SP7

# RESEARCH AND INNOVATION

## Introduction and value proposition

Current knowledge, tools and practices have achieved great impact, but will not suffice to achieve the goals of IA2030. To increase equitable vaccine coverage, expand the benefits of immunisation to additional populations, and identify and address unmet needs and emerging challenges, global and national capacity for **research and innovation** must be improved.

IA2030 Strategic Priorities (SPs) highlight specific needs in research and innovation. SP2 calls for innovative strategies to mitigate vaccine misinformation. SP3 depends upon *implementation research* and innovative, context-specific approaches to reach poorly served populations. SP4 calls for research into the vaccine-preventable burden of disease among older age groups. SP5 demands innovative delivery approaches for outbreaks and settings that require humanitarian aid.

SP7 seeks to support all of those needs by improving the *innovation ecosystem*. This ecosystem will identify and prioritise user needs, facilitate research and development (R&D) to create new and better vaccines and related products and services, and build capacity for implementation research. It will strive for breakthrough discoveries that change the landscape while advancing incremental innovations for continual improvement. In this way, research and innovation will increase the breadth and value of vaccines, expand their delivery, and help meet challenges as they emerge.

***Research*** includes a broad range of studies, ranging from immunology, pathogen characterisation, and the natural history of infectious diseases to social and behavioural research on vaccine hesitancy. It includes studies of disease burden and intervention impact that inform policy and implementation decisions.

***Innovations*** are new solutions and ways of working that can accelerate impact. Vaccine development remains the foundation of the IA2030 innovation agenda. It also has increased emphasis on innovations that improve programme reach and performance.

# Strategic priority goal and objectives

**Goal**

Innovations to increase immunisation programme reach and impact are rapidly made available to all countries and communities.

**Objectives**

- Establish and strengthen capacity at all levels to identify priorities for innovation, and to create and manage innovation
- Develop new vaccines and technologies, and improve existing products and services for immunisation programmes
- Evaluate promising innovations and scale up innovations as appropriate based on the best available evidence

# Context and challenges

**Vaccine R&D** has achieved many important successes, delivering safe and effective vaccines that save millions of lives every year.[3] It still must tackle a wide spectrum of challenges, including:

- Developing novel vaccines that go beyond recapitulating natural immunity to induce more potent and more durable protective responses.
- Enhancing the deliverability of existing vaccines by creating combination products, improving thermostability, improving containers and packaging, or using novel delivery devices such as *microarray patches*.
- Establishing platforms for the rapid development, manufacture and equitable distribution of safe, effective vaccines in response to emerging infections.[4]

Success will require advances in many areas, including:

- Basic research on innate and adaptive immune responses and the immunological and molecular characteristics of disease-causing agents.
- Animal models, correlates of protection, and controlled human infection models that facilitate pre-clinical and clinical development.
- Vaccination regimens, adjuvants and routes of administration that more precisely modulate immune responses.

***Emerging infections and outbreaks***

Pathogens causing outbreaks and global pandemics present additional challenges. These include regional outbreaks of Ebola and pandemics such as COVID-19 and pandemic influenza.

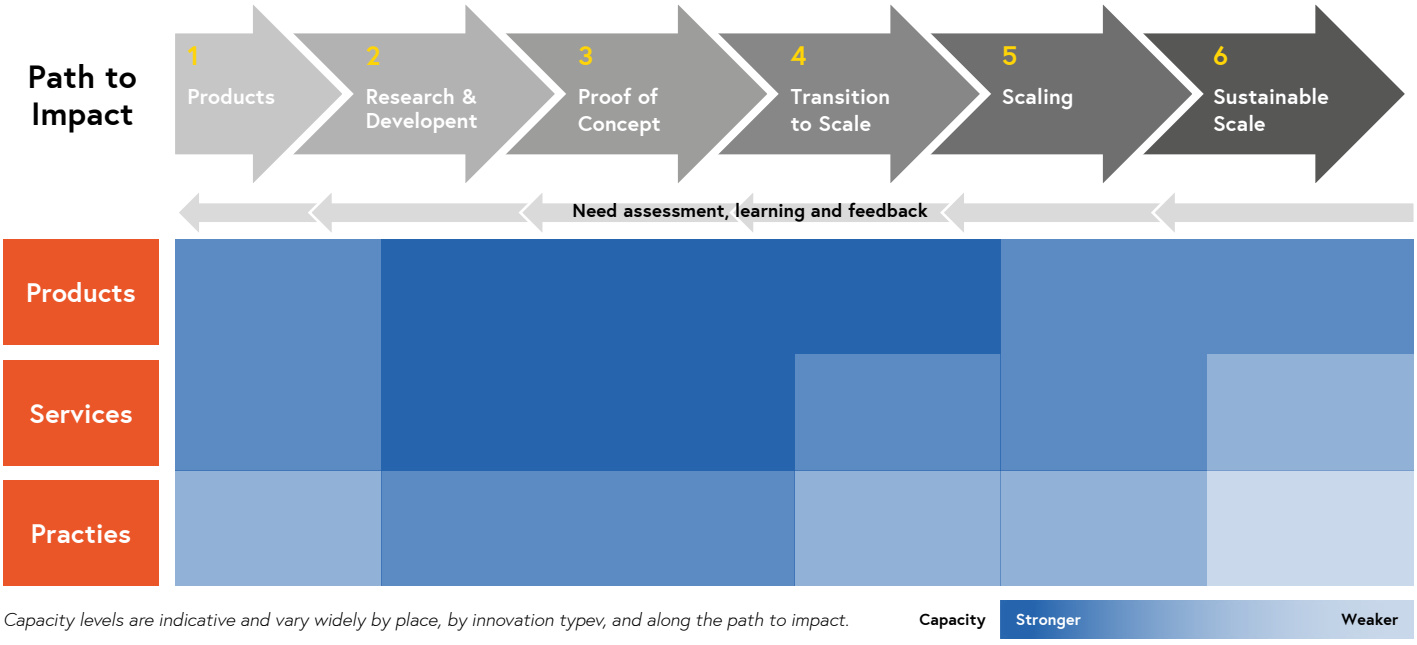
Timelines are generally very compressed, development risks high, and financial returns to developers may be short-term or small. Equitable access to pandemic vaccines pose significant diplomatic and market challenges (see Annexes 6 on Vaccine Supply and Sustainable Financing).

