLS AND DATA USES

Digital-health infrastructure – the use of technology and digital systems to support the delivery of health-care services – can improve the quality of health care, increase process efficiencies, expand the accessibility of health services, and enhance data-driven analytics and evidence-based medicine.[5] A number of digital tools have been successfully rolled out during the Covid-19 pandemic. These include platforms for case management, training and risk communication, vaccine supply chains, surveillance, contact tracing, facility and lab management, and telemedicine – all of which are crucial to informing the One Shot programme. Additional detail on digital-health tools developed during the Covid-19 pandemic can be found in the *Digital Health Tools* report from Exemplars in Global Health,[6] and some of the key examples relevant to One Shot are highlighted towards the end of this report.

More generally, a wide range of existing digital-health tools and interventions can be used across disease areas. For example, the World Health Organisation's (WHO) *Recommendations on Digital Interventions for Health Systems Strengthening* has identified at least 28 different digital-health interventions and has conducted a systematic review of the evidence for nine of them.[7] These come with specific provisions or qualifications for their use (for example, safeguards for patient privacy in targeted client communications). *Artificial Intelligence in Global Health,* a report by USAID and the Rockefeller Foundation, has a similarly comprehensive framework for identifying specific digital-health use cases.[8]

It is important to note that digital-health interventions and electronic health information have both primary and secondary uses. Primary uses are those guiding individual care; examples include clinical-decision

support, patient communications and referrals to other care providers or social-services organisations. Secondary uses go beyond individual clinical care; examples include tracking the safety of medical products, surveillance of diseases, geographic targeting of population-health interventions and resource planning for health systems. This distinction is essential because the types and granularity of data needed for each use are different. For example, secondary uses of data that aggregate information at the population level typically would not have detailed, patient-identifiable information, whereas primary uses would generally require patient-identifiable information. Data for primary and secondary uses may – but do not have to – come from the same source. Indeed, Gavi notes the importance of multi-source quality data reporting, triangulation, visualisation and use at subnational levels, and observes, "availability of a single view of immunisation, surveillance, laboratory, survey, demand and other information sources triangulated together will improve data value to multiple stakeholders and influence decision-making".[9] Therefore, governments need an all-encompassing strategy for how to collect and use data for both purposes. Both primary and secondary uses of electronic health information are key for rolling out adult vaccinations in the One Shot programme, as discussed in the section later in this paper titled "Which Digital Tools to Use for Adult Vaccines and Injectables?"

COUNTRY DIGITAL-HEALTH MATURITY

The successful deployment of digital-health tools and data requires more than just technology: it needs a comprehensive ecosystem across the country. The Global Digital Health Index, which counts the WHO among its partners, has created a framework for measuring a country's digital-health maturity, based on 19 different indicators:[10]

Key Indicators of Digital-Health Maturity

Leadership and governance

1. Digital health prioritised at the national level through dedicated bodies/mechanisms for governance
2. Digital health prioritised at the national level through planning

Strategy and investment

3. National eHealth/digital-health strategy or framework
4. Public funding for digital health

Legislation, policy and compliance

5. Legal framework for data protection
6. Laws or regulations for privacy, confidentiality and access to health information
7. Protocol for regulating or certifying devices and/or digital-health services
8. Cross-border data security and sharing

Workforce

9. Digital health integrated into health and related professional pre-service training (prior to deployment)
10. Digital health integrated into health and related professional in-service training (after deployment)
11. Training of digital-health workforce
12. Maturity of public-sector digital-health professional careers

Standards and interoperability

13. National digital-health architecture and/or health-information exchange
14. Health-information standards

Infrastructure

15. Network readiness
16. Planning and support for ongoing digital-health infrastructure maintenance

Services and applications

17. Nationally scaled digital-health systems
18. Digital-identity management of service providers, administrators and facilities for digital health, including location data for geographic information system (GIS) mapping
19. Digital-identity management for individuals for health (including master patient index, birth registry and electronic immunisation registry)

While it is beyond the scope of this paper to review all the tools and ecosystem requirements for digital health set out in previous research, we support these indicators and encourage governments and the private sector to use them or similar tools as part of their digital-health planning. All of the indicators listed in the Global Digital Health Index will be important for deploying the One Shot programme. For example:

- A properly trained and digitally fluent workforce is necessary to design, develop and deploy digital tools for adult vaccinations and injectables.

