सत्यमेव जयते
NITI Aayog

FUTURE PANDEMIC PREPAREDNESS AND EMERGENCY RESPONSE

A Framework for Action

✦✦✦

Report of the Expert Group

www.niti.gov.in

सत्यमेव जयते
NITI Aayog

FUTURE PANDEMIC PREPAREDNESS AND EMERGENCY RESPONSE-

A FRAMEWORK FOR ACTION

REPORT OF THE EXPERT GROUP

AUGUST 2024

Expert Group Members

1. Dr Renu Swarup, Former Secretary, Department of Biotechnology - Chairperson
2. Dr Soumya Swaminathan, Former Chief Scientist, WHO and Former DG, ICMR - Member
3. Dr Sujeet Singh, Former Director, NCDC - Member
4. Shri Rajib Kumar Sen, Senior Adviser (Health), NITI Aayog - Member-Secretary

---

Supported by: NITI Aayog, Health Division

1. Dr Sonali Rawal, Consultant Grade-II
2. Mr Varun Singh, Consultant Grade-II
3. Ms Neha Sharma, Young Professional

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

ADME	Absorption, Distribution, Metabolism, and Excretion
AMR	Anti-Microbial Resistance
ARB	Antibiotic Resistance Bacteria
AMTZ	Andhra Pradesh Med Tech Zone
BPPL	Bacterial Priority Pathogen List
BSL	Biological Safety Level
cCAMP	Centre for Cellular and Molecular Platforms
CBRN	Chemical, Biological, Radiological, and Nuclear
CCMB	Centre For Cellular and Molecular Biology
CCHF	Crimean–Congo Haemorrhagic Fever
CDC	Centre for Disease Control
CDSCO	Central Drugs Standard Control Organisation
CEPI	Coalition for Epidemic Preparedness Innovations
CLIA	Chemiluminescence Immunoassay
CoE	Centre of Excellence
COVID	Coronavirus Disease
CSIR	Council of Scientific and Industrial Research
CSO	Civil Society Organization
DAHD	Department of Animal Husbandry and Dairying
DBT	Department of Biotechnology
DHR	Department of Health Research
DNA	Deoxyribonucleic Acid
DoHFW	Department of Health & Family Welfare
DoP	Department of Pharmaceuticals
DRDO	Defence Research and Development Organisation
DST	Department of Science & Technology
EDA	Epidemic Diseases Act
EIS	Epidemic Intelligence Service
EGs	Empowered Groups
EGoS	Empowered Group of Secretaries
ELISA	Enzyme Linked Immunosorbent Assay
EOC-NET	Emergency Operations Centre -Network
EVD	Ebola Virus Disease
FETP	Field Epidemiology Training Program
GIS	Geographic Information System
HCW	Healthcare workers
IAPSM	Indian Association of Preventive and Social Medicine
ICAR	Indian Council of Agricultural Research
ICMR	Indian Council of Medical Research
IDSP	Integrated Disease Surveillance Programme

IEC	Information Education Communication
IHR	International Health Regulations
IHIP	Integrated Health Information Platform
INSACOG	Indian SARS-COV-2 Genomic Consortium
IP	Intellectual Property
IPD	Inpatient Department
IPPS	International Pandemic Preparedness Secretariat
IPPRS	Independent Panel for Pandemic Preparedness and Response Secretariat
JEE	Joint External Evaluation
KFD	Kyasanur Forest Disease
MDR	Multi Drug Resistant
MERS-CoV	Middle East Respiratory Syndrome Coronavirus
MoHFW	Ministry of Health and Family Welfare
mRNA	messenger Ribonucleic Acid
NADRES	National Animal Disease Referral Expert System
NBRIC	National Biomedical Resource Indigenization Consortium
NCDC	National Centre for Disease Control
NCE	New Chemical Entity
NDCT	New Drugs and Clinical Trials
NDMA	National Disaster Management Authority
NEG-VAC	National Expert Group on Vaccine Administration for COVID-19
NGO	Non-Governmental Organization
NGS	Next Generation Sequencing
NIB	National Institute of Biologicals
NIDM	National Institute of Disaster Management
NII	National Institute of Immunology
NITI Aayog	National Institution for Transforming India Aayog
NIV	National Institute of Virology
NIPER	National Institute of Pharmaceutical Education and Research
NSC	National Security Council
NTAGI	National Technical Advisory Group on Immunization
OH	One Health
OPD	Outpatient Department
PHE	Public Health Emergency
PHEDM	Public Health Emergency and Disaster Management
PHEIC	Public Health Emergencies of International Concern
PHEMA	Public Health Emergency Management Act

PHEOCs	Public Health Emergency Operations Centres
PHFI	Public Health Foundation of India
PK-PD	Pharmacokinetic-Pharmacodynamic
POC	Point-Of- Care
PPE	Personal Protective Equipment
PPER	Pandemic Preparedness and Emergency Response Framework
PRET	Preparedness and Resilience for Emerging Threats
PSA	Principal Scientific Adviser
RAT	Rapid Antigen Test
RIA	Radioimmunoassay
RCCE	Risk Communication and Community Engagement
SARS-COV2	Severe Acute Respiratory Syndrome Corona Virus 2
SEARO	South-East Asia Regional Office World Health Organization (WHO)
SEC	Subject Expert Committee
SOP	Standard Operating Procedure
THSTI	Translational Health Science and Technology Institute
UHPR	Universal Health & Preparedness Review
UNICEF	United Nations International Children's Emergency Fund
WHO	World Health Organization
ZVD	Zika Virus Disease

PREFACE

It is a matter of great honour for the Expert Group constituted by NITI Aayog on Future Pandemic Preparedness to submit the Final Report entitled "Future Pandemic Preparedness and Emergency Response —A Framework for Action". The Expert Group would like to compliment the NITI Aayog leadership, especially Dr Vinod Paul, Member (Health), NITI Aayog, for the vision to set up the Expert Group. The TOR of the group was to draw lessons and experiences, both national and global, on how COVID was managed and visualise preparedness elements and future pathways for fighting any infectious public health crisis. The Expert Group is pleased to propose recommendations based on the learnings and challenges faced during COVID -19 and other public health crises.

Preparing the proposed framework for action for future pandemic preparedness and emergency response involved several consultations with experts and stakeholders, analysing the experience so far, examining national and global success stories and identifying key gaps that need attention. The stakeholder meetings were crucial and provided valuable insights for preparing the report. The consultations included experts from multilateral organisations, academia, Indian industry, clinicians, epidemiologists, researchers, policymakers etc.

The Government of India (GoI) proactively initiated a scientific preparedness plan for future pandemic through the One Health (OH) approach. The Office of the Principal Scientific Adviser (PSA) to the Government of India, along with thirteen other Ministries/ Departments, have conceptualised the One Health Mission to have a scientific strategy to tackle future pandemics with a focus on surveillance, data management, research for developing innovative countermeasures and partnerships for an effective response.

This Expert Group noted the OH Mission's activities and integrated them into the core recommendations of the report. The proposed recommendations complement the initiatives of the OH Mission with a focus on proactive preparedness for pandemics, epidemics and outbreaks, as well as developing a robust response strategy that focuses on implementation, accountability and timely execution. Considering that the first 100 days of any public health emergency are critical, and an immediate response is essential, the proposed framework provides a road map on how the country can deliver the appropriate interventions in the first 100 days. From institutionalised governance mechanisms to a separate legislation for Public Health Emergency Management, an emergency pandemic preparedness and response fund, robust surveillance, forecasting and modelling, and innovation research ecosystem, the key recommendations cover all these aspects in detail.

Once again, the Expert Group would like to convey its special thanks to Dr Vinod Paul, for putting the group together being with us throughout the discussions and providing his valuable advice and guidance. The group also acknowledges the support from the team at NITI Aayog, Health vertical and other stakeholders who have provided valuable insights which have helped us put together a comprehensive plan of action. We hope that the recommendations will be helpful to the government and that appropriate action will be taken to implement them. We stand ready to assist in this endeavour.

The message is clear, we need to be ready for War when not at War

Sh. Rajib Kumar Sen

Dr Sujeet Singh

Dr Soumya Swaminathan

Dr Renu Swarup

EXECUTIVE SUMMARY

The COVID-19 pandemic was the worst public health emergency witnessed, which impacted humanity not just in a few nations or regions but across the world. Although the health systems had experience dealing with infectious outbreaks and epidemics, we did not have the processes and systems in place to deal with a public health emergency at this scale. NITI Aayog constituted an Expert Group to prepare a Framework for Action for Future Pandemic Preparedness and Emergency Response. The Terms of Reference for the group were to examine how we managed COVID-19 at the national and global levels, pick up the key learnings both from the success stories and challenges faced, and assess the key gaps which need to be addressed to help us prepare and respond more efficiently and effectively in any such future public health crisis.

The Expert Group did a detailed assessment and landscaping of what worked and what did not in that crisis. Series of stakeholder consultations were held with National and International experts, policy makers, researchers, clinicians, epidemiologists, funding agencies, and international organisations - all those who played a key role in COVID management.

Learning from the experience of COVID-19, the experts have realised that responding in the first 100 days of an outbreak is crucial for effective management. It is critical to be ready with strategies and countermeasures which can be made available within the first 100 days. It is essential that the proposed framework provides recommendations for a robust ecosystem so that when there is any outbreak from known or unknown pathogens, India is ready to respond in 100 days. This report provides an action plan for a 100-day response to any outbreak or pandemic. It outlines the detailed roadmap for preparedness and an implementation phase, indicating the steps on how the outbreak can be tracked, tested, treated and managed through a well-developed framework in a 100-day time frame. It suggests a structure that integrates and strengthens all existing components and builds the required components to deliver the outputs that meet the targets of a 100-day response mission.

The recommendations of the Pandemic Preparedness and Emergency Response Framework (PPER) are in four pillars:

1. Governance, Legislation, Finance and Management
2. Data Management, Surveillance and Early Predictive Warning, Forecasting and Modelling,
3. Research and Innovation, Manufacturing, Infrastructure, Capacity building/Skilling
4. Partnership, Community engagement including risk communication, Private sector partnerships, and international collaborations

The actions proposed under each of these are detailed in this report. During report preparation, an analysis was done on the challenges faced and the country's response

while managing earlier epidemics. Over the years, there has been an effort to build a robust ecosystem for managing the Epidemic/Pandemic public health challenge. A strong foundation has been laid, from developing epidemiological surveillance to piloting data input portals like the Integrated Health Information Platform (IHIP) and Integrated Disease Surveillance Programme (IDSP) to strengthening research infrastructure and capacity for innovative technology development. During COVID-19, there was an effort to plug the gaps and build those components that supplemented the existing strengths.

A separate Public Health Emergency Management Act (PHEMA) is proposed to facilitate the management of any public health crisis. The PHEMA can address various aspects beyond epidemics, including non-communicable diseases, disasters, and bioterrorism, and should be in place for a developed country. It will allow a holistic approach to health management, covering prevention, control, and disaster response. The Act would also provide for the creation of skilled public health cadres at national and state levels.

The effective management of COVID-19 was possible due to a robust governance system through the Empowered Groups (EGs) with a whole-of-government approach. It is proposed that an Empowered Group of Secretaries (EGoS) chaired by Cabinet Secretary be established for Pandemic Preparedness and Emergency Response and a well-oiled machinery is put into action which prepares and readies itself before any emergency. A well-structured scorecard mechanism should regularly monitor the progress of key targets. The priority targets would be the development of capacities for both human resource and infrastructure, the development of innovative countermeasures, appropriate high-risk financing for getting high returns, in terms of saving lives and minimising economic loss, a well-developed robust, responsive regulatory framework, and a strong surveillance network connecting epidemiological data with genomic, laboratory and clinical data.

There is a need to connect the epidemiological surveillance data with the genomic data and develop clinical correlations using hospital and lab data. A strong surveillance network is proposed, which allows community and hospital data to flow seamlessly to a unified data portal for data access and sharing across all relevant sectors. This will need a well-articulated data sharing and communication policy and assigning authority to key persons for decision-making.

Challenges faced during COVID-19 regarding an India-based forecasting and prediction modelling system, therapeutic development and platform technologies for developing prototype vaccine candidates need to be addressed through new missions and centres which have been suggested in the report.

To take effective, timely action, a Pandemic Preparedness and Emergency Response Fund needs to be established. During COVID, need-based finance packages were made available for some of the emergency response activities like genomic surveillance, vaccine and diagnostic development, research resources and shared infrastructure. However, adequate finances are also required to be made available for pandemic preparation.

The research ecosystem needs strengthening. The special high-risk innovation research fund announced by the Government as a special package —'Mission COVID Suraksha', gave the country the capability to develop indigenous vaccines for the world's most extensive vaccination programme. The private sector could successfully develop a

portfolio of vaccines including the world's first DNA vaccine, the first thermostable mRNA vaccine, the first nasal vaccine and other vaccine candidates, using different platform technologies. The high-risk fund also helped to scale up vaccine manufacturing capacities. This experience highlights the need for continued support for developing platform technologies and vaccine candidate libraries. A new Institute of Innovation for new platform technologies and vaccine research, development and manufacture, and Centres of Excellence (CoEs) for research on priority pathogens (including development of countermeasures) should get special financial allocation to prepare for future threats and be ready to deliver in 100 days of detection of a new pathogen.

Indian regulatory system needs special attention. There is a need for global harmonisation of regulatory norms to allow acceptance of regulatory data across the world's recognised regulatory authorities and a common framework for innovative technologies and accelerated response for emergency approval. The need for a clinical trial network for global multi-locational trials has been suggested. This would facilitate speedy access to globally developed countermeasures. The regulatory authority (CDSCO)needs special powers through legislation and requires technical competence strengthening and autonomy in functioning to meet these requirements.

Partnerships and coordination play a significant role in implementing an effective response during an emergency, especially centres-state partnerships and community engagement. Strengthening the existing system and developing a strong institutionalised framework is needed.

The expert group in the report has provided a blueprint for the country to prepare for any future public health emergency or pandemic and have a rapid response system. From examining the lessons learned and challenges faced during the COVID-19 pandemic to recommendations and a roadmap for governance and management of public health emergencies in the future, this report is a starting point for the country's pandemic preparedness and prevention efforts.

FUTURE PANDEMIC PREPAREDNESS AND EMERGENCY RESPONSE- A FRAMEWORK FOR ACTION REPORT OF THE EXPERT GROUP

1. Introduction

1.1 Background

As India recovers from the COVID-19 pandemic, the worst human health crisis humanity has witnessed, it is imperative that we draw lessons from the country's and the world's experiences and accordingly visualise preparedness elements and pathways for potential future pandemic(s).

The world was caught unaware when we were struck by the infectious virus SARs CoV2. It took us a while to understand the impact this virus had on life, livelihood and economic conditions, not just in the country but worldwide. We collectively fought the SARS-CoV2 challenge using a strong public health surveillance network, scientific knowledge and tools, and could successfully mitigate its impact. Worldwide, there have been several science-based measures and countermeasures to tackle this deadly virus. India, too, deployed epidemiologic, surveillance and genomic tools to contain it. We produced diagnostics, medical technologies, vaccines and drugs to treat the disease. India deployed a whole-of-government approach to managing the pandemic. It encountered numerous challenges, which are learnings for the country to better prepare for the future and have a Pandemic Preparedness and Emergency Response framework in place which allows urgent action in any such conditions and delivers impact in a 100-day mission mode time frame.

India deployed epidemiologic and genomic surveillance, IT-based data analytics, and novel technology-based countermeasures and tools to contain the deadly virus. It scaled up behavioural, clinical and therapeutic measures. Timely application of non-pharmaceutical interventions helped firm up the manufacturing of PPEs and supply chains to prevent infection and treat the disease. The country produced vaccines, diagnostics and medical technologies to meet the demand. The nation ramped up its entire machinery from R&D for new technology and product development to manufacturing, implementation, and last mile delivery. India produced and licensed seven vaccines at affordable cost and administered more than 2.2 billion doses of Made in India vaccines, almost entirely through the public health system, with an unprecedented speed.

The COVID-19 contagion is undoubtedly not the last pandemic. Given the unpredictably changing planetary ecology, climate and human-animal-plant dynamics, new large-scale infectious threats to human health are inevitable.

The WHO has warned the world that 75% of future public health threats are likely to be zoonotic threats (which could be due to emerging, re-emerging and new pathogens).