In these situations, research and innovations must urgently be translated into practice and made available to all affected people.

**Innovations in vaccine service delivery** have expanded access to immunisation. These range from improvements in supply chain management and data quality to innovations in provision of services.[5-7] While these improvements have facilitated new vaccine introductions, they have not mitigated frequent supply issues nor closed coverage gaps. Reaching everyone will require not only research to understand why some populations are poorly served but also innovation to sustainably meet their needs. Research and innovation in vaccine delivery are even more crucial for new vaccines that target populations that are not routinely vaccinated or require more complex dosing schedules.

To address these challenges, IA2030 aims to build **capacity for research and innovation**. Capacity varies widely from country to country, across different types of innovations, and along the *path to impact* (Figure 1).

**Figure 1.** Current capacity for research and innovation




*Capacity levels are indicative and vary widely by place, by innovation typev, and along the path to impact.*

Innovation is required to enhance products, services and practices, but each area has its own challenges:

- **Products** include both novel vaccines to protect against priority diseases as well as improvements to existing vaccines to increase efficacy, enhance deliverability or reduce cost. New vaccines must overcome hurdles at four stages to achieve sustainable impact: the transition from discovery to early clinical development; the shift from early clinical development to larger, more costly efficacy trials; the transition to scale; and achieving long-term sustainability.[8]

  Products can also be new technologies to facilitate vaccine administration, improved vaccine thermostabilisation processes, novel manufacturing platforms, diagnostics and laboratory methods to improve disease surveillance, supply systems equipment, and information technology hardware and software.

