Global Research and Innovation for Health Emergencies

Building the world's resilience against future outbreaks and pandemics

October 2023

World Health Organization

R&DBlueprint
Powering research
to prevent epidemics

Contents

> **We cannot make the world safer without investments in science, research and innovation.**

Tedros Adhanom
Director-General
World Health Organization

Introduction

Welcome to the 3rd edition in this WHO R&D Blueprint for Epidemics series of reports dedicated to global research and innovation (RI) for health emergencies.

Within these pages, we continue to showcase the life-saving impact of science in our ongoing battle against deadly diseases with the potential to cause epidemics and pandemics worldwide, especially those for which effective medical countermeasures remain limited or absent.

The COVID-19 pandemic has been at the centre of WHO's research endeavours over the past 12 months and our progress is reported in alignment with the priorities outlined in the 2022 Research and Innovation Achievements Report.

In May 2023, the WHO marked a significant milestone by officially declaring the end of the global emergency status of COVID-19. However, the shadow of COVID-19 still looms large and our work to monitor and manage this devastating disease remains vital.

In this report, we also present critical advances in research related to other significant pathogens that pose substantial threats, yet for which there are limited or no medical countermeasures available. This combined research approach (COVID-19 and beyond) is essential to defending our world.

Today, we stand at a crossroads in shaping global resilience, preparedness and response strategies for the next major epidemic or pandemic.

It is critical that we assimilate the lessons learned from the pandemic and harness the wealth of research knowledge, platforms and collaborative frameworks forged during the COVID-19 crisis to help protect the world from future threats.

Finally, we take a moment to honour the memory of the millions of people we have lost in the past year to devastating diseases, and we renew our commitment to combatting new or re-emerging pathogens that threaten people right across the globe.

We extend our deepest appreciation to the patients, volunteers, and their families whose participation in WHO's research has been pivotal in every study and initiative conducted in the last 12 months. Their contributions remain the cornerstone of this extraordinary global effort.

We would also like to convey our gratitude to the worldwide community of funders and partners, without whose unwavering support none of our work would be attainable.

Acronyms and abbreviations

AC advisory committee

ACT-A Access to COVID-19 Tools-Accelerator

AFIRM Agenda for Filovirus Research and Monitoring

AI artificial intelligence

ARIA Airborne Risk Indoor Assessment

ASCSoMP Advisory Committee on Safety of Medicinal Products

CCHF Crimean Haemorrhagic Fever

CEPI Coalition for Epidemic Preparedness and Innovation

CERN European Organization for Nuclear Research

CIP Coalition of Interested Parties

COVID-19 coronavirus disease

CRP collaborative registration procedure

DSMC Data Safety Monitoring Committee

EB Executive Board (WHO)

EDCARN Clinical Network/Emerging Diseases Clinical Assessment and Response Network

EID emerging infectious disease

EIOS epidemic intelligence from open sources

EPI-WIN WHO Information Network for Epidemics

EU European Union

EUL emergency use listing

EVD Ebola virus disease

EWG expert working group

FAO Food and Agricultural Organization

GACVS Global Advisory Committee on Vaccine Safety

GCP good clinical practice

GPP-EP good participatory practice for new or re-emerging pathogens

G7 Group of 7

G20 Group of 20

HAI health care-associated infection

HEPR health emergency preparedness, response and resilience

HIC high-income country

HTP high-threat pathogen

IANPHI International Association of National Public Health Institutes

IDS integrated disease surveillance

IHR International Health Regulations

IMST COVID-19 Incident Management Support Team

ICMRA International Coalition of Medicines Regulatory Authorities

IOA Integrated Outbreak Analytics

IPC infection prevention and control

ISIDORe Integrated Services for Infectious Disease Outbreak Research (EU)

IU International Unit

JFHTF Joint Finance-Health Taskforce

KPI key performance indicator

LMIC low and middle-income country

MARVAC Marburg Virus Vaccine (Consortium)

MERS Middle East respiratory syndrome

MEURI monitored emergency use of unregistered and experimental interventions

MIC middle-income country

mpox monkeypox (formerly)

MVD Marburg virus disease

NLP natural language processing

NPHA national public health agency

NAPHS national action plan for health security

NRA national regulatory authority

OIE World Organisation for Animal Health (now WOAH see below)

OHIS One Health Intelligence System

OHISS One Health Intelligence Scoping Study

PHC primary health care

PHEIC public health emergency of international concern

PHI public health intelligence

PHSM public health and social measures

PPE personal protective equipment

PPR prevention, preparedness and response

PRET Preparedness and Resilience for Emerging Threats Initiative

RCCE risk communication and community engagement

RCT randomized controlled trial

R&D research and development

REMAP-CAP Randomized, Embedded, Multi-factorial, Adaptive Platform trial for Community-Acquired Pneumonia

RI research and innovation

RPQ WHO Department of Regulation and Prequalification

SAGO WHO Scientific Advisory Group on the Origins of Novel Pathogens

SARS-CoV-2 severe acute respiratory syndrome coronavirus 2

SOP standard operating procedure

STT Solidarity Trial Therapeutics

STV Solidarity Trial Vaccines

SVD Sudan virus disease

TAG technical advisory group

TPP Target Product Profile

UHC universal health care

UN United Nations

UNICEF United Nations Children's Fund

UNEP United Nations Environment Programme

WASH water, sanitation and hygiene

WHA World Health Assembly

WHE World Health Emergencies

WHO World Health Organization

WOAH World Health Organisation for Animal Health (founded as OIE)

SECTION 1

Global research collaboration and action – at the heart of pandemic preparedness and response

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Overview

This chapter gives an overview of the significant milestones achieved in global research in the past 12 months to prevent and combat outbreaks and pandemics. This has been achieved, through the leadership of the World Health Organization (WHO) Research and Development (R&D) Blueprint for Epidemics in collaboration with an extensive network of some 50,000 researchers and scientists from around the world.

While COVID-19 research has dominated WHO's work in the past year and since 2020, equally important have been efforts to advance research on other priority diseases with epidemic and pandemic potential.

The achievements cited in this section have been pivotal in protecting the global community from the persistent threat of COVID-19. At the same time they have bolstered our ability to predict and manage outbreaks of other pathogens, including recent outbreaks of Ebola and Marburg. And they have initiated significant steps towards building the necessary tools and platforms in readiness for the next pandemic.

Through these efforts, we have collectively expanded the field of medical and non-medical countermeasures to include interventions and solutions not previously prioritized to this extent in outbreak preparation and response – including an enhanced role for social sciences, engagement and trust initiatives, which now underpin how we can effectively engage with different communities with speed during major disease outbreaks.

The COVID-19 pandemic truly saw an augmented and integrated research response which helped accelerate the testing of vaccines, treatments and diagnostics, but also underpinned public policy, regulatory and communications initiatives to tackle the spread of disease and reduce its health and social harms.

New strategic components steering future global research agenda

a) The possibility of a new pandemic convention, agreement or other international instrument

The COVID-19 pandemic laid bare vulnerabilities in the global response system, emphasizing the interconnectedness of health crises and how no one in the world is safe until everyone is safe.

In December 2021, the World Health Assembly (WHA) voted at a special session to establish an Intergovernmental Negotiating Body (INB) to draft and negotiate an international accord on pandemic prevention, preparedness and response to align and strengthen the International Health Regulations (IHR), which continue to constitute the primary global framework for managing health emergencies.

Member States of the World Health Organization (WHO) have agreed to a global process to draft and negotiate a convention, agreement or other international instrument under the WHO Constitution to strengthen pandemic prevention, preparedness and response.

A draft document will be submitted for consideration by the 77th WHA in May 2024. If ratified, this new pandemic convention, agreement or other international instrument will at a broader level help deliver a stronger global research ecosystem with a more coordinated response to future epidemics and pandemics. At the research and innovation (RI) level meanwhile, it will contribute to expediting global research, development, and equitable deployment of diagnostics, vaccines and medicines.

b) A new approach to prioritizing the most dangerous pathogens

Since 2015, WHO has implemented a comprehensive global research strategy and preparedness plan known as the WHO R&D Blueprint for Epidemics. The R&D Blueprint for Epidemic's primary goal is to accelerate the development and availability of medical countermeasures, such as vaccines and medicines, for diseases with epidemic and pandemic potential, thereby preventing large-scale health crises and saving lives during outbreaks.

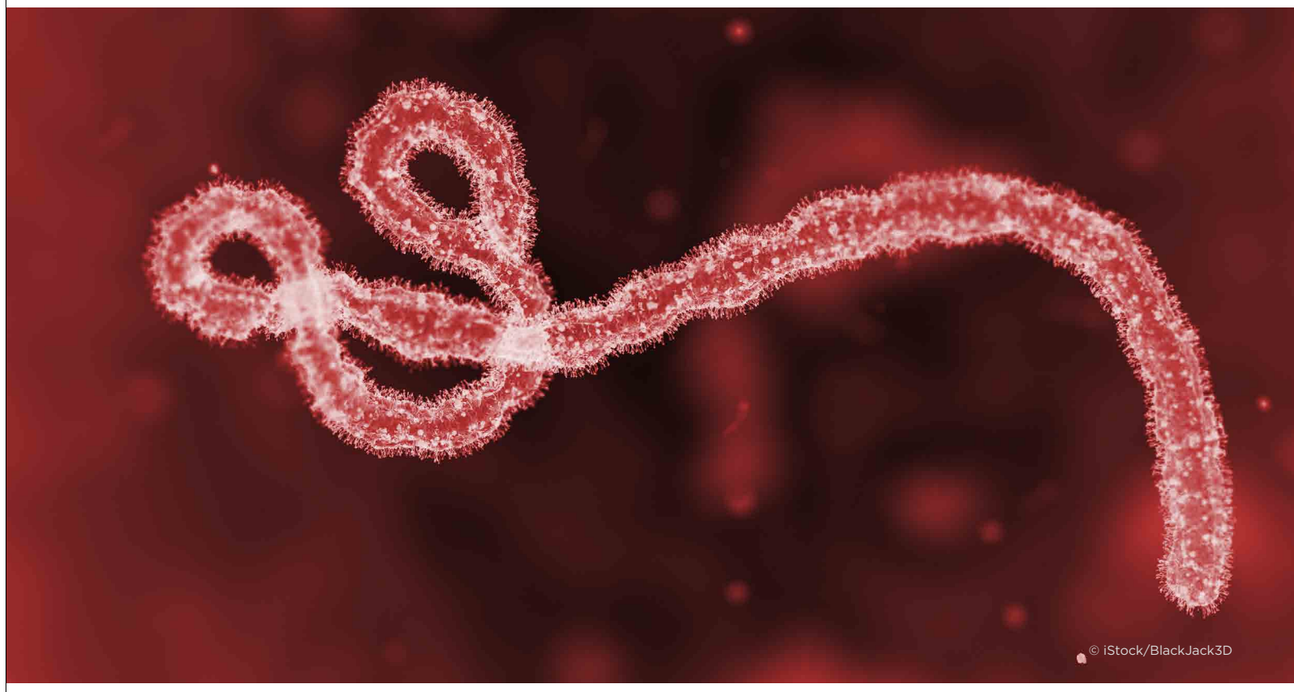
A centrepiece of this work is the WHO pathogen priority list which ensures research efforts are concentrated on diseases with epidemic or pandemic potential where medical countermeasures and limited or non-existent.

Since November 2022, a new approach is being implemented, focusing on entire classes of viruses or bacteria rather than individual pathogens. So, this year, around 300 scientists from 53 countries have independently evaluated evidence related to 27 viral families, one core group of bacteria, and "Disease X" – an unknown pathogen with the potential to trigger a severe global epidemic.

There has been growing support for this approach as it offers a framework to fast-track research and encourages research efforts on entire classes of viruses (e.g., flaviviruses), instead of just the individual strain (e.g. Zika virus). This improves the capability to respond to unforeseen strains, zoonotic viruses (an animal virus that could jump to humans), and the potential threat of a Disease X.

This new approach will help identify representative viruses (or prototypes) within a viral family as a pathfinder in generating evidence and filling knowledge gaps that may then be applicable to other viruses of threat in the same family.

Ultimately it is intended to better identify priority pathogens and accelerate global research, leading to better outcomes, faster research and a more cost-efficient use of resources.



The pivotal work of the WHO R&D Blueprint for Epidemics

The following core activities form the foundation of the work of the WHO R&D Blueprint for Epidemics to ensure the world has a robust and coordinated global response to emerging disease threats:

- **Disease prioritization:** WHO's efforts in research and innovation for diseases with epidemic or pandemic potential are grounded in a rigorous and comprehensive process. This process scientifically identifies viral and bacterial families that require collective research attention due to their epidemic threat and the absence of safe and effective medical countermeasures. The periodically updated list of prioritized viral and bacterial families is guided by evolving evidence spanning diverse domains such as science, epidemiology, socioeconomic impact, access, and equity. An updated version of this list is scheduled for release in 2024.

- **R&D Roadmaps and Target Product Profiles (TPPs):** For each prioritized viral and bacterial family, the R&D Blueprint formulates an R&D Roadmap and a TPP for the three medical countermeasures: vaccines, treatments, and diagnostics. These roadmaps function as strategic blueprints, directing crucial research initiatives focused on each priority viral or bacterial family. They draw expertise from scientists and experts across the world committed to developing safe and effective diagnostics, medicines and vaccines. The TPPs provide the vital specifications and attributes necessary in formulating vaccines, treatments or diagnostic tests.

- **Pipeline monitoring and prioritization for evaluation:** A critical activity in delivering effective medical countermeasures is the dissemination of the best available knowledge and evidence on the clinical development pipeline of candidate vaccines and treatments. This is achieved by meticulously tracking the progress of promising candidate products throughout the clinical research pipeline. An independent expert group provides advice on which ones should be given priority for evaluation in the context of an outbreak. This proactive approach facilitates the agreement on clinical trial designs and the selection of investigational products and candidates to prioritize in clinical trials during an outbreak.

- **Clinical research in the context of outbreaks and pandemics:** The WHO R&D Blueprint for Epidemics collaboratively co-sponsors clinical trials for vaccines and treatments with Ministries of Health. This collaboration involves the development of streamlined CORE research protocols, standard operating procedures (SOPs), clinical trial tools, and data platforms. Additionally, the R&D Blueprint for Epidemics invests in building capacities to conduct clinical trials in accordance with good clinical practice (GCP) standards.

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Figure 1 shows progress on the delivery of key activities within the R&D Blueprint up to May 2023

Pathogen	R&D Roadmap	Vaccines					Therapeutics					Diagnostics					Research priorities for other areas of research and innovation.
		Landscape Candidate Vaccines	TPP Vaccines	Trial design Vaccines	Simple protocol available	Regulatory pathway / consultations	Landscape Candidate Therapeutics	TPP Therapeutics	Trial design Therapeutics	Simple protocol available	Regulatory pathway / consultations	Landscape Candidate Diagnostics	TPP Diagnostics	Trial design Diagnostics	Simple protocol available	Regulatory consultations	
COVID-19	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓
MERS-CoV	✓	✓	✓	✓		✓	✓		✓			✓	✓				✓
Zika	✓	✓	✓	✓	✓	✓	✓	✓				✓	✓	✓		✓	✓
Nipah	✓	✓	✓	✓					✓	✓							✓
Lassa fever	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓	✓		✓	✓
Ebola ZEBOV	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓
Ebola SUDV	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓
Marburg	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓
Crimean–Congo hemorrhagic fever	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓			✓	✓
Rift Valley fever	✓	✓	✓	✓		✓	✓		✓		✓	✓	✓				✓
Chikungunya	✓	✓	✓	✓			✓		✓								✓
Plague	✓	✓	✓	✓		✓	✓		✓		✓					✓	
Mpox	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓
Pathogen X	✓			✓					✓								

Expanded collaborative platform for research

During the COVID-19 pandemic, WHO collaborated with over 50,000 scientists and experts worldwide, spanning the various thematic research areas covered in this report, from vaccine research to epidemiology, as well as enabling initiatives promoting the values of speed, quality, equity and trust.

The efforts of this partnership were coordinated by WHO, and thematic research areas were overseen by independent global advisory committees (ACs) and expert working groups (EWGs), which further collaborated with international, national, and local researchers. This global collaborative approach is depicted in the ensuing pages of the report.

Together, scientists and experts undertook global research and innovation to combat global pathogen threats on an extraordinary scale and at pace.

Moving forward, this global collaborative platform, catalysed by COVID-19, for research on pathogens of epidemic and pandemic threat, will continue to be the bedrock of WHO's research effort.

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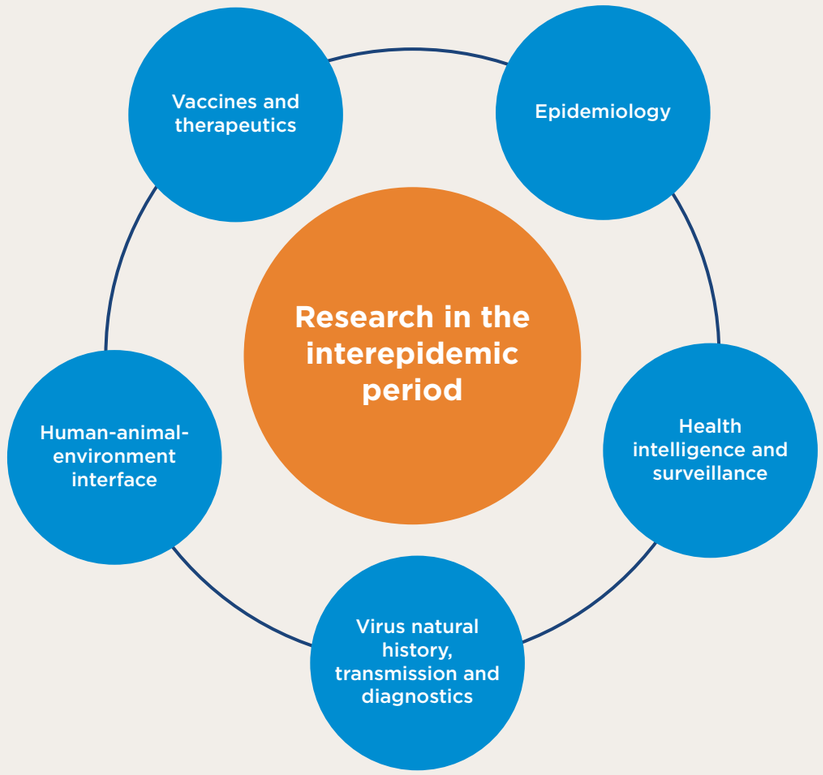
Global collaborative research approach to prevent and tackle outbreaks, epidemics and pandemics



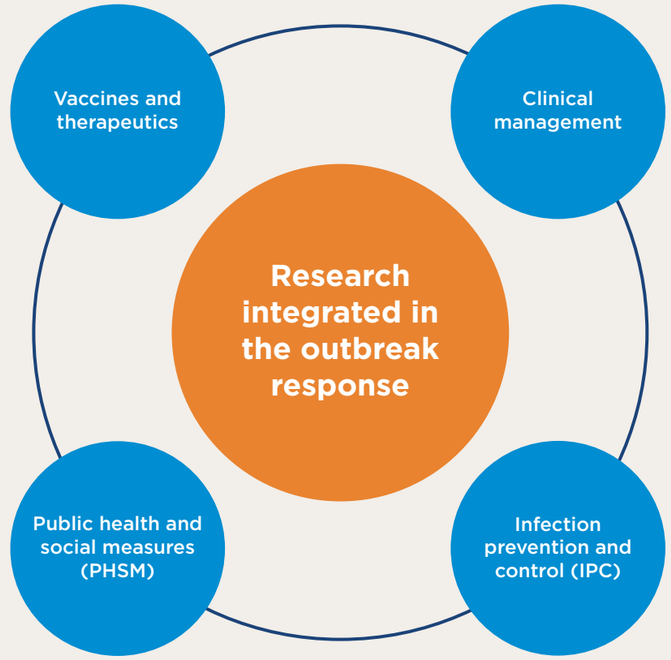


Figure 2 shows over 750 global conferences, meetings and training sessions took place across all global research and innovation areas between May 2022 and May 2023. And over 50,000 global scientists, researchers and policy, engagement and regulatory experts were in attendance. These discussions and collaborations, as well as subsequent communications between other networks, have been critical to this area of work.