Over the last two decades, seven Public Health Emergencies of International Concern (PHEICs) have been declared by the World Health Organisation (WHO). These include the H1N1 influenza (2009), Ebola Virus Disease (EVD) (2014-16, 2018-2020), Zika Virus Disease (ZVD) (2016), Poliomyelitis (2014), COVID-19 (2020), and Monkey Pox (2022). In addition, the world has tackled public health threats of SARS, Avian influenza (bird flu), MERS-CoV, and Nipah virus outbreak which have challenged health systems across countries. However, it is worth mentioning that the COVID-19 pandemic was more complex in terms of high public health impact, recurring waves and unpredictable course due to changing pathogenicity associated with virus mutations and variants. This has highlighted the importance of a targeted approach towards zoonotic and other potential pathogens that are likely to emerge in the future. Such threats could be due to emerging and re-emerging pathogens, or could also arise due to newly emerging pathogens from viruses which routinely are infective for bats or other avian populations but may cross over to humans due to frequent mutations directly or via vectors due to environmental or occupational aspects of human animal interface. Considering the above aspects, the Government of India is in the process of launching the One Health (OH) Mission, focusing on multi-disciplinary human, animal and environmental sectors through an effective integrated surveillance ecosystem, joint outbreak response system and targeted research.

While the One Health (OH) approach is crucial for addressing many pandemic threats, there are challenges from CBRN agents, threats from bioterrorism, the possibilities of deliberate release of pathogens for malicious purposes and pandemic scenarios that extend beyond its scope and require strategies which are beyond the OH approach involving national security, international collaborations with inter-disciplinary approach and high-tech systems. Further, factors like increased travel and trade due to globalisation, effects of climate change on pathogens, and determinants of pathogenicity among vulnerable groups, including emerging resistant pathogens and social determinants of health, require a separate mechanism.

Globally, countries and multi-lateral organisations are working towards preparedness to deal with novel pathogens and disease outbreaks. WHO has already identified around 30 viral and bacterial families, which could have potential for epidemics or pandemics and hence need to be targeted for future research, development of new laboratory techniques for diagnosis, and countermeasures. The WHO has revised the International Health Regulations (IHR) to reflect the post pandemic reality; Inter-governmental negotiations on a Pandemic Accord were also conducted and a global scientific framework for epidemic and pandemic research preparedness is being developed. The recent 77th World Health Assembly also highlighted the need for a collaborative surveillance framework and developing a roadmap for epidemiological capacity building at all levels and aligning with regional and global initiatives.

Therefore, it is imperative that countries also take stock of their needs and prepare a robust road map aligned with global instruments like Preparedness and Resilience for Emerging Threats (PRET) and obligations under International Health Regulations (IHR), which are legally binding on all WHO member countries for preparing and responding to future pandemic threats to public health systems.

1.2 Setting up of the Expert Group

In response to SARS-COV2, India made efforts to produce novel countermeasures and strengthened its research and development framework. These included mechanisms for funding of industry and researchers, establishment of shared resources; policy and guidelines for sharing of data, samples, regulation; public-private partnerships and global collaborations. India also invested in digital tools for pandemic response and vaccination, which helped manage data of more than 1.4 billion population. Despite this, a huge number of lives were lost, and the economy took a big hit. The country must learn from planning and implementing such a multi-modal pandemic response. More importantly, it is paramount to envision an approach on tackling a future challenge of this magnitude due to a new pathogen with even greater efficacy and speed building upon the networks and frameworks established during the Covid-19 pandemic.

Consequently, an Expert Group was set up to examine these issues in depth, consult other experts (national/global), learn from the positive experiences and challenges, and develop a detailed analysis of what worked and what did not. The report looks at the lessons learnt from the country's response and global experiences and offers a clear strategy and road map on what our preparedness should be to handle any such and even more dangerous public health crisis in future.

Terms of Reference of the Expert Group:

The Expert Group on India's Future Pandemic Preparedness was set up with the following Terms of Reference:

1. Study emerging information on pathogens with the potential to power large outbreaks in the future and suggest mechanisms for focusing on surveillance taking 'one earth one world' approach to ensure that we are prepared for diseases of potentially unknown agents.
2. With a focus on the scientific and technological approaches, tools, products and systems deployed in the COVID-19 pandemic response, prepare a synthesis report on the learnings thereof and propose preparedness pathways for the country. In particular, undertake this task with specific reference to pandemic epidemiology, forecasting, surveillance, testing and containment, virus characterisation including genome sequencing, and diagnostics, digital tools, therapeutics, medical technologies and vaccines.
3. Recommend specific action to be taken for strengthening and creating a robust ecosystem for pandemic prediction and prevention, biomedical research, and new innovative, affordable and accessible countermeasures.
    a) Further, identify gaps that exist in infrastructure, human resources and systems in this regard and recommend actions to be taken to build this at a world-class level through Atma Nirbhar effort.
    b) Suggest how to create systems that allow complete forward and backward linkages to ensure no dependency on imported raw material; and recommend building networks for clinical trials to take up disease-based vaccine and therapeutics research ensuring compliance with global regulatory standards.
    c) Recommend scale-up mechanisms to promote the capacities of our industry to become manufacturing hubs to be able to meet the needs of the country and also supply to the world.

d) Suggest improvements to strengthen the framework for data and sample sharing.

4. Provide guidance on meaningful national and international, including bilateral, multilateral, and public-private partnerships.

The Composition of the Expert Group is as follows -

- Chairperson: Dr Renu Swarup, Former Secretary to Govt of India, Department of Biotechnology
- Members:
  - » Dr Soumya Swaminathan, Former Chief Scientist WHO & Former DG ICMR
  - » Dr Sujeet Singh, Former Director NCDC
- Member Secretary: Sh. Rajib Kumar Sen, Senior Adviser Health, NITI Aayog

This report offers a blueprint for the country to prepare for any future public health emergency or pandemic to have a rapid response system. From examining the lessons learned and challenges faced from the country's response and global experience during the COVID-19 pandemic to recommendations and a roadmap for governance and management of public health emergencies in the future, this report is a starting point for the country's pandemic preparedness efforts.

Target audience - This report is intended to inform policymakers, National and State governments, partners and researchers, industry and academia working on health system resilience and preparedness for public health emergencies. It may also be helpful to the lay public.

Caveats (if any): The contents of this report are the views and recommendations of the expert group.

2. Methodology

2.1 Consultations

The Expert Group has consulted with national and international experts from public health, clinical medicine, epidemiology, microbiology, industry and academia, and senior government officials at the Centre and State level. These experts were at the frontline of the COVID-19 response at the local, national and international levels and played an important role in the policy, planning and implementation of the COVID response. Expert views on the learnings and challenges of dealing with the COVID-19 pandemic and recommendations for future preparedness were sought.

Fourteen consultations have been held with more than sixty experts.

An overview of the institutions, organizations and experts consulted are annexed at Annexure III.

» Presentation to concerned Ministries/Departments

Following the consultations with experts, members of the expert group prepared the critical recommendations for future preparedness. The recommendations were discussed with Secretaries and senior officers of concerned ministries and departments in a meeting held on 24 May 2024 at NITI Aayog; co-chaired by Member (Health), NITI Aayog and the Principal Scientific Adviser to the Government of India.

The participants welcomed the comprehensive recommendations of the expert group prepared through a thorough assessment of the current preparedness status and lessons learnt from COVID-19. Recommendations for a separate legislation managing public health emergencies, earmarking a separate Pandemic Preparedness and Emergency Response fund, strengthening surveillance and data management, and investing in research and development of countermeasures (diagnostics, vaccines, therapeutics, protective equipment) were appreciated by the participants as timely and actionable recommendations that would also serve to strengthen current activities and facilitate improved implementation.

2.2 Research

Research complementing future pandemic priorities has also been undertaken by the Expert Group. This includes research on the work being undertaken by global health organisations, multi-lateral groups like the Independent Panel for Pandemic Preparedness and Response Secretariat (IPPRS), the 100 days Mission, etc. Published literature on the COVID-19 pandemic, evolving science about the SARS-CoV2 pathogen, COVID-19 disease and its sequelae have also been considered by the Expert Group in its deliberations. Details of key references are included at Annexure IV.

3. Lesson from the Past -dealing with epidemics in the last two decades

Between 2009- 2022, WHO has declared seven Public Health Emergency of International Concern (PHEICs) —Influenza A in 2009, poliomyelitis in 2014, Ebola West Africa in 2014, Zika in 2016, Ebola Democratic Republic of Congo 2018, COVID-19 in 2020 and Monkey-pox in 2022. Public Health Emergency of International Concern (PHEIC), as per IHR, is "an extraordinary event which is determined as per IHR decision instrument (1) to constitute a public health risk to other countries through the international spread, and (2) to potentially require a coordinated international response". Further, during the last few years, many countries have witnessed the occurrence of several infectious diseases, outbreaks/public health threats which were potential pandemic threats both outside and inside the country, which resulted in the loss of lives, property, and economic consequences.

Important events/outbreaks during last two decades (which caused pandemic threat) are described below. These also have the potential to cause future pandemics; hence, preparedness measures should also be developed to manage their outbreaks.

Event/Outbreak	Description	Learnings
SARS in 2003	The first infectious disease in this century, which started in two provinces of China, spread to over 50 countries in a very short time through international travel and resulted in around 850 deaths within a period of 3-4 months. Highly infectious and contagious; R_0 of around 8 spread primarily through respiratory mode. A multi-country high-level expert group got exposed in a group meeting in Hong Kong Hotel (event) which caused multi-country spread during air travel and also after return. Countries used ad hoc measures in absence of any international provisions, primarily on basis of past experience.	• Need for International legally binding rules/ regulations. • Novel pathogens are difficult to identify and hence the primers and probes for developing diagnostic tests/facilities take time and; thus, detection of infection among exposed persons is a challenge during the initial phase. • Need for core capacities for screening, sample collection and quarantine facilities at international airports.

Avian Flu (H5N1)	Since 2005 onwards, repeated outbreaks in birds (primarily in poultry) have caused significant harm to at-risk human populations. In 2024, H5N1 has been circulating among cattle farms in the US, and a few human cases have been reported.	• An effective strategy of surveillance of at-risk populations and culling sick birds was developed as a coordinated surveillance and response plan for both human and animal sectors. This helped the country in effective containment and prevented spillover of infection among at -populations from birds. • A standing committee on zoonosis was established following avian influenza.
H1N1 pandemic *(pandemic declared as PHEIC))*	Emerged in 2009 in Mexico, it spread through respiratory routes to over 74 countries, causing about 491000 lab-confirmed cases and 18449 deaths. This was the first pandemic to be declared as PHEIC in accordance with IHR (2005).	• IHR (2005), a legally binding regulation, was in place. • Countries were developing core capacities as per IHR at points of entry and inside the country for surveillance and response. • Countries adopted public health measures like screening at POEs, early detection of suspects, quarantine, contact tracing of suspect surveillance and management of cases in isolation in dedicated wards. • Public health measures were helpful in mitigating and delaying the entry of infection. • Need for coordinated surveillance between Points of entry and in-country surveillance system.

Ebola Outbreaks ***(2014-2016)*** ***(2018-2021)***	Multiple Ebola outbreaks (around 7 since 1976) occurred in different regions of Africa. The epidemics in the west African countries were significant from the perspective of international spread in over 7 countries in Europe and the threat of spread in other countries via international travellers.	• Efforts to control these outbreaks involved screening, surveillance of exposed, contact tracing, data management, laboratory testing, and health education, including use of PPEs. • Public health efforts were much more effective, limiting entry into the country.
MERS-CoV	Outbreaks in the Middle Eastern countries have been regularly occurring since 2012 and are potential threats from the perspective of international spread via travellers, for e.g. in South Korea in 2015, leading to 186 cases and around 34 deaths.	• Zoonotic diseases, particularly highly infectious diseases that spread via respiratory/ droplets route could be challenging to prevent. • Most of the threats leading to pandemics were due to novel viruses of zoonotic origin, possibly transmitted through the human-animal interface. • Infectious diseases having a respiratory mode of transmission are dangerous.
Zika Virus disease	A disease transmitted via Aedes mosquitos has already spread to over 90 countries and has been detected in over 12 states in the country.	• ZVD- a disease with over 80% asymptomatic cases and mild clinical symptoms with full recovery cannot be prevented using public health measures directed towards travellers. • Effective vector surveillance and control is essential to prevent entry and transmission of vector-transmitted diseases. • Need for multi-sectoral collaborative surveillance.

4. COVID-19 Learnings and Challenges

The COVID-19 pandemic (2019-23) caused by the SARS-CoV-2 virus emerged in late 2019 and quickly spread worldwide. The world was caught unaware and although there were strategies for managing outbreaks and epidemics, developing and deploying countermeasures for the different outbreaks, the magnitude of the problem faced when the pandemic hit us was overwhelming and required urgent coordinated action. It resulted in millions of deaths, widespread illness, and significant economic and social disruptions. Efforts to control the spread of the virus included cluster containment, disruption of social gatherings, lockdowns, travel restrictions, mask mandates, and the development of vaccines and mass vaccination.

The country had a well-developed strategy-based response system for earlier outbreaks, which effectively implemented and successfully managed the disease. However, there were challenges faced and key gaps noted in the ecosystem which need urgent attention for better management of any future public health crisis. These lessons are important to plan a road map for future pandemics. Some of the key issues are listed below -

4.1 Governance

i. The whole–of-government, whole-of-society approach, and inter-departmental, inter-ministerial, and centre-state coordination worked well during COVID -19.
ii. Role of Empowered Group Systems, National Task Forces – NTAGI & NEG-VAC were critical for quick decision-making and interagency coordination
iii. Science-based evidence played a key role in informed decision-making. This evolved with a scientific understanding of the pathogen and disease,
iv. The role and responsibility of each agency and organisation however, required more clarity, and the mechanisms for close coordination of agencies to work together were not in place.
v. Risk communication systems need to be established. What was missing in COVID management was a well-developed communication mechanism which allowed data to flow both ways.
vi. The need was also felt for a well-defined rapid response SOP/instruction document and delegation of powers to empower key officials to act without going through the multilayered hierarchal process. This was essential for speedy time-bound action.

4.2 Legislation

i. The National Disaster Management Act (NDMA) was enforced – enabling Centre and State government to respond quickly and implement public health measures.
ii. However, a need is felt for a specific Public Health Act.
iii. Provisions of NDMA are not entirely suited for a public health emergency and its public health and clinical management.
iv. The previous epidemic act has a limited scope and is not suited to the modern approach for pandemic/epidemic management.

4.3 Surveillance and Data management

i. The Disease agent was a novel virus of zoonotic origin. A One Health Approach was needed to tackle this

ii. Data collection, management and analysis were the key issues.
   - There were several data portals for human disease – IDSP, IHIP (an Integrated Health Information Portal) apart from State portals. Additionally, multiple data sources like ICMR COVID-19 (https://cvstatus.icmr.gov.in/) test data and data collected in segregated portals.
   - The National Animal Disease Referral Expert System (NADRES) provides monthly livestock disease forewarning at the district level which is published in the form of a monthly bulletin to alert the animal husbandry departments, both at the National and state levels, to take appropriate control measures.
   - Centre & State dashboards had collected data. However, it is imperative to integrate this data for a proper analysis. Modelling, forecasting and early warning based on our data was a missing gap. This requires not just data flow from the networks but also human resource capacity to analyse and develop predictive models.
   - The challenge was to get a seamless flow of this data, data integration for proper data analysis using epidemiological intelligence and access to relevant stakeholders for different types of research, development of countermeasures, and prediction models. A continuous, uniform, interoperable data flow is essential from state to centre, from field sites, connected with laboratory and clinical/hospital networks.
   - Surveillance was a critical aspect of COVID management. While there was a solid existing epidemiological surveillance through the IDSP network, the gap was a well-integrated surveillance network for pandemics like COVID-19. Hence, in April 2020, special efforts established a dedicated Special Surveillance System (S-3), i.e., https://covid19.nhp.gov.in for data capture from the district level on surveillance, logistics planning including hot spot data on quarantine, and patient management. Digital platforms – like Aarogya Setu mobile tracking Bluetooth-based app for contact tracing & information dissemination - to lab and S3 system; CoWIN platform – played a very important role in vaccination and individual risk assessment.

iii. The INSACOG Network on Genomic Surveillance was helpful in identifying new strains, but there was limited capacity across the country. This network linking epidemiological and genomic surveillance should be strengthened and connected with clinical surveillance and hospital networks.

iv. The INSACOG potential could not be optimally utilised as the linkages with state laboratories of primary and secondary health care centres and the private sector needed strengthening. For future pandemics, INSACOG can function in a hub and spoke model with centre-state partnership and active involvement of the private sector both for hospital network and genomic surveillance. Mathematical modelling systems must be in place to connect epidemiological, genomic surveillance and clinical data for early prediction and warning.

v. Wastewater analysis and serological surveillance also helped identify the spread of viruses; this should be done regularly.
vi. Hence a unified, comprehensive National Data Portal that aggregates all information about the virus and disease spread from various sources is suggested to identify trends and quickly predict surges/next outbreaks, including data from scientific research and predictive modelling.