- Standards and interoperability are essential so that digital tools used for adult vaccinations and immunisations can integrate with other tools and do not exist in silos.

- Underlying infrastructure is crucial so that these tools stay online and are connected to immunisation registries in the cloud (a component of indicator 19).

Digital-Health Opportunities With the One Shot Programme

The goal of vaccinating the world against Covid-19 has had significant implications for the life-course approach to immunisation, which entails vaccination across an individual's full lifespan, responding to the needs and disease risks at different life stages.[11] First, the disruption of routine immunisations for children during the pandemic has led to a renewed focus on improving long-standing programmes in childhood immunisation.[12] Second, vaccination during Covid-19 represents the most comprehensive global effort to engage adults in preventative medicine, and the integration of Covid-19 vaccination with routine immunisation programmes will be an important step towards ensuring the efficiency and sustainability of these programmes.[13] Third, the infrastructure created during Covid-19 – especially digital-health applications that have transformed how vaccines are managed and delivered – has laid the foundations for the deployment of an innovative pipeline of novel adult vaccines and of long-acting injectables that can serve therapeutic or prophylactic functions.[14]

The introduction of modern digital technology can increase the coverage of routine immunisation, and the pandemic has shown the need to extend digitally enabled immunisation programmes for the global adult population.[15] In this section, we explain the reasons for applying digital-health applications to life-course vaccinations and prophylactic injectables, and which tools should be used.

WHY APPLY DIGITAL HEALTH TO LIFE-COURSE VACCINATIONS?

Individual vaccinations are relatively straightforward to administer to patients from a clinical perspective, since they typically require a limited number of clinical encounters and can usually be administered by a range of health professionals, such as community health workers, nurses, midwives and

pharmacy technicians. (By contrast, managing complex and chronic conditions requires multiple clinical encounters with different types of clinicians and extensive care coordination.)

However, as we saw during the Covid-19 pandemic, rolling out adult vaccines at scale can be difficult because of the need to reach different patient populations, ensure the appropriate timing of dosing, secure supply chains, educate the clinical workforce and engage patients. This is a challenge faced by high-income and low- and middle-income countries (LMICs) alike. As Gavi points out, it will be important to "develop a guide to rapidly adapt digital-health global goods for expanding use cases in emergencies. Countries should not have to mix and match their in-country systems during an emergency."[16]

As an example of the complexity of managing the full portfolio of adult vaccinations at the population level, Figure 1 provides the adult-vaccination schedule that is recommended by the US Centres for Disease Control and Prevention (CDC). For illustrative purposes, we have also added the following: two approved preventative-health products – the Covid-19 vaccine and HIV injectable pre-exposure prophylaxis (PrEP); and two products that are currently undergoing clinical trials, both of which might not be rolled out in the United States – the investigational tuberculosis (TB) vaccine and the investigational respiratory syncytial virus (RSV) vaccine. In the United States, there are at least eight products required for all individuals at some point in their life and a similar number that patients might be eligible for. Many require multiple doses or annual shots. While adult-vaccination schedules will certainly vary by geography based on epidemiological factors, most will have a similar level of complexity. This complexity creates the need for patient- and clinician-facing population-level tools that can manage the rollout of vaccines.