Activities and outputs of the global research community to prevent and combat outbreaks and pandemics

Delivered between May 2022 and May 2023 and coordinated by the WHO R&D Blueprint

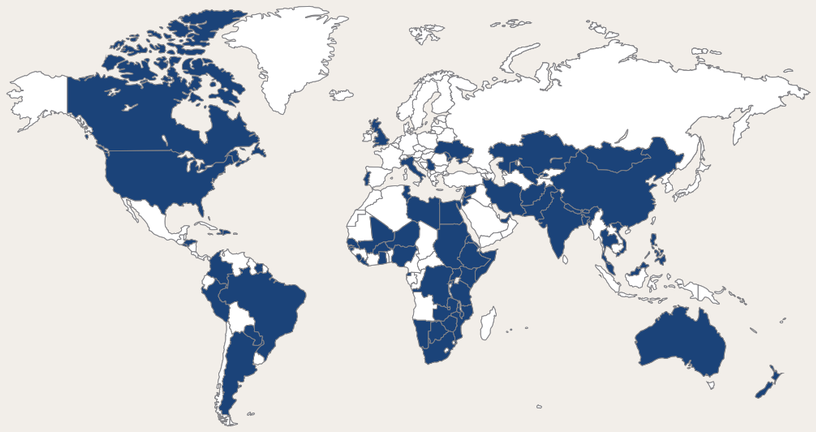
144
The number of peer reviewed publications generated

775 (estimate)
The number of global conferences, meetings and training sessions held

96
The number of WHO publications, reviews and assets produced

56,212 (estimate)
The number of global scientists, researchers and policy, engagement and regulatory experts that have participated in the events outlined above

Figure 3 depicts all of the countries across the globe that have participated in WHO coordinated research activities between May 2022 and May 2023. Activities have been diverse and include a range of countries that took part in large global clinical trials to test vaccines and treatments for COVID-19.



Countries that participated in research activities, coordinated by WHO, to prevent or combat outbreaks and pandemics between May 2022 and May 2023

Research and innovation key achievements 2022-2023

Follows is a summary of the latest research achievements, coordinated by WHO and partners, targeting COVID-19 and other key pathogens in the last 12 months across the broad spectrum of critical research areas delivered before, during and after an outbreak.

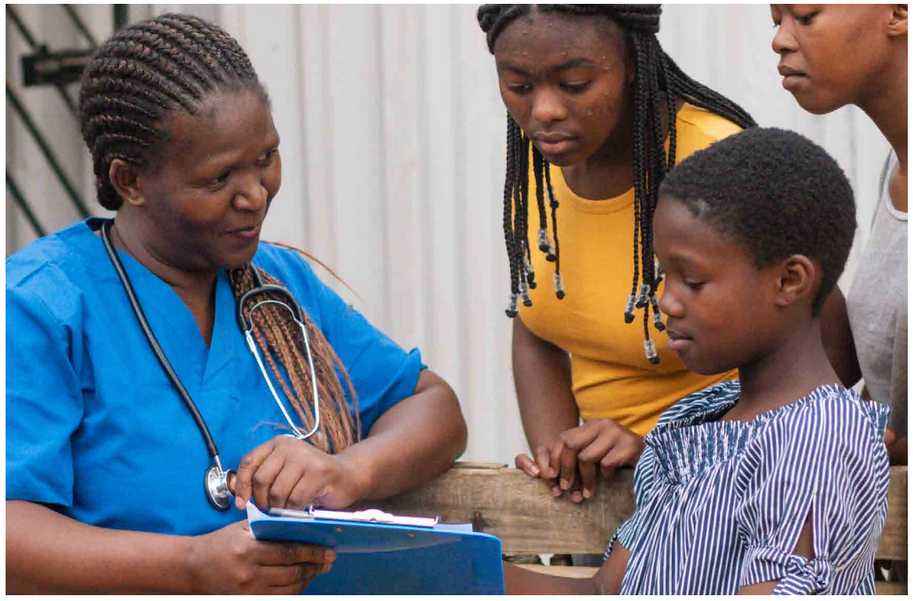
Follows are some highlights of this coordination and research work, all undertaken in the last 12 months. This brief summary helps spotlight the real breadth and impact of the global research effort in this area.

1 Global trials test the effectiveness of promising treatments against major health threats

Since the early stages of the COVID-19 pandemic, numerous randomized controlled trials (RCTs) have been initiated to address unmet clinical needs. Notably, global platform trials have emerged as an evaluation approach in clinical research in response to outbreaks and pandemics. Examples of trials include the WHO Solidarity trials, RECOVERY, the Randomized, Embedded, Multi-factorial, Adaptive Platform trial for Community-Acquired Pneumonia (REMAP-CAP), among others.

The outcomes of several of these trials have influenced the development of guidelines globally for the treatment of COVID-19 patients.

The Solidarity PLUS global platform trial has evaluated seven potential treatments in the clinical management of COVID-19. These drugs were chosen after careful consideration by independent experts for their potential to reduce mortality. Across the whole trial, thousands of patients have been randomized in over 50 countries with 600 hospitals taking part.



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2 Global trials test the effectiveness of promising vaccines against major health threats

WHO facilitated worldwide research efforts to develop and deploy COVID-19 vaccines, and sponsored numerous consultations to support research to determine the most effective way to evaluate and use COVID-19 vaccines. Similarly, it supported consultations on vaccine evaluation for Plague and Marburg, Sudan. WHO also sponsored the Solidarity Trial Vaccines (STV) of COVID-19 vaccines. This continues to collect vaccine efficacy data from thousands of volunteers. In 2024, WHO will publish safety and efficacy data on a COVID-19 vaccine from the STV.

Clinical trials of potential vaccines against Ebola (in Uganda) and Marburg disease (in Tanzania/Philippines) were also coordinated and planned in 2022 at rapid pace – but strong infection control and public health measures, as part of the emergency response, were effective in reducing prevalence rates of both diseases to undetectable levels. The trials may still take place in the future if further outbreaks occur.

These global platform clinical trials testing both vaccines and treatments are now seen as an approach to provide robust high-quality global answers to important public health questions.

The experience has indicated that clinical trials in the context of outbreaks need to be of high quality. Affected countries (and local researchers) must be in the driving seat and part of a global collaborative effort to design CORE protocols. These must be discussed and pre-approved ahead of time.

Since outbreaks often occur in areas with very limited infrastructure and can be of short duration, the trial design needs to allow for possible innovation. Importantly research must be fully integrated in the outbreak response team's remit. In brief, trial design in the context of outbreaks necessitates and benefits from innovation and simplification of procedures. This should not affect quality however. Simple does not and must not mean low quality.

3 Global and national collaboration to help drive improvements in rapid detection, monitoring and tackling of emerging pathogens crossing the human-animal-environment interface

The newly established WHO Scientific Advisory Group on the Origins of Novel Pathogens (SAGO) has continued to work with a range of national and local partners to improve the rapid detection, monitoring and evolution of emerging zoonotic pathogens and ensure coordination of rapid control measures. As part of this work, the Food and Agriculture Organization (FAO), the World Organisation for Animal Health (WOAH) and the World Health Organization (WHO) have rolled out national bridging workshops in 46 countries so the food, animal health, human health, and agriculture sectors strengthen their collaboration at the human-animal-environment interface, while improving their compliance to international standards.

4 New epidemiological initiatives help drive better data, decisions and outcomes

The WHO Unity Studies global initiative has provided a pandemic preparedness and readiness framework for conducting epidemiological studies to rapidly assess pathogen transmissibility, population susceptibility/immunity and infection severity – as well as aid identification of population groups in need. The data will help target interventions and assess their effectiveness.

Meanwhile researchers working collaboratively to assess indoor airborne risk have been producing evidence and tools to inform actions to mitigate airborne transmission of SARS-CoV-2. The group has, in consultation with a wide range of national and international experts, developed an innovative online tool to assess the risk of SARS-CoV-2 airborne transmission in indoor residential, public and health care settings (https://partnersplatform.who.int/aria) as well as training tools for using it.

5 Supporting the delivery of better surveillance of dangerous pathogens across the world

Health emergency intelligence and surveillance has helped support better global and national surveillance by providing technical input into a deep dive study implemented by the International Association of National Public Health Institutes (IANPHI)

This has explored the status of national surveillance systems and the extent to which integrated data surveillance (IDS) systems have been developed and operationalized. Key recommendations included establishing and formalizing professional networks to strengthen workforce, building an environment of interoperable data and systems across all sectors, and strengthening national public health agencies (NPHAs) to catalyse key surveillance systems.

6 A key global clinical database/platform has been expanded to log and identify the clinical impact of dangerous pathogens on patients

The pivotal WHO Global Clinical Platform was originally set up for COVID-19 - but now includes clinical data for cholera, filoviruses (generic), mpox and acute hepatitis of unknown origin. The database, which stores over one million anonymized, standardized patient files from around the globe is a critical resource for the global research community to increase understanding of the clinical impact on patients of new or re-emerging infectious pathogens.

7 Infection prevention and control (IPC) continue to be rigorously evaluated against different pathogen threats

Major literature reviews have been undertaken, and peer-reviewed articles published, to underpin evidence-based IPC recommendations for COVID-19, mpox, Ebola and Marburg disease. This work has included comparing the effectiveness of medical masks versus filtering facepiece respirators for health workers providing care to COVID-19 patients, as well as developing standards for disinfection of surfaces, laundering of linens, and hand hygiene in health care and community settings on caring for patients with mpox.

Another major area of work was evaluating infections and exposure risks, for health workers.

8 Providing vital support for low and middle-income countries (LMICs) in accelerating regulatory clearance for lifesaving COVID-19 medical interventions

WHO regulatory teams assisted national regulatory authorities (NRAs) in nearly 150 LMICs to issue approximately 5,500 expedited regulatory clearances for agreed emergency use listing (EUL) COVID-19 vaccines.

9 Driving and promoting key international standards for the manufacturing, licensing and approval of medical interventions to combat deadly pathogens

The biological standardization research area delivered key international measurement standards to facilitate the development and regulatory convergence of vaccines, diagnostics and therapeutics relevant to priority pathogens.

10 Updating ethics guidance to underpin research and clinical actions during a pandemic

All actions to combat pandemics should be ethical, inclusive and sustainable. One key example of recent work in this area has been updating the pivotal monitored emergency use of unregistered and experimental interventions (MEURI) ethical framework. This provides the world with definitive ethical guidance for the expanded use of unproven clinical interventions outside clinical trials during public health emergencies – a practice which surged during the COVID-19 pandemic.

11 Supporting local action to engage communities in policy and research during pandemics

Community engagement work is important before, during and after an outbreak.

Engaging communities early in the research process can help researchers understand the questions that are most relevant to key populations and help them design clinical trials and other studies that affected groups are willing to participate in.

WHO has delivered tools, materials and capacity-building resources for local and national teams to work with communities and key stakeholders to develop and deliver research on key pathogen threats (such as COVID-19, mpox and Ebola), including clinical trials testing new medical interventions to address these threats.

12 Expanded capacities for evidence and analytics to strengthen risk communication, community engagement and infodemic management for emergency response

The actions that members of the public take make a big difference in outbreaks.

Strong risk communication and community engagement (RCCE), and infodemic management, are key to promote uptake of public health and safety measures (PHSM) and to build and maintain trust.

Increasingly evidence and analytics are used to underpin these technical areas of emergency response. Over the past 12 months alone, 150+ studies were conducted at country and regional level, with multiple waves of data collection and analysis, to inform policy and practice. The new WHO-led Trust Initiative also aims to deepen and develop the global health community's understanding of trust and translate this understanding into concrete actions that build trust prior to epidemics and sustain it during emergencies.

In the area of infodemics, over 1,300 infodemic managers from 142 countries have now been trained in infodemiology and evidence-based approaches to managing infodemics.

Global research – building on the lessons learned during the pandemic

While COVID-19 still affects virtually every part of the world, its health, social and economic effects have been significantly reduced, thanks to the medical countermeasures and other tools we now have. Global research has played a major role in developing these protective measures and in moving COVID-19 from a state of 'global health emergency' into a new era of monitoring and management.

In the final chapter of this report, we discuss how the global research community is already learning the hard-won lessons from the pandemic, and building on the connections and platforms that were made. This is to ensure the world is ready for the next event.

SECTION 2

The research conitinuum – critical work delivered before, during and after outbreaks

The history and value of the research continuum – delivering critical work before, during and after outbreaks

The Constitution of the World Health Organization (WHO) states that one of WHO's key roles is to promote, conduct and coordinate research in the field of health.

In May 2015, the 68th World Health Assembly (WHA) welcomed the development of an R&D Blueprint for Epidemics, in consultation with Member States and relevant stakeholders, for accelerating research and development (R&D) in epidemics or health emergency situations where there are no, or insufficient, preventive and therapeutic medical countermeasures.

The vision of the WHO R&D Blueprint for Epidemics is a world where diagnostics, medicines and vaccines are available to prevent and respond to epidemics across the world.

The Mission of the WHO R&D Blueprint for Epidemics is to achieve its vision by coordinating and accelerating global research work to:

- target diseases that threaten humanity
- develop diagnostics, medicines and vaccines fast
- respond to outbreaks, preventing epidemics

The mission also calls for a comprehensive end-to-end approach to research. It is essential before, during and after outbreaks and pandemics. We will look at the achievements and priorities of different research areas in detail in this section.

Finally, it is important to stress that coordinating and accelerating global research must promote universal values.

With regards to a collaborative effort to ensure access to medical countermeasures, some have emphasized the importance of speed and sometimes cost in responding to future pandemics. It is equally important to take a broader view that recognizes the primary importance of quality, equity in availability, and trust in the product's safety and efficacy.

The COVID-19 pandemic saw a truly augmented and integrated research response which helped accelerate the testing of vaccines, treatments and diagnostics, but also underpinned public policy, regulatory and communications initiatives to tackle the spread of disease and reduce its health and social harms.

The WHO R&D Blueprint for Epidemics's mission calls for a comprehensive end-to end approach to research. It is essential before, during and after epidemics.

The COVID-19 pandemic truly saw an augmented and integrated research response which helped accelerate the testing of vaccines, treatments and diagnostics, but also underpinned public policy, regulatory and communications initiatives to tackle the spread of disease and reduce its health and social harms.

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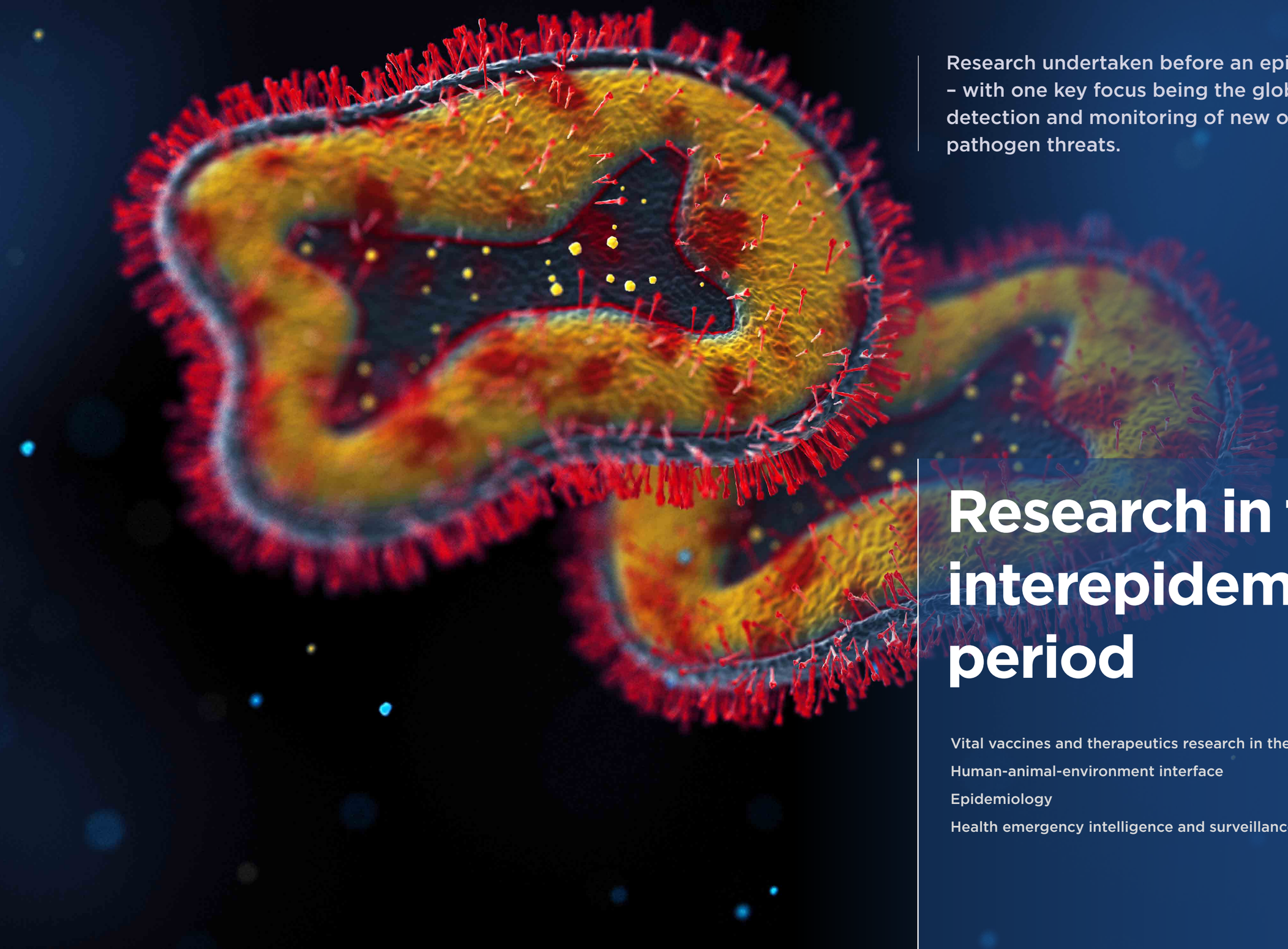
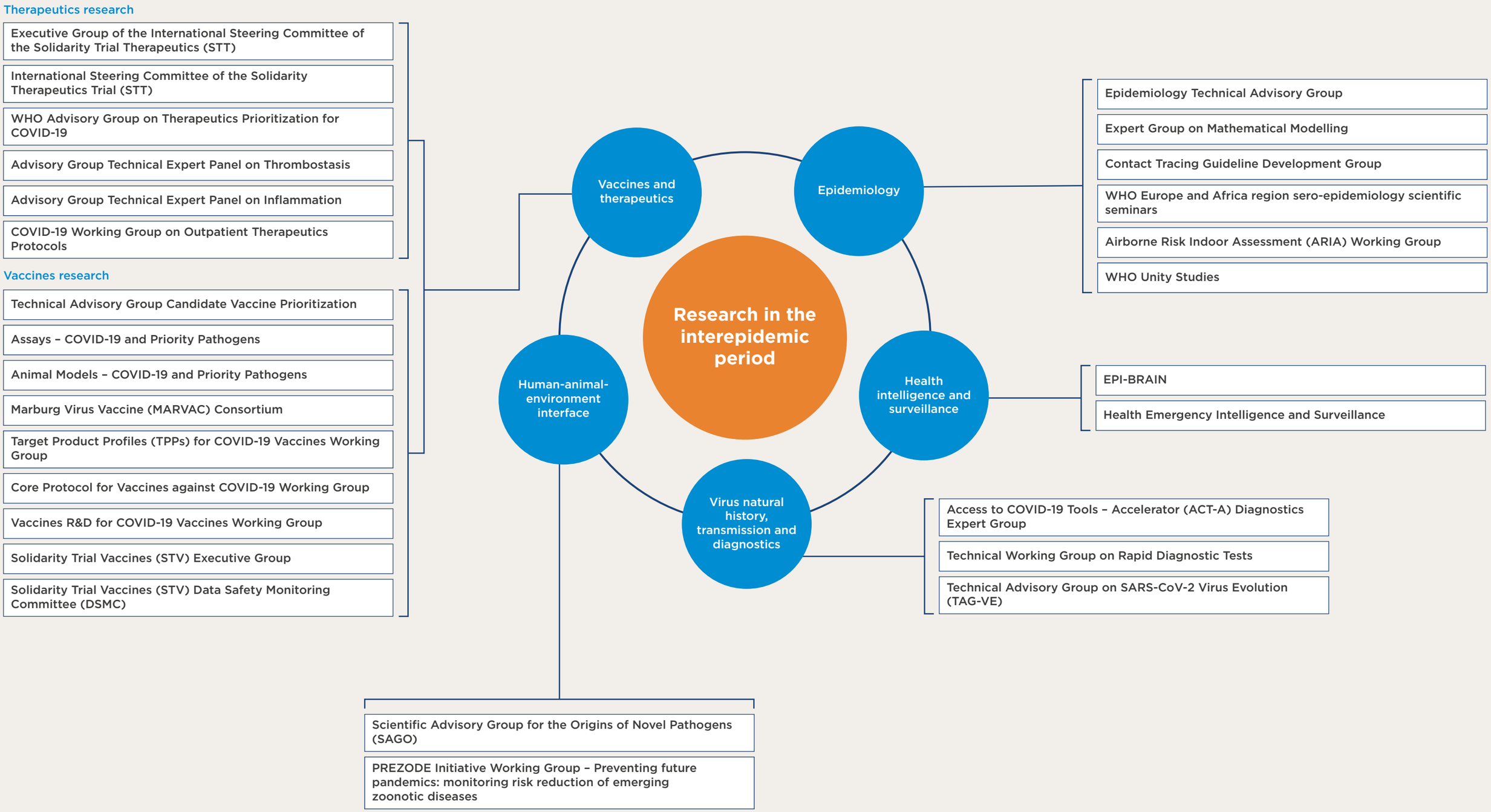


Research undertaken before an epidemic is critical – with one key focus being the global prioritization, detection and monitoring of new or existing pathogen threats.