4.4 Research and Development, translation and product development

i. Public and private collaborations were a strong factor for efficient pandemic management. It has been well established that there is sufficient capacity and competency in industries both in innovative research and manufacturing and the pieces of the ecosystem have existed in the translational value chain. The rapid tests and low-cost tests developed by ICMR, and other institutes were required to be linked with relevant industries for bulk manufacturing. However, there was a need for creating a structured mechanism linking research bodies like ICMR and the private sector with appropriate industries under the overall framework for pandemic management. A well-laid-out validation network is essential for the development of diagnostic kits.
ii. Vaccine candidates were developed, and manufacturing capacities were scaled up. This was possible due to the High-Risk Innovation Funding Mission COVID Suraksha. India's strength in diagnostics and vaccines needs to be developed in a proper framework involving research, regulatory bodies and industries. This could also serve as a valuable resource for the entire Southeast Asia region.
iii. Animal challenge facilities, BSL3 network, validation labs, and bio repositories were set up. The challenge was to have systems in place that allow access to the shared infrastructure and access to biological and clinical material and samples. We need the tools and instruments, including MoUs and Material Transfer Agreements which provide necessary access.
iv. Start-ups played a significant role in the manufacturing of low-cost PPEs, sanitisers and other protective gear like face masks. We, however, need forward and backward linkages and uninterrupted supply chains to ensure a large-scale cost-effective production.

4.5 Regulatory Reforms

i. Although we quickly developed a rapid response regulatory framework to respond to our requirements for COVID-19, the regulatory system was not geared up for accelerated emergency authorisation. The need for regulatory process harmonisation and clear guidelines for new technology is of utmost importance.
ii. The established guidelines and SOPs and the technical competence to understand the complexities of new technologies need strengthening. Since we did not have harmonized global regulatory guidelines, this delayed the approval of products already approved by other recognized national regulators.
iii. A well-established, globally accepted clinical trial site network was also essential for trials of products developed by other global groups.

5. Future Pandemic threats: Public Health Challenges and Preparedness

Evidence suggests that the risk of emerging infectious diseases due to known and unknown pathogens, particularly of zoonotic (animal, avian and wildlife) origin, has increased over time due to the intensification of international travel, trade and livestock husbandry, as well as increasing human population density and changing interactions between humans and wild animals. These drivers of disease emergence are likely to continue and intensify, and additional drivers of ecological change and disruption, such as climate change and global warming, are likely to further amplify disease emergence risk.

The WHO has initiated a global process to update the list of priority pathogens—agents that can cause outbreaks or pandemics—to guide global investment, research and development (R&D), especially in vaccines, tests and treatments. The current list includes COVID-19, Crimean-Congo haemorrhagic fever, Ebola virus disease and Marburg virus disease, Lassa fever, Middle East Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS), Nipah and henipaviral diseases, Rift Valley fever, Zika and Disease 'X'. The 2024 Bacterial Priority Pathogen List (BPPL) includes 15 families of antibiotic-resistant (ABR) pathogens grouped into critical, high and medium categories of priority for R&D and public health measures. In addition, 200+ scientists from 53 countries independently evaluated the evidence related to 30 viral families to identify priority viral pathogens. Research on pathogens and categorization as agents which can or which have the potential for casing epidemics and pandemics is a dynamic process, coordinated by WHO. Periodically WHO expert group updates the list of priority pathogens. The current (as of June 2024) list of priority pathogens is placed at Annexure II.

In the face of current and future pandemic threats, the importance of collaborative surveillance cannot be overstated. The key challenges are timely detection of early warning signs, the identification of emerging and new pathogens (which could potentially lead to future pandemic threats), the assessment of the public health impact and the implementation of multi-disciplinary surveillance to capture various dimensions of a disease and its impact. It is imperative that collaborative surveillance in community and health facilities is established for the regular assessment of the impact of CBRN agents on transmission, morbidity, severity and mortality in the community, thereby enabling proactive planning.

In addition, the following epidemiological aspects of infectious diseases/agents may also pose specific challenge to public health strategies:

i. Diseases with large asymptomatic carriers contributing to transmission and possible health impact, like spontaneous vaginal delivery in pregnant women, may be associated with congenital microcephaly.
ii. Highly pathogenic agents causing high mortality and high rate of transmission Ro > 5 or so
iii. Infectious diseases with Resistant pathogens (viruses, bacteria and fungi)
iv. Diseases with a reservoir in domestic animals (largely asymptomatic like CCHF), birds, cattle, pigs, bats etc.
v. Diseases with unknown transmission routes (milk, food, touch, droplets, air etc.)

Strategy: Given future threats, the traditional public health surveillance strategy should be aligned with new initiatives focused on:

i. Global Preparedness: Pandemics have the potential for cross-border spread and, hence, country preparedness needs to align regional and global core capacities for robust collaboration and communication to prevent or mitigate cross-border spread.
ii. Cross-sectoral and cross-border collaboration: for enhancing coordination between public health authorities, disaster management agencies, and other relevant sectors to manage pandemic threats effectively.
iii. Risk assessment and community engagement: Strategy for assessment of potential future risks, allowing possible misconceptions and rumours during outbreaks and ensuring accurate information dissemination and community cooperation.
iv. Resource Availability: Ensuring necessary funds and resources are available to support pandemic response efforts.
v. One Health Approach: Developing the multi-hazard plan, strategy, SOPs, and processes for implementation for coordinated surveillance and response to zoonotic and other emerging infectious diseases.

These challenges highlight the need for proactive preparedness to strengthen public health systems and response capabilities in the face of current and future potential pandemic threats.

6. Recommendations

While over the years, we have had many outbreaks, and the country has built response mechanisms both at the centre and state level, including community engagement, the onset of COVID-19 was a situation which brought out the key challenges in the system and highlighted the specific gaps which need to be addressed. Clearly, we cannot wait for the next infectious pathogen to strike before we act. We need a well-articulated action plan which gives us a clear road map on how we should prepare in advance and keep our tools and capacity ready so that without wasting any time, an emergency response which begins action on day zero and gives the required results to have disease prevention, mitigation and control is in place within 100 days.

Accordingly, a **Pandemic Preparedness and Emergency Response (PPER) framework for action** is proposed for consideration. The PPER aims to have a well-developed framework in place that will make the system ready for any future public health crisis and deliver a response in a 100-day time frame. The framework keeps the preparedness in peacetime to respond to emergency war.

Based on our learnings from earlier epidemics and the key actions taken and strategy followed to manage the COVID pandemic, it is evident that a special focus must be placed on sustaining the efforts made and addressing the challenges faced with a well thought-out action plan that can respond to a public health emergency in the shortest period of time.

Post-COVID, there has been a proactive approach by the Government, and One Health (OH) Mission has been launched, which focuses on Surveillance, Research, Data management, Outbreak management and Pandemic preparedness.

The OH Mission focuses on:

i. Surveillance with emphasis on Priority pathogens, especially, viral families and representative or prototype viruses within each family
ii. Bacterial threats in the context of Anti-Microbial Resistance (AMR)
iii. Data management and analysis
iv. Research and development covering medical countermeasures, including diagnostics, drugs and vaccines
v. Building on lessons from the COVID.19 pandemic

In addition to the areas covered under OH Mission, some key actions are proposed under PPER for consideration. The recommendations are under four pillars:

6.1 Governance, Legislation, Finance and Management

6.2 Data Management, Surveillance and Early Predictive Warning, Forecasting and Modelling

6.3 Research and Innovation, Manufacture, Infrastructure, Capacity building

6.4 Risk Communication, Community engagement, Private sector partnerships, and International collaborations

Key Recommendations

Governance, Legislation, Finance and Managementv

- Enacting a new Public Health Emergency Act
- Creating an institutionalised empowered governance mechanism for Public Health Emergencies. An Empowered Group of Secretaries on PPER chaired by the Cabinet Secretary
- A Continuous Monitoring Group to be constituted co-chaired by the Secretary Health and Secretary DHR
- A well-defined SOP manual for rapid response to be prepared
- Setting up of a special Pandemic Preparedness and Emergency Response fund for all PPER activities of surveillance, data management, forecasting and modeling, research, innovation and manufacture, development of counter-measures, infrastructure and capacity building

Surveillance, Data Management, Forecasting, Modelling, Early Predictive Warning

Creating a well-connected/integrated robust surveillance network linking epidemiological, genomic and clinical data, including humans, animals and the environment.

- Establishing a harmonized system for data collection, access, sharing, analysis, and a unified data portal for infectious diseases
- Building a strong modelling and forecasting network for early prediction of emerging threats
- Creating a strong biosecurity network of BSL3 and BSL 4 facilities for characterization and epidemiological study of all priority pathogens and known/ unknown pathogens

Research & Innovation, Manufacture, Infrastructure, Capacity Building

- Focused research on priority pathogens to develop countermeasures
- Development of countermeasures -diagnostics, drugs, vaccines
- Allocating Pandemic Preparedness and Emergency Response fund for High-risk Research and Innovation
- Setting up an Institute of Innovation for New Platform technologies and vaccine research, development and manufacture
- Scaling manufacturing capacities and logistic supply chains for availability of counter measures Creating strong forward and backward linkages with vertical integration to develop strong supply chains, for countermeasures

Creating Centres of Excellence for Skilling Human Resources in identified gap areas

Risk Communication, Community Engagement, Private Sector Partnerships and International Collaborations

- Setting up of a specialised Risk communication unit with Pre approved SOPs and protocols for release and dissemination of information on a regular basis to different stakeholders

Having pre-approved instrument, guidelines and agreements for Private sector participation in

- surveillance, research, manufacture and disease management including testing, vaccination and treatment
- Community engagement SOPs to be developed for proper disease management Building strong Partnership models at Centre, State, district and community level and collaboration with the international organisations

The proposed PPER Framework encompasses the One Health Mission and its activities of Surveillance, Research, Data Management and Infrastructure networks.

The PPER Framework proposes a road map and Action Plan for preparing for any Public Health Emergency and delivering a well-articulated response in 100 Days.

The recommendations recognise existing frameworks, identify gaps that need to be strengthened and suggest how this Action plan could be implemented.

Some key recommendations are listed below. Those areas/activities taken up under the OH Mission can be further strengthened and integrated with the implementation plan proposed under the PPER Framework.

6.1 Governance, Legislation, Finance and Management

i. Enacting a new Public Health Emergency Management Act (PHEMA)
ii. Creating an institutionalized empowered governance mechanism for Public Health Emergencies - An Empowered Group of Secretaries on PPER chaired by the Cabinet Secretary
iii. Constituting a Monitoring Group co-chaired by the Secretary Health and the Secretary Dept. of Health Research (DHR)
iv. Preparing a detailed SOP (implementation manual) for rapid response to biological threats
v. Setting up of a special Pandemic Preparedness and Emergency Response fund for all PPER activities of surveillance, data management, forecasting and modelling, research, innovation and manufacturing, development of countermeasures, infrastructure and capacity building

6.2 Data Management, Surveillance and Early Predictive Warning, Forecasting and Modelling,

i. Creating a well-connected/integrated robust surveillance network linking epidemiological, genomic and clinical data, including humans, animals and the environment.
ii. Establishing a harmonised system for data collection, access, sharing, analysis, and a unified data portal for infectious diseases.
iii. Building a solid modelling and forecasting network for early prediction of emerging threats.
iv. Creating a strong biosecurity network of BSL3 and BSL4 facilities for characterisation and epidemiological study of priority and known/unknown pathogens (in animals and humans).

6.3 Research and Innovation, Manufacturing, Infrastructure, Capacity building/Skilling

i. Multi-disciplinary research on priority pathogens
ii. Development of countermeasures - diagnostics, therapeutics, vaccines, protective equipment

iii. PPER fund for High-risk Research and Innovation
iv. Setting up an Institute of Innovation for New Platform technologies and vaccine research and development
v. Scaling manufacturing capacities and logistic supply chains for the availability of countermeasures, and stockpile management.
vi. Creating strong forward and backward linkages with vertical integration to develop resilient supply chains for countermeasures
vii. Creating Centers of Excellence for Skilling Human Resources in identified gap areas.

6.4 Partnership: Community engagement including risk communication, Private sector partnerships, and International collaborations

i. Setting up a specialised risk communication unit in MoHFW (NCDC) with preapproved SOPs and protocols for dissemination of information regularly to different stakeholders
ii. Having preapproved instruments, guidelines and agreements for Private sector participation in surveillance, research, and manufacturing
iii. Community engagement SOPs are to be developed for clinical care, including preventive measures, testing, vaccination, and treatment
iv. Building strong mechanisms for centre-state collaboration during emergencies with well-defined responsibilities, accountability and reporting structures

6.1 Governance, Legislation, Finance and Management

6.1.1 Governance

The unique aspect of managing the COVID pandemic was the empowering governing mechanisms - the Empowered Groups constituted for COVID-19 pandemic management were crucial to facilitating a rapid response and urgent action to address the unique challenges faced.

As a learning, it is therefore essential emphasise building systems that are active not just in wartime but also in peacetime. What is needed is institutionalised empowered systems like those built at COVID times to ensure effective collaboration and operationalisation for preparing for pandemics and responding on priority. It is proposed that a **Standing Empowered Group of Secretaries (EGoS) for Pandemic Preparedness and Emergency Response (PPER) should be constituted** and chaired by Cabinet Secretary and Co-Chaired by Member Health NITI Aayog and PSA, with all concerned departments and agencies and nodal officers from States/UTs represented at the level of Secretary as Members. EGoS would monitor preparedness and give required directions and approvals for the essential governance mechanisms, financial budgets and other approvals necessary required with the approved governance framework for the OH Mission and other pandemic-related activities.

For future preparedness, it is imperative to institutionalise the existing governance structures and develop Standard Operating Procedure (SOP) for rapid response, which is essential to act in different emergency situations. Therefore, operational manuals/SOPs with local and global learnings for epidemic/pandemic times must be prepared. The operative mechanism should be institutionalised, and drills should be performed (like war-room operations of armed forces) as a preparedness measure. It is proposed that the systems developed during COVID-19 should be institutionalised for the whole of government approach to facilitate rapid inter-government response.

The progress of the action plan needs to be continuously monitored through a scorecard developed with defined targets and milestones. A PPER monitoring working group chaired by Secy Health and Secy DHR will monitor the progress on a continuous basis through the scorecard and report to the EGoS.

- A Standing Empowered Group of Secretaries (EGoS) for Pandemic Preparedness and Emergency Response (PPER) should be constituted to prepare and monitor preparedness during peace times - to guide on governance, finance, R&D, surveillance, partnerships and collaborations, and other necessary functions that can be ramped up for immediate response in a public health emergency
- EGoS to be chaired by Cabinet Secretary and Co-Chaired by Member, Health, NITI Aayog, and PSA, with all concerned departments and agencies represented at the level of Secretary as Members. This will connect with the approved governance framework for the OH Mission and other pandemic related activities.
- EGoS to establish separate empowered working groups for each area in the time of any emergency, like the Empowered Groups during COVID-19.

Engagement with States: Centre-State Coordination

In India, health being a state subject there have been challenges in managing outbreak-prone diseases, and we need special focus on inter-state and centre-state collaboration particularly to strengthen some of the following areas:

i. Data flow on outbreak prone diseases for planning surveillance and response strategies.
ii. Coordination and data sharing amongst relevant nodal officers, since infectious diseases and public health events are not limited within district/ state boundaries.
iii. Creation of sentinel sites in state hospitals and laboratories for surveillance and sample collection for genome sequencing. Transportation of samples to identified laboratories of the centre has been quite challenging during pandemic times. This system needs better coordination.
iv. There were specific challenges related to supplies of Viral Transport Medium (VTM), testing kits, PPEs, Vaccines and other logistics at the state level, it is therefore essential that the EGoS-approved SoPs should give specific instructions in this regard.
v. The availability of finances for emergency procurements, deploying HR during surges, and involving private sector labs and hospitals at the state level need special attention.