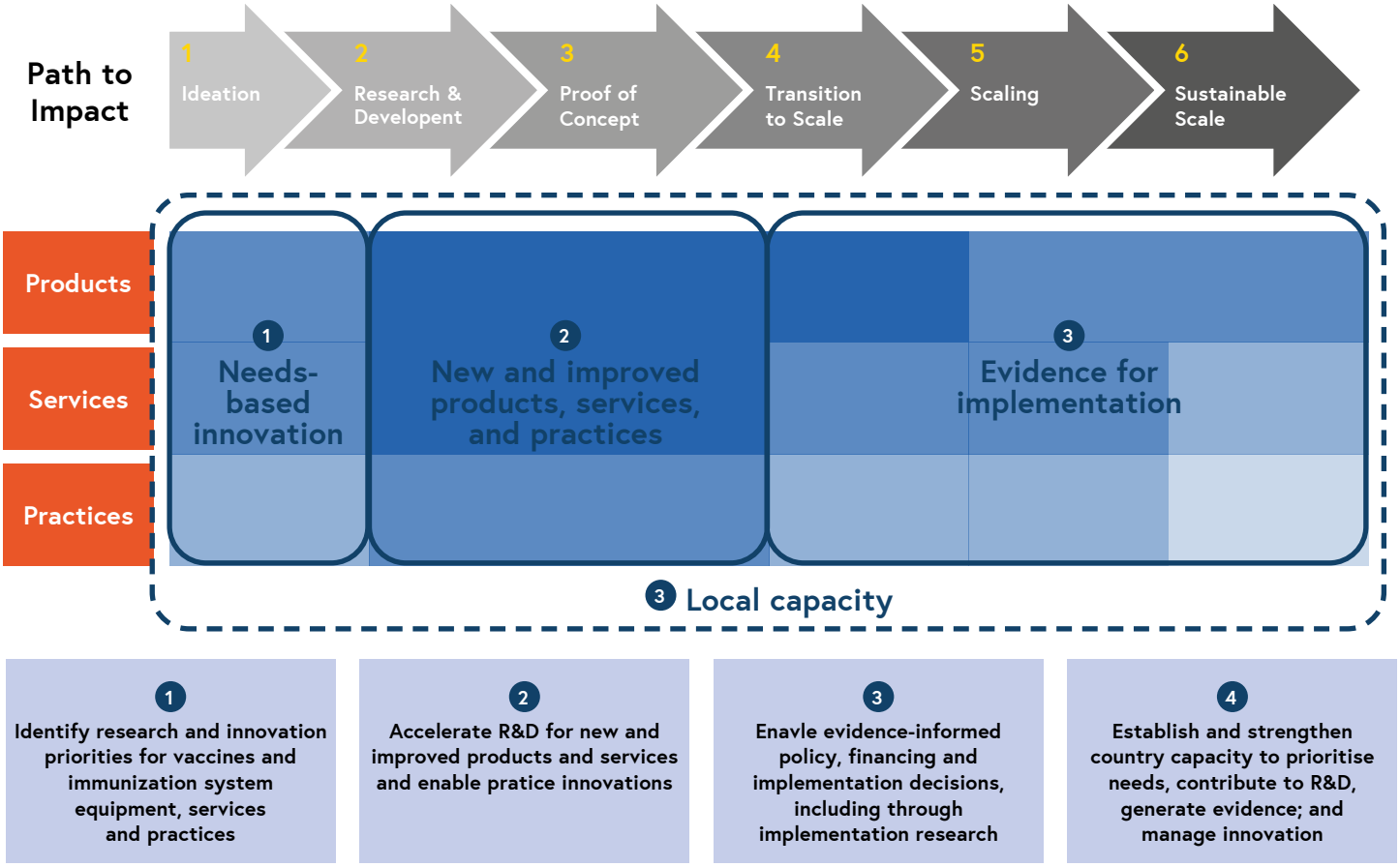
- **Service** innovations are new ways of managing and delivering vaccines to meet population needs. These innovations can involve applying new tools and technologies, such as geographic information systems. They can also be third-party services to improve the delivery of vaccines. Examples include innovations in how data are managed and used, such as logistics management information systems, electronic immunisation registries, and disease surveillance systems. One challenge is to ensure that innovative services are informed by user needs and perspectives, especially gender-specific and community-specific concerns, to increase the likelihood that they are widely adopted.

- **Practices** are programmatic innovations that improve how local decisions are made and how immunisation services are provided. Examples include workflow adjustments to improve efficiency and resilience, and the use of text message reminders to increase uptake and timeliness of vaccination, and innovative ways of addressing vaccine hesitancy.[9] Delivering universal health care requires innovative practices to reach poorly served populations. Practice innovations face challenges such as lack of resources, aversion to risk, and lack of mechanisms for dissemination, sharing and scale-up. Addressing these challenges requires a culture of innovation and leadership that encourages grassroots problem solving.

For all types of innovations, rapid progress to sustainable scale requires alignment among stakeholders; clarity on needs at the outset and on key decisions at each stage; collection of data to inform downstream decision making; and looking beyond narrow attributes such as cost effectiveness to consider full societal value.

To build capacity for research and innovation, IA2030 defines four key focus areas (Figure 2). These focus areas are interdependent. For example, "local capacity" includes the ability to convey to the wider global community the need for external solutions; these requirements inform "needs-based innovation"; this drives the development of "new and improved products, services and practices".

**Figure 2.** Research and innovation key focus areas




# Key focus areas

## Needs-based innovation

Strengthen mechanisms to identify research and innovation priorities according to community needs, particularly for the underserved, and ensure that these priorities inform innovations in immunisation products, services and practices.

### Key evidence and gaps

Experience shows that innovation must be connected to the needs of health systems and communities to achieve impact. Innovations have not been implemented at scale for numerous reasons. For example, lack of sufficient consultation in design or user testing has led to limited applicability of innovations and uncertainty in true demand.[10] Better mechanisms to capture and articulate the needs of health systems and communities will help ensure innovations are well-suited to those needs.

Clarity on needs is necessary but not sufficient to achieve impact at scale. Inventors, developers and manufacturers must have incentives to invest their time and resources. While public and philanthropic funding has accelerated

vaccine development, for most product innovations formidable resource gaps remain in late-stage product development, meeting diverse regulatory requirements, and achieving implementation at scale.

Needs-based innovation for services and practices will require better coordination between different stakeholders. Links between different disciplines can also give rise to new ideas and opportunities. For example, vaccines could play an important role in combating antimicrobial resistance, by reducing the use of antibiotics, or by improving immunity to frequently drug-resistant pathogens. Multidisciplinary collaboration will be needed to identify and address data gaps, define what interventions are needed and how they can be used, prioritise among pathogens, and agree on a path forward.