Research in the interepidemic period

Research in the interepidemic period: Global network of expert groups/committees coordinated by the WHO R&D Blueprint for Epidemics



Vital research preparations to combat the next global threat

In the interepidemic period, all research areas, ranging from epidemiology to health intelligence and surveillance, learn lessons from previous outbreaks and make intensive preparations for the next event. Each area broadly analyses and publishes evidence to help formulate forward plans, guidance, actions and resources to be rapidly enacted and deployed when the next outbreak occurs.

Focusing on the centrepiece role of vaccines and therapeutics research, work during the interepidemic period and beyond:

- provides reliable data to evaluate the quality of vaccines and therapeutics
- promotes the equity of their distribution
- facilitates trust in their safety and efficacy
- ultimately saves lives and improves outcomes in future outbreaks and pandemics

For viral and bacterial families identified as being major outbreak/pandemic risks, WHO has convened and will continue to convene consultations to develop R&D Roadmaps for vaccines, therapeutics, and diagnostics.

This pivotal work during the interepidemic period leads to:

Global and regional level

- Development of a **landscape of candidate products** in the pipeline and their status regarding development and evaluation
- Creation of **Target Product Profiles (TPPs)** outlining the public health perspective
- **Pre-outbreak trial design** considerations
- **An independent process for prioritization** of vaccine and therapeutics candidates for inclusion during trials conducted in the context of outbreaks
- **A virtual process** to ensure that candidate vaccines and therapeutics are funded and available for rapid international delivery in vials thus deployment for use in studies that will collect data that are needed
- An open convening of **collaborative scientific networks** to rapidly conduct/support research during outbreaks
- Identification of **research priorities** for other areas
- Creation/maintenance of **legal and insurance frameworks** needed to conduct studies of investigational vaccines and therapeutics

Country and subregional level

- Development of a **collaborative research framework** (including all key international stakeholders) with the countries at risk in the driving seat including in protocol design and implementation
- **Ministries of Health designated researchers** and research institutions (to lead research during outbreaks) being identified and collaborating across various countries at risk
- Clarity regarding **national regulatory pathways**
- **Pre-approved CORE protocols** for both randomized controlled trials (RCTs) and expanded access use and/or MEURI. Approval by national regulatory authorities (NRAs) and ethics committees in countries at risk for use during an outbreak integrated as part of the outbreak response
- **Support of national research capacity** of designated national research institutions for the implementation of pre-approved research protocols

Human-animal-environment interface

The interaction of humans, animals and the environment in a changing world

Introduction

An estimated 75% of emerging infectious diseases are of zoonotic origin. Recent examples include mpox, COVID-19, Ebola and Middle Eastern respiratory syndrome (MERS).

The key aim of this research thematic area is to better understand the interface between humans, animals and the environment regarding zoonotic pathogens of epidemic and pandemic potential to reduce the risk of transmission.

Objectives

- **Assessing the origins of novel pathogens of epidemic and pandemic potential**
  The WHO Scientific Advisory Group on the Origins of Novel Pathogens (SAGO) was established in November 2021 following the World Health Assembly (WHA)'s recommendations. These gave the WHO Director-General the mandate to bring together international experts from diverse backgrounds to guide scientific and collaborative studies into the origins of all emerging and re-emerging high-threat pathogens (HTPs), including SARS-CoV-2, to prevent future epidemics and pandemics.

- **Developing risk mitigation strategies at the human-animal-environment interface**
  Newly emerging zoonotic diseases often come with limited knowledge on the animal reservoirs and/or major routes of transmission between animals and humans. Increasing our collective understanding of the susceptibility of animals, risks of reservoir formation, the evolution of pathogens in animal hosts, modes and drivers of transmission between animals and humans, and new interfaces between human and animals in a changing environment, is critical to establishing effective risk mitigation strategies during public health crises.

- **Fostering multisectoral collaboration to jointly manage zoonotic threats**
  Effective response to zoonotic disease outbreaks requires coordination between the human, animal, and environment health sector (among others). The Quadripartite Organizations - the Food and Agriculture Organization of the United Nations (FAO), the United Nations Environment Programme (UNEP), the World Organisation for Animal Health (WOAH, founded as OIE), and WHO – are supporting Member States with resources to enhance operational collaboration between all sectors relevant to manage zoonotic diseases. They have launched the One Health Joint Plan of Action which outlines the commitment of the four organizations to collectively advocate and support the implementation of One Health.

Increasing our collective understanding of the susceptibility of animals, risks of reservoir formation, the evolution of pathogens in animal hosts, modes and drivers of transmission between animals and humans, and new interfaces between human and animals in a changing environment, is critical.

Achievements

Follows are the main achievements in human-animal-environment interface research for COVID-19/other key diseases and pathogens in the past 12 months:

1 Assessing the origins of novel pathogens of epidemic and pandemic potential

WHO published SAGO's first preliminary report on 9 June 2022. In this report, SAGO provided WHO with key recommendations on critical studies that are needed to better understand the emergence or re-emergence of pathogens with epidemic and pandemic potential.

The report also included a plan for its upcoming global framework for studying the emergence of pathogens by outlining critical studies needed in human and animal studies at the human-animal interface and in the environment where and when such pathogens are detected.

For SARS-CoV-2, SAGO offered its recommendations on critical studies that continue to be urgently needed in China and around the world that would provide additional information and contribute to a better understanding of how SARS-CoV-2 entered the human population and spread.

In December 2022, SAGO published a second report summarizing its recommendations for studies to be conducted to better understand the origins and factors for the emergence and re-emergence of mpox using the global framework. To date, SAGO has held 17 plenary meetings, including two face-to-face meetings, and numerous working group meetings.

2 Understanding susceptibility of animals, risks of reservoir formation, the evolution of pathogens in animal hosts, and modes of transmission between animals and humans

WHO is working together with international organizations, national institutions, academia, and other partners in charge of animal health, to improve the rapid detection, monitoring and evolution of emerging zoonotic pathogens and to ensure coordination of rapid control measures.

As an example, for the risk of spillback of emerging zoonosis from humans to animals, during the COVID-19 pandemic, SARS-CoV-2 was shown to have a large animal host range, established continuous circulation in a wildlife reservoir (white-tailed deer), and infected pets and farmed fur animals.

Circulation in animals may hamper elimination strategies for pathogens, but SARS-CoV-2 also quickly adapted to novel hosts, resulting in viral evolution. On the other hand, continuous spillover from animal reservoirs into the human population leads to local human suffering. But it also harbours the constant risk of a wider spread in the human population, as seen in the 2022-2023 multicountry outbreak of mpox.

Working with our partners at FAO and WOAH, several documents were published including joint risk assessment and guidance on increasing surveillance in animals, as well as on reducing the risk of spillover and spillback.

3 Fostering multisectoral collaboration to jointly manage zoonotic threats

Taking a multisectoral, One Health approach is necessary to address complex health threats at the human-animal-environment interface, such as emerging zoonotic diseases. The Tripartite Organizations – FAO, WOAH and WHO – have rolled out National Bridging Workshops in 46 countries. These allow the different sectors to strengthen their collaboration at the human-animal-environment interface, while improving their compliance to international standards and regulations.

In addition, over 20 countries have installed a One Health catalyst to implement the resulting joint One Health roadmaps to improve collaboration, and more than 50 countries have used the Tripartite Zoonosis Guide (TZG) operational tools to improve their collaboration in critical technical areas for managing zoonotic threats, such as joint risk assessment or joint surveillance and information-sharing.

Future priorities

Follows are the main priorities for 2023-2024 in human-animal-environment interface research in this area:

- The next SAGO output is the "WHO global framework to define and guide studies into the origins of emerging and re-emerging pathogens of epidemic and pandemic potential", which SAGO hopes to finalize by the end of Q4 in 2023. The SAGO will continue to meet in plenary and working groups to apply the global framework to advancing our understanding of where the SARS-CoV-2 virus originated. The SAGO will also apply the global framework to other emerging or re-emerging pathogens, as it has done for mpox.

- There is an urgent need to increase and fund the development, coordination and implementation of multisectoral research agendas in the context of emergencies, to rapidly fill critical knowledge gaps at the human-animal-environment interface impacting the response capacities to zoonotic threats.

- Enhancing coordination between the various institutional actors involved in zoonotic disease management remains a priority. The development of joint technical capacities needs to be further promoted to improve countries' preparedness for zoonotic disease outbreaks, using operational tools developed by the Quadripartite and its partners. An institutionalized, multisectoral environment will also promote optimal use of practical research conducted at the human-animal-environment interface.

Epidemiology

Producing key evidence and standardizing protocols to underpin the world's readiness and response to dangerous pathogens

Introduction

The epidemiology research area has focused on two key initiatives in this period: airborne risk indoor assessment (ARIA) and the WHO Unity Studies.

Follows are the objectives, achievements and future priorities for these pivotal initiatives.

Collaborating to assess indoor airborne risks (ARIA)

Providing evidence and tools to inform actions to mitigate airborne transmission of SARS-CoV-2

The European Organization for Nuclear Research (CERN) and WHO have had a mutual collaboration agreement since 2013. During COVID-19, the two organizations have identified a new area of mutual interest: airborne transmission of SARS-CoV-2.

The departments of Epidemic and Pandemic Preparedness (EPP), Strategic Health Operations (SHO) and Environment, Climate Change and Health (ECH) have had an ongoing collaboration with CERN for the past two years to develop this project.

Objectives

- Convene a multidisciplinary working group to define a standardized algorithm to quantify airborne risk transmission in indoor settings.
- Develop an online, user-friendly tool to enable users and building managers to assess airborne risk transmission in residential, public and health care settings and therefore implement risk reduction measures; the tool is composed of a complex model that was developed to quantify the risk of SARS-CoV-2 airborne transmission in a standardized manner (using a standardized model) in residential, public and health care settings). It is essential to informing non-pharmaceutical risk reduction measures, such as increasing ventilation, air cleaning and disinfection, source control interventions, and controlling the occupancy, as well as to communicating the risk and enabling informed decisions by the occupants.
- Provide a standardized methodology manual and recommended threshold values for this model to inform policy and regulatory interventions related to indoor air quality and infectious diseases.
- Adapt and apply the model to other respiratory infections.

Achievements

Follows are the main achievements of the the collaborative research to assess indoor airborne risks (ARIA) for COVID-19/other key diseases and pathogens in the past 12 months:

1 Key evidence review and risk assessment tools to underpin this work

The ARIA Working Group has so far convened numerous times throughout 2022 to conduct a rapid review of building ventilation and transmission of airborne diseases, reviewed all relevant airborne risk assessment tools published, reviewed and presented during the International Society of indoor Air Quality and Climate (ISIAQ) webinar "modelling infection risk from indoor aerosol exposure to SARS-CoV-2", as well as the COVID Airborne Risk Assessment (CARA) tool presented during a WHO expert panel meeting.

2 Delivery of innovative online tool to assess SARS-CoV-2 airborne transmission risk in different settings

The working group has, in consultation with national and international expert members of the WHO's Global Infection Prevention and Control Network (GIPCN), the WHO's Environment and Engineering Control Expert Advisory Panel (ECAP) for COVID-19, the WHO's Expanded Programme on Immunization (EPI) Group, and the WHO Secretariat, developed an online user-friendly tool to assess SARS-CoV-2 airborne transmission risk in indoor residential, public and health care settings (https://partnersplatform.who.int/aria). A manual on the method and application of the creation of this tool was developed and will be soon made available online, alongside a training course on OpenWHO.

Future priorities

What follows are the research priorities for 2023-2024 related to airborne transmission of SARS-CoV-2, with implications for other airborne pathogens and future outbreaks/pandemics thereof.

The first three objectives are intrinsically linked in providing public health guidance on the inhalation (airborne) transmission mechanism of SARS-CoV-2. The fourth objective aims to study the possibility of developing a novel mechanism to automatize and systematize knowledge extraction from literature reviews, and applying this model to additional pathogens.

WHO would like to expand this project to:

- further improve the ARIA web app to increase accessibility and accuracy
- further improve the model and, most importantly, expand to other respiratory pathogens (e.g. TB, influenza, etc.)
- enable automatic data extraction to update model parameters (this was previously done by hand through multiple systematic reviews for each variable)
- automatize and improve the systematic literature review process through the development of a "natural language processing (NLP) engine" for systematic reviews

Unity Studies

Creating equitable opportunities for enhanced surveillance, operational capacity-building and global knowledge-sharing

Objectives

The WHO Unity Studies global initiative provides a pandemic preparedness and readiness framework for conducting targeted investigations and epidemiological studies that are critical to the risk assessment of any emerging or re-emerging respiratory pathogens of pandemic or epidemic potential.

The WHO Unity Studies initiative is intended to be used to rapidly assess transmissibility, estimate population susceptibility/immunity and infection severity, aid identification of population groups in need to target interventions, and assess effectiveness of interventions (e.g. vaccine effectiveness).

Achievements

The Unity Studies provided a standardized and timely international investigation framework during the COVID-19 pandemic. The suite of existing pandemic preparedness early investigation protocols was rapidly adapted for SARS-CoV-2 and promoted globally for the implementation of standardized and quality investigations and epidemiological studies.[1] Of note in the last 12 months:

1 Global data analysis and tools to inform key public health actions

Aggregation and analysis of global results shared with WHO has facilitated several pooled analyses generating much needed robust and comparable results to inform national, regional and global public health actions.[2,3,4]

2 Tools and guidance help connect researchers and investigators to implement key investigations and epidemiological studies

In parallel, this work has led to the development of guidance and tools to help the optimal design and critical appraisal of investigations and epidemiological studies by supporting partners.[5,6,7] An external evaluation[8] showed that the initiative created equitable operational research and enhanced surveillance opportunities, connected researchers and investigators and expertise across countries, and facilitated study implementation.

3 Delivery of key seminars and online workshops

Continuation of monthly seroepidemiology scientific seminars in WHO Africa and Europe regions. Provision of online workshops and tailored support on statistical analysis and data management in collaboration with key partners, Serotracker, University of Melbourne, and EpiConcept.

4 Showcasing investigations and epidemiological studies from low and middle-income countries (LMICs)

To reduce the publication bias towards high-income countries (HICs), development of a Special Issue on Unity Studies in Influenza and Other Respiratory Diseases (the "Journal"). The special issue shall consist of approximately 23 manuscripts from only LMICs who have participated in the Unity Studies initiative.

Future priorities

Building on the lessons learned during the COVID-19 pandemic and for the Unity Studies to be operational during a future pandemic, WHO is planning to:

- update and develop standardized protocols for disease-specific aspects and others that are fit for purpose for any novel respiratory virus of pandemic potential
- build a global network of sites, which can be primed to conduct one or more country-specific standardized, pre-planned and pre-approved investigations and epidemiological studies in the event of a pandemic
- support quality implementation and dissemination of results through the development and use of toolkits for (i) WHO and (ii) implementing partners. Real-time data-sharing and other processes involving multisite data coordinated by WHO to enable timely sharing of results
- publish online and open-access the Special Issue on Unity Studies in Influenza and Other Respiratory Diseases (the "Journal")

The WHO Unity Studies initiative is intended to be used to rapidly assess transmissibility, estimate population susceptibility/immunity and infection severity, and aid identification of population groups in need.

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Health emergency intelligence and surveillance


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Health emergency intelligence and surveillance work has the aim of catalysing transformation in collaborative surveillance across all levels and serving countries by connecting, innovating, and strengthening capabilities to produce better data, analytics and decisions.

Through its “innovate” role, it aims to transform academic research into pioneering new tools and approaches that fit country and regional contexts.

Objectives

One of three strategic objectives of health emergency intelligence and surveillancw work is introducing and adapting effective solutions to meet country needs to improve the analysis and sharing of high-quality surveillance data. This entails enhancing decision-making through the integration of data from a broad range of sources by pioneering innovative approaches.

Achievements

Follows are the main achievements of health emergency intelligence and surveillance work for COVID-19/other key diseases and pathogens in the past 12 months:

1 International Association of National Public Health Institutes (IANPHI) integrated disease surveillance (IDS) – global study

This area of work provided technical input into a deep dive study implemented by the IANPHI to explore the status of national surveillance systems and the extent to which IDS systems have been developed and operationalized.

This study was divided into three projects which includes: i) a systematic literature scoping review ii) a survey of IANPHI members, and iii) seven deep dives in three high-income countries (HICs), and four low and middle-income countries (LMICs), undertaken April-October 2022.

The study led to six key recommendations:

- Guiding definition for IDS
- Establishing and formalizing professional networks to strengthen workforce
- Facilitating opportunities for surveillance research, evaluation and learning
- Aligning resource needs with sustainable investment and funding
- Building an environment of interoperable data and systems across all sectors
- Strengthening national public health agencies (NPHAs) as catalysts for IDS

2 Anomaly detection for public health intelligence (PHI)

PHI digital solutions such as the epidemic intelligence from open sources (EIOS) system, and the communities that use them, do not currently utilize automated threat detection, identification, and alerting – a need that was made increasingly evident through the COVID-19 pandemic. The challenge faced is the ability to rapidly identify meaningful patterns, evolving changes and parallel threats, with a data influx that continues to exponentially grow.

This complex and innovative initiative incorporates automated mechanisms to identify unusual or unexpected events for PHI. Areas covered include the emergence of new COVID-19 strains, unusual increases in counts or affected populations, events linked to vaccination, and new rumours or misinformation campaigns.

3 Integrated Outbreak Analytics (IOA)

Integrated Outbreak Analytics (IOA) applies a multidisciplinary approach to understanding outbreak dynamics and to inform outbreak response. It is primarily a field-based initiative that leverages support from national, regional, and international experts to reinforce pre-existing local capacity to better respond to outbreaks and their impacts on communities in a holistic and evidence-based manner. Its members consist of experts from organizations and institutions with an international public health emergency mandate and/or a global health operational research agenda.

In 2022, a standing IOA cell was established in the Democratic Republic of Congo (DRC), and several short-term IOA cells were set up during emergencies. In addition, operational research into the case for collecting, analysing and utilizing sex-disaggregated data and gendered data to inform outbreak responses was conducted.

4 Global One Health Intelligence Scoping Study (OHISS)

Vast amounts of data are captured across the One Health spectrum yet are insufficiently coordinated and leveraged to support better integration of health services across the human, animal and environmental sectors.

This study set out to develop best practices and a framework for an improved platform for effective sharing of One Health information. This entailed mapping of existing information systems and platforms within Tripartite Organizations, international organizations, other international systems/ networks, and the programmes within WHO Member States.

5 Mpox Analytics and Parameter Repository

In efforts to better understand the 2022 multicountry mpox outbreak, a specialized community of practice of infectious disease modellers was established to access, analyse and understand data on mpox transmission dynamics, as well as inform interventions to reduce risk for further spread.

The challenges they had to overcome included:

- limited access to data as well as limited insights from the data available
- limited sharing and comparison of models and related components
- lack of sharing of analytical tools (e.g. packages used)
- lack of central content repository
- limited adoption of collaboration and communication tools beyond email

In leveraging the Repository, an initiative led by the WHO Hub for Pandemic and Epidemic Intelligence, a virtual space was made available to stakeholders from Ministries of Health and national action plans for health security (NAPHSs) to test and jointly develop models. This allowed for joint comparison of models, relevant assumptions, estimates and projections, prior to wider release.