Accordingly, it is suggested that a seamless coordination between the State/UTs and the centre is an essential pre- requisite for effective pandemic preparedness. During COVID this coordination played a vital role in the mitigation of the impact on morbidity and mortality. Hence, it is recommended that:

i. At the State/UT level, a senior officer should also be designated as the Nodal Officer for coordinating all activities related to pandemic preparedness and response.
ii. Outbreak-prone diseases and diseases or events with potential for cross-border spread/impact need to be coordinated by the designated nodal officer and the central surveillance unit of NCDC.
iii. SSU and DSU need to ensure proper data uploading and real-time sharing with CSU to detect, assess, and notify outbreaks or events of public health significance.
iv. Competency building training needs to be completed in a time-bound, manner.
v. All events declared as PHEIC or potential PHEIC need to be under MoHFW, GOI and the nodal officer should be responsible for coordinating all the activities related to pandemic preparedness in the respective State/UT.
vi. The nodal officers of five State/UTs should be ex-officio members of the EGoS proposed to be set up under the Cabinet Secretariat on a rotation basis.

» Every State/UT to have a designated senior officer as a Nodal Officer
» Nodal officer to be responsible for: coordinating activities for pandemic preparedness and response; proper dissemination of data/information as and when required
» EGoS under Cabinet Secretariat to have Nodal Officers of a few States as members

6.1.2 Legislation

A key factor to be considered is the need for a special Public Health Legislation. At the Central level, two laws – the Epidemic Diseases Act (EDA) 1897 and the National Disaster Management Act (NDMA) 2005, direct the legal framework on PHEs. During COVID-19, the pandemic was managed under the National Disaster Management Act 2005. While this provided the required powers for taking necessary actions on priority, especially at the central and state levels, there are key areas of medical health which need to be tackled with special powers and provisions for which a special Medical Emergency or Public Health Emergency Management Act (PHEMA) is essentially required.

The NDMA 2005 was enacted after the 2004 tsunami; it was not designed to cater to health emergencies. It does not specifically define public health emergencies or epidemics. It focuses on managing several types of disasters, including natural disasters (such as earthquakes, floods, and cyclones) and man-made disasters (such as industrial accidents, chemical spills, and nuclear incidents). It provides a comprehensive framework for disaster preparedness, response, mitigation, and recovery at the national, state, and district levels.

The Epidemic Diseases Act (EDA) 1897 authorises the Central and State governments to take measures and prescribe regulations to be observed by the citizens to contain the spread of a disease. The law outlines a set of rudimentary elements, including travel restrictions, examination and quarantine of persons suspected of being infected in hospitals or temporary accommodations, and statutory health inspections of any ship or vessel leaving or arriving at any port of call. However, over the years, no standard or model rules and regulations have been prescribed as a corollary to the law nor has it been amended.

The EDA 1897 does not define “dangerous”, “infectious”, or “contagious diseases”, or “epidemic”. It contains no provisions for the processes required for dissemination of drugs/vaccines, and the quarantine measures and other preventive steps that need to be taken. Further, the EDA 1897 only confers powers and does not describe the government’s duties in preventing and controlling the epidemic, nor does it explicitly state the rights of the citizens during the event of a significant disease outbreak.

The International Health Regulations (IHR) require States to undertake measures during a PHE including communication of public health information to the WHO and the regulation of travellers and vessels at ports of entry into the country that national authorities can best address. A PHE also requires interstate coordination and the regulation of the movement of people and goods, as was evident during the COVID-19 pandemic which necessitates central intervention. Further, effective PHE response also requires capacity building at the state, district and local levels. The absence of modern, overarching legislation specifically targeted at PHEs has meant that capacity and expertise for PHE preparedness and response needed to be faster to develop at all levels.

A Public Health Emergency Management Act can address various aspects beyond epidemic, including non-communicable diseases, disasters, and bioterrorism.

It allows for a holistic approach to health management, covering prevention, control, and disaster response. The Act would also create public health cadres at national and state levels.

This special provision act would empower public health agencies to take urgent action. A first responding lead agency responsible for implementing this Act should be identified. This allows for immediate rapid response by all health agencies, organisations, and departments with no time lag. This also allows building a workforce which is always trained and in peacetime has full preparedness to be the first responder on war outbreak.

Declaration of Public Health Emergency Management Act (PHEMA) with special provisions at the centre and state levels will facilitate priority action for-

- Building the required expertise for PHE preparedness and response at national, state and local government levels
- Repositioning of personnel for special tasks
- Regulation of travellers and vessels at ports of entry into the country
- Interstate coordination and the regulation of the movement of people and goods
- Communication of public health information, dealing with infodemic
- Accelerated development and regulatory approval of diagnostics, therapeutics and vaccines
- Special Procurement provisions for necessary goods and services for emergency response
- Coordination with international organisations and countries for a PHEIC
- Carrying out the government's duties in preventing and controlling the epidemic

Globally, such Acts exist. Countries such as the United Kingdom, Canada, and the United States of America (USA) have in place more comprehensive and updated legislation to deal with public health emergencies. The Public Health Service Act is a United States federal law that was enacted in 1944. This Act provided a legislative basis for public health services in the United States. The Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 was enacted March 13, 2013, as a law by the 113th United States Congress. The Act amends the Public Health Service Act to extend, fund, and improve several programs designed to prepare the United States and health professionals in the event of a pandemic, epidemic, or biological, chemical, radiological, or nuclear accident or attack. The Act clarifies the authority of different US officials, makes it easier to reassign personnel to respond to emergency situations temporarily, and alters the process for testing and producing medical countermeasures. The Act is focused on improving preparedness for any public health emergency.

The Public Health Service Act established the federal government's quarantine authority for the first time. It gave the United States Public Health Service responsibility for preventing the introduction, transmission and spread of communicable diseases from foreign countries into the United States. The

Public Health Service Act granted the original authority for scientists and special consultants to be appointed “without regard to the civil-service laws”, known as a Title 42 appointment.

6.1.3 Finance and Management

During COVID management, special financial packages were made available on an emergency basis for all activities, from surveillance to research, testing, tracking, treatment, health infrastructure, vaccination, etc. For effective preparedness and response to any future outbreak, epidemic, pandemic or public health crisis, it is essential that a **special Pandemic Preparedness and Emergency Response Fund** is established. This fund should be **specially earmarked for all activities being proposed under the PPER Framework**. The aim of the fund would be to be fully prepared in advance so that we are ready to deliver in any emergency in a 100 days time frame. This fund should be deployed as per the requirement assessed and approved by EGoS.

6.2 Data Management, Early Predictive Warning and Surveillance, Forecasting and Modelling

6.2.1 (a) Data Management (Generation/Sharing/ Analysis)

The COVID-19 pandemic threw up particularly important aspects for predicting disease trajectory in affected areas, epidemiological monitoring of morbidity and mortality, countermeasure development, clinical management, treatment, and effectiveness monitoring. Mutations leading to variants of concern associated with unpredictable transmission rates and severity even in exposed/infected persons required harmonised, interoperable data collection, seamless flow of data across different systems and most importantly, data analysis, for proper interpretation to facilitate speedy decision-making. Hence, it is important that **all data portals must be integrated.**

- Build a single unified data platform and integrate all data portals for data sharing along with an advanced system for data analysis. At present, data availability and sharing pose a challenge, specifically the seamless sharing of raw data, which affects the analysis of data and the drawing of meaningful inferences.
- Utilise IHIP and IDSP data to design the outbreak module in case of a future outbreak and further strengthening of IHIP and IDSP system.
- Work on further development in data collection, with its optimal management, and archiving, systems in place for training, capacity building, and integration with modelling systems after due analysis.

Generation of data on clinical, genomic, serological surveys, and immunological surveys will help build predictable modelling systems, which thereby will provide a defined strategy for intermittent lockdown and restricting the spread in a contained and controlled manner. This is possible if existing data systems are integrated and a **Unified Data Management System** is maintained. This can then be supported by the setting up of an Analytical Cell at the National level to extract the data from different sources and further interpret it effectively as per requirement. Surveillance data on environment, sewage, hospitals, and community to be integrated into the system along with the genomic and serological data.

6.2.1 (b) Data Communication

Data Communication is a critical component and needs to be conveyed in a timely and correct manner:

i. An empowered **Data Analysis and Reporting Unit to be established at NCDC**, which is headed by a senior level technically competent person who is empowered to allow access and sharing of data and is responsible for timely Data communication to the right agencies including public communication
ii. A **manual of pre-approved delegated powers to be available** to allow such data communication, sharing and access.

6.2.2 Surveillance

The country already has a strong surveillance network from centre to state to district level. This massive system exists in the remotest areas. All components of this system should be strengthened and connected to work in a harmonised, auto pilot mode that gets ignited as soon as the first warning sign is received. This surveillance system needs connection and close coordination between the centre, state, and district with laboratories, hospitals and points of entry (airports, ports and international border) surveillance systems.

In unknown pathogen-driven disease epidemics and pandemics, the key aspect to be considered is the need for a robust surveillance network.

- Strengthen and connect all components of the existing surveillance system to work in a harmonised, autopilot mode that gets ignited as soon as the first warning sign is received with precursor for regular testing of the system
- Building a strong surveillance system including both public and private sectors with a One Health approach including biosecurity and focus on surveillance at border, ports of entry.
- Developing strong community surveillance (trend-data time) system; especially in susceptible areas/hot spots, so that an alert can be generated when something goes wrong.
- Strengthen real-time surveillance to include the rate of rise and severity of a disease to understand the severity of the pandemic on the ground, incorporating the use of Artificial Intelligence and new tools and technologies.
- Strengthening the Genome sequencing Network at the country level to monitor the genetic variations in the pathogen and study the linkages between the genomic variants and epidemiological trends. INSACOG needs to be strengthened.
- Reinforce Wildlife/Animal sector surveillance, as it has been a weak link in the surveillance
- Setting up a Regional Surveillance Network and further connecting it with Genomic surveillance, specially to monitor the trans-boundary movement of pathogens

Epidemiological surveillance should have Genomic surveillance as an integral component on one end and hospital surveillance data on the other end. Key actions required are:

I. Emergency Operations Center – Network (EOC-NET)

During various outbreaks and pandemics, Public Health Emergency Operations Centres (PHEOCs) have played a key role in monitoring the ground level situations, providing them necessary feedback through a roster of experts and ensuring regular quality data flow. Apart from the Ministry of Health, EOCs are functioning under various ministries, including NDMA and SDMA, up to the district level. However, there is need to ensure that EOCs and PHEOCs are established to cover all districts of the country and integrate for maximizing the use and output through mutual sharing and convergence.

The **Emergency Operations Centre-Network (EOC-NET) will be a specialized network infrastructure designed to enhance communication and coordination** within various Emergency Operations Centres (EOC) working in isolation for specific hazards. EOCs serve as central command and control facilities during crises like natural disasters or pandemics. The EOC-NET plays a crucial role in facilitating real-time information exchange, collaboration, and decision-making among various emergency response agencies and stakeholders. It incorporates advanced communication technologies, data sharing platforms, and secure channels to ensure seamless information flow and coordination within the EOC. The effectiveness of the EOC-NET is vital for prompt and efficient emergency responses, enabling responders to share critical data, assess situations, and deploy resources strategically. This integration of technology underscores a commitment to improving overall preparedness and resilience in the face of unexpected events.

II. Focused attention on Bats:

Most viral pathogens in humans have animal origins and arise through cross-species transmission. Over the past 50 years, several viruses, including Ebola virus, Marburg virus, Nipah virus, Hendra virus, severe acute respiratory syndrome coronavirus (SARS-CoV), Middle East respiratory coronavirus (MERS-CoV) and SARS-CoV-2, have been linked to various bat species. Despite decades of research on bats and the pathogens they carry, the fields of bat virus ecology and molecular biology are still nascent, with many questions largely unexplored, thus hindering our ability to anticipate and prepare for the next viral outbreak. More than 200 viruses have been associated with bats and almost all are RNA viruses; probably owing to their remarkable ability to adapt to changing environmental conditions through a higher genetic variability. In fact, RNA viruses have higher mutation rates compared to DNA viruses as the viral RNA polymerases lack proofreading activity.

The natural reservoirs for Marburgvirus and Ebolavirus are both fruit and insectivorous bats. Recently, two new subtypes evolutionarily distinct from all others – H17N10 and H18N11 – were detected in different fruit bat species in Central and South America. Further, Influenza A virus is an uncommon promiscuous virus with a wide host range including humans, pigs, and birds.

The first hantavirus isolated from bats was the Hantaan virus, the etiological agent of haemorrhagic fever with renal syndrome. Successively, although hantaviruses were identified in other bat species, to date, no bat-to-human transmission of hantaviruses has been observed. This pathogen has been identified as having the risk of spreading to humans and having pandemic potential.

Hence, focusing on One Health approach for bat-human interface is imperative.

III. Setting up a Regional Consortium for Molecular Surveillance

As the world witnessed the global impact of the COVID-19 pandemic and the critical role of surveillance, it is important to consider some effective preventive measures and prepare ourselves to counter emerging infections in future efficiently. The neighbouring countries are the most vulnerable when a communicable disease

spreads. Scientific intervention is one of the valuable tools which can curb the disease burden between adjacent countries. Therefore, a well-established regional collaboration platform for molecular surveillance of emerging and re-emerging diseases will be advantageous since India has a long border shared with many of the neighbouring nations, which enhances the chance of spreading infectious diseases across the border. This transboundary movement of pathogens includes zoonotic pathogens, and a One Health approach and should be adopted. The countries which could be included in this regional consortium are those which have similar concerns and would require stringent monitoring of transboundary movement of pathogens.

The INSACOG network for Genomic surveillance of SARS CoV-2 is well established today across the country, across states and in different departments. The network is linked to epidemiological surveillance and clinical or hospital networks. This provides a distinctive advantage of strong surveillance and an early warning of any clinically important pathogen. A virtual network can be established by considering the scientific bodies of the participating countries as well as several veterinary research organisations for continuous surveillance of infections and screening of emerging novel mutations among circulating strains.

Biology of the disease progression and transmission in the neighbouring countries is important to take proper decisions on the future preventive measures and health policies. The participating countries' population density, hygiene habits and public health policies are unique in each case. Hence, addressing the burden of viral diseases with respect to these unique characteristics would be beneficial. Confirmed decisions can be taken about international travel between the countries.

This joint scientific venture between the participating countries will enable the viral genomes of patients to be analysed quickly with the application of standardised guidelines. Such a regional consortium can prepare the countries for future pandemics which could quickly adopt preventive measures.

IV. Setting up of the National Biosafety & Biosecurity Network:

The current COVID-19 pandemic crisis has highlighted the need to **develop a "National Biosecurity and Biosafety Network" across the country**. There is a need to have a better surveillance system with advanced diagnostic facilities and customary network facilities to tackle pathogens affecting humans, livestock, and animals, including marine life as well as plants, integrating several areas of activities to address issues on Biosecurity and Biosafety. It is essential to integrate animal and human pathogens as a 'One Health' issue, rather than to treat them as separate entities in the manner that has been adopted thus far in the country.

An integrated approach would be needed to strengthen the nation on the biosecurity and biosafety front, and various aspects of research and development need to be developed, such as a) pathogen identification b) clinical profiling c) disease epidemiology d) platform technology for vaccine development e) drug development f) treatment strategies and e) disease surveillance etc. Currently, no one organisation, institute or network, puts in concerted efforts

on these focused areas to manage viruses. Therefore, it is very important to establish a new generation network,"National Biosecurity and Biosafety Network", for preparedness to tackle the future epidemic/pandemic. The most critical component of the National Biosecurity and Biosafety Network would be surveillance of known pathogens/diseases outbreak forecasting, and discovery of unknown emerging pathogens and development technologies for responding to their threat. This would need to be a network across all concerned Ministries and agencies – NCDC, DBT, ICMR, DRDO, ICAR, etc. Such a network has been proposed as a part of the One Health Mission and should be operationalised on priority.

The National Biosafety Biosecurity Network would have state-of-the-art laboratory facilities dedicated to defending the nation against biological threats. This network would support preparedness, planning and response and should have a network of laboratories which include biocontainment facilities (BSL-2, 3 & 4), biorepositories with research capacities for characterisation of the biological agents, which include bacterial, fungal & viral culture; PCR & Genomic sequencing and access to high throughput infrastructure which allows generation of high-quality data to address the challenges and guide policy and decision making.