**Strategic interventions**

**Link actors in the system.** Stakeholders include communities, immunisation programme staff, healthcare professionals, government, regulators, industry, and academia within countries and at the regional and global levels. These may be non-profit organisations, non-governmental organisations, civil society organisations, product development partnerships, and other public-private partnerships. Integration and coordination among stakeholders can be improved through:

- Platforms to collect and share programmatic insights and learnings from ministries of health and implementing partners to inform research and innovation agendas. At the regional level, these platforms can enable cross-learning and adapting and scaling innovations.
- Stronger links between innovators, health systems and communities to ensure that innovations are responsive to community needs.
- Mechanisms to give early guidance on data requirements for global policy recommendations and national adoption decisions, so that these considerations can be addressed in the course of R&D.
- Collaboration on shared roadmaps and initiatives such as the Sustainable Development Goal (*SDG*) Global Action Plan for Healthy Lives and Well-being for All.[11]

**Identify research and innovation priorities.** Vaccine R&D priorities have historically been driven by the needs of high-income countries and by the interests of technical partners and funders. In recent years, global priority setting has become more transparent and systematic, as WHO, Gavi and other stakeholders have created mechanisms to align stakeholders around research and innovation priorities for low-resource settings. These mechanisms include the *Product Development for Vaccines Advisory Committee* (PDVAC), which advises WHO on priority pathogens and technologies where there is a public health need, the WHO *R&D Blueprint for Action to Prevent*

*Epidemics*, and the Gavi *Vaccine Innovation Prioritisation Strategy* (VIPS). Led by Gavi and its partners, VIPS drives delivery and packaging innovations to meet the needs of Gavi-supported countries. In addition, the Pandemic Influenza Preparedness (PIP) Framework is an innovative mechanism for sharing influenza viruses with pandemic potential and for equitable access to vaccines and other benefits, which aligns stakeholders around a shared strategy for pandemic influenza preparedness.

As well as defining priorities, these mechanisms provide guidance to innovators by defining technical R&D roadmaps and establishing preferred product characteristics (PPCs) and target product profiles (TPPs) to optimise public health impact. These documents provide strategic and technical guidance to product developers.[12]

These mechanisms need to be continued and strengthened. In addition, the Country-led Assessment for Prioritisation on Immunisation (CAPACITI) approach should be implemented to communicate country priorities and preferences for procurement and R&D and to strengthen multi-criteria decision making in immunisation. CAPACITI will improve alignment between country priorities and the global mechanisms that foster innovation.

For innovative services and practices, priorities are more fragmented. There are few unified definitions of core problems and shared innovation agendas. *In this coming decade, more systematic and evidence-based approaches will be needed to set priorities for innovations that meet real-world needs*.

**Incentivise innovation linked to shared priorities.** In many cases, commercial incentives and the potential for health impact are sufficient to drive R&D for priority vaccines and services. When commercial incentives are smaller, as for products and services needed solely in low-income markets, or higher risk, as for products developed in anticipation of regional outbreaks or pandemics, additional incentives may be needed to drive innovation. These incentives can be provided through mechanisms such as product development investments and advance market commitments, as discussed in the annexes for SP6, Supply and Sustainability.

Organisations that provide incentives for innovation should consider resource needs along the entire *path to impact*. These needs can be greatest in the transition to scale, before full adoption and sustainable revenue streams have been achieved. Together, research innovation priorities and these incentives will help new products overcome the first two hurdles to sustainable scale, from discovery to clinical development, and then from early- to late-stage clinical trials.

**Assumptions and risks**

In many low-resource settings, it is difficult to prioritise needs for vaccine R&D due to incomplete data in many areas, including burden of disease, socioeconomic impact, and barriers to delivery. Generating better data for priority-setting is discussed further in Section 4.3.

## New and improved products and services

Accelerate the development of new vaccines, technologies, and improvements to existing products, services and practices, while ensuring continued progress on vaccines for priority targets, including, among others, human immunodeficiency virus (HIV), tuberculosis, malaria and emerging infectious diseases.

### Key evidence and gaps

R&D is underway for many high-priority pathogens and diseases (see box). Multiple organisations and public-private partnerships are actively developing vaccines against additional pathogens, such as emerging infectious diseases, norovirus, and *Staphylococcus aureus*.

**Priority pathogens and diseases for low- and middle-income countries** (PDVAC 2019)[1]

Enterotoxigenic *E. coli*, gonococcal disease, group A streptococcus, group B streptococcus, herpes simplex virus, human immunodeficiency virus, influenza (next-generation vaccines), malaria, respiratory syncytial virus, *Shigella* and tuberculosis

**R&D Blueprint priority diseases** (April 2020)[2]

COVID-19, Crimean-Congo haemorrhagic fever, Ebola virus disease and Marburg virus disease, Lassa fever, Middle East respiratory syndrome coronavirus and severe acute respiratory syndrome, Nipah and henipavirus diseases, Rift Valley fever, Zika and "disease X", a pathogen currently unknown to cause human disease

In addition, R&D is underway to improve existing vaccines and disease control strategies, for example, through regimens that extend the duration of protection and second-generation products with improved efficacy, safety, deliverability, or cost effectiveness. The extensive list of pipeline vaccines at https://www.who.int/immunization/diseases/en/ shows that vaccine R&D remains an high priority activity.