Future priorities

Follows are the main priorities for 2023-2024 of health emergency intelligence and surveillance work:

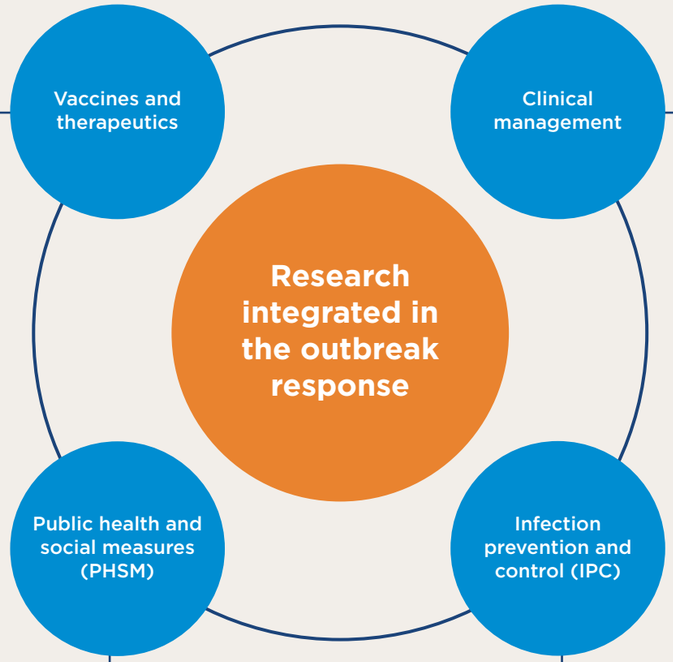
- In collaboration with IANPHI, socialize and support the implementation of the six resulting recommendations in the context of health emergency preparedness response and resilience (HEPR).
- Following the current prototyping and testing stages, incorporate the new mechanisms and solution into existing PHI digital solutions, with further iteration and scaling with the community of users.
- Continue to document of the added value of using IOA to inform decision-making processes during public health emergencies. IOA assessment of the current integration of sex and gender data across the outbreak response, and participatory assessment of the capacity of response actors to systematically integrate the collection, analysis and use of sex-disaggregated data and gender data into the response, are critical priorities.
- Protype, develop and scale a global One Health intelligence System (OHIS).
- Outline potential future transmission scenarios for mpox beyond the ongoing 2022-2023 outbreak, and be able to foresee the potential spreading dynamics, within and outside the men who have sex with men (MSM) community through expert consultation.

During a disease outbreak, different plans and strategies across all the research areas are rapidly enacted.

A core focus of this phase is delivering major clinical trials of promising vaccines and treatments quickly and robustly.

Research integrated in the outbreak response

Research integrated in the outbreak response: Global network of expert groups/committees coordinated by the WHO R&D Blueprint for Epidemics



Therapeutics research

- Executive Group of the International Steering Committee of the Solidarity Trial Therapeutics (STT)
- International Steering Committee of the Solidarity Therapeutics Trial (STT)
- WHO Advisory Group on Therapeutics Prioritization for COVID-19
- Advisory Group Technical Expert Panel on Thrombostasis
- Advisory Group Technical Expert Panel on Inflammation
- COVID-19 Working Group on Outpatient Therapeutics Protocols

Vaccines research

- Technical Advisory Group Candidate Vaccine Prioritization
- Assays – COVID-19 and Priority Pathogens
- Animal Models – COVID-19 and Priority Pathogens
- Marburg Virus Vaccine (MARVAC) Consortium
- Target Product Profiles (TPPs) for COVID-19 Vaccines Working Group
- Core Protocol for Vaccines against COVID-19 Working Group
- Vaccines R&D for COVID-19 Vaccines Working Group
- Solidarity Trial Vaccines (STV) Executive Group
- Solidarity Trial Vaccines (STV) Data Safety Monitoring Committee (DSMC)

Clinical management

- WHO O2CoV2 - Oxygen Requirements and Approaches to Respiratory Support in COVID-19 Patients in LMICs study
- O2CoV2 International Steering Committee
- Clinical Severity Working Group
- Therapeutics and COVID-19 Guideline Development Group
- Clinical Management of COVID-19 Guideline Development Group
- Drugs to Prevent COVID-19 Guideline Development Group
- Filovirus Viral Haemorrhagic Fever (VHF) Working Group
- Mpox Guideline Development Group
- PMA Expert Working Group – Heparin, SGLT2
- Post-COVID-19 Expert Working Group
- Atlas for Mpox Lesions Working Group
- Clinical Characterization and Management Working Group
- Risk Factors for Severe or Fatal COVID-19 in the Paediatric Population
- Clinical Network/Emerging Diseases Clinical Assessment and Response Network (EDCARN)
- Neurology and COVID-19 Global Forum

Public health and social measures (PHSM)

- Public Health and Social Measures (PHSM) Working Group
- Public Health and Social Measures (PHSM) Methods Working Group (informal)

Infection prevention and control (IPC)

- Infection Prevention and Control (IPC) R&D Expert Group
- Global Infection Prevention and Control (IPC) Network
- WHO Infection Prevention and Control (IPC) Hub
- Infection Prevention and Control (IPC) in the Context of COVID-19: Guideline Development Group
- Infection Prevention and Control (IPC) for Ebola/Marburg Disease Guideline Development Group
- Clinical Management and Infection Control for Mpox Guideline
- Working Group Reviewing Mpox Disinfectant Protocol
- Public Health Emergencies of International Concern (PHEIC) Working Group (and subgroups)

Vital vaccines and therapeutics research in the outbreak response

At the heart of the global response against deadly outbreaks

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Despite research being essential in underpinning preparations for outbreaks and pandemics, the unpredictable nature of these events means core uncertainties will only ever be addressed by conducting research during the health emergencies themselves.

All research areas will rapidly adapt and refine their pre-epidemic plans and put them into action to help in the coordinated collaborative research effort.

With their capability to prevent and treat serious illness over an extended period of time, vaccines and therapeutics are an essential component of any integrated response to outbreaks and pandemics. A core focus of this outbreak phase is delivering major clinical trials of promising vaccines and treatments quickly and robustly.

While speed (and sometimes cost) in responding to future pandemics is often emphasized, it is imperative to take a broader view that recognizes the primary importance of vaccine quality, equity in availability, and trust in a product's safety and efficacy.

Drawing on these key principles, R&D Roadmaps will be refined and developed during a disease outbreak or pandemic. This leads to:

Global and regional level

- Development of an **updated list of prioritized vaccine and therapeutics** candidates for inclusion during trials conducted in the specific outbreak
- **Activation of the facilitated process** to ensure that prioritized candidate vaccines and therapeutics are promptly deployed for use in studies integrated into the outbreak response. Such studies are initiated within two weeks of the declaration of an outbreak
- Prompt convening of the relevant **collaborative scientific networks** to update on the situation and mobilize support research during the specific outbreak
- **Support for RI priorities** previously identified and mobilized
- Activation of **legal and insurance frameworks** needed to conduct studies of investigational vaccines and therapeutics

Country and subregional level

- **Ministries of Health designated researchers** and research institutions (to lead research during outbreaks) activated and engaged with relevant international scientific networks
- **Final approval of CORE protocols** for both randomized controlled trials (RCTs), and expanded access use and/or MEURI obtained
- **Support of national research capacity** of designated national research institutions for the implementation of pre-approved research protocols mobilized to fill any remaining gaps

The key steps involved in the development and evaluation of medical countermeasures (MCMs) are also summarised in Figure 4 on page 52.

Achievements

Follows are the main achievements in vaccines and therapeutics research for COVID-19/other pathogens in the past 12 months:

1 Completing core elements of R&D Roadmaps for the majority of priority pathogens

As noted above, WHO has completed elements of R&D Roadmaps for most of the pathogens on its 2018 priority list of diseases with epidemic or pandemic potential.

2 Convening experts to update R&D Roadmaps for specific virus families

Recently, WHO refined this strategy and convened multiple consultations to support updated R&D Roadmaps for beta-sarbecoviruses, filoviruses, and mpox.

3 Ensuring rigorous, transparent approaches to reliable data collection to build public confidence

During an emergency such as a pandemic, there can be pressure to make decisions quickly based on limited clinical data. But public confidence in vaccines and therapeutics depends on the rigour and transparency with which data are collected. WHO has convened consultations to discuss approaches to collecting reliable data during the COVID-19 pandemic, and plans more of such meetings for priority viral and bacterial families.

4 Global consultations on the most effective use of COVID-19 medical countermeasures

WHO facilitated worldwide research efforts to develop and deploy COVID-19 vaccines and sponsored numerous consultations to support research to determine the most effective way to evaluate and use COVID-19 vaccines. Similarly, it supported consultations on vaccine evaluation for Plague, and Marburg, Sudan.

5 Sponsoring the global Solidarity platform trials for COVID-19 vaccines and therapeutics

WHO sponsored the global Solidarity Trial Vaccines (STV) of COVID-19 vaccines and the Solidarity Trial Therapeutics (STT) and Solidarity Plus. These continue to collect critical efficacy data. In early 2024, WHO will publish safety and efficacy data for both trials.

Future priorities

Follows are the main priorities for 2023-2024 in vaccines and therapeutics research in this area:

- The WHO R&D Blueprint will continue to refine existing R&D Roadmaps and complete additional viral and bacterial R&D Roadmaps, including for key viral families and bacteria identified in the current pathogen prioritization process. WHO will also convene a consultation to discuss current needs and gaps for plague vaccines.
- WHO will continue to convene experts to discuss and provide advice on seamless clinical trial designs, an approach used by developers in the COVID-19 pandemic to rapidly collect data, and which holds promise for other priority viral and bacterial families.
- Starting in 2023, WHO has convened international meetings to discuss standards for performing and reporting observational vaccine effectiveness studies in the context of outbreaks and pandemics. Such studies were an important part of the COVID-19 pandemic response, but were not always well conducted and it is important to consolidate learning from the pandemic.
- WHO will convene experts to discuss results and lessons learned from the global Solidarity platform trials for COVID-19 vaccines and therapeutics, sponsored by WHO.
- WHO will convene experts to discuss development and validation of correlates of protection for priority pathogens, potentially to allow vaccine efficacy to be predicted by immunogenicity data in certain cases.

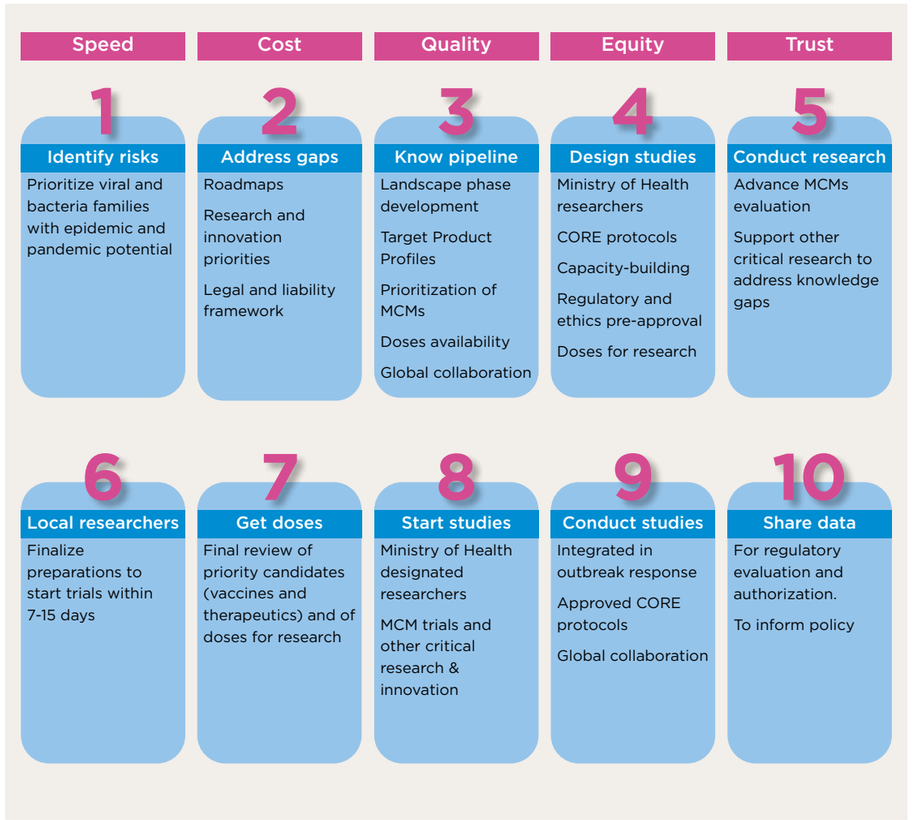
Coordinate and facilitate worldwide research efforts to develop vaccines and therapeutics to address future outbreaks and pandemics.

The central role of research in future outbreak and pandemic response, as well as the dependence of rapid and trustworthy results upon international collaboration, free of political considerations, is widely recognized. WHO has the mandate and ability to coordinate such public health preparation and response on a global level.

WHO will continue to:

- convene consultations on ethical and regulatory approaches to vaccines and therapeutics against priority pathogens
- facilitate the pandemic treaty discussions. They will also contribute to building global plans for pandemic/outbreak medical and non-medical countermeasures
- further promote coordination of funders, researchers, regulators, developers, governments, NGOs, prescribers, and end-users via global forums, to create a transparent and open network of networks

Figure 4 shows the key steps involved in the development and evaluation of medical countermeasures (MCMs) – as part of WHO R&D Blueprint for Epidemics

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Filoviruses family research and innovation – a pathfinder

Filovirus outbreaks are a major challenge for African countries, and due to the lethal nature of the disease they cause, have considerable epidemic potential.

Based on previous experience, WHO and the Ministries of Health of the affected countries have been developing and implementing plans to speed the deployment of candidate vaccines and therapeutics for clinical studies in the context of future outbreaks.

Although in the most recent outbreak of Sudan virus in Uganda, novel candidate vaccines were available for the initiation of efficacy studies in record time (within 79 days), WHO's goal is to make vaccines available for clinical evaluation within days 7-15 of outbreak identification in a subsequent outbreak, as has been done during Ebola Zaire outbreaks since 2016. For Zaire Ebola virus (ZEBOV) since 2016, ring vaccination has started 4-13 days after the outbreak has been reported to WHO.

Since 2022, WHO has been facilitating the formation of a research consortium led by Ministries of Health designated researchers. This is prepared to rapidly deploy filovirus candidate vaccines and therapeutics and will generate necessary clinical efficacy data in a future filovirus outbreak, integrated in the outbreak response. It will use pre-approved multiphase CORE protocols whose implementation will be led by researchers and institutions designated by Ministries of Health.

The R&D Blueprint for Epidemics and the Marburg Virus Vaccine (MARVAC) Consortium experts and collaborators launched a new filovirus research roadmap entitled Agenda for Filovirus Research and Monitoring (AFIRM).

WHO and MARVAC are planning a workshop to build on this new filovirus agenda and the important lessons learned such as the Uganda experience.

The planned objectives of the workshop are to:

- foster collaboration for evaluating filovirus candidate vaccines and therapeutics within outbreak responses, led by Ministries of Health and national research teams
- give the opportunity to national researchers and authorities to discuss existing trial protocols for candidate filovirus vaccines and therapeutics towards final consensus on key trial design attributes
- support a framework for an OPEN collaborative network of designated filovirus researchers in "at risk" countries with MARVAC members and other stakeholders. The framework aims to support clinical research preparedness and ensure that clinical research is integrated promptly into future outbreak responses

It is anticipated that representatives of all countries at risk of filovirus outbreaks will attend, including:

- Ministry of Health representative
- Ministry of Health-designated research institutions and primary investigators (PIs) who will lead the research integrated in the outbreak response
- Ministry of Health national regulatory authority (NRA) and ethics committee
- Members of the MARVAC Consortium
- Other invited experts

The workshop will be hosted by the Ministry of Health and organized by the three levels of WHO – global, regional and country.

Clinical management

Optimizing clinical management of COVID-19 patients and clinical care in large-scale health emergencies

Introduction

The Clinical Characterization and Management Working Group of the R&D Roadmap has brought together approximately 60 clinicians and researchers from around the world with the shared objective of accelerating the generation and dissemination of knowledge about the optimal clinical management of patients with COVID-19.

Our activities in the past year build on projects previously established and reported. In addition, working group members have been active in many other areas, including responses to other outbreaks of emerging and re-emerging infectious diseases, sharing this overall goal, and harmonized with, though not coordinated by, the working group. This work has evolved in three broad areas.

Achievements

Follows are the main achievements in clinical management research for COVID-19/other key diseases and pathogens in the past 12 months:

1 Development of metrics for the characterization and stratification of COVID-19

Following on from our earlier creation of a Minimal Common Outcome Measure set for COVID-19 (Lancet ID, 2020), we have used a Delphi process to produce a clinical case definition of Post-COVID Condition (Lancet Infect Dis. 2022 Apr;22(4):e102-e107) and developed a core outcome set for studies of Post-COVID Condition (Lancet Respir Med 10(7):715-724). Work to develop revised severity criteria for COVID-19 is ongoing.

2 Developing guidance and providing advice on emerging issues in the ethics of infectious diseases

We developed a novel method for the rapid pooling and reporting of data from recently finished and ongoing clinical trials – the prospective meta-analysis (PMA) – and a working sub-group – the REACT Working Group – to develop these.

We coordinated the publication of these in JAMA, working with the editorial team there to expedite publication, as well as to facilitate simultaneous publication of the participating trials in JAMA or its affiliated journals, as appropriate.

We further worked with the guidelines working group and the BMJ to incorporate these as well as the living COVID-19 guidelines. We followed up our PMA on the use of corticosteroids (JAMA 2020) and interleukin-6 receptor antagonists (JAMA 2021) with a PMA on full-dose anticoagulation (manuscript submitted, under review), and of SGLT2 inhibitors (manuscript submitted, under review). An additional PMA on antiplatelet agents (ASA and P2Y12 inhibitors) has been discussed but deferred, pending completion of the two active meta-analyses.

In addition, we worked with partners to use the Living Network Meta-Analysis approach to evaluate therapeutics for COVID-19 on a rolling basis and rapidly inform the WHO COVID-19 clinical practice guidelines. This has led to 13 updates of the WHO living guidelines.

3 Clinical studies of oxygen availability and respiratory support strategies in low and middle-income countries (LMICs)

A critical challenge during the pandemic, particularly in LMICs, was the ability to provide oxygen and respiratory support to patients with severe COVID-19. Compounding that challenge was a paucity of information on what resources were available and how they were being used.

We have undertaken an analysis of the availability of medicinal oxygen during the pandemic (under review) and initiated the WHO O2CoV2 study, a prospective cohort study of oxygen use, respiratory resources, and clinical outcomes in more than 3,000 patients from 23 different LMICs.

Data were shared with study investigators at online meetings 1-3 May 2022. They will be reported, and used to inform the design of a planned collaborative platform trial to evaluate the relative clinical and resource effectiveness of differing strategies for respiratory support for severe acute respiratory infections (planned for 2024).

4 Access to investigational products for high-threat pathogens (HTPs) under the MEURI framework as an adjunct to randomized controlled trials

Since mid-2022, the WHO Clinical Research Working Group has supported the implementation of MEURI protocols during three outbreaks: i) Access to tecovirimat for mpox under an emergency use protocol, ii) access to antivirals, including mAbs for Sudan virus in Uganda (descriptive analysis ongoing), and iii) access to antivirals for Marburg virus in Equatorial Guinea (manuscript submitted, under review).

5 Collection of standardized individual clinical and facility level data using the WHO Clinical Platform to inform public health response

Since the inception of the pandemic, WHO has launched the Clinical Platform that now hosts over one million anonymized hospitalized patient files and has informed multiple clinical characterization and management reports for COVID-19 (see bibliography) around the world. This is as well as periodically updating the COVID-19 clinical dashboard that provides the public with interactive sessions with global and regional data.

More recently, WHO expanded the scope of this platform to provide standardized clinical case record forms and a data platform for other emerging infectious diseases (EIDs), including cholera, filoviruses (generic), mpox and acute hepatitis of unknown origin. Contribution of data is ongoing in all of these areas.

6 Key performance indicators

Development of transparent and trustworthy key performance indicators (KPIs) is important to monitor and evaluate interventions. This was indeed the case during the pandemic where large-scale investments were made to scale up medical oxygen production at national and sub-national levels. The Oxygen Emergency Task Force (part of the ACT-A) partners asked WHO to provide guidance on this aspect. WHO conducted a Delphi process to publish the first global KPIs on the medical oxygen ecosystem.

Future priorities

As the pandemic has waned, we have begun to shift our focus to address longer term needs for an effective future pandemic response, and to consider how the lessons learned during the COVID-19 pandemic can be applied to advance a global health goal of continuously improving and equitable health care for all, informed by clinical science that is integrated into the provision of that care.