The proposed National Biosafety and Biosecurity Network should focus on the following:

i. A network of at least 2-3 strategically funded research laboratories which have the capacities and capabilities to prepare the country for future pandemics would include
   - A network of biosafety containment facilities BSL-2, BSL-3 & BSL-4
   - Well-characterised biorepositories for viral and bacterial pathogens such repositories should have well-characterised reference cultures for panel threat pathogens and through a network of surveillance laboratories, they should build the stock and maintain the pathogens which are likely to be a threat hazardous. This would be for humans, animals and plants.

ii. Expansion and strengthening of BSL 4 facilities in the country, which are a mandatory requirement for handling risk group 4 organisms. These facilities should be well prepared and maintain viral strains of all major diseases which have already caused epidemics/pandemics or are likely to be a cause of such future crises.

iii. A network of BSL-3 facilities, that can handle pathogen and strains that can be quickly used as reference sample. Mobile diagnostic laboratories (with high containment) should be established under the BSL2/3 laboratories for deployment in the event of an epidemic.

iv. Genome sequencing centres which are linked to these repositories continuously access different viral strains which have been collected or identified through surveillance studies and generate genomic sequences from them. This is important to help us to initiate our research quickly with speed without wasting any time as and when any epidemic situation arises.

v. Centres of Excellence in the country that continuously train human resource on the latest technologies related to viral research.

vi. The network of research laboratories nationwide of the best scientific groups across different agencies to be brought together and supported for research on infectious and zoonotic diseases.

vii. At least 2 to 3 Centres of Excellence should be established, which would study not just epidemiology but also related aspects regarding transmissions, genetic structure, etc., and would play a significant role in the diagnostic testing and disease management.

viii. Strengthening Centres of Diagnostic Development which can create platform technologies that would help quickly develop new diagnostics in response to any major disease outbreak. While such an immediate response was seen in the case of COVID-19, but for other zoonotic diseases, the country is still dependent on imported kits and reagents. An emergency vaccine bank should be established for agents which are exotic to the country (stockpiling). These vaccine banks can source its vaccines either from within or outside the country. A network of diagnostic test labs to be continuously monitored with trained human resources and infrastructure for conducting tests with the ability to scale up when the need arises. The large network of laboratories across agencies which have been brought together as validation and testing centres for COVID 19 need be strengthened.

ix. The key to the success of the proposed National Network would be to hire personnel with very high levels of training and competence and to offer an ecosystem conducive to undertaking globally competitive research and development activities.

6.2.3. Forecasting & Modelling

Modelling during pandemics is helpful in the assessment of the course of the epidemic/pandemic and the trajectory of cases, morbidity and mortality. These are crucial for public health agencies in ensuring future preparedness regarding provision of PPEs, quarantine and isolation beds, human resource, etc for making policy decisions and implementing policy. However, for development of predictive models, the relevant institutes depend on reliable multi-source data along with epidemiological determinants like incubation period, reproductive number R_0 (the average number of secondary infections caused by an infected individual in a fully susceptible population) and Rt (the current transmission dynamics during an outbreak), secondary attack rate etc. for short-term forecasting on likelihood of different trajectories in different areas and populations in the immediate future. A key challenge during COVID was the lack of a strong Indian forecasting and modelling network, availability of reliable data on cases, testing, demographics and inconsistent reporting. Further, amid ever-evolving uncertainty faced during the pandemic. The models should also account for uncertainties in transmission rates, incubation periods, and other factors particularly with variants that have different public health impacts.

It is proposed to **build a strong scientific framework for Epidemiology Forecasting and Modelling** to develop prediction models based on reliable Indian data at par with global standards. This will also allow the creation of mathematical models for predicting transmission dynamics of infectious diseases and monitoring the effectiveness of countermeasures, including vaccination, in different scenarios driven by variants.

It is recommended to create a **Network of Centres for mathematical modelling**, with a partnership between academicians, the private sector, the public sector, hospitals, etc. We need to build capacities and have trained human resources with different skill sets.

Developing an Early Warning and Predictive Modelling for epidemic and pandemic trend

- Build a strong Epidemiology Forecasting and Modelling Network of Centres of Excellence to develop prediction models based on Indian epidemiological data and make these models at par with global standards
- The use of AI and other emerging technologies would be critical for such modelling efforts
- The data from surveillance systems - community, laboratory, clinical, hospital, genomic, sewage etc. is a critical source for such modelling efforts
- DST may launch this Epidemiological Forecasting and Modelling Network in a mission mode for early prediction.
- The ICMR National Institute for Research in Digital Health and Data Science can be a nodal institute; however, the network should involve competent groups in IITs, research institutes both public and private, supported financially by DST, O/o PSA, Dept. of Education and philanthropic and private funds.
- Create Centres of Mathematical Modelling to build capacities in new technologies and Human Resource

6.3 Research and Innovation, Manufacturing, Infrastructure, Capacity building/Skilling

6.3.1 Research & Innovation

Infectious, emerging and re-emerging zoonotic epidemics are a significant threat to public health. Coronaviruses are a group of related viruses that are mainly considered to cause diseases in mammals, birds and humans. During the last two decades, it has spilt over three times by zoonotic pathways with genetic modification and emerged as Severe Acute Respiratory Syndrome Coronavirus 1 (SARS-CoV-1), Middle East Respiratory Syndrome Coronavirus (MERS-CoV) and Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). SARS-CoV-2 is highly pathogenic, and human-to-human spread makes it more virulent.

COVID demonstrates that research and innovation have played a leading role in our fight against the pandemic. Our risk-taking ability allowed new platform technologies for vaccines and a range of diagnostics to be developed indigenously. High-risk funding through Mission COVID Suraksha gave us the desired results and was critical in building the levels of research competence in both the public and private sectors. It is imperative that this is promoted, and a strong Research and Innovation ecosystem is built.

The robust ecosystem that existed before COVID for research and innovation, especially in the healthcare sector, was a strong foundation on which the COVID countermeasure development activities were scaled. From basic research capacities to shared infrastructure for translational research, all these were critical value chain components for affordable product development. During COVID, the scientists successfully developed several new platform technologies and a strong portfolio of candidate vaccines - mRNA, DNA, Nasal vaccine etc.

A need-based strengthening of the ecosystem was done. However, there were challenges faced, and there is a need to plug the gaps. The key challenge was the need for established protocols and SoPs for sharing biological and clinical samples and the need for more centres for characterization of viruses. When the Chinese and US research groups released the first gene sequence of the Virus, they started immediate action for developing the countermeasures. Candidate vaccine libraries were quickly worked upon, and the development of vaccines on different platform technologies was pushed on an accelerated scale. Access to the characterised virus strain and assay panels allowed quick development of diagnostics which were needed essentially in large numbers to track the disease. While the country had the competencies to take up these tasks, time was lost in building the processes for them. The first characterised virus strain was available only with NIV, ICMR in April, and that was made available to Bharat Biotech, who then developed Covaxin in partnership with ICMR.

The Empowered Group for Emergency Management Chaired by Dr Vinod Paul, Member NITI Aayog, issued guidelines for sharing of biological and clinical data, and also sample sharing and managing of biorepositories for access to these clinical samples. Subsequently, the notified biorepositories played an important role in making available the assays required for developing diagnostic kits.

The other key challenge in developing diagnostic kits was the dependency on imported reagents and enzymes. Mechanisms such as the DBT-led NBRIC and the cCAMP and AMTZ centres brought together different industries and startups, who provided the required reagents, enzymes, etc. This enabled a speedy indigenous manufacture of large quantities of diagnostic kits.

These capacities, tools, and instruments to enable priority action should now implemented so that during any emergency, action begins on day one. It is, therefore, essential to establish mechanisms for supporting research & development of innovative countermeasures on a continuous basis. Some specific actions are

i. There is an urgent need to allocate the **High-Risk Innovation Research and Development Fund** from the special fund for pandemic preparedness and emergency response for:
   - supporting Research & Development for diagnostics, therapeutics and vaccines,
   - capacity building both Human Resources and Infrastructure
   - cutting-edge technology development

ii. Fund to be earmarked and positioned with Department of Expenditure; to be released to concerned Ministries/Departments on the recommendation of EGoS

iii. Financial support for basic, applied and translational research across the value chain for continuous development of:
   - new prototype vaccine candidates and vaccine libraries for the priority pathogens
   - platform technologies
   - New drug molecules for priority infectious diseases and antibiotics for tackling the issue of AMR
   - New highly specific and sensitive diagnostics for each identified pathogen

iv. Supporting and encouraging the industry and startup ecosystem to be part of this high-risk innovation research

v. Set up a **Network of Centres of Excellence (CoE) for research on priority pathogens.** Research efforts to focus on priority pathogens in the priority list released by WHO.

vi. New emerging pathogens identified through One Health, national surveillance or recombinant research efforts to be studied, characterized and maintained in designated repositories

vii. Develop diagnostics, therapeutics and vaccines for an identified prototype pathogen from the priority pathogen family

viii. Centres that have access to Bio Safety Level (BSL) 3, BSL 4 laboratories and biorepositories to be part of the National Biosecurity Network

ix. ICMR, DBT, CSIR, NCDC to be part of the CoEs

- Establish a special High-Risk Innovation Research and Development Fund for Pandemic preparedness and Emergency response
- Establish a Vaccine Science & Development Institute
- Launch National Mission on Therapeutics and novel drug development
- Development of novel diagnostics (such as molecular diagnostics)
- Development of vaccines, antimicrobials, and monoclonal antibodies in a PPP mode
- Set up a Network of Centres of Excellence (CoE) for research on priority pathogens

Development of Countermeasures

Diagnostics

When COVID struck the world, the first challenge was the development of testing capacity. Testing was important for tracking the disease and finding treatment solutions. A large number of sensitive and specific diagnostic kits were needed. There were urgent demands on the few global manufacturers who had developed the diagnostics with high specificity and sensitivity. There was massive pressure on supply chains because of increasing global demands. Countries were accelerating their indigenous development. In India, there exists a strong medical diagnostics start-up ecosystem and industry. These were given the responsibility, along with a number of academic laboratories, to develop indigenous diagnostic kits.

The work started in a mission mode; however, faced huge challenges. While kits were developed indigenously, India was entirely dependent on the import of reagents and enzymes. The other challenge was the validation of new diagnostics, for which notified validation centres were required. It was also essential that the necessary assay panels were made available, which required the availability of clinical samples, access to virus culture and biorepositories were needed. These challenges were overcome, and within three months, India built the required competencies and started manufacturing kits in the desired numbers.

It is now recommended that this ecosystem should be further strengthened. The focus should be on the development of novel diagnostics (such as molecular diagnostics) for the identification of emerging infections from new pathogens.

- **Case study – Disease "X "outbreak – Diagnostic kit Development, validation and Access for Distribution in Market.**

In the event of a Disease outbreak, the immediate development and deployment of a diagnostic kit for public diagnosis and subsequent treatment is crucial to prevent the rapid spread of the disease. This process involves three major activities as follows:

a) Diagnostic Kit development: Value chain of Raw materials

Diagnostic kits come in two types: Immuno Diagnostic tests and Clinical Chemistry & Molecular Biology tests. Immuno Diagnostic tests (Platforms: Lateral Flow Assay (LFA) kits, Enzyme-linked Immunosorbent Assay (ELISA), Chemiluminescence Immunoassay (CLIA), Radioimmunoassay (RIA)) and Clinical Chemistry & Molecular tests (Technologies: Biochemistry/Clinical Chemistry, Microbiology, Serology tests, Polymerase Chain Reaction (PCR)).

Most raw materials for these tests, such as Chemicals, Reagents, Enzymes, Primers, Probes etc. are locally available. Specialised items like nanoparticles, radioisotopes, antigens, antibodies etc. might be needed., supply chains for these should be built.

Timeline: Common raw materials have a lead time of 1-2 weeks (Local availability). Specialised materials that are imported take 1-2 months to deliver. Therefore, all dependency on imported material should be removed, and indigenous manufacture and supply chains developed.

b) Testing & Validation: Laboratory infrastructure for testing and reference samples.

The final stage of diagnostic kit development is testing, which includes internal and external validation.

i. Internal Validation: Reference samples or controls can be sourced from authorized bodies (e.g., AIIMS, NIV, ICMR Centres) for internal performance evaluation (Specificity and Sensitivity).

ii. External Validation: Kit are sent to accredited labs (e.g., ICMR, CDSCO, NIB, NIV) for validation. These labs test the kits using available reference samples and provide results to the manufacturer.

iii. Regulatory Approval: The above results are submitted to CDSCO to obtain a license for manufacturing and sale.

Timeline: The testing, validation, and regulatory licensing process takes more than 2- 3 months. It is crucial that we build a robust system for validation and have approved protocols and processes in place to ensure the accuracy and reliability of the diagnostic kits. In emergencies, CDSCO may audit the manufacturing facility and expedite licensing based on test reports on conditional basis, with full performance reports to be submitted once the outbreak is under control.

c) Distribution/ Deployment in the market: Access, Distribution, Logistics.

The next step for the licensed kit is distribution to testing centres and healthcare outlets (e.g., pharmacies etc.). Key logistics considerations include:

i. Quantity and Type: Based on the outbreak's nature (endemic, pandemic, epidemic), scale, and location.

ii. Central Warehouses: These Facilities have temperature control and use inventory management systems to track stock levels, expiration dates, and distribution, reducing logistics time.

iii. Transportation: Plan for transporting kits from central storage to local distribution points, ensuring temperature control with systems like cold storage if necessary.

iv. Distribution Strategy: Kits are distributed based on outbreak severity and population density in coordination with local health departments.

Timeline: This varies depending on the outbreak location and the source of kit manufacturing or central warehouses. The plan of action and SOPs for this should be in place and notified.

An immediate Mission is to be started for developing the kits for the identified priority pathogens.

Drugs and Therapeutics

A focused **National Mission on Therapeutics** and **novel drug development should** be launched. The Council of Scientific and Industrial Research (CSIR) could lead with the National Institute of Pharmaceutical Education and Research (NIPER) and other laboratories in PPP model with Industry.

During COVID, the country faced a situation where, while several therapies and drugs were available for treatment, the required drugs were not available as repurposed, or new drug development for specific disease targets is still in a nascent stage. Over the years, while capacities have been built for infrastructure, international partnerships etc., what needs to be added is a coordinated effort to take initial discovery research leads/hits to product development through the value chain right up to manufacture and licensure/market authorisation involving various stakeholders. This effort can now be given the required momentum by bringing together the public and private sectors, researchers, manufacturers etc. to meet a targeted goal of developing drugs for priority pathogens A Mission on Therapeutics for priority pathogens needs to be launched urgently.

Drug discovery efforts can be undertaken against viruses of pandemic potential for which two key major approaches can be deployed for the identifying of direct antiviral drugs in the event of a pandemic: 1) Repurposing of approved drugs and 2) Identification of novel compounds. Each approach has its advantages and disadvantages. Whichever approach one chooses, compounds must be characterized and taken up to Phase 1 clinical trials to establish the safety of compounds. This way, compounds are primed and ready for a Phase 2 study should the need arise. In the event of a pandemic, a limited Phase 2 in patients should be planned and discussed with the Regulator to establish the efficacious dose range and safety considerations.

1**) Repurposing of approved drugs** (*Figure 1*): Over 19,000 FDA-approved drugs have a full clinical package and dosing information. If repurposed for a different indication, this group of compounds does not have to go through Phase 1 studies unless the doses predicted for human use fall outside the approved range.

The approved drug library should be purchased and screened against a panel of viruses in whole-cell screening assays. Criteria for hit selection should be defined. Such compounds should be evaluated for pharmacokinetics by the oral and intravenous route in the efficacy species and then tested in vivo in the appropriate model. The ED50 should be determined, as well as a PK-PD correlation. If PK data are available for a higher species, allometric scaling should be utilised to determine the therapeutic dose in humans. No further toxicity testing would be needed if this falls within the approved dose range. If the dose is predicted to be higher than the approved dose range, the regulator may require Tox studies in rodent and non-rodent species, as well as a Phase 1 study. A discussion with the regulator would be needed at this stage to decide on the clinical development and regulatory strategy.

2) Identification of novel compounds (*Figure 2*): There are two options. The first would be to screen a library of compounds for activity against a panel of viruses. Such compounds should be evaluated for in vitro ADME, followed by pharmacokinetic studies. Compounds with PK profiles suitable for oral dosing should be tested for toxicity in the in vivo models and in rodent and non-rodent species for toxicity,

following all requirements for NCE development as per NDCT 2019 rules. Studies should be undertaken to understand the mechanism of action.

The second approach would be to conduct an in-silico screen against specific viral targets, such as RNA polymerase, helicase, etc., selecting compounds that show affinity for essential viral proteins for more than one class of viruses. Such compounds should be tested for antiviral activity and target-specific activity. Medicinal chemistry and structure guided/AI guided drug design should be used to optimize the compounds. As with the other approaches, pharmacokinetic profiles, efficacy in vivo and toxicity studies should be undertaken for the best compounds. Toxicity studies should be undertaken as per NDCT 2019 rules.