Figure 1

THE US CENTRES FOR DISEASE CONTROL AND PREVENTION ADULT-VACCINATION SCHEDULE

Recommended vaccination for adults who meet age requirement, lack documentation of vaccination or lack evidence of past infection	Recommended vaccination for adults with additional risk factors or another indication	Recommended vaccination based on shared clinical decision-making	Clinical trial	No recommendation/ not applicable

Vaccine	19-26 years	27-49 years	50-64 years	≥65 years
Influenza inactivated (IIV4) or Influenza recombinant (RIV4)	1 dose annually			
OR				
Influenza live, attenuated (LAIV4)	1 dose annually			
Tetanus, diphtheria, pertussis (Tdap or Td)	1 dose Tdap each pregnancy; 1 dose Td/Tdap for wound management			
	1 dose Tdap, then Td or Tdap booster every 10 years			
Measles, mumps, rubella (MMR)	1 or 2 doses depending on indication (if born in 1957 or later)			
Varicella (VAR)	2 doses (if born in 1980 or later)		2 doses	
Zoster recombinant (RZV)	2 doses for immunocompromising conditions		Single dose for those aged 60 years and above	
Human papillomavirus (HPV)	2 or 3 doses depending on age at initial vaccination or condition	27 through 45 years		
Pneumococcal (PCV15, PCV20, PPSV23)	1 dose PCV15 followed by PPSV23 or 1 dose PCV20			1 dose PCV15 followed by PPSV23 or 1 dose PCV20
Hepatitis A (HepA)	2 or 3 doses depending on vaccine			
Hepatitis B (HepB)	2, 3, or 4 doses depending on vaccine or condition			
Meningococcal A, C, W, Y (MenACWY)	1 or 2 doses depending on indication			
Meningococcal B (MenB)	2 or 3 doses depending on vaccine and indication			
	19 through 23 years			
Haemophilus influenzae type b (Hib)	1 or 3 doses depending on indication			
The following diseases are not included in the CDC's adult-vaccination schedule; added for illustrative purposes				
Covid-19	1 or 2 doses, depending on manufacturer, and 1 booster			1 or 2 doses, depending on manufacturer, and 2 boosters
	Second booster, depending on risk status			
HIV (injectable PrEP)	Following diagnostic test, initial dose, 2nd dose at 4 weeks, then follow-up doses every 8 weeks			
TB (Investigational vaccines M72/As01E)	Following diagnostic tests for HIV and TB, initial dose, 2nd dose at 4 weeks			
RSV (Investigational vaccine AReSVi-006)			Single dose for those aged 60 years and older	

Source: Adapted from CDC

Experience gained during the Covid-19 pandemic highlights the importance of digital tools for the rollout of adult-vaccination programmes. One of Gavi's technical briefs for its Digital Health Information Strategy, *Covid-19 Innovations and Digital Applications for Routine Immunisation*, has outlined the use cases for the most used (defined as in more than ten countries) digital tools for Covid-19 in LMICs, including CommCare, District Health Information Software 2 Tracker (DHIS2 Tracker) and Open Data Kit (ODK). In particular, Gavi highlighted the versatility and broad uptake in multiple countries of the DHIS2 platform – for which it provides investment and technical assistance for development and implementation – across various scenarios, from surveillance through to vaccine stock management and the issuance of vaccine certificates.[17]

A digital-health system with immunisation strategy at its core would also enable a much broader set of use cases for other disease areas. Because of the universal and comprehensive nature of vaccination programmes, successfully setting up electronic health information to track these programmes would have the effect of establishing longitudinal patient medical records and master patient index solutions, all of which are foundational for a wide range of health-care use cases. Therefore, governments should collaborate with health-care and technology partners to develop strategies that permit links between immunisation registries and electronic health records (EHRs) while preserving patient privacy.

It will be important not only to design these systems, but also to convince governments of their importance. As Gavi recommends, the global health community should "document positive Covid-19 innovation experiences that can be packaged and presented in ways that national ministries of health and other implementers of the Essential Programme for Immunisation (EPI) can use and adapt for routine immunisation. This could take the form of a written guide, videos of case studies, and a series of training workshops and webinars."[18]

WHICH DIGITAL TOOLS TO USE FOR LIFE-COURSE VACCINES AND INJECTABLES?