Challenges for developing innovative services include a limited understanding of contextual constraints, end-user needs, and decision-maker priorities; poor ability to identify innovations from the field and from other sectors that could be applied more widely; later-stage tests that do not reflect real field environments and constraints; and funding that is insufficient or does not permit rapid "test and learn" cycles.

An enabling environment for R&D is required to accelerate the development of vaccines, other products and services. This environment must have adequate regulatory capacity to provide appropriate oversight and manage risks throughout the product lifecycle. Strengthening the enabling environment for R&D will address the second hurdle on the path to sustainable vaccine impact, from early clinical development to large efficacy trials.

### Strategic interventions

**Accelerate R&D for new and improved products and services.** R&D for priority vaccines can be accelerated by investing in basic research, including on the fundamentals of innate and adaptive immune responses and the immunological and molecular characteristics of disease-causing agents. Further progress will come through the development, standardisation and application of controlled human infection models, and through greater use of correlates

of protection and other tools for accelerated regulatory approval. For many priority diseases, greater capacity for clinical research on vaccines is needed in the regions most affected by the disease. Wherever possible, public sector funding of research activities should include clauses that facilitate low- and middle-income country access to the resulting products and, where appropriate, to production technologies.

Technology accelerators like Gavi's *INFUSE* and the World Food Program Innovation Accelerator can support the development of innovative services. These accelerators provide financing and multidisciplinary support such as training in *human-centred design* and user testing, technology platform support, partner networking, business model refinement, and human resources. Digital solutions to improve immunisation programme design, management and monitoring should be developed in alignment with Principles for Digital Development and the Principles of Donor Alignment for Digital Health.[13]

**Anticipate implementation.** New products and services should be developed with a focus on how they will be implemented and integrated with other health services and practices. In addition to the PPCs and TPPs discussed above, this will require partnerships earlier in development to incorporate user perspectives and increase the likelihood of adoption.

For services, multi-donor innovation funds that support test deployments and help countries fund wider adoption at scale could expand the range of service and product providers available to countries. Donor-funded programmes should provide for step-by-step integration of innovations into existing public sector systems to ensure sustainability and promote knowledge sharing between countries.

**Public-private partnerships** for service delivery can increase the reach, flexibility, and quality of public sector systems, especially in response to shocks and disruptions. For example, Ghana Health Services contracted with Zipline to provide emergency shipments of vaccines and pharmaceuticals. As COVID-19 struck, that service pivoted to routine delivery of vaccines to ensure uninterrupted supply. As countries plan their expansion of services to include potential COVID-19 vaccines, partnerships with private sector logistics providers can help to rapidly scale delivery.

**Improve regulatory environment to reduce delays and uncertainty.** Regulatory capacity is limited in many low-income countries. In addition, country-to-country differences in regulatory requirements, procedures and expectations create barriers to the development and wider availability of new products. To facilitate the availability of new and improved vaccines:

- WHO should provide guidance to national regulatory authorities on international standards to assure the quality, safety and efficacy of vaccines for priority diseases to enable WHO prequalification of vaccines.

- WHO should provide guidance to manufacturers on requirements for prequalification, particularly on data requirements that go beyond those of national regulatory authorities, and on correlates of vaccine-induced protection.

Innovators should engage regulatory decisionmakers early in the development of innovative products and processes.

- Countries that produce vaccines should ensure that rigorous safety standards are defined, addressed and effectively communicated so that safety concerns do not contribute to reduced confidence in vaccines.
- Countries are encouraged to standardise registration processes for imported vaccines and use facilitated regulatory pathways to accelerate access.

- All countries should establish effective and flexible pathways to address public health emergencies. These may include flexible and expedited regulatory processes for clinical development and registration/importation of vaccines in cases of strong public health need, such as clinical trials during outbreaks and human infection studies in endemic regions. Countries are encouraged to avoid duplication and to rely on other authorities for evaluation and decisions in public health emergencies.

- Regulators and manufacturers should consider ways to minimise, and preferably avoid, the use of animals for the development of medical products.[14]

**Ethically manage risks and benefits.** Development of vaccines and vaccine administration technologies is governed by well-established processes to protect the interests of participants in clinical research studies and, over the longer term, to preserve trust in immunisation. It is essential that countries have systems in place to ensure effective oversight of clinical research, including clinical trial approvals and ethical review of clinical trial proposals.

As part of their ethical responsibilities, clinical trial sponsors should ensure that they have mechanisms in place to identify and manage any health harms arising during studies. They should also include access provisions to ensure that individual and communities that have borne the risks during clinical evaluation of new interventions also receive the benefits of these innovations.

Innovations that alter how immunisation programmes are managed or how services are organised have less potential to cause harm and are therefore subject to less stringent oversight. Nevertheless, the potential for adverse effects should always be considered and used to inform the design of pilot studies or implementation research projects.

**Assumptions and risks**

This KFA assumes that intellectual property issues that limit innovation and add to transaction costs can be addressed, for example through partnerships, release of funding contingent on access provisions, open access patent pools, or other mechanisms. It assumes that complexity and uncertainty related to access and benefit sharing provisions will not inhibit innovation, especially for products that address emerging pathogens.