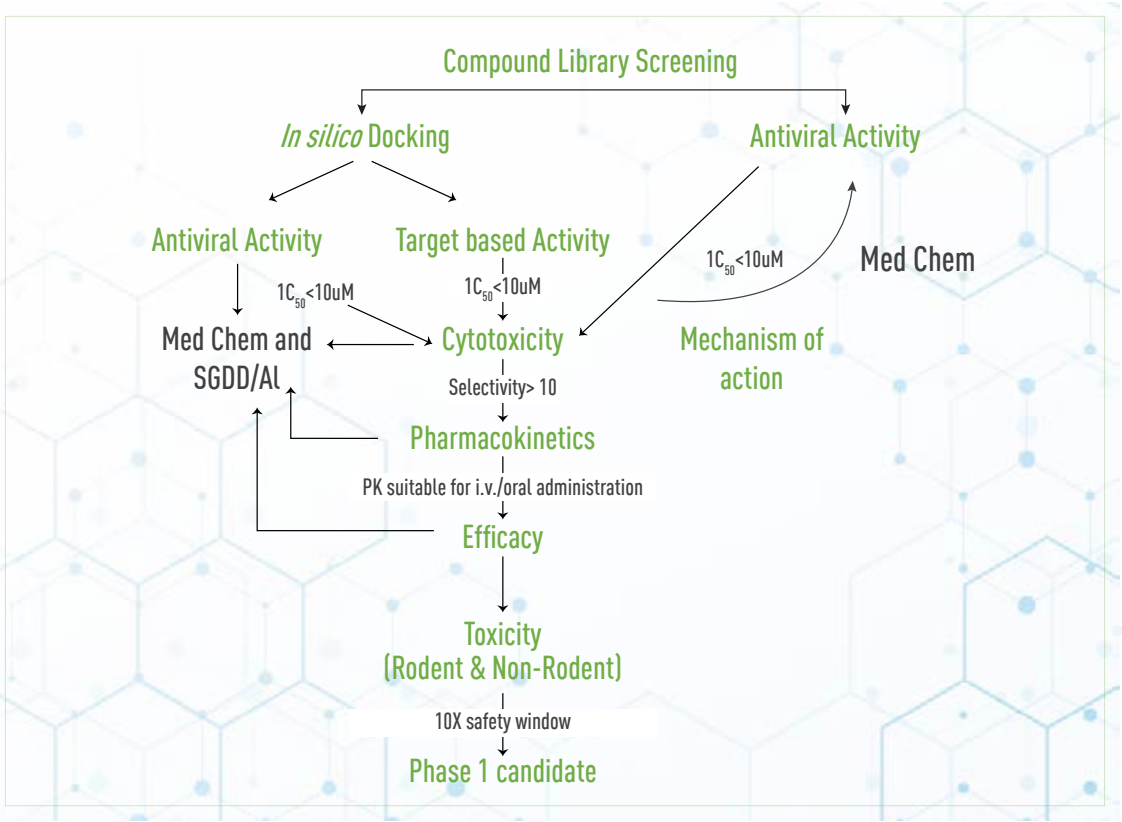
For this, capacities need to be built for the following:

- Antibody Library: Develop and maintain a naïve human antibody library that can be quickly screened to produce antiviral antibodies.

Figure 1: Repurposing of approved drugs

- Library of Compounds: Maintain a library of antiviral and antimicrobial compounds that can be rapidly screened against new pathogens.
- Animal Models and Simulations: Develop and validate animal models and computer simulations for testing drug efficacy and safety.
- Robust AI-based Platforms: Develop in silico methods to quickly predict the protein structure that could be used to design drug molecules and vaccine candidates.

Figure 2: Identification of novel compounds



A PPP model involving public and private organisations would be important. Companies with experience in antivirals/drug discovery should be involved. Manufacturers of drugs that are being repurposed should be encouraged to participate. Where Intellectual Property (IP) may not allow compounds to be repurposed, discussions with manufacturers should be initiated early.

Vaccines

During COVID, one of our major success stories was the development of a portfolio of vaccines on different platform technologies. India built partnerships with the private sector, provided necessary shared infrastructure for discovery, research and candidate development, immunoassay labs were set up which were of global standards and recognised as a part of the CEPI global network for vaccine trials. Animal challenge facilities, clinical trial network were the other key components which facilitated the development and manufacture of the world's first DNA Vaccine, mRNA vaccine, nasal vaccine, and others on different platforms.

This was possible because of the high-risk innovation funding made available and creation of an ecosystem for vaccine development, validation and manufacture. Using these facilities and competencies to establish platform technologies (e.g., mRNA, viral vectors, protein expression systems) that can be quickly adapted to new pathogens is important.

Establish an **Innovation and Vaccine Science & Development Institute**:

- Conduct active research on vaccine development, including basic and translational research and development of innovative technology platforms,

candidate vaccine libraries

- To set up the institute with the lead by DBT and collaborative partnership with other Institutes of ICMR, DST, CSIR, etc. Existing institutes such as THSTI, NII and others like NIV, CCMB, etc, and facilities created during Covid such as immunoassay labs, animal facilities, clinical trial network sites, etc., can be part of the network
- The One Health Mission/Centre approach to be adopted for operational management and governance with the involvement and participation of all concerned Agencies/Ministries
- Support public-private partnerships and involve all stakeholders, including Start-ups
- Focus on both Human and Animal Health for research and manufacture of prototype vaccines, new platforms and candidate vaccines
- Include scientific ways for new adjuvant development and all integral components for scale up and manufacture of vaccines

Biological threats may encompass outbreaks of infectious diseases, pandemics, accidental release of pathogens from the laboratory and also deliberate release pathogens to create public health threats.

India is a signatory to the Biological Weapon Convention. As per the Ministry of External Affairs Gazette notification dated 18th June 2016 under section 26 of the Weapons of Mass Destruction and their Delivery System (Prohibition of Unlawful Activities) Act 2005 (21 of 2005), appointment of Advisory Committees has been notified. The advisory committee on biological weapons and related items is being chaired by the Department of Biotechnology.

In India, The Weapons of Mass Destruction and their Delivery Systems (Prohibition of Unlawful Activities) Act, 2005 prohibits unlawful activities, concerning weapons of mass destruction and their delivery systems and for matters connected therewith or incidental thereto. As per the provisions of the Act- **"**No person shall unlawfully manufacture, acquire, possess, develop or transport a biological or chemical weapon or their means of delivery".

There is a need to strengthen the preparedness aspects for dealing with biological disasters and unforeseen events in view of biowarfares. The Biological Weapons are not necessarily the new and emerging pathogens. As per WHO, Biological agents like anthrax, botulinum toxin, and plague can pose a difficult public health challenge, causing large numbers of deaths in a short amount of time. Biological agents capable of secondary transmission can lead to epidemics.

It is proposed that the following may also be considered for Pandemic Preparedness and Emergency Response:

- To support research, development, and innovation in sensor-based detections of biowarfare agents, including toxins
- R & D support for development of newer decontamination strategies and PPEs
- Development of Prophylaxis: R & D support to develop newer vaccine platforms
- Development of therapeutics: R & D support to develop broad-based antibiotics. Development of antivirals, particularly for diseases like smallpox.

- Some toxins are classified as potential biowarfare- R&D support to develop anti-toxin drugs

6.3.2 Regulatory Reforms

Regulation plays a vital role in developing new innovative products and making them available and accessible to the public, not only in the country but across borders. During COVID, a rapid response regulatory framework was developed, which facilitated the approval and authorisation of a number of products – vaccines and diagnostics, which were crucial for the COVID management strategy. There were challenges faced in getting accelerated approvals and in the global harmonisation of regulatory protocols. Accessibility of innovative products could have been speeded up if we had a well-developed clinical trial network accepted by international regulatory authorities. Acceptance of regulatory data across National regulatory authorities also needed to be included.

» A well-harmonised regulatory system to be developed with other globally recognised regulators for mutual acceptance of regulatory data

» Accelerated approval pathways and protocols to be prepared and pre-approved

» Subject Expert Committees (SECs) should be strengthened with technical competence in different fields with a training program for experts

» A strong Clinical Trial network and adaptive Clinical Trial methodology should be developed to expedite the development of drugs/devices/diagnostics. Also, the Licensing of Products/Technologies process should be simplified/expedited.

» Inclusion/recognition of a few well-equipped district hospitals and the AIIMSs and INIs in the Clinical Trail Network.

» The existing Central Drugs Standard Control Organisation (CDSCO) to be made an Independent Regulatory Authority, with the Chief Regulator technically proficient and having special powers of making Rapid Regulatory Approvals. The Chief regulator is to be directly reporting to the Minister of Health and in the rank of Secretary to the Govt of India

It is therefore essential that to prepare for future pandemics and respond urgently to emergencies there are major initiatives which need to be taken:

i. A robust Clinical Trial system for conducting systematic clinical trials, with the inclusion/recognition of a few well-equipped district hospitals, in addition to the AIIMSs and INIs should be developed. A good example is the participation of District Hospitals in the Plasma trial for COVID.

ii. Ear-marked clinical trial teams, with the required expertise to carry out robust clinical trials from appropriate organizations (such as the ICMR Clinical Trial Unit and AIIMS System) need to be identified for launching necessary trials on short notice. Further, this should not be mixed with regulatory trials.

6.3.3 Capacity and competency building in Mission Mode

Presently, there is a need for competent human resources in IDSP units, RRTs, One Health surveillance and response, an all-hazard approach in CBRN, IHR,

and laboratory techniques and IT infrastructure like PHEOCs to carry out epidemiological analytics at various levels. There is also need for:

i. Capacity building of scientific professionals and bringing in international experts for collaboration in research areas.
ii. Establishing infrastructure and techniques for high-quality Next Generation Sequencing (NGS)
iii. Harnessing new-age technologies such as AI and GIS (Geographic Information System)
iv. Competencies to handle all biological threat agents and putting in place a bio-security network proposed through the National Security Council (NSC) connecting all BSL3 and BSL4.

Proposed mechanism:

i. Assessment of training needs regarding competencies of various HR involved in pandemic preparedness.
ii. Documenting the number of HR people to be trained and the available training courses for building competencies.
iii. Identify gaps and areas for strengthening.
iv. Develop a roadmap for ensuring appropriate training of relevant HR from district to apex level in mission mode during the next 1 to 2 years.
v. Collaborate with private public health institutes, international bodies, and other partner agencies that have the required competent technical and financial resources to partner with NCDC in specific areas.
vi. MoHFW & NCDC may prepare a roadmap for specific nation-wide programs to be taken up in mission mode for technical competencies like IDSP surveillance and response, IHIP data portal, epidemiological intelligence, and one health approach for multi-disciplinary data analytics.

Challenges:

» Surveillance capacities for data capture and analytics at all levels (740 districts and 35 states/UTs) and provision of surge capacity.
» Community, laboratory and health facilities including tertiary hospitals
» Public and Private sector
» Trainings for Rapid response teams: Field Epidemiology Training Program (FETP), Epidemic Intelligence Service (EIS), Sector connect, Public Health Emergency and Disaster Management (PHEDM)
» Advanced competencies: data analytics using AI, Laboratory capacities (NGS) and data integration (One Health)
» Public health response support for CBRN
» Mission mode: Development of a roadmap Involving all government, international and partner NGOs (which are currently providing support) for ensuring country-wide training in a maximum of one year.
» Identification of core mentors from NCDC, ICMR, NIDM, WHO, CDC and other NGOs etc.

6.3.4 Resilient Supply Chains

Developing capacities for indigenous manufacturing of consumables/equipment such as swabs, masks, PPEs, sanitisers, oxygen cylinders, ventilators, etc, by identification and attaining self-sufficiency of critical components (such as zeolite for oxygen concentrators) is especially important for the pandemic-scenarios when international supply chains are constrained. Further, ensuring access to essential supplies such as filter adjuvants, and mapping the supply of critical items to have an uninterrupted strong supply chain and be resilient for future pandemic should be ensured.

- Institutionalisation of supply chain systems: Proper forward and backward linkages to be established for ensuring robust supply chains of all essential components and ingredients for development of countermeasures.
- Develop capacities for indigenous manufacturing of consumables/equipment such as swabs, masks, PPEs, sanitisers, oxygen cylinders, ventilators, etc., for new pathogens
- Develop capacities for components for indigenous development and manufacture of diagnostics and vaccines –such as reagents, adjuvants, VVMs, etc.

It is important to have parallel systems in place for meeting supply-chain constraints, such as an alternative source of oxygen supply through the steel industry, during the COVID-19 Pandemic. The requirements of different pandemics may be different. Each case scenario must be kept in mind while planning the supply chain.

6.4 Partnership: Community engagement including risk communication, Private sector partnerships and international collaborations

6.4.1 Community involvement and Engagement with Private Sector

Risk assessment and community engagement are the pre-requisite for effective planning of surveillance and control strategies during outbreaks, emergencies and pandemics. WHO also underlines the importance of **Swift Assessment** (within 24-72 hours) of a public health event or outbreak report as an essential element for an early response and containment. However, rapid assessment needs to be followed with a **Comprehensive Assessment** to enhance in-depth understanding of the situation, risk characterisation and plan subsequent interventions for affected and at-risk community. During COVID-19 pandemic, it has been well appreciated that community involvement plays a key role in public health measures like surveillance and response for effective mitigation and for non-pharmaceutical measures like the creation of containment zones and lockdown for preventing the spread of infection in new areas. Further, as the pandemic progressed, the need for home quarantine, home isolation and timely referral gradually scaled up community involvement with the whole of society approach. Thus, it is crucial to engage with communities transparently with current/available scientific knowledge and evidence to empower communities for public health efforts during pandemics. During the early phase of pandemic, the non-scientific information/rumours on virus contamination of articles, survival of the virus on various surfaces and possibilities of routes of transmission required active community involvement to spread awareness about scientific facts, government strategies and knowledge about measures for disinfection, effective personal protective gears and treatment therapies to alley panic and build public confidence in government efforts.

The Ministry of Health proactively established a control room first at NCDC, followed by control rooms in the Ministry of Health and health departments in States for providing updated information on disease agents, spread and available protective measures. As the pandemic spread to newer areas at an alarming pace, measures like closure of schools, cinemas, social gatherings were aggressively applied to reduce transmission through person-to-person contact. The widespread use of non-scientific measures created fear psychology, disrupting social and workplace fabrics.

However, there is a need for the establishment of defined structures for community involvement, SOPs and specific competency-based HR for Risk Communication and Community Engagement (RCCE) and actively engaging with communities for timely management of infodemic and rumours.

» Develop strategies and guidelines for working with communities especially at the local level for managing PHEs especially for:
  - implement public health and social measures for disease prevention,
  - restricting movement of people and goods,
  - information dissemination, managing infodemics, etc.

» Linkage with health NGOs and CSOs for last-mile connectivity

» Models for engaging with the private health sector for disease management and especially for ensuring surge capacities in the Indian context should be developed. For example, learnings from States: Maharashtra- engaged the private sector to ensure the availability of hospital beds for COVID-19 patients

Private sector involvement:

In India, the private sector caters to nearly 60% of the population, and primarily provides clinical management and laboratory services. The IDSP data on IHIP, which is mainly from the public sector needs to be complemented with private sector data from laboratories and hospitals particularly on epidemic-prone diseases, to assist in monitoring the outbreak trends and distribution. Further, the private sector also plays a crucial role in providing early warning signals for outbreaks and distribution (time, place, person) of increased transmission. Clinicians and labs in private sector often provide initial signals even in unusual diseases like H3N2, Nipah virus, Zika, Kyasanur Forest Disease (KFD) etc. The different phases of COVID-19 pandemic involving the private sector complemented government efforts, particularly the surge in the need for testing of samples from suspects, quarantine & isolation beds in hospitals and supporting genome sequencing. Hence, it is important to develop a dynamic repository of labs and health facilities at all levels (district, state and centre) with details of testing competencies and beds with available human resources in health facilities are maintained. Additionally, the SOPs/MoUs needed along with clarity on supplies and costing for tests and relevant authorities can also fine-tune health care.

The role of private sector and NGOs can be broadly grouped into 3 phases:

1. Pre-pandemic or inter-pandemic phase:
   a) Surveillance: Providing data on outbreak-prone diseases and other events of public health significance related to IHIP.
   b) Firming up institutional arrangements for involving testing laboratories, hospitals and doctors for clinical care (quarantine, isolation and intensive care services) during pandemic times.
2. Pandemic phase:
   a) During pandemic surges/waves, private sector labs and hospitals should be involved. When the system is overburdened, labs are needed for timely testing and sequencing. The community should be supported in tests for confirmation and tracking of infection, severity markers, antibody estimation, and advanced tests like genome sequencing.
   b) Providing Hospital data on Outpatient Department (OPD) and Inpatient Department (IPD) cases, morbidity, severity and mortality data. Data on clinical therapies, drug efficacy and side effects.

c) Private sector research centres can coordinate with public sector laboratories of DBT, ICMR, and CSIR for the development of primers, probes, and low-cost tests (like Rapid Antigen Test (RAT), Point- of-Care (POC) tests etc.) including advanced procedures like vaccine development, sewage sequencing.
d) Private sector laboratories' involvement in modelling and developing predictive indicators, epidemiological surveillance, genome sequencing, and sewage surveillance is also important.
e) Private sector plays a very important role in community awareness and IEC.
f) Partnership between the public and private sector is a critical factor for the development of drugs and therapeutics, vaccine candidates and platform technologies and to support the development of appropriate PPEs and other protective equipment.