This section presents a list of tools that could be used for the One Shot programme. Of course, these would need to be adapted to local contexts, and their use is contingent upon having the right foundational elements, such as appropriate regulation, digital infrastructure including internet connectivity, and access to hardware like phones and tablets. For countries with low digital maturity, transitioning from paper-based

systems to digital systems for core public-health and health-care services, including immunisation registries, is an important first step. This list builds on a set of digital solutions proposed by Gavi in its report.[19] All of these tools should be designed in gender-intentional ways that account for the differential impact of cultural contexts and power relationships on women, men and children in promoting equitable access to vaccines, as detailed in this report from Gavi.[20]

Immunisation (and Prophylactic-Injectable) Registries

Electronic immunisation registries (EIRs) are common tools for tracking vaccination status across populations. There is evidence that they improve the quality, availability and accessibility of data about routine immunisations.[21] However, less than half of LMICs have implemented an EIR.[22] An immunisation registry could serve as the foundation for any digital tools related to adult immunisations; it would provide information on the entire eligible patient population and could incorporate or provide data for use cases at the individual patient, clinical worker and population levels (described in more detail later in this section), especially in countries that either do not currently have an adult EIR, or countries that successfully established one for Covid-vaccine rollout but have not yet implemented them for other immunisations. New prophylactic injectables, such as those for HIV and high blood pressure, can also be incorporated into registries as they come to market. The Better Immunisation Data (BID) Initiative has identified key functionalities for electronic immunisation registries that are particularly important, including for LMICs. These are:

- Registration and search
- Vaccine administration
- Client management
- Stock management
- Reports

It will be vital to (re)design EIR implementations to ensure that they are flexible enough to operate alongside other digital tools already in the health system and to add data elements, modules, and other functionality for new use cases and clinical interventions over time. These include systems for civil registration and vital statistics (CRVS). It will also be imperative to engage stakeholders, including management teams, clinicians, communities and patients to ensure sufficient awareness, understanding and the ability to use additional functionality as it is added. Indeed, Gavi recommends that countries "develop and implement Covid-19 digital-health-information transition plans through participatory co-design process with EPI to extend what has worked and scaled during the pandemic to routine immunisation programmes."[23]

Patient-facing, provider-facing and population-health tools could then integrate with EIRs and EHRs used to manage patient care. It should be noted that the integration and application of digital-health tools and electronic immunisation registries can be complicated, requiring a methodical approach that takes into account the prevailing digital landscape within any given setting.

Patient-Facing Tools (Typically for Primary Data Uses)

- **Patient identification and validation:** Digital tools can help to ensure that the right patient is eligible for the right health-care services. Digital patient IDs, which are suitable for all use cases and which integrate with the wider digital infrastructure, are central to this process.

- **Patient registration and follow-ups:** Digital solutions can assist patients in scheduling primary-care visits to receive their initial doses of vaccines or preventative injectables and any follow-on doses that may be required. Digital tools can also be used to remind patients of required or upcoming doses, particularly for injectables like cabotegravir (a PrEP for HIV) that require sustained but infrequent follow-up doses.

- **Patient communication and engagement:** Digital tools can be used to deliver patient education on vaccine eligibility, safety and efficacy, and possibly to deliver incentives such as conditional cash transfers (CCTs). Patient education would be especially important in contexts where there is low awareness of a product or where stigmatisation may lead patients or caregivers to avoid seeking health information. For example, confidential patient-communication tools could facilitate patient engagement about sensitive products like the human papillomavirus (HPV) vaccine and HIV PrEP. These tools could also be supported by trusted community sources that play a key role in engaging the community.

- **Patient feedback mechanisms** to ensure health-system responsiveness and appropriate care.

Provider-Facing Tools (Typically for Primary Data Uses)

- **Integration with diagnostics:** Electronic linkages between lab reports and medical records can allow providers to better assess if a patient meets the diagnostic requirements for a product. For instance, GSK's investigational TB vaccine regimen, if approved for wide use, would require providers to know the patient's TB status and possibly their HIV status.[24] Digital linkages between laboratory-information

management systems (LIMS) and registries, clinical-decision support tools and EHRs can help providers identify whether a patient has received a diagnostic test and the results of that test. These connections between EHRs and LIMS would also facilitate efficient requests for diagnostic tests and the delivery of results.