## Evidence for implementation

Shorten the path to maximum vaccine impact by using implementation and operational research, as well as by enabling evidence-informed policy and implementation decisions based on needs, benefits and risks.

### Key evidence and gaps

The third and fourth hurdles on the path to sustainable impact are the transitions from vaccine licensure to broad-scale implementation and then to sustainable scale. Overcoming these hurdles requires evidence for decision making and *implementation research*.

Countries need accurate data and state-of-the-art analyses of relative benefits for policy-making, product choices and financial decisions. These decisions are especially complex where value propositions are less clear-cut and in the context of high risks and uncertainties, such as for vaccines that prevent morbidity rather than mortality or that are developed in anticipation of emerging infectious diseases.

Implementation research focuses on health systems operations and how they absorb innovations. It can help to identify and understand the challenges and opportunities along the *path to impact*, to inform and optimise implementation decisions and strategies, and to set the stage for sustainability. Research can also strengthen people-centred service delivery by improving the understanding of community needs and the needs of the underserved and disadvantaged populations, particularly unvaccinated children. Taking these factors into account in service design and delivery can help reach underserved populations. Since most caregivers are women, understanding how gender influences access to services and treatment by health workers is important to improving uptake. Social and behavioural research can inform approaches to building public trust and confidence in immunisation.[15] Behavioural insights and harnessing cutting edge social behaviour change approaches, such as integrated marketing techniques and human-centred design, can improve the development and testing of innovative products, services and practices.

### Strategic interventions

**Enable evidence-informed policy, financing, and implementation decisions.** Generate and disseminate evidence on the properties, impact, and value of new and improved vaccines and technologies, services and practices to inform policy and implementation decisions. Ministers of health and Regional and National Immunisation Technical Advisory Groups (*RITAGs* and *NITAGs*), should help drive research agendas.

Key evidence considered should include local disease burdens, the role of vaccines in integrated disease control strategies, whether an innovation reduces inequities, and economic considerations such as cost-benefit ratio, returns on investment, and the costs of inaction. Evidence needs extend beyond conventional measures such as mortality reduction to include impact on morbidity and indirect benefits.

**Apply implementation research.** It is important to analyse potential implementation barriers earlier in product development and to increase research into the practicalities of moving beyond early clinical trials and pilot phases into deployment at scale.

This research can also help to expand the benefits of vaccination to age and risk groups outside regular childhood schedules, to underserved and hard-to-reach populations, to communities in outbreaks and emergency settings, and to additional geographical areas as disease patterns shift in response to climate change. This research should apply a *gender lens* and consider how gender barriers contribute to low uptake in underserved populations. Generating this evidence will require greater capacity for research across many disciplines in low- and middle-income countries.

**Build capacity for research.** Improve the understanding of research capacity needs in low- and middle-income countries and invest in their capacity to conduct research. This should include capacity to provide evidence for decision making and to inform implementation, as well as to conduct surveillance for changes in disease epidemiology (such as serotype replacement and antimicrobial resistance) and vaccine safety.

### Assumptions and risks

The value of a new product, service or practice is not always sufficient to drive its implementation: For example, countries may find it difficult to pay more for a new product that is better suited to reaching marginalised populations, or to follow NITAG recommendations for the implementation of new vaccines. To reduce the risk that the full potential of innovations is not realised, the evidence generated should address the needs of decision makers as fully as possible. The evidence should include comprehensive assessments of the value of innovations to inform advocacy and accountability activities.

## Local capacity

Build local capacity to address programmatic challenges and maximise impact by co-creating, sourcing, adopting and scaling innovations.

### Key evidence and gaps

**Countries need the capacity to manage innovation.** This includes the capacity to identify research and innovation needs and priorities at all levels of the immunisation system. It includes shaping target product profiles and vaccine value assessments to ensure that new products serve their identified needs. It also includes identifying challenges that could have technology solutions, such as in logistics and data management.

Managing innovation includes devising new services and practices, as well as evaluating, selecting and implementing new products and services. Digital technologies hold particular promise in identifying underserved populations, improving community engagement, streamlining delivery, and monitoring outcomes, but present a special set of challenges. Dedicated capacity is needed to manage digital innovations.

Local problem solving is vital to implementing resilient systems but is often limited by aversion to risk and lack of resources. Successful solutions remain local due to lack of mechanisms for dissemination and scale-up.[16] More capacity is needed to enable, design, prototype and test innovations in the contexts where they will be used and to disseminate and scale programmatic innovations.

*Human-centred design* can improve the utility of innovations and promote their uptake. It entails taking multiple approaches to understand local contexts and using rapid "test and learn" cycles to test innovations and minimise the risk of failure. Existing funding streams are insufficient and not structured to encourage this rapid prototyping approach.