3. Post Pandemic phase:
a) Monitoring mutations, variants and hospital data (like re-infection by variants and cases among vaccinated persons).
b) Providing information on unusual presentations (loss of smell or taste, symptoms of gastric upset, long-term impact (long covid, side-effects of steroids etc.)

6.4.2 Communication

Regular clear communication of policies, plans, and implementation strategies from government authorities to HCW at all levels (national, state and district) and to the community is essential for building trust among people and implementing mitigation and management strategies. Effective communication to HCWs (those engaged in surveillance, sample collection and providing clinical care) is also required to focus on the importance of several types of data (epidemiological, laboratory and hospital) and ensure regular data uploading for enabling data analytics. Such a communication plan is central to pandemic preparedness. Also, capacities have to be developed in the scientific community for communicating clearly and succinctly with the media and general public. Further, communication must be in both directions - grass-root to top level and vice versa.

- A special Risk Communication Unit to be established at NCDC, Ministry of Health, with a Senior officer as the Head who has the responsibility of releasing communication updates for all sections of organisations, including communities and public
- Strategic Communication Plan for building trust among people and implementing mitigation and management strategies essential for managing a PHE
- Build capacities in the scientific community for communicating clearly and succinctly with the media and public
- Develop strategies and capacities for infodemic management (behavioural science expertise within NCDC, health ministry)
- Partnering with UNICEF and other social science institutes on developing a robust communication framework for pandemic threats

Communication requires specific competencies and coordination between technical experts (public health, microbiologists, and clinicians), IT, social media, and communication for development of appropriate data formats, Information Education Communication (IEC) material, and monitoring tools.

6.4.3 Collaborations and Partnerships

Partnership and collaboration were the key to scientific success. Collaborations were seen between different agencies such as:

i. Academia and Industry
ii. Centre and state
iii. Central Departments and Ministries
iv. National and International research institutes, organisations and agencies

However, it was noted that it was the existing partnerships which worked well and were taken forward. New partnerships took a long time to fructify. It is therefore imperative to **put in place pre-agreed protocols and MoUs for data, knowledge sharing, technology transfer and licensing, intellectual property right management** etc. which will be important during any public health emergency.

- Put in place Pre-agreed MoUs, protocols, agreements and other instruments for data, sample, knowledge sharing and collaborative funding
- Institutionalize collaborative learning during peacetime while preparing for the future
- Establish collaborations between institutes such as the ICMR and NCDC to bring efficiencies for reducing delays and costs for testing novel pathogens.
- International partnerships and networks to be aggressively developed for information sharing and technology transfer; cultivate South-South co-operative partnerships while focusing on self-sufficiency.
- Collaborate with WHO (WR, India and SEARO) CDC (CDC, India and US – CDC) and partner agencies.

India has been globally recognised for its strength in biotechnology and biomedical research, and there are important bilateral, multilateral, and agency-specific collaborations which can be strengthened to develop robust systems for pandemic preparedness and response. Partnerships and continuous dialogue with WHO and other globally recognised national regulators are important to be prepared for global regulatory approvals of countermeasures developed.

7. Continuous Monitoring of progress to assess action taken

To ensure that the Action Plan is being implemented as per the targets that are laid out in the framework, it is essential to have a proper system to monitor the progress of each step during the preparedness to be able to deliver in any emergency. It is therefore essential to:

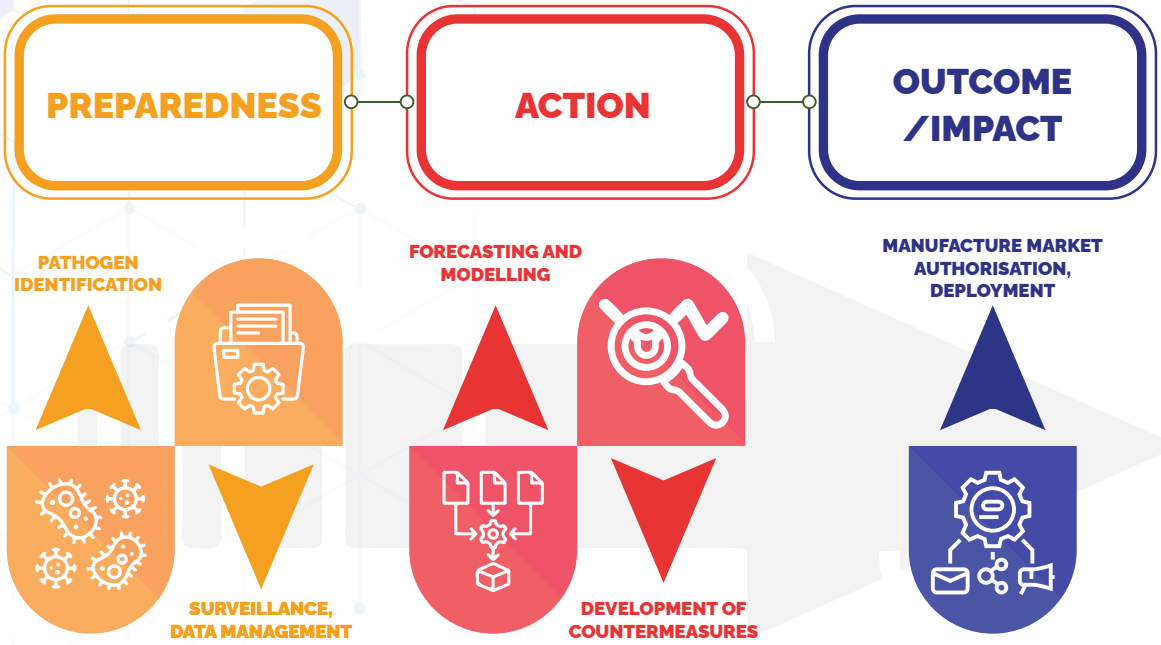
i. Establish a continuous monitoring mechanism. For this, the EGoS for Pandemic Preparedness and Emergency Response to set up a **Working Group for Monitoring Progress** regularly, preferably quarterly
ii. Develop a **Scorecard system** with well-defined priority targets; the data should be collected and fed into an online portal
iii. Regularly track defined parameters, including the research pipeline, human resource and funding systems
iv. Surveillance systems to be activated for any ongoing disease outbreaks in pilot/ sentinel sites
v. Participate in WHO peer review Joint External Evaluation (JEE)/ Universal Health & Preparedness Review (UHPR) system to check capacities and competencies

A well-developed scorecard is needed for continuous monitoring. The scorecard should have a very elaborate set of parameters that can be regularly assessed. An indicative list can be -

i. R&D ecosystem readiness
ii. Funding for diagnostics, therapeutics and vaccines
iii. Research on the WHO List of priority pathogens
iv. Capacities for surveillance, forecasting and modelling, AI and new technologies, clinical trials
v. Unified Data portal and data-analysis unit
vi. Forecasting and modelling simulation exercises
vii. Rapid response SOPs for data and sample sharing, data communication, accelerated regulatory approvals
viii. Pre-agreed MoUs for international cooperation and partnership, including technology transfer and licensing.

We do not need to wait for an outbreak to test this framework. The system can be tested on three or four priority pathogens already a threat in our country -Nipah, Zika, Monkey pox, H5N1 to begin with. Cultures of these pathogens have been isolated and are deposited at the ICMR -NIV; this could be a starting point. The preparatory phase should take 3-6 months, and then the entire system should be set in motion. Each step should be monitored to ensure that the system is ready to deliver in 100 days.

A 100 Days Mission



Preparing for Future Pandemic - A 100 Days Mission Framework

Preparedness

- Public Health Emergency Management Act
- EGoS on Pandemic Preparedness and Emergency Response
- A high- risk innovation and research fund for pandemic preparedness and response
- A robust surveillance system with a well connected genomic, epidemiological, clinical and hospital network
- Unified Data management system
- Forecasting and Modelling
- Study and research on Priority Pathogens
- Well characterised and sequenced strains maintained in a network of repositories
- Development of prototype candidates for diagnostics and vaccines for each priority pathogen
- Pre Approved SoPs for Accelerated Regulatory Approval, Data communication, International Agreements

100days Response

- Tracking the infection and pathogen identification
- Development of sensitive diagnostics and manufacture at scale
- Vaccine development for specific pathogen and manufacture
- Therapeutics /drugs developed
- Forecasting and modelling exercise to give early prediction to put in management protocols in identified hot spots
- Rapid response teams to be positioned on day one
- Data analysis to be on a continuous basis and feed into research groups ,state health and clinical systems
- Characterised and sequenced strains, biological and clinical samples and validation assays to be shared across organisations
- Harmonized regulatory systems and accelerated regulatory approval SOPs to facilitate new countermeasures EUA

Output and Impact

Countermeasures to be available at scale for mass deployment for public health

- Continuous epidemiological ,clinical and genomic surveillance data for disease management in hot spots
- Rapid response teams on ground to take urgent action as per SoPs
- Regular risk communication
- Continuous community engagement

Efficient Prevention ,treatment and management of disease with minimal infection levels

8. Indicative Timelines

To mount a considered response to a public health emergency in the first 100 days, the proposed systems and processes detailed in this report should function well before any emergency. An indicative time frame for action on the recommendations of this report is given below, which outlines which actions should commence in the immediate short term (3 to 6 months), in the medium term (6 to 12 months) and which may require a longer time frame (18 to 24 months).

i. Indicative time frame for key steps (1): 3 to 6 months

- Setting up an EGoS for Pandemic Preparedness
- Approval for a Special Pandemic Preparedness and Emergency Response Fund
- Preparing a framework for monitoring of identified targets as per scorecard
- Operationalisation of One Health Institute: for coordinated collaborative surveillance & research
- Institutionalisation of the Epidemiological and INSACOG framework and SOP for regional expansion
- Develop the SOP Document for Data sharing and Risk communication
- Nation-wide capacity building roadmap for surveillance and response

ii. Indicative time frame for key steps (2): 6 to 12 months

- Engaging with states and other ministries.
- Develop a framework for collaboration and partnership with TORs with pre-agreed MoUs, protocols, agreements and other instruments for data, samples, knowledge sharing and collaborative funding
- Integration of all data portals, including ICMR and NCDC data, on a single platform and coordination, SOPs developed with Scientific research bodies and relevant ministries.
- Approval for a High-Risk Innovation Research Fund
- Establishing a Vaccine Science & Development Institute
- Initiating Priority Pathogen research through the Centre of Excellence Network
- Launching a Regional Consortium for Surveillance with neighbouring countries

iii. Indicative time frame for key steps (3): 12 to 24 months

- Approval of a New Public Health Emergency Management Act
- Setting up an Epidemiological Forecasting and Modelling Network
- Launching a Mission on Therapeutics and Drug Development
- Setting up a National Biosecurity Biorepository Network
- Giving Autonomy to the Regulatory body with well-developed approved SOPs for Accelerated Emergency Use Authorisation for innovative technologies and innovative products and provision for fast-tracking during pandemics
- Having a well-established capacity-building training programme at all level

ANNEXURE - I

F.No. 15(3)/2023-H&FW
Government of India
NITI Aayog

Sansad Marg, New Delhi-110001
Dated the ~~20th~~ 21st June, 2023

Office Memorandum

Sub: Constitution of Expert Group on Future Pandemic Preparedness - regarding

As we recover from the COVID-19 pandemic, the worst human health crisis witnessed by humanity, it is imperative that we draw lessons from the country and global experience, and visualize preparedness elements and pathways for possible future pandemic(s). Accordingly, it is proposed to set up an Expert Group which will study these issues in depth, consult other experts (national/global), and come up with a very detailed analysis of what worked and what did not work. The Report will look at the lessons learnt from within the country's response and global experience, and offer a clear strategy and road map on what our preparedness should be to handle any such and even more dangerous public health crisis in the future.

2. The constitution of the Expert Group will be as follows:

1	Dr Renu Swarup- Former Secretary, DBT	Chairperson
2	Dr Soumya Swaminathan- Former Chief Scientist WHO and Former DG ICMR	Member
3	Dr Sujeet Singh- Former Director NCDC	Member
4	Sh. Rajib Kumar Sen, Senior Adviser(H), NITI Aayog	Member Secretary

Note- Additional member(s) may be added with the approval of the Chairperson. The Expert Group may also interact with Professionals and Government Officials as deemed necessary.

3. The Terms of Reference (ToR) of the Expert Group on India's Future Pandemic Preparedness will be:

a. Study emerging information on pathogens with the potential to power large outbreaks in the future and suggest mechanisms on how to focus on surveillance taking one earth one world approach to ensure that we are prepared for diseases of potentially unknown agents.
b. With a focus on the scientific and technological approaches, tools, products, and systems deployed in the COVID-19 pandemic response, prepare a synthesis report on the learning thereof, and propose preparedness pathways for the country. In particular,

undertake this task with specific reference to: pandemic epidemiology, forecasting, surveillance, testing, and containment; virus characterization including genome sequencing; and drugs, diagnostics, digital tools, therapeutics, medical technologies, and vaccines.

c. Recommend specific action to be taken for strengthening and creating a robust ecosystem for pandemic prediction, biomedical research, as well as the new innovative, affordable, and accessible counter-measures.
   I. Further, identify gaps that exist in infrastructure, human resources, and systems in this regard and recommend actions to be taken to build this at a world class level through Atma Nirbhar effort.
   II. Suggest how to create systems that allow complete forward and backward linkages to ensure that there is no dependency on imported raw materials, and recommend building networks for clinical trials to take up disease based vaccines and therapeutics ensuring compliance with global regulatory standards.
   III. Recommend scale up mechanisms to promote the capacities of our industry to become manufacturing hubs to be able to meet the needs of the country and also supply to the world;
   IV. Suggest improvements to strengthen the framework for data and sample sharing.
d. Provide guidance on meaningful collaborations, both national and international, including bilateral, multilateral, and public-private partnerships.

4. The Expert Group will interact with NITI Aayog and other Government organizations periodically to discuss relevant issues relating to the point mentioned in the ToR above.

5. The outstation Members of the Expert Group shall be entitled for TA/DA, as per their entitled class in terms of Ministry of Finance, D/o Expenditure's O.M. No. 19030/1/2017-E.IV dated 13.07.2017 and O.M. No. 19047/1/2016-E.IV dated 14.09.2017.

6 . This issues with the approval of the competent authority and in concurrence with IFD Memo dated 09.06.2023.

(Shoyabahmed Kalal)
Deputy Secretary (Health)
Tele No. 23096602

To;

Expert Group Chairperson and Members

Copy to:

1. PPS to VCH, NITI Aayog
2. Sr. PPS to Member (Health), NITI Aayog
3. PSO to CEO, NITI Aayog
4. PS to SA (H), NITI aayog.

ANNEXURE - II

WHO List of Priority Pathogens and diseases

A. Virus:

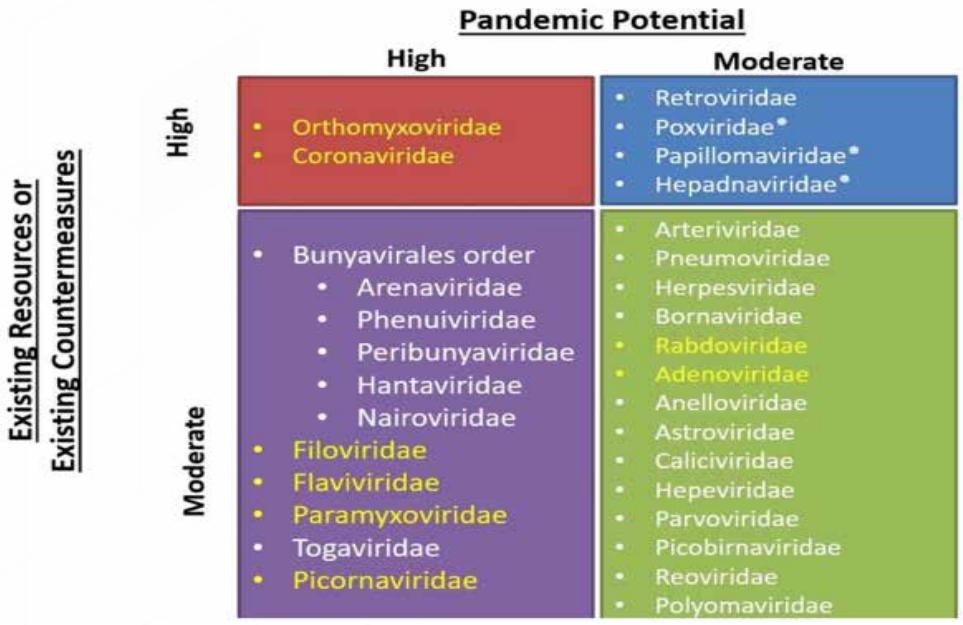
Around 200+ scientists from 53 countries are independently evaluating the evidence related to 30 viral families. The number of pathogens that could trigger the next pandemic has grown to more than 30, and now includes influenza A virus, dengue virus and monkeypox virus, according to a recent updated list published by the World Health Organization (WHO). Families and pathogens that were prioritized in 2024 as compared to 2017 and 2018 prioritization process.