- **Clinical-decision support and risk stratification:** Digital tools could provide individualised guidance about whether patients are eligible for a specific product based on their demographic and risk profile. For example, inclisiran is a prophylactic injectable indicated only for adults with high cholesterol or atherosclerotic cardiovascular diseases who require additional lowering of low-density lipoprotein (LDL) cholesterol.[25] Digital tools that use advanced analytics to help determine whether patients are likely to benefit from products like inclisiran can aid clinicians in targeting patients with appropriate treatments.

Population-Level Tools, for Public Health and Industry (Typically for Secondary Data Uses)

Many of these uses will be relevant for the timely detection of vaccine-preventable diseases[26] and for the type of "decision-making toolkit" described by Gavi as needed at the sub-national level.[27]

- **Surveillance and epidemiology:** Public-health tools to understand the epidemiology of disease in a given geography are essential for prioritising resources, planning interventions and measuring their impact. These tools include notification of public-health events from the point of diagnosis and incorporate electronic case reporting, electronic vital-records systems and syndromic surveillance systems.

- **Pharmacovigilance:** Digital solutions can be deployed to monitor and assess vaccine safety and efficacy, especially for new products. For instance, patients or providers could electronically report adverse reactions or breakthrough infections after a vaccination. For example, the V-Safe programme used by the CDC deployed digital, self-reported data from patients to determine whether Covid-19 vaccines were safe for pregnant women.[28]

- **Clinical-trial design and delivery:** These tools will enable more efficient delivery of clinical trials for novel vaccines and prophylactic injectables, especially those undergoing late-phase trials that require large study populations. This includes faster identification of suitable trial sites, more effective participant recruitment and trial matching, and more effective long-term follow-up. For instance, a forthcoming phase III trial for an investigational TB vaccine will seek to enroll a large

number of patients across several countries. This could be facilitated by digital-enrolment tools being integrated into EHRs, as well as immunisation registries and other tools to identify and recruit large numbers of suitable participants. Providers may be alerted about a clinical trial with enrolment-eligibility criteria that are met by a patient's diagnosis and demographic characteristics. Alternatively, patient portals may include functionality that enables patients to indicate their interest in being notified of any forthcoming trials for clinical indications that may be relevant to them.

- **Population targeting:** Digital tools can help with risk stratification that would inform the rollout of certain products via population-health programmes, such as by identifying and targeting populations at greater risk of a disease based on geographic location. For example, vaccinations in the context of ring vaccination strategies, where patients are targeted for vaccination after a possible exposure to an infected person in an outbreak setting, could use digitally enabled contact tracing and GIS to strategically target vaccines where they are most needed.

- **Pathogen genomic sequencing:** Digital tools for the analysis and sharing of genomics data would lead to an expedited understanding of pathogen evolution. This information could inform decisions about population-health measures and R&D for adapting and developing products to respond to emerging infectious-disease threats.

- **Supply-chain management and inventory:** Some products, such as Pfizer's messenger ribonucleic acid (mRNA) Covid-19 vaccine, require a supply chain that can transport and deliver the product to the point of care while maintaining stable, cold (or ultra-cold) temperatures to prevent spoilage. Digital supply-chain management systems (DSCMS) can improve visibility of the supply chain and enable coordination by integrating data from all stakeholders in the chain. This allows for real-time, accurate monitoring of transport and temperature integrity, thereby enabling quicker responses to any disruptions. Furthermore, DSCMS would secure data-sharing to ensure product authenticity.

Concrete Steps to Accelerate Digital Health Through One Shot

Governments and the private sector should act now to take advantage of this critical and exciting window of opportunity to bring about the One Shot vision and accelerate digital health more widely. Below, we set out key actions that leaders can take to sustain and advance investments they have already made in digital health during the pandemic. Some of these recommendations are specific to digital health for adult vaccinations and injectables, and others are applicable to digital health in general. (For ease of reference, we have marked with an asterisk those recommendations that are not specific to adult vaccinations and injectables). That said, we recommend undertaking all these actions with a focus on adult vaccinations, injectables and associated health-system capabilities, specifically because of the significant levels of investment in this area over the past three years and the ongoing political momentum to roll out these types of products.