**Strategic interventions**

**Ensure countries and communities have resources and capacity to manage innovation.** National governments should establish structures to manage innovation. To build capacity for innovation, governments and technical partners can implement training in innovation for impact and taking innovations to scale. They can create continuous learning opportunities for national and local managers. They can establish platforms that develop regional and national capabilities for design thinking and problem solving and increase access to local design thinking capability. They should connect to local and regional innovation accelerators that promote entrepreneurial innovations.

**Build an enabling** *innovation ecosystem* in alignment with the Development Innovation Principles.[16] Many actions will contribute to the innovation ecosystem. Stakeholders should:

- Formalise and legitimise **innovation as a discipline** and build awareness of the potential for innovation through communication, and training such as that created by the International Development Innovation Alliance (IDIA).[17] Lessons learned and best practices should be documented and shared though a knowledge-sharing platform.

- Develop and share an **innovation toolkit** that: establishes a common lexicon and understanding of the role of innovation in health systems; supports *CAPACITI, human-centred design* approaches, and continuous quality improvement; and fosters collaboration between disciplines. The toolkit should include frameworks for supporting innovation to scale, including regulatory and risk management and working with local entrepreneurs and universities.

- Promote **inclusive innovation**, with a focus on supporting the poorest and most vulnerable. Women and adolescent girls, including those with disabilities, should play a decisive role in the design, testing, learning and adoption of innovative solutions, and should be engaged as both recipients of innovation and by supporting them with tools and resources as innovators.

- Identify and support **innovation entrepreneurs** closer to the problems and challenges faced by immunisation programmes. Mechanisms should add to local capacity (rather than disrupt existing resources) and could include innovation hubs, accelerators and *sprint support*.

- **Create constant feedback loops and foster iterative learning,** including "test and learn" cycles. Adopt more agile approaches for innovation in digital tools, management and practices.[16]

- **Coordinate with wider innovation efforts,** including those in non-health sectors, such as the Technology Facilitation Mechanism for the Sustainable Development Goals;[18] WHO innovation initiatives at all levels of the organisation; efforts funded by bilateral, multilateral, national and regional agencies for R&D; and institutes of science and technology.

**Build capacity to develop and manage digital solutions** by adapting existing data tools and systems, standardising approaches, and supporting the development of digital global goods to avoid "reinventing the wheel".

Stakeholders should establish funding mechanisms to ensure there is a robust market for software as a service to avoid creating fragmented and unsustainable digital products. They should highlight important challenges in alignment with country plans so solution developers are addressing pressing problems and promote the collaborative development of digital health global goods.[19]

Linking developers with local ecosystems of digital accelerators and sprint support will enhance their capacity. Donor support should be aligned with *Principles for Digital Development* and the *Principles of Donor Alignment for Digital Health*.

**Assumptions and risks**

Innovation requires leadership commitment, resources, a supportive ecosystem, and a willingness to learn quickly and iterate. Stakeholders must be committed to use of innovation to achieve the goals of IA2030 and to investment in local capacity for innovation.

# Definitions

- Country-led Assessment for Prioritisation on Immunisation (*CAPACITI*): a systematic, structured and transparent approach for evidence-based immunisation decision-making. It aims to strengthen the ability of low- and middle-income countries to evaluate vaccination options according to their priorities and programme context, both to support national immunisation programme decisions and to inform vaccine development and investment decisions. Based on the *total systems effectiveness (TSE)* approach. See https://www.who.int/immunization/research/meetings_workshops/31_Giersing_TSE.pdf for additional information.

- *Correlates of vaccine-induced protection*. Immune markers that have been clinically validated to correlate with vaccine-induced protection. See https://apps.who.int/iris/bitstream/handle/10665/84288/WHO_IVB_13.01_eng.pdf for additional information.

- *Design thinking* is an iterative problem-solving process based on understanding the user, identifying alternative strategies and solutions, iteration, experimentation, and learning through multiple "test and learn" cycles.

- *Gender lens* refers to examining how gender differences and relations affect how a product or service is perceived and accessed. Applying a gender lens to understanding the current context and designing innovations can reveal opportunities and mitigate risks. Using a gender lens to analyse power structures and roles within a specific context can provide important insights into whether an investment supports or exacerbates imbalances in gender-related power.

- *Human-centred design* is a creative problem-solving approach that puts the people served at the centre of the innovation process. It applies *design thinking* to the development of products, services, processes, messages, experiences and environments.

- *Implementation research* focuses on understanding what, why, and how interventions work in real world settings, testing approaches to improve them, and overcoming the barriers and constraints for their introduction and scale-up. It includes operational research, which is the discipline of using models to aid decision making in complex problems.

- *Innovation for Uptake, Scale and Equity in Immunisation (INFUSE)* is a Gavi programme to improve vaccine service delivery by connecting high-impact, proven innovations with the countries that need them most.

- *Innovation ecosystem*. Enabling policies and regulations, finance, informed human capital, supportive markets, energy, transport and communications infrastructure, a culture supportive of innovation and entrepreneurship, and networking assets, which together support and enable innovation. For more information, see https://www.idiainnovation.org/ecosystem.

*Microarray patches* (MAPs). Devices with microscopic projections that are applied to the body like a small bandage, penetrating the skin's outermost layer to deliver a drug or vaccine.