The following next steps that pertain to each of the numbered achievements show how this can be applied in the future:

- Develop and apply standard methods to develop disease severity classification for other emerging infectious diseases (EIDs).
- Apply rapid evidence synthesis and transformation into clinical practice guidelines for other EIDs to improve care in a timely fashion.
- Develop and implement a WHO interventional trial on non-invasive respiratory interventions for severe acute respiratory infections/acute hypoxemic respiratory failure in LMICs using a collaborative approach amongst clinical platform trial networks.
- Develop a standard approach to the operalization of expanded access protocols to ensure MEURI principles are maintained.
- Develop a pan-respiratory pathogen clinical surveillance tool to augment epidemiologic data and inform readiness and response for circulating respiratory pathogens with epidemic and pandemic potential.
- Develop and implement observational, multicountry and multisite cohort studies for EIDs to enhance our understanding of clinical evolution and clinical management to improve clinical both short and longer term outcomes.
- Develop other key performance indicators (KPIs) for other key interventions that support scalable safe clinical care during health emergencies.

Infection prevention and control (IPC)

Readiness and response research and innovation (RI) for public health emergencies

Introduction

The COVID-19 pandemic highlighted significant gaps in the understanding of how transmission modes influence prevention measures and what are the most effective practical tools for protection and control in the context of emergencies due to novel high-threat pathogens (HTPs) of epidemiologic concern.

Objectives

In collaboration with experts from many countries, the WHO Infection Prevention and Control (IPC) team focused on the following research areas:

- Understanding risk factors in exposures to SARS-CoV-2 and other pathogens in the health care work environment.
- Rethinking existing IPC medical devices and equipment based on key enabling technologies.
- Defining pragmatic protocols for guiding local implementers in executing safe and effective IPC practices.
- Working with laboratory experts to bridge knowledge gaps on how to deactivate novel pathogens.
- Establishing research and innovation (RI) priorities which should be brought to the attention of the international community.

Achievements

Follows are the main achievements in IPC research for COVID-19/other key diseases and pathogens in the past 12 months.

1 **Peer-reviewed publications of COVID-19 IPC work**

With respect to COVID-19, the team supported and/or coordinated studies resulting in 13 peer-reviewed publications in the last year.[1]

2 **Global case control study assessed SARS-CoV-2 infection risk factors for health workers**

The IPC team led a global case control study assessing risk factors for health workers, which included data from 121 health care sites across 21 countries and is now under peer review for publication. Its findings indicate that SARS-CoV-2 infection risk was associated with non-adherence to personal protective equipment (PPE), not performing hand hygiene consistently, and being in close contact with infected patients; however, the study suggests that there was no difference in infection risk between the type of masks worn for routine care.

3 **Tested innovative approaches with facepiece respirators[2] in the community**

A novel surveillance approach was piloted in community settings using poly-vinyl alcohol strips embedded in filtering facepiece respirators to enable capture of exhaled breath as a non-invasive testing approach for SARS-CoV-2.

4 **Delivered a major trial comparing medical masks versus filtering facepiece respirators**

WHO supported the data analysis portion of a randomized controlled trial (RCT)[3] comparing medical masks versus filtering facepiece respirators for health workers providing care to COVID-19 patients.

5 **Conducted virtual tabletop simulations[4] to aid learning**

A study on virtual tabletop simulations for helping IPC teams implementing international guidance into their specific clinical contexts was conducted, demonstrating that simulation tools can provide significant benefits to IPC and safety improvements worldwide.

6 **Delivered key studies[5] on decontamination procedures**

Studies on decontamination procedures were conducted, including the use of Methylene Blue (MB) photochemical treatment, demonstrating the efficacy of MB + light (ultraviolet, phosphorescent or sunlight) in decontaminating medical masks, filtering facepiece respirators, and other PPE items contaminated with a range of dangerous pathogens.

7 **Assessed the safety of reusing decontaminated medical masks and other protective equipment**

Researchers also assessed the safety of reusing medical masks and filtering facepiece respirators decontaminated with MB, finding no persistent risk of chemical exposure to the wearer when MB is applied for decontamination at recommended levels. In the study, 13 face shield designs were tested in the laboratory and among 600 health workers in middle-income countries (MICs); users reported preferences towards face shields due to good communication, secure fixture, good visibility, comfort and fashion.

8 **Various key studies – including scoping review on barriers[6] to PPE implementation**

A scoping review on barriers to PPE implementation and interventions concluded that effective PPE measures implementation involves multilevel transdisciplinary complexity and relies on context-driven implementation strategies, which should leverage solid collaboration among local and international health bodies. Finally, a live systematic literature review commissioned by WHO to assess risk factors for SARS-CoV-2 infection in health workers[7] is on its 18th update in 2023.

9 **Analysing innovative methods – including using drones[8] to improve access to IPC supplies**

A simulation study demonstrated how a scalable fleet of drones can be used to improve accessibility of essential supplies, equipment and remote care in remote areas. A systematic literature review was also delivered and published exploring the use of key enabling technologies (i.e. robots, internet of things and artificial intelligence – AI) for IPC.

10 **IPC studies and work beyond COVID-19**

Beyond COVID-19, other pathogen thematic research areas included: i) mpox deactivation protocol to provide reference standards for disinfection of surfaces, laundering of linens, and hand hygiene in health care and community settings where patients with mpox are cared for; ii) better understanding of contextual factors linked to IPC measures in relation to Ebola disease management in health facilities and Ebola treatment units (ETUs) through an ethnographic study, survey, and in-depth interviews of health workers in multiple countries; iii) systematic literature reviews to support evidence based IPC recommendations for COVID-19, mpox, Ebola and Marburg disease; iv) two systematic reviews to understand the burden of health care-associated (HAI) infection and antimicrobial resistance in primary care facilities, as well as effectiveness of interventions to prevent pathogens spread in these settings; v) a position paper describing IPC research needs for IPC for Ebola disease and Marburg disease is under development through a research prioritization exercise with contributions from an expert panel.

11 **Working group for IPC in public health emergencies**

A working group for IPC in public health emergencies has been established with a mandate to identify best response and implementation approaches and define immediate and longer term IPC research priorities and implementation considerations.

12 **IPC Hub continuing to monitor IPC implementation worldwide**

At the same time, the WHO IPC Hub has been progressing a programme of work for monitoring IPC implementation worldwide. The first WHO global survey on IPC programme at the national level conducted in 2021-2022 showed that only 3.8% of 106 participating countries met all the WHO IPC minimum requirements; however, it also showed improvement of several IPC indicators compared with 2017-2018.

Future priorities

Plans for the coming year for the World Health Emergencies (WHE) IPC programme of work are to strengthen IPC preparedness, operational readiness and response in the context of public health emergencies, including:

- IPC technical guidelines for Ebola and Marburg disease, and mpox
- health care-associated infection (HAI) cluster and outbreak investigation handbook for health facilities for epidemic-prone respiratory infections
- a scientific brief on IPC and water, sanitation and hygiene (WASH) innovations in emergencies

Plans for the coming year for the IPC Technical and Clinical Hub programme of work to strengthen IPC in primary health care (PHC) include the launch of a suite of WHO resources with a focus on PHC. These are:

- an assessment tool on IPC minimum requirements for PHC care facilities[9]
- an infographic and inventory document to facilitate PHC workers' access to all available WHO resources for the prevention of surgical site infection[10]
- a training package for improving IPC in PHC and to pilot implementation of an IPC improvement package

Public health and social measures (PHSM)

Providing global evidence on the effectiveness and impact of PHSM for emergency preparedness and response

Introduction

Public health and social measures (PHSM) are an essential part of critical interventions during health emergencies alongside medical countermeasures. PHSM refer to a broad array of non-pharmaceutical interventions implemented by governments, individuals and communities to reduce the risk and scale of transmission of epidemic and pandemic-prone infectious diseases.

Objectives

- Conduct global monitoring and reviews of PHSM data and research to support countries in accessing and using multidisciplinary and context-specific knowledge about PHSM to strengthen understanding about PHSM effectiveness, unintended negative consequences and implementation strategies.
- Strengthen PHSM research methodology and capacity to support countries in conducting research using a harmonized conceptual understanding of PHSM and addressing methodological, legal, ethical and political challenges of PHSM research.
- Increase precision in PHSM decision-making to support countries in developing their own equitable, context-specific PHSM policies that are informed by robust evidence while taking into account epidemiological and socioeconomic impacts.
- Systematically integrate PHSM into existing health emergency management plans, policies, financing, governance and leadership in all relevant sectors at national, subnational and local levels across the health emergency spectrum of action.

Achievements

Follows are the main achievements for 2023-2024 in PHSM research in this area:

1 Global research agenda 2021-2030

WHO is developing a global research agenda on PHSM during health emergencies to strengthen the global evidence base on its effectiveness and impact. This research agenda is developed through a multistep, consultative process. Urgent research priorities for PHSM in the context of COVID-19 have been compiled through a global public survey, following the identification of six research themes at the global technical consultation on PHSM in 2021.

2 Conceptual framework of PHSM

WHO is developing a conceptual framework of PHSM to have a shared language, structured thinking and understanding of how PHSM operate to reduce risk and scale of transmission, to enable a comprehensive description of measures, their stringency, target population, settings, outcomes and other factors influencing their effectiveness. The initial draft framework was published in 2023.

WHO is developing a global research agenda on PHSM during health emergencies to strengthen the global evidence base on their effectiveness and impact.

3 A series of global evidence reviews

Preliminary results of the global evidence reviews on i) the effectiveness and impact of PHSM, and ii) social protection policies to mitigate the unintended negative consequences of PHSM during the COVID-19 pandemic are available.

4 PHSM 2023-2025 planning

A WHO high-level global PHSM workplan was developed with six WHO regions to set the pace of global actions and uphold the sense of urgency, quality and scale needed to address future health emergencies through PHSM in a systematic and evidence-informed manner.

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Future priorities

To support countries in PHSM implementation during future health emergencies that is informed by the best available evidence on its effectiveness and impact, as well as equitable and context-specific, the PHSM initiative is focusing on the following research activities in 2023-2024:

- Develop PHSM study protocols: To ensure the high-quality and timely generation of data on the effectiveness of PHSM during health emergencies, WHO is developing study protocols for several diseases and interventions. The protocols will be accompanied by key considerations to address ethical and implementation challenges in conducting effectiveness research for emergency preparedness and response.
- Develop global guidance on PHSM monitoring: WHO is developing a global multi-hazards guidance and online toolkit for monitoring PHSM policies and implementation to facilitate systematic and harmonious data collection and use for PHSM decision-making across countries.
- Launch of the global PHSM research database: It will contain the latest global, multilingual, multidisciplinary literature including living systematic reviews and visualization of indexed literature against the global PHSM research agenda and conceptual framework. This facilitates timely monitoring of the implementation of the global PHSM research agenda and functions as the living mapping of PHSM research.
- Finalization of the global research agenda: The second public survey to identify research priorities for PHSM using a multi-hazards approach was launched in October 2023 and the complete research agenda for 2021-2030 will be published thereafter.

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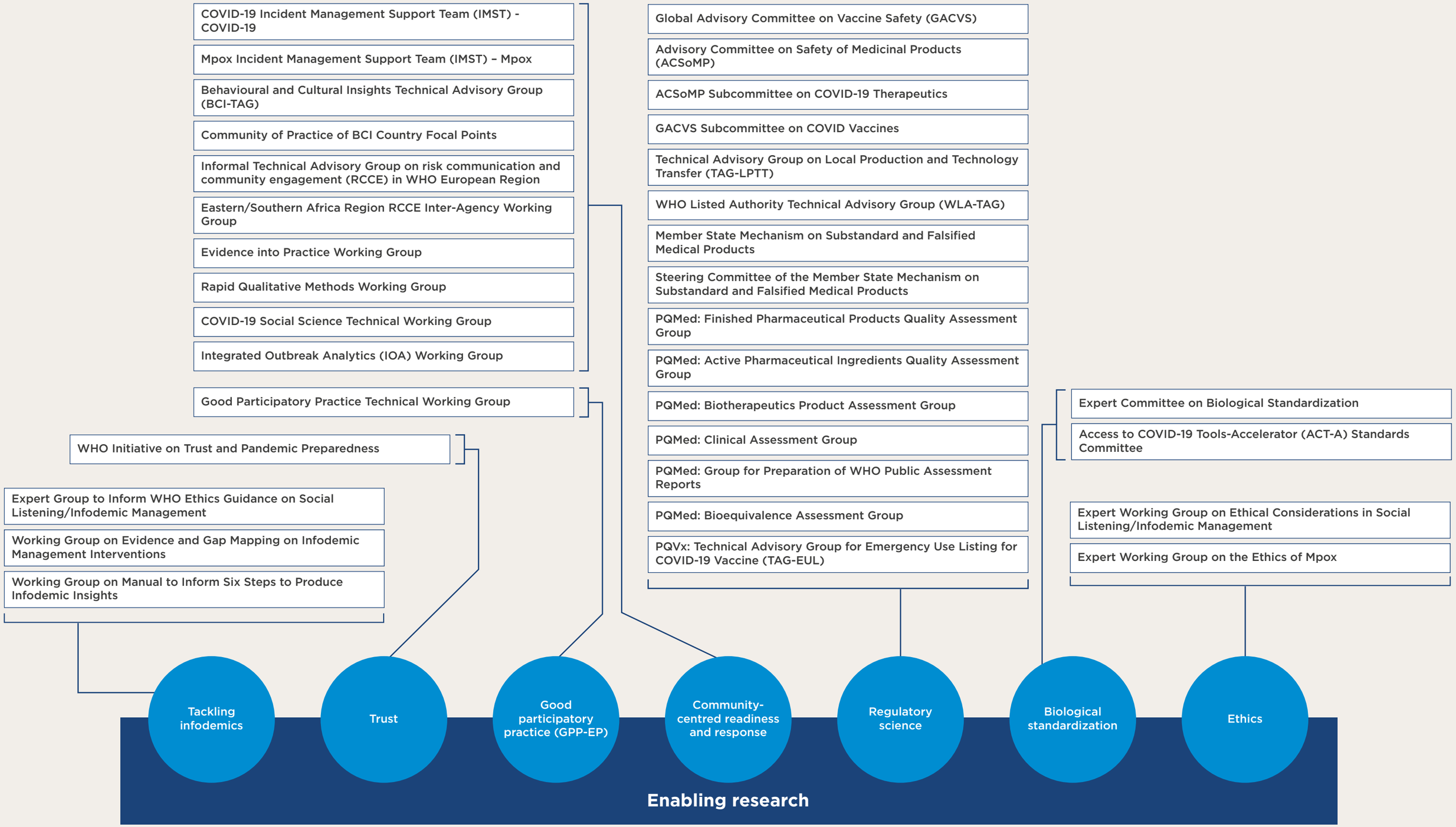
The delivery of effective medical countermeasures and wider policies to combat a disease outbreak is underpinned by a wide range of research areas. They all coordinate and work together enabling the global research effort before and during an outbreak.

Enabling research

Enabling research: Global network of expert groups/committees coordinated by the WHO R&D Blueprint for Epidemics



Regulatory science

Regulatory systems are integral to the public health response: working together to accelerate equitable access to vital medical products

Introduction

Efficient and effective regulatory systems are cornerstones in providing affordable, timely and equitable access to quality-assured diagnostics, medicines and vaccines at all times. But they are even more important during epidemics and pandemics. The COVID-19 pandemic has shown us the critical role of regulators in ensuring the continued supply of existing medicines as well as evaluating the quality, safety and efficacy of investigational treatments and vaccines for emergency use.

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Achievements

Follows are the main achievements in regulatory science research for COVID-19/other key diseases and pathogens in the past 12 months:

1 Facilitating procurement decision-making across the globe to enable greater access to vital medical countermeasures against COVID-19

In a world where 70% of national regulatory authorities (NRAs) have inadequate or weak regulatory systems, the Department of Regulation and Prequalification (RPQ) at WHO has facilitated procurement decision-making of the COVAX Facility, the Global Fund, UN agencies and Member States from low and middle-income countries (LMICs) by assessing investigational diagnostics and vaccines using the WHO emergency use listing (EUL) procedure, and prequalifying medical products. By the end of 2022, RPQ prequalification teams had recommended 42 in vitro diagnostics and 11 COVID-19 vaccines for EUL, and prequalified nine medicines and three biologicals for COVID-19 treatments, as well as 87 cold-chain equipment and immunization devices.

2 Providing vital support for LMICs in expediting regulatory clearance for life-saving COVID-19 vaccines, diagnostics and treatments

In parallel, WHO regulatory teams assisted NRAs in nearly 150 LMICs to issue approximately 5,500 expedited regulatory clearance for EUL listed COVID-19 vaccines. This was through regulatory reliance and a special EUL mechanism to share regulatory information with NRAs under a confidentiality agreement. According to a study published in 2022,[1] ten EUL COVID-19 vaccines contributed to the delivery of 842 million doses of vaccines in LMICS in 2021, averting between 5.1 million and 7.6 million deaths.

With WHO's behind-the-scenes support, over 1.95 billion doses of COVID-19 vaccines have been delivered to 146 countries through COVAX Facility to date. In addition, 40 million quality-assured diagnostic tests and over 32,000 treatment courses of COVID-19 antivirals were distributed through the pandemic response consortium to LMICs. RPQ pharmacovigilance team supported countries and regions with robust guidelines, tools, and innovations for the safety surveillance of COVID-19 vaccines, and, through the Global Advisory Committee on Vaccine Safety (GACVS), provided swift and timely guidance on emerging safety signals.

Strengthening regulatory systems and building capacity for well-trained regulatory experts requires substantial time, investment and commitment within each country. Thus, coordinated efforts to support NRAs during the interepidemic period are essential steps towards building resilient systems against future outbreaks and pandemics. Furthermore, well-functioning regulatory systems are an essential foundation for successful execution of technology transfers, as well as sustainable and consistent local production of diagnostics, medicines and vaccines.

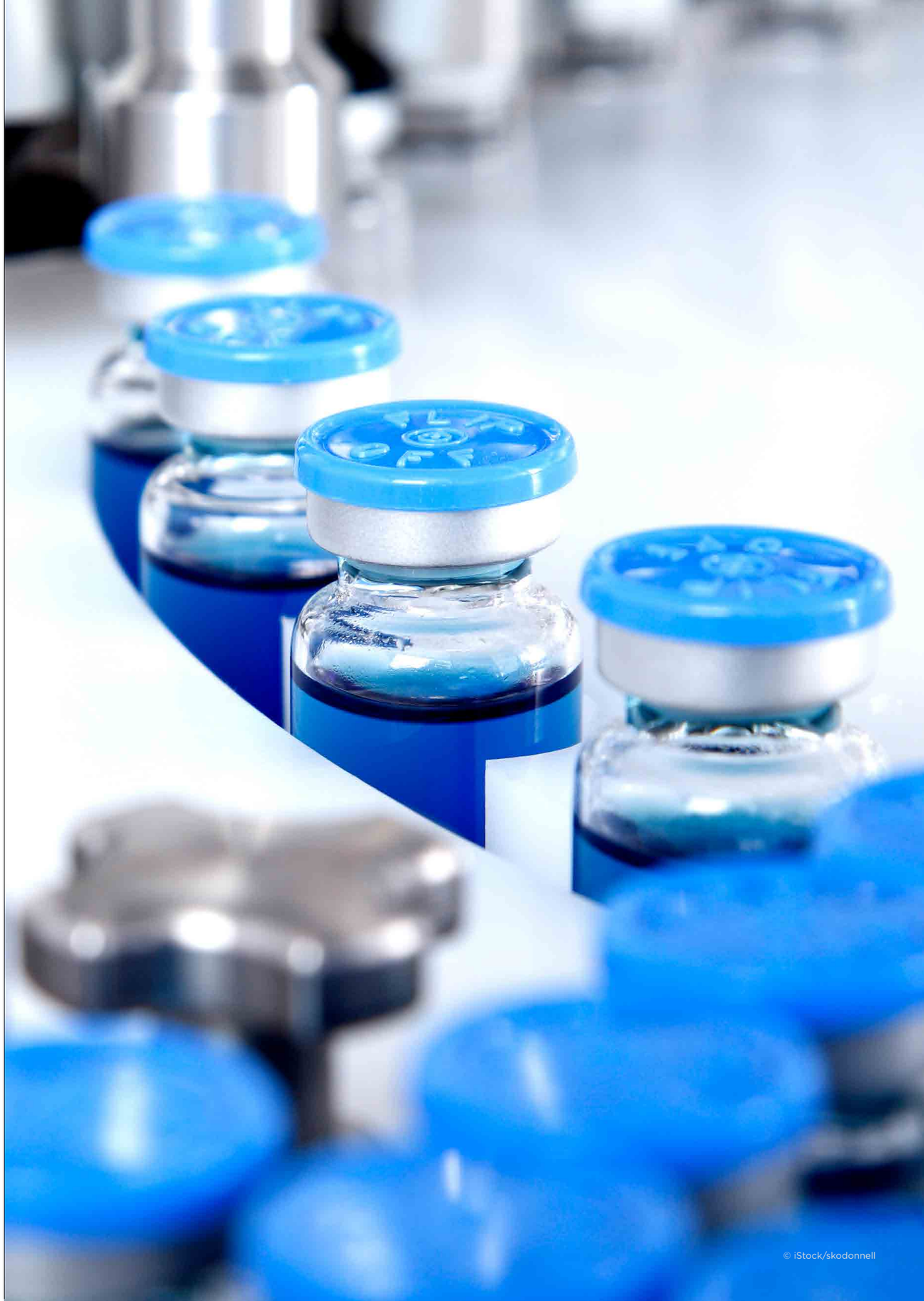
3 Supported national regulatory authorities (NRAs) in LMICs through technical assistance, training and benchmarking, towards functional maturity in medical products regulation

In the past two years, 12 NRAs have reached functional maturity level in medical products regulation and there are numerous other NRAs undertaking the self-benchmarking. Meanwhile, thousands of regulators from around the world have participated in the WHO Department of Regulation and Prequalification (RPQ) subject-specific training programmes to gain in-depth knowledge and build expertise.