RECOMMENDATIONS FOR MINISTRIES OF HEALTH

Ministries of health should take a holistic view of their digital-health strategy, allowing for the use of both primary and secondary data by a range of stakeholders, and invest in secure, cloud-based technology. They should specifically invest in adult-immunisation registries and build on digital tools launched or scaled during the pandemic. They should prioritise transitioning current paper-based systems to digital platforms and also invest in the digital infrastructure needed to conduct epidemiological research and surveillance to inform adult-immunisation programmes. To do this, governments can:

- Assess the strength of their existing immunisation registries and put in place plans to integrate adults into these registries (if they are not already included), and to integrate digital platforms that are already in use.

- Take stock of the digital-health tools and investments made since the beginning of the pandemic to identify the most promising technologies and applications that can support the development and delivery of other novel vaccines and prophylactic injectables.

- Focus on developing the capabilities to track and analyse national immunisation trends, including by cross-referencing census data, in support of further development of adult-vaccination strategies and integration with routine vaccinations.

- *Invest in and create incentives to expand the most successful technologies and applications to other use cases, including more comprehensive adult preventative medicine and longitudinal patient medical records.

- *Continuously monitor, evaluate and improve specific digital-health tools, especially those rolled out rapidly as part of pandemic response.

- *Invest in enablers of digital-health tools, such as network readiness, foundational epidemiological and surveillance tools, secure cloud-based data storage and workforce development. This will require upfront and recurring investments in technology development and setup, deployment, integration and interoperability, sustained operations and scaling. For more detail on investments and cost buckets required to implement digitally enabled health systems, see the WHO's Digital Implementation Investment Guide.[29]

Case Study: Integrated e-Diagnostic Approach in Burkina Faso [30]

Integrated e-Diagnostic Approach (IeDA), a tablet-based app co-created by the government of Burkina Faso and the Swiss non-profit *Terre des hommes* (Tdh), supports health workers with decision-making and management of childhood illnesses. It builds on the CommCare platform developed by Dimagi, a US-based for-profit that offers technology for social impact.

The app has achieved significant impact and scale at the primary health-care (PHC) level. It delivers more than 250,000 consultations per month through 1,700 rural PHC facilities and 6,300 health workers. IeDA's scale and familiarity were key to its rapid repurposing and deployment as a knowledge platform for pandemic management at the grassroots level.

A central reason for its success was the role Burkina Faso's health ministry played in the early integration of the IeDA app and its underlying CommCare platform into the country's national digital-health strategy. Working with Tdh and Dimagi, the ministry ensured that IeDA integrated

fully with the country's health-care infrastructure, and that key indicators collected through IeDA were automatically transmitted to the national health-information system. The government also ensured it eventually owned the app by facilitating its transfer from Tdh.

IeDA also demonstrates the importance of integrating with existing systems like CommCare and DHIS2, and building smaller applications that work on top of these. This will provide options for a migration strategy from existing technology and delivery mechanisms to future state solutions.

RECOMMENDATIONS FOR REGULATORS

Regulators, including ministries of health, should create a regulatory environment that can mandate the collection and sharing of relevant data, with the necessary privacy protections and security in place. They should specifically ensure that regulations create adult-immunisation registries, allow for the creation of longitudinal patient records that are built off or link to these registries, and foster innovations in patient- and population-health management (including for novel products such as adult vaccines). Regulators should develop tailored strategies to harness the power of cloud-based technologies while upholding national data-sovereignty laws. Specifically, regulators can:

- Mandate use of immunisation registries and associated technologies and data standards.

- *Develop strong regulations for security, privacy, product certification and data sharing (including across borders). Regulation will protect patients and incentivise innovation by industry by creating clear rules of the road.

- *Review laws pertaining to data sovereignty and cloud-based data storage to ensure that laws guarantee privacy and security while allowing the public sector and partners to use data for the purpose of achieving public- and population-health goals.