- *National Immunisation Technical Advisory Groups (NITAGs)*. Multidisciplinary groups of national experts responsible for providing independent, evidence-informed advice to policy makers and programme managers on policy issues related to immunisation and vaccines. See https://www.who.int/immunization/sage/national_advisory_committees/en/ for additional information.

- *Path to impact*. The steps required to realise the potential of an innovation. For products, this typically includes discovery, product development, clinical and economic evaluation, regulatory oversight, policy processes, and delivery at scale. For services and practices, the pathway to impact varies widely depending on the innovation and its context. Paths to impact can include scaling, replicating, diffusing and mimicking.

- *Prequalification (PQ)*. A WHO process to provide advice to procurement agencies and countries on the acceptability, in principle, of particular vaccines. This includes a thorough review of the evidence generated by the manufacturer on the efficacy, immunogenicity and safety of the product. It also includes a visit to the production site in close coordination with the national regulatory agency of the country where the production site is located. See https://www.who.int/immunization_standards/vaccine_quality/pq_system/en/ for additional information.

- *Product Development for Vaccines Advisory Committee (PDVAC)*. Provides independent and expert advice to WHO to accelerate product development of vaccines and technologies that are urgently needed and ensure they are appropriately targeted for use in low- and middle-income contexts. Advice is related to pathogen areas with candidate vaccines or technologies, generally at the phase 2 stage of clinical evaluation or earlier, and prior to the development of WHO policy on use. See https://www.who.int/immunization/research/committees/pdvac/en/ for additional information.

- *Regional Immunisation Technical Advisory Groups (RITAGs)* Committees that provide WHO Regional Directors and countries in the respective regions with recommendations on regional immunisation priorities and strategies in the light of regional epidemiological and social issues. See https://www.who.int/immunization/sage/regional/en/ for additional information.

- *Research and Development Blueprint for Action to Prevent Epidemics*. A global strategy and preparedness plan for the rapid activation of R&D activities during epidemics. https://www.who.int/blueprint/en/

- *Sprint support*. Dedicated support provided to early-stage entrepreneurs and innovators developing a product or service, often through technology accelerator programmes. Typically, entrepreneurs are selected through a

rigorous process and form a cohort that moves through the programme together. The entrepreneurs may be provided with seed funding, technical assistance and support, mentoring, coaching and space to develop their idea. Skills developed typically include human-centred design, investor and customer relations, strategic business development, and marketing.

- *Sustainable Development Goals (SDGs).* The world's shared plan to end extreme poverty, reduce inequality, and protect the planet by 2030 as adopted by 193 countries in 2015. See https://sustainabledevelopment.un.org/sdgs for additional information.

- *Vaccine Innovation Prioritisation Strategy (VIPS)* is an effort by Gavi to drive product innovation to better meet country needs and support Gavi's goals on immunisation coverage and equity. VIPS is consulting with country stakeholders as part of the process of prioritising delivery and packaging innovations in vaccine product attributes for Gavi countries. See https://www.who.int/immunization/research/meetings_workshops/30_MenozziA_VIPS.pdf?ua=1

# Resources

### Cross-cutting

- Whistler Principles to Accelerate Innovation for Development Impact: https://www.international.gc.ca/world-monde/international_relations-relations_internationales/g7/documents/2018-05-31-whistler-development-developpement.aspx?lang=eng

- IDIA Insight: Scaling Innovation: https://static1.squarespace.com/static/5b156e3bf2e6b10bb0788609/t/5b1717eb8a922da5042cd0bc/1528240110897/Insights+on+Scaling+Innovation.pdf

### KFA1 – Needs-based innovation

- WHO Research and Development Blueprint for Action to Prevent Epidemics: https://www.who.int/blueprint/en/

- Gavi Vaccine Innovation Prioritisation Strategy: https://www.who.int/immunization/research/meetings_workshops/30_MenozziA_VIPS.pdf?ua=1

- KFA2 – New and improved products and services

- WHO Preferred Product Characteristics (PPCs) and Target Product Profiles (TPPs): https://www.who.int/immunization/research/ppc-tpp/en/

- Common Principles of Design and Global Health: https://static1.squarespace.com/static/5b0f1011b98a78f8e23aef4e/t/5b2c9c7c2b6a2872d6ba62a3/1529650301604/POSTER_COMMON+PRINCIPLES+OF+DESIGN+%26+GLOBAL+HEALTH.pdf

### KFA3 – Evidence for Implementation

- Theobald, et al., Implementation research: new imperatives and opportunities in global health: https://www.sciencedirect.com/science/article/pii/S0140673618322050

- WHO Strategic Advisory Group of Experts on Immunization (SAGE): https://www.who.int/immunization/policy/sage/en/

### KFA4 – Local Capacity

- UNDP Innovation Facility: https://www.undp.org/content/undp/en/home/2030-agenda-for-sustainable-development/partnerships/sdg-finance--private-sector/innovation.html

- Principles for Digital Development: https://digitalprinciples.org/principles/

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