Future priorities

WHO has declared COVID-19 to no longer be a public health emergency of international concern (PHEIC). However COVID-19 remains a global health threat. Leveraging the lessons learned from the COVID-19 pandemic, we also need to prepare for other outbreaks and epidemics. Given this, here are the main priorities for 2023-2024 in regulatory science research – and the work of RPQ teams – in this area:

- Continuing to assess quality, safety and efficacy of vaccines, diagnostics, medicines and biologicals that are essential for COVID-19, as well as for diseases affecting LMICs, promoting and providing relevant training for implementing good regulatory practices[2] and good reliance practices[3] to build strong, efficient and sustainable regulatory systems.
- Continuing assisting NRAs in particular in LMICs to assess weakness in their regulatory systems through the WHO Global Benchmarking Tool.[4]
- Contributing further to coordinated regulatory harmonization, conversion and collaboration efforts through the WHO Coalition of Interested Parties (CIP).[5]
- Expanding the collaborative registration procedure (CRP)[6] to enable market entry and national marketing authorizations for prequalification products. Further support countries and regions to enhance their ability to collect, assess and act on safety data and to implement WHO Global Safety Advisory Committees'[7] recommendations.
- Providing specialized technical assistance for strengthening sustainable local production and technology transfer to improve access to quality, safe and effective health products.
- Documenting and analysing the unprecedented agility, flexibility, innovative regulatory approaches and collaborative efforts of a number of regulatory agencies and networks, for example, the International Coalition of Medicines Regulatory Authorities (ICMRA)[8] during the COVID-19 pandemic, to identify bottlenecks and develop coordinated strategies to build resilient and efficient regulatory mechanisms against outbreaks and pandemics for the future.



Biological standardization

Helping increase access to life-saving vaccines, treatments and diagnostics

Introduction

The core focus of biological standardization is to provide international standards to facilitate harmonization of global regulatory requirements, accelerate approval processes, and increase access to diagnostic, preventive and therapeutic medicinal products.

Achievements

Follows are the main achievements in biological standardization research for COVID-19/other key diseases and pathogens in the past 12 months:

1 Delivery of key international measurement standards

International written and measurement standards have been developed through global collaborative effort to facilitate development and regulatory convergence of vaccines, diagnostics and therapeutics, relevant to priority pathogens and beyond.

Measurement standards help assay validation and assessment towards assured quality, and enable comparison of results from different assays or vaccine clinical trials.

The use of the WHO International Standards of SARS-CoV-2 Antibody is important for interpreting results from vaccine clinical trials by providing the basis for the expression of the antibody titres in International Unit (IU).

In particular, from the results from efficacy trials for various vaccine candidates, for example, correlate of protection can be defined as IU/mL. Faced with an evolving antigenically diverse pathogen, there are challenges in maintaining the continuity of the unitage while still providing biologically relevant reference preparations.

WHO international measurement standards have been established to support the development and evaluation of diagnostic, preventative and therapeutic products for infectious diseases including priority pathogens:

- Second WHO International Standard of Anti-SARS-CoV-2 immunoglobulin
- First WHO International Standard of Antibodies to SARS-CoV-2 variants of concern
- First WHO International Reference Panel of Antibodies to SARS-CoV-2 variants of concern
- First WHO International Standard of SARS-CoV-2 antigen
- First WHO International Standard of Lassa virus RNA for NAT-based assays
- First WHO International Standard of Anti-chikungunya virus immunoglobulin G
- First WHO International Standard of Rift Valley fever virus antibodies for use in neutralization assays (serum)
- First WHO International Standard of Rift Valley fever virus antibodies for use in binding assays (serum)

2 Delivery of training and support tools

Following the establishment of WHO standards, continuous support has been provided to users by, for example, organizing trainings and webinars. A WHO manual for the preparation of reference materials for use as secondary standards in antibody testing focusing on SARS-CoV-2 has been developed. Such need for WHO support was reinforced by the unprecedented level of demand for the First WHO International Standard for Anti-SARS-CoV-2 immunoglobulin. This manual provides guidance on the preparation, characterization, calibration, storage and distribution of antibody secondary standards. A future implementation workshop to provide help to users is also being planned.

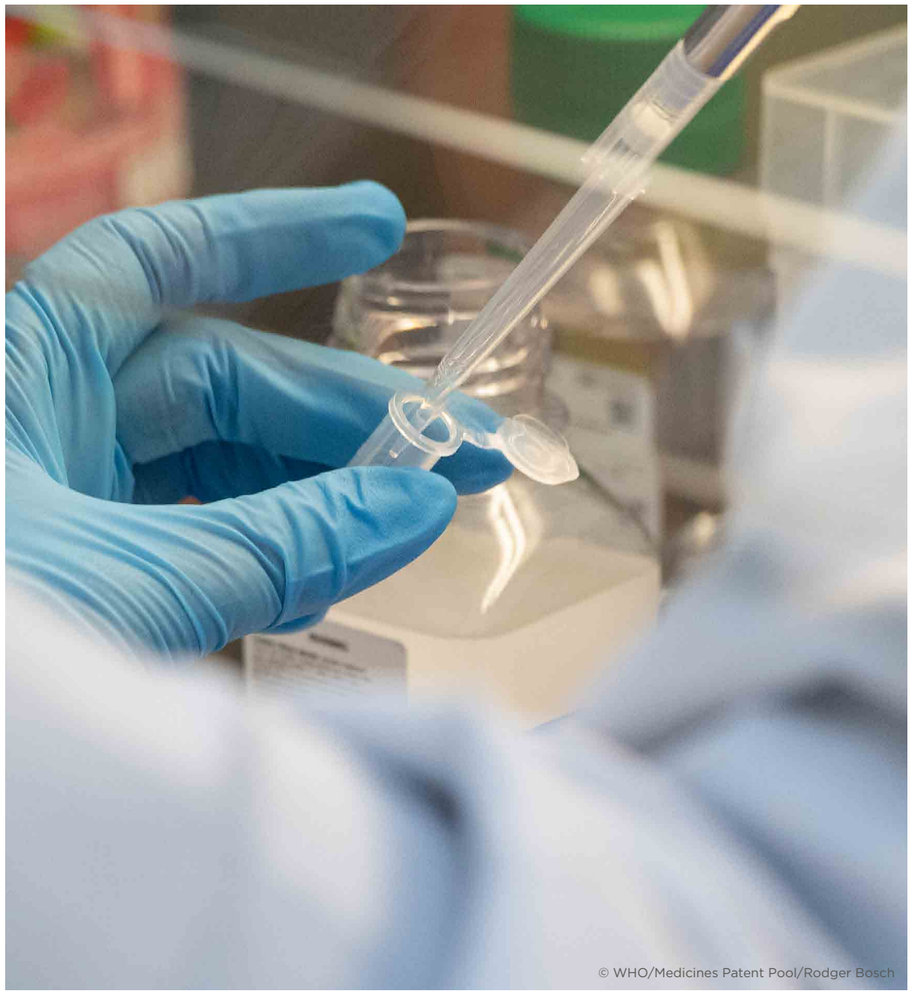
3 Production of key guidelines

Recognizing the paucity of regulatory advice specific to the evaluation of monoclonal antibodies and related products for use against infectious pathogens, guidelines for the production and quality control of monoclonal antibodies and related products intended for medicinal use; and guidelines on the non-clinical and clinical evaluation of monoclonal antibodies and related products intended for the prevention or treatment of infectious diseases, have been developed in broad consultation with worldwide stakeholders.

This is to facilitate harmonization of global regulatory requirements, accelerate approval processes, and increase access to such products that play an important role in rapid response to public health emergencies caused by emerging infectious agents, while continuing to assure their safety and efficacy.

Other relevant WHO guidance that has been developed includes:

- Guidelines on evaluation of biosimilars
- WHO global model regulatory framework for medical devices including in vitro diagnostic medical devices



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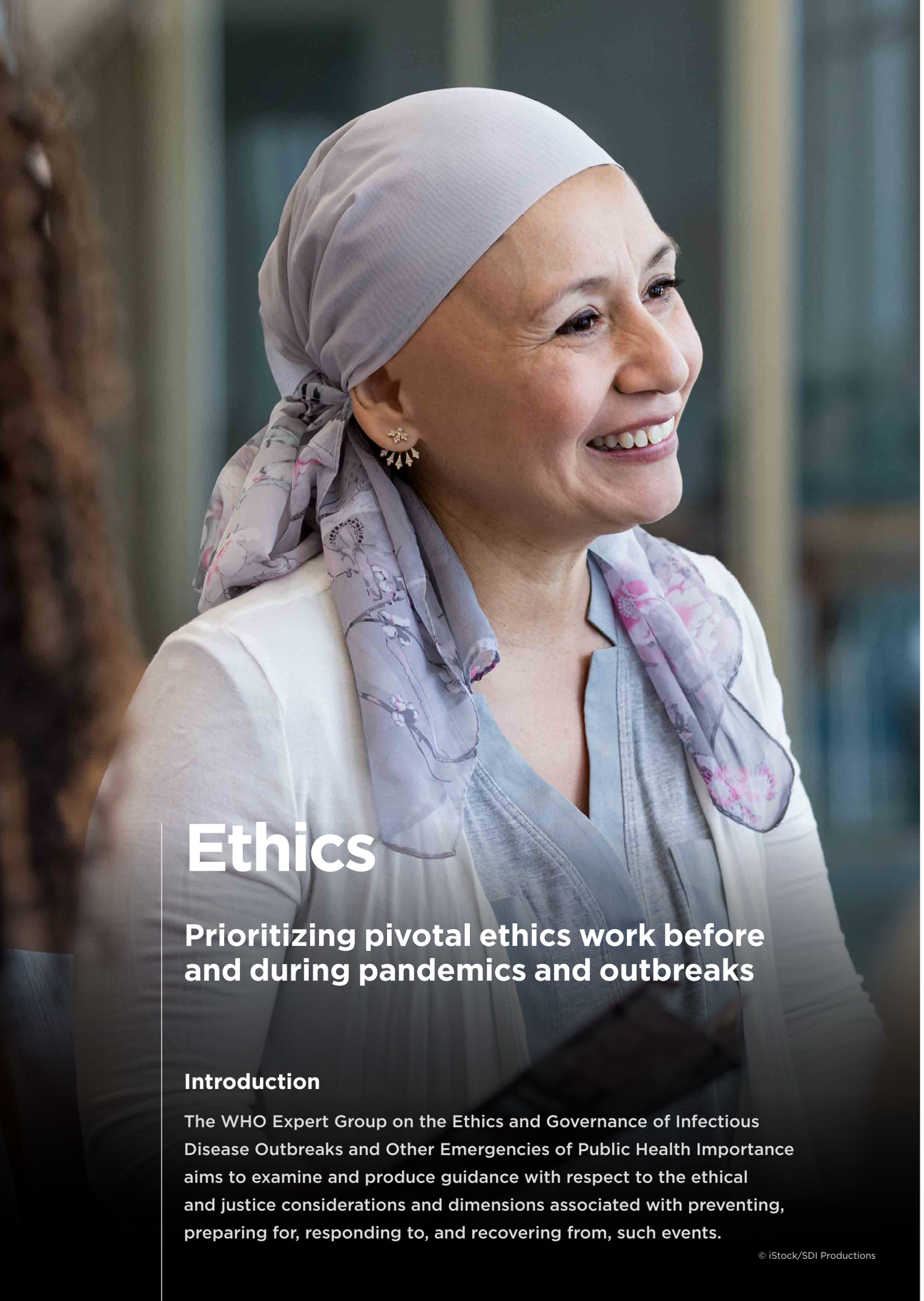
Future priorities

During the COVID-19 pandemic, a number of standards have been developed and updated to assist regulators and manufacturers in the evaluation of the quality, safety and efficacy of vaccines, monoclonal antibodies and other biologicals. As part of the preparation for future outbreaks and pandemic situations, the following priorities for 2023-2024 in setting standards by the Norms and Standards for Biologicals team have been defined:

- Review of needs for new or replacement standards for public health emergencies and organization of activities with the aim to meet the needs of WHO Member States.
- Timely development of international measurement standards for emerging disease pathogens by WHO collaborating centres coordinated by the Norms and Standards for Biologicals team.
- Review and establishment of standards for public health emergencies through the Expert Committee on Biological Standardization.
- Development of guidelines on regulatory preparedness for authorization and post-authorization activities for human pandemic and other public health emergency vaccines in importing countries.
- Preparation of a key document with special consideration for COVID-19 monoclonal antibodies as an addendum to the WHO guidelines on the nonclinical and clinical evaluation of monoclonal antibodies and related products intended for the prevention or treatment of infectious diseases.
- Continuous provision of technical assistance to countries to facilitate regulatory evaluation of vaccines and biotherapeutic products.
- Promotion of science-based regulation of biologicals with a focus on standardization of vaccines, monoclonal antibodies and other biologicals for public health emergencies.
- Organization of the activities to facilitate implementation of the standards for public health emergencies into regulatory and manufacturing practices.

International written and measurement standards have been developed through global collaborative effort to facilitate development and regulatory convergence of vaccines, diagnostics and therapeutics, relevant to priority pathogens and beyond.



Ethics

Prioritizing pivotal ethics work before and during pandemics and outbreaks

Introduction

The WHO Expert Group on the Ethics and Governance of Infectious Disease Outbreaks and Other Emergencies of Public Health Importance aims to examine and produce guidance with respect to the ethical and justice considerations and dimensions associated with preventing, preparing for, responding to, and recovering from, such events.

Objectives

Follows are the objectives of the WHO Expert Group on the Ethics and Governance of Infectious Disease Outbreaks and Other Emergencies of Public Health Importance:

- Develop and revise WHO guidance on ethics and governance matters and related tools for infectious disease outbreaks, including on research, public health measures, and equitable allocation.
- Discuss and advise on ethical and governance aspects of preparedness for emergencies of public health importance and infectious disease outbreaks, as needed.
- Where needed, help facilitate the implementation of related WHO ethical and governance guidance documents into policy and practice.
- Support WHO and Member States in responding to ethical and governance issues as they arise in terms of preparedness and response for emergencies of public health importance and infectious disease outbreaks.

Achievements

Follows are the achievements of the WHO Expert Group on the Ethics and Governance of Infectious Disease Outbreaks and Other Emergencies of Public Health Importance for COVID-19 and other key diseases and pathogens in the past 12 months:

1 Updating ethics guidance on COVID-19

The working group has updated earlier guidance documents, e.g. on ethical considerations for mandatory vaccination, in light of evolving evidence and developments on COVID-19.

2 Developing guidance and providing advice on emerging issues in the ethics of infectious diseases

The working group has initiated the generation of new ethics guidance on emerging issues of importance, for example the ethics of social listening and infodemic management. It has recently published a guidance document on ethical issues in mpox. The group has also provided advice in response to inquiries from various WHO units and initiatives, for example on allocation principles for distributing scarce malaria vaccines, as well as the distribution of therapeutics within the ACT-Accelerator.

3 Generating evidence on ethics committees during COVID-19

In a global empirical study and a dedicated satellite meeting at the Global Summit of National Ethics Committees 2022 in Lisbon, the working group mapped the experiences of ethics review committees worldwide during the COVID-19 pandemic. It has thereby laid the foundations for an evidence-based assessment and improvement of ethics capacities for future epidemic outbreaks.

4 Bridging gaps between ethics and public health decision-making

Following up on the WHO Pandemic Ethics and Policy Summit hosted by the Expert Group in December 2021, a meeting report has been published and a programme of work is being developed which identifies priority issues in bridging gaps between ethics advice and its implementation in public health decision-making.

5 Breaking new ground in research ethics during public health emergencies

The working group has published a comprehensive update of the ethical framework for the use of unproven clinical interventions outside clinical trials during public health emergencies (the MEURI ethical framework), a practice that has surged during the COVID-19 pandemic.

6 Outreach and engagement

A range of video presentations and panel discussions on current ethical issues in infectious disease outbreaks were made available through the Epidemic Ethics Network at https://epidemicethics.tghn.org/seminars/

Future priorities

Follows are the main priorities for 2023-2024 in ethics research in this area:

- Updating WHO guidance on the ethics of infectious disease outbreaks in light of lessons learned from COVID-19.
- Providing ethics guidance on the transition from the COVID-19 pandemic to the endemic stage.
- Monitoring and integrating advice on ethics and justice in epidemic and pandemic preparedness into relevant WHO initiatives (e.g. the Pandemic Treaty), and revisions (e.g. of the International Health Regulations – IHR).
- Generating ethics-to-policy tools for translating, integrating and implementing ethics in public health decision-making, response efforts, and ethical preparedness.
- Convening global stakeholders to develop new research ethics oversight and governance models for implementation under the WHO clinical trials resolution.
- Exploring models of "ethical governance" to support future global and regional mechanisms for the delivery of medical countermeasures in infectious disease outbreaks.
- Continuing the implementation of WHO quality assurance, norms and standards in the development of WHO ethics guidance documents.

Bridging the gap between ethics and decision-making

Research and health policy during the COVID-19 pandemic raised a number of important ethical issues and questions – for example around the allocation of vaccines, therapeutics and diagnostics across the world.

But policy decisions during the pandemic did not always engage meaningfully with the ethics dimension.

To improve the role of ethics in policy-making, mutual learning must occur between ethicists and policy-makers. This should involve the inclusion of ethicists in policy-making processes, and ethicists integrating and operationalizing advice more effectively, e.g. into checklists, where appropriate.

This was one of the main findings of a summit convened by the Expert Group and the WHO Health Ethics and Governance Unit during the pandemic (December 2021). The event was attended by experts from all WHO regions and served as a catalyst for much needed empirical, theoretical and normative work to better understand and improve "ethics to policy" input in pandemic prevention, preparedness and response.

The WHO Director-General, in his opening remarks, highlighted that "ethics is fundamental in every area of health" and urged policy-makers to "keep ethics at the heart of decision-making".

Many examples of the successful inclusion of ethicists at the policy table locally, regionally, nationally, and internationally were cited.

Participants drew attention to a number of key moral failures and global health injustices during the pandemic and beyond, such as the hoarding of vaccines and administration of booster shots in rich countries, while other parts of the world had to wait for their first doses.

Further information is available in the Meeting Report of the WHO Pandemic Ethics & Policy Summit.

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Community-centred readiness and response

Data driving action

Introduction

Health emergencies start and end at local levels.

Pandemics and outbreaks have a more significant impact on resource-poor areas, where people face challenges such as fractured infrastructure, weak governance, fragile health systems, food insecurity, and limited access to clean water. Community-centred approaches bring together the knowledge, expertise and assets of local communities and key stakeholders to develop acceptable, feasible and relevant preparedness and response actions.

This approach considers the social and behavioural aspects of health emergencies alongside biomedical perspectives. To achieve inclusive, accountable and equitable community-centred action, responders require rapid and practical social and behavioural data and analytics.

Models emerged, and were tested, during the COVID-19 pandemic and have been successfully applied to other health emergencies.