Case Study: HealthConnect in South Africa [31]

HealthConnect is a set of tools for Covid-19 communication and risk passports, developed by the South African government in collaboration with Praekelt.org. The programme provides on-demand disease information, tools for users to assess their own Covid-19 risks based on their symptoms and up-to-date guidance for health workers.

The tools have been used by tens of millions of people in South Africa, reaching nearly two-thirds of college students and staff, processing over 10 million screenings and saving more than $20 million in costs.

Notably, the South African government has been extremely stringent in ensuring compliance with regulatory standards. South Africa's rigorous standard-setting and strict regulatory environment are deeply rooted in its history of putting civil rights and equity at the forefront of public-interest considerations.

That South Africa was successful in quickly designing HealthConnect was not a case of compromising standards, but the result of its familiarity with establishing digital-health tools while upholding national standards. In the case of HealthConnect, it drew on the experience of its MomConnect initiative, which was also based on WhatsApp's application programming interface (API) and chatbot platform, and provides information on maternal health and related health services.

RECOMMENDATIONS FOR INDUSTRY

Industry should develop new digital tools and business models and use its technical expertise to support governments and regulatory bodies with standards development and product implementation. Businesses should specifically capitalise on the existing momentum from Covid-19 adult vaccinations to build new use cases on existing successes and to support governments in overcoming regulatory and technical challenges. Specifically, industry can:

- *Provide technical expertise and inputs to governments as they identify high-value use cases.
- *Expand on existing digital innovations and rigorously monitor and evaluate the performance of digital pilots and tools so that only evidence-based, effective tools are deployed and scaled.
- *Develop solutions that can integrate or operate with existing systems.
- *Advocate for and contribute to standards development that would allow for interoperability of different systems.

- *Invest in enablers, such as workforce readiness and skills transfer, that will create the foundation for long-lasting digital-health ecosystems.
- *Provide cloud-based and mobile solutions using best practices from cloud hosts and the telecom industry as appropriate.

Case Study: Smart Health in Uganda [32]

The Smart Health app is a digital-health management tool used in Uganda by 7,800 community health workers (CHWs) who were trained by the non-profit social enterprise Living Goods.

The app provides guidance for CHWs on routine diagnostics; processes and workflows across several areas including pregnancy, childhood diseases, nutrition and family planning; and immunisation tracking. During Covid-19, it has become a key tool to equip CHWs to respond to the significant surge in health demands and to decentralise health-service provision.

The ability of the app to pivot rapidly and effectively towards strengthening community health needs during Covid-19 is a result of deep collaboration between industry, non-profits and government. Living Goods has been developing closer partnerships with the Ugandan government, as well as with a coalition of important actors in community health (Amani Global Works, Integrate Health, Last Mile Health, Lwala Community Alliance, Medic, Muso, Partners in Health, Pivot, Possible, VillageReach and VITAL Pakistan).

As a champion of Uganda's digital-health approach and a key shaper of its policy through high-level working groups, Living Goods was able to steer Medic – the developer of Smart Health – through the app-design process thanks to its understanding of community needs, from on-the-ground experience of CHWs to workflows and infrastructures. This results in a modular digital design that is very easy to use and adaptable to changing government priorities.

RECOMMENDATIONS FOR GLOBAL AND REGIONAL HEALTH ORGANISATIONS AND PARTNERS

Global and regional health organisations, together with their partners and donors, should commit to investing in national digital-health strategies, integrated health-system strengthening, the creation of globally available digital-health products, and the sharing of information among peers. Investments in digital health should focus on cross-cutting and interoperable infrastructure, including longitudinal medical records and immunisation registries, to avoid siloed systems and programmes.

Conclusion

Achieving the One Shot vision for standing up global life-course vaccination programmes as part of a dual strategy to promote population health and pandemic preparedness will require a multi-pronged and sustained effort. Digital capabilities and infrastructure will be a fundamental part of this work and require both the right incentives and regulatory environment from government, and the right tech solutions from the private sector.

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Endnotes

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