These include partnerships that strengthened risk communication and community engagement (RCCE),[1] as well as for rapid integrated outbreak analytics at a local level.[2]

Infrastructure for providing routine social and behavioural evidence production, along with advancements in rapid methods for evidence production, have further contributed to policy and response improvement.[3,4,5]

The achievements reported here result from activities across all levels of WHO, partnerships with academic networks and initiatives from operational partners, including through the Global Outbreak Alert and Response Network (GOARN) supported initiatives, such as the RCCE Collective Service[6] and Integrated Outbreak Analytics (IOA).[7]

Objectives

- Learn from the COVID-19 pandemic with regards to integrating community-centred approaches to build readiness for future shocks.
- Build fit-for-purpose structures and capacity for social research to inform action in a future public health emergency.
- Systematic, institutional inclusion of social evidence for readiness and response.

Achievements

Community-centred research drives readiness and response action that is acceptable, feasible and relevant to affected populations. It is most impactful when owned and delivered at local and national levels.

Follows are the achievements in the past 12 months across the three levels of WHO:

1 Conducted 150+ rapid studies to strengthen practice

Over the past 12 months alone, 150+ rapid studies were conducted to strengthen RCCE practices, including among marginalized groups, for COVID-19, mpox, Sudan Ebola Virus Disease (SVD), Marburg Virus Disease (MVD), cholera, the conflict in Ukraine and earthquakes in Turkey and Syria, and other health emergencies.

Community-centred approaches bring together the knowledge, expertise and assets of local communities and key stakeholders to develop acceptable, feasible and relevant preparedness and response actions.

2 Developing systems and process for routine use of data to drive practice

Infrastructure for data-driven social approaches were developed - including the Collective Service Data for Action platform.[8] Technologies for person-centred risk communication interventions, such as rapid testing of public health messages were also created.

Advances were made in a promising operational model for rapid production and use of evidence from multiple perspectives to strengthen local level response to health emergencies through Integrated Outbreak Analytics (IOA).

3 Delivered evidence syntheses on social/behavioural dynamics in health emergencies

Evidence syntheses to identify gaps[9] and key considerations for social and behavioural dynamics of health emergencies were delivered. Briefings and best practice approaches,[10,11,12,13,14,] including for IOA were also produced.

4 Expanded partnerships and collaborations to drive change through evidence and analytics

New collaborations were forged including engagement of civil society organizations in research that led to policy change.[15] For example, one organization conducted operational research on the prevalence of COVID-19 infections among health workers, resulting in national standard operating procedures (SOPs) for protecting health workers in emergencies, setting a flagship example to countries in the region.

5 Key work of working and advisory groups

Over 15 advisory and working groups convened to inform readiness and response at all three levels of WHO.

Future priorities

Follows are the main priorities for 2023-2024 in community-centred research in this area:

- Integrate lessons from recent health emergencies into updated technical guidance, including for RCCE and best practice in rapid evidence production.
- Advance methods, technologies, infrastructure and capacity for evidence-informed technical expertise to drive community-centred readiness and response via IOA and other initiatives.
- Consolidate tools and products for effective RCCE, for example, community conversation kits, an evidence-informed intervention for frontline health workforce to communicate with affected populations.

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Tackling infodemics

Promoting a resilient and healthier information environment

Introduction

An infodemic is an overwhelming amount of information, including mis- and disinformation, that accompanies health emergencies such as outbreaks and other health crises.

Infodemics contain questions, concerns, information voids (where people seek credible, accurate information but cannot find it), and circulating mis- and disinformation. When people's questions and concerns about a health topic are not addressed, and when they cannot find accurate health information that is relevant to them and in acceptable formats when they need it, it is more likely that their attention will turn to sources of health information that are less credible.

A digitized information environment has sped up information exchange through digital media which affects also offline conversations and can cause information overload and confusion. In the digitized information environment, individuals can be part of multiple online and offline communities simultaneously, thus concurrently discussing topics with others from local and global contexts in communities with which they share some common interests, values, or activities.

At the same time, the digitized information environment is designed to promote content and narratives that are closely aligned with people's interests, values and identities. In such a noisy context, circulating narratives can challenge how effectively and rapidly health authorities can respond to health emergencies, not only through infodemic management strategies, but also through communications, community engagement, and design, delivery and quality of health services.

It has therefore become imperative to find ways to clearly discern and demonstrate the burden of infodemics on our individual and collective health outcomes so that interventions may be created to mitigate its harms.

Infodemic management helps us i) understand the information environment in which individuals and communities live and interact, ii) gain insights into affects people's health perceptions and behaviour, iii) diagnose possible harmful patterns that emerge in the information environment, and iv) provide recommendations and strategies to mitigate those harms.

WHO is developing tools to provide an evidence-based response to the infodemic to strengthen epidemic and pandemic response activities and is fostering the growth of the field of infodemiology.

In future, all emergencies and pandemics will be accompanied by infodemics that will be better addressed with the tools and insights developed today.

Objectives

Aligned with the WHO public health infodemiology research agenda, WHO's specific objectives contribute to infodemiology by:

- promoting an infodemiology research agend
- Measure the burden of infodemic
- connecting research to practice through a WHO infodemic management training programme and evidence-based infodemiologist's toolbox
- promoting implementation science, evidence generation and publication in infodemiology-related topics
- developing an evidence map and gap analysis for frameworks of interventions and infodemiology
- promoting the development of ethical frameworks for infodemiology applied to social listening and infodemic management

Achievements

Follows are the main achievements in research to tackle infodemics for COVID-19/other key diseases and pathogens in the past 12 months:

1. Promotion of public health research agenda for managing infodemics.
2. Calls for papers on infodemiology.
3. Establishment of five working areas of collaboration towards measurement of burden of infodemic.
4. 1300+ infodemic managers from 142 countries now trained in infodemiology and evidence-based approaches to infodemic management and actively participating in a community of research and practice.
5. WHO principles and strategies to mainstream infodemiology and infodemic management into training and learning programmes at universities, professional associations and applied professional programmes such as field epidemiology programmes.
6. OpenWHO channel on infodemic management with eight courses, including infodemiology methods.
7. Evidence mapping and gap analysis reviewing implementation of the public health research agenda, infodemic management frameworks and interventions.
8. Ongoing development of methods and tools for automated social listening of conversations in social media and other digital public data sources.
9. Ongoing development of evidence-based scalable social inoculation interventions.
10. Tools and protocol for measuring information diet and linking it to health outcomes.
11. Ongoing delivery of tools for analysis of digital information environment, such as Early AI-supported Response with Social Listening (EARS) platform, piloted for COVID-19 and COVID-19 vaccines, now recalibrated to respiratory pathogen social listening.
12. A manual for how to develop infodemic insights report in six steps for field responders, with accompanying job aids and training programme.
13. A risk assessment approach to assess narratives for risk to health and wellbeing, and prioritize emergency response and strategies.
14. Methodology for developing a social listening taxonomy for infodemic monitoring and integrated analysis, including taxonomies for COVID-19, mpox and respiratory pathogens.
15. Ongoing development of an ethical framework for social listening and infodemic management.

16. Analysis of lived experience and impact of COVID-19 infodemic on field responders.
17. Infodemic insights informing outbreak response of COVID-19, mpox, mass gatherings (e.g. the Olympics and Football World Cup) and other emergencies.
18. Development of analytical methods and deep dive analyses on specific topics (e.g. pandemic fatigue, trust in evidence and health information, stigmatization of vulnerable populations, etc.).
19. Policy brief on COVID-19 infodemic management.
20. (ongoing) Analysis of current use of social media analysis tools in health, with recommendations for future tool requirements.

Future priorities

Despite widespread recognition of the importance of infodemic management in response to the COVID-19 pandemic, mpox, and other outbreaks and health emergencies since then, there is still much to learn about the use, implementation and effectiveness of infodemic management tools, methods and interventions, and how they are integrated into the emergency preparedness and response.

Promoting the science of infodemiology aims to strengthen the global evidence base on infodemic management to inform the development of action-oriented guidance, support options, mechanisms and tools for infodemic managers and emergency programme managers.

Follows are the main priorities for 2023-2024 in tackling infodemics in this area:

- Boost global research collaborations and networks in measuring information exposure and burden of infodemic.
- Establish a global network for research and training in infodemiology.
- Advocate for research in areas of research gaps that have been identified in the evidence gap map, with particular attention paid to health system impacts and emergency preparedness.
- Continue developing practical tools for field responders in rapidly generating evidence to inform infodmeic resilience strategies and infodemic response in emergencies.
- Develop policy analyses and recommendations to build health system and community resilience to future infodemics.
- Review the evolution of infodemic management teams globally, and related professionalization of the functions in health authorities.
- Identify five strategies each that can be scaled before and during emergencies to build resilience to infodemics and support a more effective infodemic management response by health authorities.

WHO Initiative on Trust and Pandemic Preparedness

The COVID-19 pandemic has highlighted trust as an important determinant of successful pandemic response and leadership, a prerequisite for the uptake of interventions and behaviour change among communities, and a crucial factor contributing to community resilience.

A recent study looking at the factors influencing infection rates across countries found that those with the lowest COVID-19 infection rates had the highest levels of trust.[1] This included both trust in governments and interpersonal trust.

Trust is multifaceted, dynamic and complex: it can wax and wane as an epidemic or pandemic evolves. Furthermore, trust is highly context-specific, influenced by social, historical and political factors. In order to embed trust as a critical element of pandemic preparedness at both global and national levels, it will be necessary to deepen and develop the global health community's understanding of trust and translate this understanding into concrete actions that build trust prior to epidemics and pandemics and sustain it during emergencies.

To deliver on this need, the WHO Department for Epidemic and Pandemic Preparedness and Prevention is leading a new initiative on trust and pandemic preparedness.

Objectives

- Build the research and evidence base in line with the **global architecture for health emergency prevention, preparedness, response and resilience** for trust in the context of epidemics and pandemics including defining the dimensions of trust, the contextualization and localization of trust, the factors that erode trust, and the interventions that protect and sustain trust.

- Support an inclusive, Member State-led process to develop a "**Trust Platform**", that includes a global community of research and practice and tools to measure and build trust.

Achievements

Follows are the main achievements in research relating to the parameters of the Trust Initiative for COVID-19/other key diseases and pathogens in the past 12 months:

1 Launch of a WHO webinar series on trust and pandemic preparedness

WHO has launched a new series of webinars discussing determinants, interventions and experiences around trust in the context of pandemic preparedness. To date, three webinars featuring multidisciplinary experts reaching several thousand people took place on:

- trust and pandemics[2]
- the shifting landscape of trust – history, leadership and communities[3]
- the digital information ecosystem and trust[4]

2 Establishment of a working group on trust and pandemic preparedness

Led by the Department of Epidemic and Pandemic Preparedness and Prevention, a working group consisting of global experts researching multifaceted aspects of trust, as well as members from departments across the WHO, is being formed. The working group will shape the priority activities of the initiative and ensure seamless collaboration across research institutions, implementing partners, and relevant WHO departments.

Future priorities

Follows are the main priorities for 2023-2024 for the WHO Initiative on Trust and Pandemic Preparedness:

- Advance global research on the role of trust for pandemic preparedness: The purpose of this workstream is to collate, synthesize and generate the evidence necessary to define the dimensions of trust in the context of epidemics and pandemics. This workstream will include a diverse and representative community of researchers.

- Build a global community of research and practice: The purpose of this workstream is to ensure that all relevant stakeholders, including Member States, WHO staff at all three levels, partners and researchers, are invited to co-develop and shape the WHO Initiative on Trust and Pandemic Preparedness through consultation processes, information-sharing sessions, and co-hosting of events. The workstream will also deliver a community of practice for exchange of good practice, to support implementation of the initiative and to ensure localization of the tools.

- Develop tools to measure trust in the context of pandemic preparedness: The purpose of this workstream is to translate the findings of the research workstream and the engagement workstream into two tools:

  - the Trust Pulse – a high-level index to measure in real-time levels of trust
  - the Pandemic Trust Implementation Tool – a set of interventions that can be adapted/localized at a national and community level to build trust prior to epidemics and pandemics, and to sustain trust during emergencies

The pandemic has highlighted trust as an important determinant of successful pandemic response and leadership, a prerequisite for the uptake of interventions and behaviour change among communities, and a crucial factor contributing to community resilience.

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Good participatory practice for clinical trials of new or re-emerging pathogens (GPP-EP)

Evidence-driven community engagement in clinical trials

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Good participatory practice for clinical trials of new or re-emerging pathogens (GPP-EP) provides principle-based guidance to effectively engage stakeholders in the design and conduct of prevention and treatment trials for emerging and re-emerging pathogens.

Clinical trials of medical countermeasures for new or re-emerging pathogens can produce significant breakthroughs in discovering life-saving medicines, diagnostics, and vaccines during public health emergencies.

These trials are delivered in tough emergency contexts with accelerated timelines to produce results as quickly as possible. Multi-stakeholder engagement during the desgn, deployment and dissemination of clinical trials is key for implementation to be acceptable, relevant and trusted.

With the increasing frequency and complexity of health emergencies caused by emerging pathogens, such as novel viruses or other infectious agents, it is essential to establish transparent and respectful practices that engage communities and safeguard their rights.

Learning lessons from HIV prevention trials, in 2016 WHO developed GPP-EP to normalize and standardize this work for clinical trials of novel medical countermeasures delivered during public health emergency events. WHO has taken significant steps to promote GPP-EP through a programme of work centred on practical approaches to implementation and uptake.

Objectives

- Provide focused, bespoke technical support for GPP-EP for clinical trials delivered in public health emergencies.
- Develop a suite of generic tools, training and communications products in readiness for rapid adaptation and use in future public health emergency-related clinical trials.
- Build network of expert GPP-EP practitioners.

Achievements

Follows are the main achievements in GPP-EP for COVID-19/other key diseases and pathogens in the past 12 months:

1 Delivered practical evidence-informed materials to be rapidly activated in new trials

Practical tools, materials, and online training materials were created for implementing guidance and evidence-informed good participatory practice for new or re-emerging pathogens (GPP-EP) in clinical trials conducted in low-resource settings. The resources were developed and pre-positioned for rapid adaptation for future trials.[1,2]

2 GPP-EP activity delivered to engage stakeholders/ communities on the Solidarity Trial Vaccines (STV)

Coordination, and delivery of GPP-EP for the Solidarity Trial Vaccines (STV), an international multicentre, multi-vaccine, adaptive, shared placebo, event-driven, individually randomized controlled clinical trial that aimed to evaluate the efficacy and safety of promising new COVID-19 vaccines. The trial recruited over 20,000 people in the Philippines, Colombia, Mali, Kenya and Sierra Leone in 2022.

3 GPP-EP activity delivered to engage stakeholders/ communities on the Tokomeza Ebola trial

Trial specific materials and bespoke training programme were developed and delivered in Uganda in readiness for the launch of the Tokomeza Ebola trial, a ring-vaccination adaptive clinical trial to evaluate the safety and efficacy of promising vaccine candidates against Sudan ebolavirus.

4 Strategic and practical GPP-EP counsel delivered around Lassa fever

Highlighted GPP-EP relevance and strategic entry points for development of research protocols for Lassa fever clinical trials.

5 Key work of working and advisory groups

Regular meetings were held for the GPP-EP technical advisory group and working groups to inform readiness and response for GPP-EP.

Future priorities

Follows are the main priorities for 2023-2024 for GPP-EP:

- Learn from GPP-EP work delivered for COVID-19 and other emergency-relevant clinical trials around the world.
- Integrate lessons to update GPP-EP tools and products to drive best practice in public health emergency clinical trials, particularly those using novel trial designs.
- Expand network of GPP-EP practitioners.

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SECTION 3

Building on the global research response to the pandemic to combat the next one

Building on our defences to get ahead of the next global threat

Throughout history, research has played a fundamental role in combatting deadly diseases that have threatened people and communities across the world.

During the dark, devastating and uncertain times at the start of the COVID-19 pandemic, science gave the world hope that we would see better days and humanity could be saved. And it delivered across a wide range of research areas. Crucially it gave us effective vaccines and treatments in record time.

But as the pages of this report show, its achievements were also instrumental across the whole emergency response. For example, research confirmed how the virus was transmitted, provided vital evidence that underpinned infection prevention and control (IPC) and informed the public and policymakers about variants - their transmissibility, virulence and how best to protect ourselves from them.

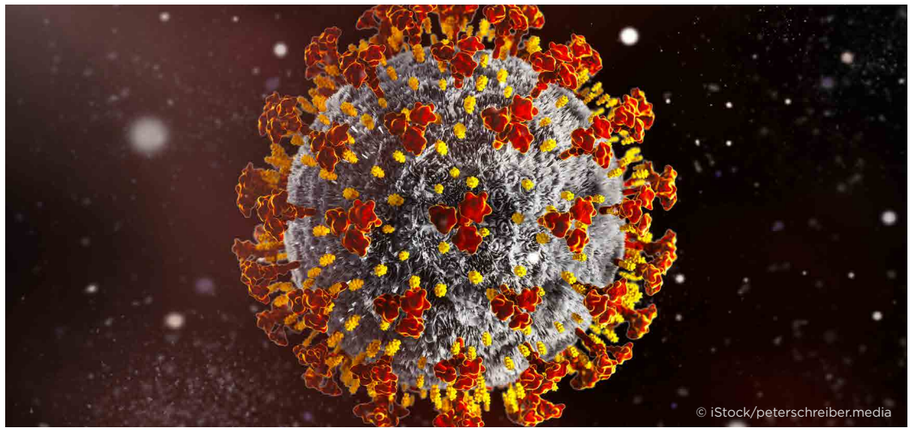
There is no doubt that all these measures working together helped save millions of lives. And it showcased, possibly for the first time, every aspect of research and innovation being fully utilized in an emergency response.

While COVID-19 still inflicts a significant toll in many parts of the world, the pandemic has now moved out of the acute phase and was recently declared an established and ongoing health issue which no longer constitutes a public health emergency of international concern (PHEIC). There can be no doubt that global research has played a key role in delivering this historic milestone.

However, the fact remains that outbreaks of deadly new pathogens will happen again in future: we cannot prevent them. What we can do is learn from history and build on the research knowledge and structures gained during the pandemic to fortify us against future ones.

As we saw in Section One, WHO is collaborating closely with key global and national organizations to agree and deliver mechanisms and activities to bolster our resilience against other deadly pathogens and the next pandemic.

Our main enemy is complacency. We must use this post-pandemic window of opportunity wisely and tirelessly to ‘get ahead’ of the next global threat – global resilience to outbreaks and pandemics will only come with global agreements and major monetary, human resource and knowledge investment. The work has started but must continue at pace.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Ten priority research activities/themes to combatting future outbreaks and pandemics

We now bring the focus right back to the specific future role that research and innovation can play in preparing and responding to the next epidemic or pandemic.

And by bringing together global research infrastructure activities with national capacity-building initiatives, we outline ten key areas that can enhance, prioritize and build the role of research in defending the world from future disease and pathogen threats.

Many of these activities link with, and form part of, the broader framework of health emergency preparedness and response within the a possible new pandemic convention, agreement or other international instrument and other global policy initiatives in this area.

1 Increase resources for research and innovation (RI) worldwide

Additional resources for research and innovation are needed to purchase vaccines, treatments and diagnostics, as well as fund logistics to ensure rapid distribution and access of products.

Funding should be available pre-pandemic – with the ability to be rapidly scaled in the event of a large-scale health emergency. In addition, we need to identify how current research funding organizations can efficiently focus their resources to address pivotal research questions to combat new or re-emerging outbreaks.

2 If there is uncertainty give randomization the opportunity to yield trustworthy evidence

Randomized studies are feasible where there is uncertainty about the benefits of medical countermeasures. A key assumption underlying the need for large-scale randomized evidence is that it is often necessary for reliable assessment of moderate effects on mortality or severe disease.

During epidemics and pandemics, trials need to generate data to answer important public health questions (actionable information). It is important to continue to help develop robust CORE protocols for trials for priority viral and bacterial family diseases.

3 Expand the use of simple large platform trials employing core protocols

If trials are collaborative, it is important to use simplified procedures and focus on the questions of public health importance. The adaptive nature of these trials introduces a level of flexibility that enables the swift inclusion of promising new therapeutic agents into the clinical evaluation process, while also permitting the discontinuation of underperforming interventions based on interim evaluations.

Platform trials contribute significantly to the establishment of an efficient research ecosystem that can enhance clinical trial capacity, ensuring long-term sustainability in a manner that is both coordinated and collaborative across diverse institutions spanning different countries.

Simple trials serve as a pivotal conduit for bridging the gap between clinical trials and frontline health care providers and patients. The integration of trials into health care delivery systems and the outbreak response teams serves to enhance the involvement and engagement of frontline health care providers, patients and communities.

In so doing, platform trials have the potential to bolster trust in clinical trial processes and foster increased participation in clinical trials across countries both during interludes between epidemics and in the epidemic period itself.

4 Consider generating large-scale randomized evidence during epidemics and pandemics

Open-label randomized controlled trials (RCTs) during outbreaks are feasible and desirable where there is uncertainty about the benefits of vaccines and treatments. Moreover, when the supply of doses may be limited, RCTs are a fair way to distribute them. A key assumption underlying the use of large-scale randomized evidence is that it is often necessary for reliable assessment of moderate effects on mortality or severe disease.

One main requirement in such studies is that they should not interfere with ordinary vaccination or administration of the intervention. No additional duties should be added for health care workers in managing and delivering vaccinations or treatments with participating individuals. Follow-up depends on what is locally possible.

Huge, randomized comparisons need not be expensive, and could nimbly and rapidly resolve some uncertainties. Preparedness during the years between pandemics should involve revising trial regulations to make open-label randomized studies as easy as mass vaccination.

5 Adopting a ‘One Health’ approach that encompasses the human-animal-environment interface is critical to global health security

Health emergency preparedness and response is multisectoral, and future research must engage communities and stakeholders across the ‘One Health’ spectrum, i.e. human, animal and environmental domains.

Environmental degradation and ecosystem loss (through global deforestation, for example) combined with the trade in wildlife and wildlife products can greatly increase the risk of spillover events with epidemic and pandemic potential.

At a research level it is imperative that we:

- increase our collective understanding of key issues such as the evolution of pathogens in animal hosts, the modes and drivers of transmission between animals and humans, and new interfaces between humans and animals in a changing environment. Doing this will help us to develop stronger health emergency preventive strategies as well as bolster our preparedness, response and resilience.
- develop early warning systems that link three ways (human, animal and environment) and beyond to help detect spillovers of disease in humans, domestic animals and wildlife at the point when containing them is still an option.

6 Interconnected global laboratory capacity for pathogen/genomic surveillance

Across the globe, we need better, more coordinated global epidemic intelligence and surveillance achieved by:

- enhancing and expanding laboratory capacity/networks
- providing incentives for sharing pathogens, biological samples and genomic data
- harnessing the latest technology driving innovations to increase availability of key data, develop state-of-the-art analytic tools and predictive models for risk analysis, and link communities of practice around the world
- providing access to surge capacity during emergencies through agreements to utilize regional and/or global auxiliary capacity
- addressing surveillance ‘black spots’

7 Research for community protection and to promote trust

Global trust has been shown to be a vital determinant of pandemic preparedness and response. It can help encourage understanding and uptake of research and policy interventions to reduce pathogen transmission and promote the health and wellbeing of local communities.

More broadly, we need to integrate evidence from social sciences and infodemiology into health emergency preparedness and response, including:

- advancing global research to drive equitable, ethical policy and practice for community protection, including on the role of trust
- boosting global research collaborations and networks to strengthen national and local capacity for evidence to drive key International Health Regulations (IHR) capacities of risk communication and community engagement (RCCE) and infodemic management
- building engagement and communications initiatives with the public around a strong evidence base which takes into account local cultural issues, context and audiences

8 Agile, well-resourced national health systems to protect health workers and patients

Strong and agile national health systems with robust primary health care (PHC) services are key to detecting cases, saving lives and protecting livelihoods in a health emergency.

Future research must support clinical care that is safe, scalable and equitable. Innovative and effective infection prevention and control (IPC) that protects patients, health workers and communities is key within this.

Resilient health systems must be agile, flexible and sufficiently resourced to surge their capacity during a health emergency while maintaining essential services.

9 Strengthen research capability in every country and incorporate research systems into their emergency preparedness and response systems for epidemic infectious diseases

To enhance the capability to proactively address future outbreaks and promptly identify emerging epidemics for effective response, including the successful execution of priority research, it is imperative to prioritize the strengthening of key health systems elements (e.g. surveillance, outbreak investigation, and diagnostic capabilities) in all countries.

it is important to aid the establishment of sustainable foundational capacities at the intersection of health care systems and research so as to better equip countries for both research during interepidemic periods and the facilitation of fundamental research during epidemics and pandemics. Such proactive measures can significantly contribute to global health security by effectively responding to and researching emerging health threats.

10 Build equitable global manufacturing capacity that is pandemic-ready

Manufacturing capacity to deliver effective vaccines, treatments and diagnostics rapidly needs to be more equitably distributed across the world.

This can be achieved through strengthened regulatory, legal and enabling frameworks to scale manufacturing platforms for emergency use medical countermeasures with robust agreements for technology transfer.

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Vaccines research

- A WHO-Strategic Research Agenda for Filovirus Research and Monitoring (WHO-AFIRM) https://www.who.int/publications/m/item/a-who-strategic-research-agenda-for-filovirus-research-and-monitoring-----(who-afirm)
- Accelerating the licensure of Lassa vaccines: Generating robust evidence on vaccine efficacy and safety. HYPERLINK "https://www.who.int/news-room/events/detail/2022/10/25/default-calendar/save-the-date---accelerating-the-licensure-of-lassa-vaccines--generating-robust-evidence-on-vaccine-efficacy-and-safety"Accelerating the licensure of Lassa vaccines: Generating robust evidence on vaccine efficacy and safety (who.int)
- Improving Vaccine Effectiveness Studies: A Vital step before the next pandemic HYPERLINK "https://www.who.int/news-room/events/detail/2023/09/14/default-calendar/improving-vaccine-effectiveness-studies--a-vital-step-before-the-next-pandemic"Improving Vaccine Effectiveness Studies: A vital step before the next pandemic (who.int)
- Integrating Research into Outbreaks: How can we prepare for the next Marburg outbreak? HYPERLINK "https://www.who.int/news-room/events/detail/2023/03/10/default-calendar/who-consultation---integrating-research-into-outbreaks--how-can-we-prepare-for-the-next-marburg-outbreak"Integrating Research into Outbreaks: How can we prepare for the next Marburg outbreak? (who.int)
- Lassa Fever Research and Development (R&D) Roadmap HYPERLINK "https://www.who.int/publications/m/item/lassa-fever-research-and-development-(r-d)-roadmap"Lassa Fever Research and Development (R&D) Roadmap (who.int)
- Solidarity Trials Core Protocol - Ring vaccination trial to evaluate the efficacy and safety of a Sudan ebolavirus vaccine in Uganda https://www.who.int/publications/m/item/solidarity-trials-core-protocol---ring-vaccination-trial-to-evaluate-the-efficacy-and-safety-of-a-sudan-ebolavirus-vaccine-in-uganda
- Solidarity Trials Core Protocol - Randomized trial to evaluate the efficacy and safety of select therapeutic agents in the treatment of Ebola Disease https://www.who.int/publications/m/item/solidarity-trials-core-protocol---randomized-trial-to-evaluate-the-efficacy-and-safety-of-select-therapeutic-agents-in-the-treatment-of-ebola-disease
- WHO Working Group on vaccine prioritization - review of Sudan ebolavirus vaccine candidates https://www.who.int/news-room/events/detail/2022/11/07/default-calendar/who-working-group-meeting-on-sudan-ebolavirus-candidate-vaccines---review-of-uganda-outbreak-and-existing-vaccine-candidates
- WHO Sudan ebolavirus candidate therapeutics working group meeting on RCT protocol https://www.who.int/news-room/events/detail/2022/11/04/default-calendar/who-sudan-ebolavirus-therapeutics-working-group-meeting-on-rct-protocol
- WHO Sudan ebolavirus therapeutics subgroup meeting on candidate treatments to consider for inclusion in an RCT https://www.who.int/news-room/events/detail/2022/11/02/default-calendar/who-sudan-ebolavirus-therapeutics-sub-group-meeting-on-candidate-treatments-to-consider-for-inclusion-in-an-rct
- WHO Sudan ebolavirus vaccines working group - RCT design and operational considerations https://www.who.int/news-room/events/detail/2022/10/28/default-calendar/who-sudan-ebolavirus-vaccines-working-group-meeting---rct-design-and-operational-considerations
- WHO Working Group on vaccine prioritization - review of Sudan ebolavirus vaccine candidates https://www.who.int/news-room/events/detail/2022/10/26/default-calendar/who-working-group-meeting-on-sudan-ebolavirus-candidate-vaccines---review-of-uganda-outbreak-and-existing-vaccine-candidates
- WHO Sudan ebolavirus therapeutics and trial design subgroups meeting on RCT https://www.who.int/news-room/events/detail/2022/10/21/default-calendar/who-sudan-ebolavirus-therapeutics-and-trial-design-sub-groups
- WHO Sudan ebolavirus therapeutics subgroup meeting on trial design https://www.who.int/news-room/events/detail/2022/10/13/default-calendar/who-sudan-ebolavirus-therapeutics-sub-group-meeting-on-trials-designs
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- WHO Sudan ebolavirus therapeutics subgroup meeting on candidate treatments to consider for inclusion in an RCT https://www.who.int/news-room/events/detail/2022/10/07/default-calendar/who-working-group-meeting-on-sudan-ebolavirus-candidate-vaccines---review-of-uganda-outbreak-and-existing-vaccine-candidates
- WHO Sudan ebolavirus vaccines working group - RCT design https://www.who.int/news-room/events/detail/2022/10/07/default-calendar/who-working-group-meeting-on-sudan-ebolavirus-candidate-vaccines---rct-design
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- WHO Sudan ebolavirus vaccines working group - review of Uganda outbreak and existing vaccine candidates https://www.who.int/news-room/events/detail/2022/08/20/default-calendar/who-working-group-meeting-on-sudan-ebolavirus-candidate-vaccines---review-of-uganda-outbreak-and-existing-vaccine-candidates
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  - Cohort study to measure COVID-19 vaccine effectiveness among health workers
  - COVID-19 vaccine effectiveness against severe acute respiratory infections (SARI) hospitalizations (test-negative case-control design)
  - COVID-19 vaccine effectiveness estimation using the screening method
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  - Assessment of risk factors for COVID-19 in health workers: protocol for a case-control study
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Community-centred readiness and response

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4 Monitoring behavioural insights related to COVID-19 - PubMed (nih.gov)

5 Global survey on COVID-19 beliefs, behaviours and norms - PubMed (nih.gov)

6 The Collective Service is a collaborative partnership between WHO, IFRC, UNICEF and supported by GOARN, that brings together a wide range of organizations engaged in policy, practice, and research for RCCE to ensure expert driven, collaborative, consistent and localized RCCE support reaches governments and partners involved in the national response to COVID-19 and beyond – https://www.rcce-collective.net/

7 Integrated Outbreak Analytics (IOA) was developed during the 10th (2018-20) Ebola outbreak in the DRC. It is an approach that brings together multiple data types, disciplines, and sources to better understand and explain outbreak dynamics and their impacts on communities. It is focused on collaborative partnership across operational and academic actors in support of outbreak response and on rapid, operational analytics to support decision-making.

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- Risk Communication and Community Engagement in Action During Ukraine's War: A RCCE rapid needs assessment was conducted across the countries receiving Ukrainian refugees during the initial weeks of the war to examine the health needs, perceptions and concerns reported by Ukrainian refugees, along with the capacity of each country to respond to these needs. Conducted in 6 countries of the WHO European Region
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- Social Behavioral Dashboard (February 2021): Displays over +1 million data points through 47 indicators in 197 countries on COVID-19 and social behavioural change, which assist governments and partners to understand the key issues and concerns of communities regarding COVID-19. Users are located in Europe (45.11%), Americas (33.07%), Africa (12.94%), Asia (11.10%).
- Social Data Tracking: Since March 2020, 650+ studies and reports have been compiled within 197 countries. The Collective Service developed and launched the social data tracker dashboard in January 2022, which has been visited by 725 users.
- Community Feedback Mechanism (CFM) Tracker: Monitors CFMs led by Collective Service's partners to support RCCE response on PHE and other crises. The mapping initiated in 2022, helped to identify 135 mechanisms across 80 countries and 33 organizations. This tool has been viewed 945 times since February 2022.
- Inter-agency Community feedback monitoring in Eastern and Southern Africa: Led by the ESAR Inter-agency Working Group, a monthly community feedback monitoring has been conducted since June 2020. Thirty-five monthly reports have been generated and disseminated gathering feedbacks from 21 organizations allowing for operational recommendations to be made. The Collective Service supports the development of a Joint Report, which triangulates online and offline community feedback collected by different organizations
- Country-level Community Feedback Mechanism Support. Technical support on Community Feedback monitoring through capacity building, data management assistance and data visualization support. Community Feedback Mechanisms supported: DRC (Ebola, COVID-19), Eswatini (COVID-19), Zimbabwe (COVID-19), Lesotho (COVID-19), Uganda (Ebola), South Africa (Floods). Collective Service has also provided 4Ws mapping support for coordination at the regional and country level.
- Data Snapshots: The Data for Action team conducted a series of data snapshots presenting situations on SBC. Nine data snapshots have been produced on COVID-19 highlighting populations inequity on vaccine access and demand. Recent snapshots were produced on Monkeypox.
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- Focus Groups Discussions to collect qualitative data on COVID-19 vaccine acceptance amongst vulnerable groups, conducted in 7 countries with 112 participants in total.

- Vaccine Confidence Survey KAB study - two rounds of data collection in 2021 and 2022 to understand knowledge of COVID-19 vaccines and drivers of vaccine hesitancy in the Western Pacific Region. Conducted in 14 countries (including Pacific Island countries) with 24,117 respondents in total (circa 1000 respondents per country, per round, in non-PICs and 500 for PICs).
- Perceptions and Behavioural Insights on COVID-19 KAB – longitudinal, cross-sectional study – five rounds of data collection to observe COVID-19 including vaccination knowledge, attitudinal and behavioural shifts and trends between 2021 and 2022, conducted in 7 countries with 17,505 respondents in total (circa 500 respondents, per country, per round).
- WPRO COVID-19 Social Listening Report Regularly monitoring the latest social media trends and hot topics (including rumours and misinformation) in WPR, to identify the community's questions, concerns, information gaps, knowledge, attitudes, and behaviours, as well as any needs, challenges, and opportunities that arise. In 2022, a total of 28 reports were generated.
- WPRO Mpox Social Listening Report A total of 27 reports were produced on a weekly or bi-weekly basis.
- Desk-based and primary research conducted in 2021 to understand the role of closed messaging channels for risk communication and its potential in promoting health messages and engaging with communities during public health emergencies.
- COVID-19 Behavioural Insights survey A study conducted with Malaysian Research Institute on Ageing (MyAgeingTM), Persiaran MARDI-UPM, Universiti Putra Malaysia (UPM) to capture information gaps, knowledge, attitudes, and behaviours related to COVID-19. The study was launched in September 2020.
- COVID-19 Community perception survey. Four rounds of data collection from 2020 until 2022, jointly implemented with MRCS (Malaysian Red Crescent Society), IFRC and UN OCHA. This longitudinal study was aimed at following the perceptions of risk related to COVID-19 and COVID-19 vaccines and has help to inform both the communication activities as well as decision-making. COVID-19: Community perceptions in Malaysia - Community Engagement Hub
- Community perception survey among undocumented migrant communities in Sabah. WHO engaged with a local non-governmental organization called "ANAK (Advocates for Non-discrimination and Access to Knowledge) to run a survey, focus group discussions and a WhatsApp quiz among migrant and other vulnerable communities in State of Sabah from November 2020 until February 2021. The aim of these activities was to understand the knowledge, attitudes and practices about COVID-19 among the communities, barriers to access healthcare and stigma and discrimination they might face.
- Social listening and infodemic management. Social listening mechanism was set up in 2020 to support the COVID-19 response in Malaysia and Brunei Darussalam. Based on localization of an innovative research methodology, a co-created bespoke infodemic taxonomy, and a linguistic based emotion matrix designed to capture citizens' emotions, external partner "Marble Global" was delivering daily snapshots with key insights to WHO and MOH, weekly reports through regular meetings and monthly analysis of key topics and trends that were shaping public's perceptions related to protective behaviours and vaccines. This system included rumours and mis/dis information alert and repository.
- Call for Innovations: Imagine The World Anew. This was an open call for innovations organized in early 2021 by WHO, Impact Hub KL, Social Entrepreneurship to Spur Health (SESH), Social Innovation in Health Initiative (SIHI) and the University of North Carolina. The purpose of this open call was to mobilize large numbers of youth in Malaysia, and through their voices, inform and contribute to the formulation of the national health policies related to COVID-19. The call for innovations had three categories under which people could apply: Youth-Led Social Innovations in Health, Youth messaging for COVID-19, Futures Thinking and Strategic Planning. https://www.who.int/malaysia/news/detail/20-04-2021-calling-for-youth-voices-to-reimagine-the-future-by-changing-our-present
- Research project with Wikimedia to raise health awareness in Malaysia WHO conducted online research with the Wikimedia Community User Group in Malaysia, to understand if there is a knowledge and information gap among the population on various health topics including about COVID-19. Based on the findings of the research, the team organized a first ever article writing competition seeking to increase awareness and coverage of multiple health topics in the Malay language on Wikipedia. https://www.who.int/malaysia/news/detail/15-04-2021-who-partners-with-wikimedia-to-raise-health-awareness-in-malaysia
- "Research study to assess the status of mental health among the semi-rural population in Malaysia, during the COVID-19 pandemic. The study was conducted with the Southeast Asia Community Observatory (SEACO) and the Jeffrey Cheah School of Medicine and Health Sciences at Monash University. The project had 3 objectives: to assess the status of mental health (anxiety and depression) during covid-19 pandemic among the semi-rural population in Malaysia and to identify the association of relational aspects such as social connectedness and loneliness, and mental health status; to explore the relationships and interactions of the mental health providers/community health workers (CHW) and the person seeking help in an existing community-based mental health programme; to identify the enablers and barriers to earning the communities' trust and to build long term relationship and shared interest". https://www.who.int/malaysia/news/feature-stories/item/malaysia-trials-digital-community-to-protect-mental-health-during-covid-19
- Mental Health and Psychosocial Support for COVID-19 positive patients. This project called "Homecare" aimed to provide support to the marginal and hard to reach communities including the B40 families, indigenous, migrants including refugees, asylum seekers and undocumented, as well as the stateless people. This project was implemented together with the Malaysian Red Crescent Society and the Ministry of Health in Malaysia. It had two main components during the summer of 2021 and through the peak of Delta cases in Malaysia: Mental Health and Psychosocial Support for COVID-19 positive patients, working closely with Malaysia COVID-19 Assessment Centre (CAC): to make outbound calls for cases under home monitoring identified by CAC as asymptomatic and in high-risk groups; to call and follow up with the patients to obtain information on their current health status and do constant monitoring.; to collect data and evidence from the communities and inform and tailor decision-making and COVID-19 response. Distribution of COVID home kits that included oximeters, thermometers, medicines, info kits. (10.000).

- Behavioural insights (BI) research project to test the "Living with the virus" communications strategy in Malaysia. The objective of the BI intervention was to understand what the optimal content and format of "Living with the Virus" communications materials is, and to maximize comprehension and intention among the population to perform the desired behaviour/s during the COVID-19 pandemic. The project aimed to: investigate the effectiveness of current communications targeted to the population and in particular their impact on encouraging the desired "Living with the virus" behaviours; test the existing "Living with the virus" package of materials against alternative options informed by evidence and data; provide concrete recommendations to the Ministry of Health for the current "Living with the virus" communication materials, and; propose new content based on the findings for the next phase of public communication. https://www.who.int/malaysia/news/feature-stories/item/using-behavioural-science-in-communication-to-improve-health-in-malaysia
- Evaluation Study on Demand Generation for COVID-19 and Booster Vaccines among Vulnerable Populations.
  To strengthen the RCCE efforts of the DOH, WHO, and UNICEF, WHO Philippines, through a contracted institution, evaluated and measured the impact of the COVID- 19 prevention and vaccine-related RCCE materials produced in the Philippines. Specifically, the assessment aimed to achieve the following objectives:
  1. Determine how WHO-DOH-UNICEF communication materials contributed to the achievement of RESBAKUNA: Kasangga ng BIDA's campaign objectives.
  2. Determine the association between the 'Sa Boosters: PinasLakas' campaign and booster uptake.
  3. Generate insights and provide specific recommendations that will inform the development of the DOH's communication, social mobilization, and advocacy activities to strengthen vaccine trust and confidence.
  4. Establish a protocol for evaluating advocacy tools as part of periodic reassessment by the DOH team.
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Tackling infodemics

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- Trial specific: STV Suite of engagement and learning materials for standardized best practice

WHO Headquarters in Geneva
Avenue Appia 20
1202 Geneva
Telephone: +41-22-7912111

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