	2017	2018	2024		
Family	**Priority Pathogens**	**Priority Pathogens**	**PHEIC risk**	**Priority Pathogens**	**Prototype Pathogens**
Adenoviridae			Low-Medium		Recombinant Mastadenovirus
Adenoviridae			Low		
Low-Medium	Arenaviral hemorrhagic fevers including Lassa Fever	Lassa Fever virus	High	Mammarenavirus lassaense	Mammarenavirus lassaense
Anelloviridae			High		Mammarenavirus juninense
Arenaviridae			High		Mammarenavirus lujoense
Arenaviridae			Low		Mamastrovirus virginiaense
Bacteria			High	Vibrio cholerae serogroup 0139	
Bacteria			High	Yersinia Pestis	
Bacteria			High	Shigella dysenteriae serotype 1	
Bacteria			High	Salmonella enterica non typhoidal serovars	
Bacteria			High	Klebsiella pneumoniae	
Bornaviridae			Low		Orthobornavirus bornaense
Coronaviridae	Middle East Respiratory Syndrome Coronavirus	Middle East Respiratory Syndrome Coronavirus	High	Subgenus Merbecovirus	Subgenus Merbecovirus
Coronaviridae	Other highly pathogenic coronaviral diseases such as Severe Acute Respiratory Syndrome	Severe Acute Respiratory Syndrome	High	Subgenus Sarbecovirus	Subgenus Sarbecovirus

	2017	2018	2024		
Family	**Priority Pathogens**	**Priority Pathogens**	**PHEIC risk**	**Priority Pathogens**	**Prototype Pathogens**
Filoviridae	Filoviral diseases Ebola	Ebola virus disease	High	Orthoebolavirus zairense	Orthoebolavirus zairense
Filoviridae	Filoviral diseases Marburg	Marburg virus disease	High	Orthomarburgvirus marburgense	
Filoviridae			High	Orthoebolavirus sudanense	
Flaviviridae	Zika virus	Zika virus	High	Orthoflavivirus zikaense	Orthoflavivirus zikaense
Flaviviridae			High	Orthoflavivirus denguei	Orthoflavivirus denguei
Flaviviridae			High	Orthoflavivirus flavi	
Flaviviridae			High		Orthoflavivirus encephalitidis
Flaviviridae			High		Orthoflavivirus nilense
Hantaviridae			High	Orthohantavirus sinnombreense	Orthohantavirus sinnombreense
Hantaviridae			High	Orthohantavirus hantanense	
Hepadnaviridae			Low		Orthohepadnavirus hominoidei genotype C
Hepeviridae			Low		Paslahepevirus balayani genotype 3
Herpesviridae			Low		
Nairoviridae	Crimean Congo Haemorrhagic Fever	Crimean Congo Haemorrhagic Fever	High	Orthonairovirus haemorrhagiae	Orthonairovirus haemorrhagiae
Orthomyxoviridae			High	Alphainfluenzavirus Influenzae H1	Alphainfluenzavirus Influenzae H1
Orthomyxoviridae			High	Alphainfluenzavirus Influenzae H2	
Orthomyxoviridae			High	Alphainfluenzavirus Influenzae H3	
Orthomyxoviridae			High	Alphainfluenzavirus Influenzae H5	Alphainfluenzavirus Influenzae H5
Orthomyxoviridae			High	Alphainfluenzavirus Influenzae H6	
Orthomyxoviridae			High	Alphainfluenzavirus Influenzae H7	
Orthomyxoviridae			High	Alphainfluenzavirus Influenzae H10	
Papillomaviridae			Low		
Paramyxoviridae	Nipah and related henipaviral diseases	Nipah and henipaviral diseases	High	Henipavirus nipahense	Henipavirus nipahense
Parvoviridae			Low		Protoparvovirus carnivoran

	2017	2018	2024		
Family	**Priority Pathogens**	**Priority Pathogens**	**PHEIC risk**	**Priority Pathogens**	**Prototype Pathogens**
Peribunyaviridae			Low		Orthobunyavirus oropoucheense
Phenuiviridae	Severe Fever with Thrombocy-topenia Syndrome		High	Bandavirus dabieense	Bandavirus dabieense
Phenuiviridae	Rift Valley Fever	Rift Valley Fever	High		Phlebovirus riftense
Picobirnaviridae			Low		Orthopicobirnavirus hominis
Picornaviridae			Medium	Enterovirus coxsackiepol	
Picornaviridae			Medium		Enterovirus alphacoxsackie 71
Picornaviridae			Medium		Enterovirus deconjucti 68
Pneumoviridae			Low-Medium		Metapneumovirus hominis
Polyomaviridae			Low		
Poxviridae			High	Orthopoxvirus variola	
Poxviridae			High		Orthopoxvirus vaccinia
Poxviridae			High	Orthopoxvirus monkeypox	Orthopoxvirus monkeypox
Retroviridae			Medium	Lentivirus humimdef1	Lentivirus humimdef1
Rhabdoviridae			Low		Genus Vesiculovirus
Sedoreoviridae			Low		Genus Rotavirus
Spinareoviridae			Low		Orthoreovirus mammalis
Togaviridae			High	Alphavirus chikungunya	Alphavirus chikungunya
Togaviridae			High	Alphavirus venezuelan	Alphavirus venezuelan
Pathogen X	Pathogen X	Pathogen X		Pathogen X	

Note: Prioritization of pathogens by WHO is a dynamic process and it is pertinent to refer to the latest updated list for the purpose of pandemic preparedness planning process.



B. Bacteria:

- The 2024 BPPL includes 15 families of antibiotic-resistant (ABR) pathogens, grouped into critical, high, and medium priority categories for R&D and public health measures.
- Critical priority gram-negative bacteria that are resistant to last-resort antibiotics, such as Acinetobacter baumannii and various pathogens in the Entero bacterales order, as well as rifampicin-resistant (RR) Mycobacterium tuberculosis, because of their ability to transfer resistance genes, the severity of the infections and disease they cause and their significant global burden, particularly in LMIC.
- High-priority bacteria: Salmonella and Shigella due to their increasing resistance to existing treatments and the high burden of infection associated with these pathogens, particularly in LMIC.
- Other high-priority pathogens are antibiotic-resistant Pseudomonas aeruginosa and Staphylococcus aureus due to their global threat, especially in healthcare settings. Also included are Neisseria gonorrhoeae, which present distinct public health challenges due to the emergence of multidrug-resistant (MDR) strains, limiting treatment options.
- The medium-priority category includes Group A and B Streptococci, Streptococcus pneumoniae, and Haemophilus influenzae, particularly in vulnerable populations in resource-limited settings.

Diseases:

The WHO priority diseases are:

- COVID-19
- Crimean-Congo haemorrhagic fever
- Ebola virus disease and Marburg virus disease
- Lassa fever

- Middle East respiratory syndrome coronavirus (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS)
- Nipah and henipaviral diseases
- Rift Valley fever
- Zika
- “Disease X” *

Ref:

1. Pathogens prioritization: A scientific and Research framework for epidemic and pandemic research preparedness. WHO – R&D Blue print Powering research to prevent Epidemics; Health Emergencies, June 2024.
2. WHO Bacterial Priority Pathogens List, 2024 Bacterial pathogens of public health importance to guide research, development and strategies to prevent and control and antimicrobial resistance.
3. Emerging viral diseases from a vaccinology perspective: preparing for the next pandemic - nature immunology December 14, 2017: Barney S Graham and Nancy J Sullivan

ANNEXURE - III

Future Pandemic Preparedness and Emergency Response – Experts Consulted

Fourteen separate consultations have been held with more than sixty experts.

The detail of the individuals and the institutions consulted is below:

I. Government Representatives

1. Prof. Ajay Kumar Sood, Principal Scientific Advisor to the Govt of India
2. Dr Rajiv Bahl, Secretary Department of Health Research and Director General ICMR
3. Sh. Arunish Chawla, Secretary Department of Pharmaceuticals
4. Dr Atul Goel, Director General Health Services
5. Dr Rajeev Singh Raghuvanshi, Drugs Controller General of India (DCGI), CDSCO
6. Sh. Krishna S. Vatsa, Member NDMA
7. Vaidya Rajesh Kotecha, Secretary, Department of AYUSH
8. Dr Sanjeev Khosla, Director, CSIR IMTECH
9. Prof. K Vijayaraghavan, Former Principal Scientific Advisor to the Govt of India
10. Mrs Preeti Sudan Former Secretary, Ministry of Health & Family Welfare
11. Prof. Ashutosh Sharma, Former Secretary, Department of Science & Technology
12. Dr Ram A Vishwakarma, Director, CSIR-IIM, Jammu
13. Prof. Balram Bhargava, Former DG, ICMR
14. Dr G Satheesh Reddy, Scientific Advisor to Minister of Defence, GoI
15. Mr Safi Ahsan Rizvi, Advisor (Mitigation), NDMA
16. Dr Ashok Kumar, ADG (Animal Health), Indian Council of Agricultural Research (ICAR)
17. Dr Parvinder Maini, Scientific Secretary, Office of PSA
18. Dr Nitin Kumar Jain, Scientist G, DBT
19. Dr Anita Aggarwal, Head (SEED)
20. Dr Abhijit Mitra, Animal Husbandry Commissioner, Department of Animal Husbandry and Dairying (DAHD)
21. Dr Aruna Sharma, Deputy Commissioner, DAHD
22. Sh. Saikat Sarkar, Adviser (Trade), Department of Agriculture, Cooperation & Farmers Welfare
23. Dr A. Raghu, Dy. DGHS, Ministry of AYUSH
24. Dr Himanshu Chauhan, Joint Director National Centre for Disease Control (NCDC)

II. Government Leadership

1. Shri Rajesh Bhushan, Former Secretary, Ministry of Health & Family Welfare Govt. of India
2. Shri Amit Mohan Prasad, Additional Chief Secretary, Government of Uttar Pradesh
3. Mohd. Suleman, Principal Secretary, Government of Madhya Pradesh
4. Dr J Radhakrishnan, Commissioner, Govt. of Tamil Nadu Tamil Nadu
5. Shri JV Prasad Rao, Former Secretary, Ministry of Health & Family Welfare

III. Industry

1. Dr Kiran Mazumdar Shaw, Executive Chair, Biocon
2. Dr Vijay Chandru, Co-founder and Chair, Strand Life sciences
3. Shri Pankaj Patel, Chairman, Cadila Healthcare
4. Dr Sanjay Singh, CEO, Gennova Biopharmaceuticals Ltd.
5. Dr Prasad Kulkarni (Executive Director), Serum Institute of India
6. Hasmukh Rawal (Managing Director)/ Mylab Discovery Solutions
7. Dr Jitendra Sharma, Managing Director & CEO, AMTZ
8. Dr Satish Reddy, (Chairman), Dr Reddy's Laboratories
9. Dr Heulwen Philpot, Head of Secretariat, International Pandemic Preparedness Secretariat (IPPS) and team

IV. Technical Institutions

International Institutions

1. Dr Ana Maria Henao-Restrepo, Co-Lead R&D Blueprint for Epidemics, WHO Health Emergencies programme
2. Dr Jeremy Farrar, Chief Scientist WHO
3. Dr Richard Hatchett, CEO, Coalition for Epidemic Preparedness Innovations (CEPI)
4. Dr Mariangela Simao, Director ITPS Brazil
5. Mr Bill Rodriguez, CEO, FIND
6. Mr Seth Berkley, Former CEO, GAVI
7. Dr Rick Bright, Former Sr. Vice President, Rockefeller Foundation
8. Dr Meghna Desai, Country Director, Centers for Disease Control and Prevention (CDC), India
9. Dr Heulwen Philpot, Head of Secretariat , International Pandemic Preparedness Secretariat (IPPS) and team

National Institutions

1. Dr Pavana Murthy, NPO Surveillance and Response, WHO India
2. Prof. Saumitra Das, Dept. of Microbiology and Cell Biology, Indian Institute of Science (IISc)
3. Prof Sudhanshu Vrati, Executive Director, Regional Centre for Biotechnology (RCB)
4. Retd. General Dr Madhuri Kanitkar, Vice-Chancellor, Maharashtra University of Health Sciences (MUHS)
5. Prof. Manindra Agrawal, Dept. of Computer Science & Engineering, IIT-Kanpur
6. Dr Sanket V Kulkarni, Joint Director, NCDC
7. Dr Saurabh Goel, Joint Director, NCDC
8. Dr Pramod Kumar Garg, Executive Director THSTI
9. Dr Heulwen Philpot, Head of Secretariat, International Pandemic Preparedness Secretariat (IPPS) and team

V. Clinicians, Microbiologists, Virologists and Epidemiologists

1. Dr NK Arora, NEG-VAC (National Expert Group on Vaccines)
2. Dr Gagandeep Kang, Director BMGF (former head THSTI)
3. Dr K. Srinath Reddy, President PHFI
4. Dr Shiv Kumar Sarin, Institute of Liver and Biliary Science (ILBS), Delhi

5. Dr Sanjay Pujari, Director Institute of Infectious Diseases, Pune
6. Dr Lalit Dar, Professor, Dept. of Microbiology, AIIMS New Delhi
7. Dr Aakash Shrivastava, Additional Director, NCDC
8. Dr Randeep Guleria, former Director AIIMS
9. Dr Naveet Wig, Professor, Dept of Medicine, AIIMS New Delhi
10. Dr Raman R Gangakhedkar, Former Head - Division of Epidemiology, Communicable Diseases, ICMR
11. Dr Nivedita Gupta, Scientist F, ICMR New Delhi
12. Dr Tarun Bhatnagar, Scientist, ICMR – National Institute of Epidemiology, Chenna
13. Dr Priya Abraham, Former Director, National Institute of Virology Pune
14. Dr Manoj Murhekar, Director ICMR – National Institute of Epidemiology, Chennai
15. Dr Subhash Salunke, Senior Adviser, Public Health Foundation of India (PHFI), Delhi
16. Dr Giridhar R. Babu, Professor, Public Health Foundation of India (PHFI), Delhi
17. Dr J.M Deshpande, Former director, Enterovirus Research Centre Mumbai
18. Dr Sanghamitra Ghosh, President, Indian Public Health Association (IPHA)
19. Dr A. M. Kadri, President, Indian Association of Preventive and Social Medicine

ANNEXURE - IV

Key References

i. **From Emergency Response To Long-Term Covid-19 Disease Management: Sustaining Gains Made During The Covid-19 Pandemic Report by WHO (May 2023);** https://www.who.int/publications/i/item/WHO-WHE-SPP-2023.1

The Report talks about the Global Strategic Preparedness, Readiness and Response Plan (SPRP) for the period 2023-2025. In 2023, WHO updated the global strategy to reflect the evolving situation and outline a strategy for the next two years (April 2023-April 2025) to support countries in transitioning, when and as appropriate, towards integrating the COVID-19 pandemic response into broader infectious disease prevention and control programmes. The updated 2023-2025 COVID-19 strategy outlines practical, high-level actions that need to be sustained as response activities are adjusted to address the drivers of SARS-CoV-2 transmission and prioritizes activities that will continue to lessen the impact of the COVID-19 disease. Activities outlined are organized to reflect management and integration of COVID-19 activities along the five core components of WHO's proposed global health architecture for health emergency preparedness, response and resilience. The components are emergency coordination, collaborative surveillance, community protection, safe and scalable care, and access to countermeasures.

ii. **A WORLD AT RISK - Annual report on global preparedness for health emergencies by Global Preparedness Monitoring Board (September 2019);** https://www.gpmb.org/docs/librariesprovider17/default-document-library/annual-reports/gpmb-2019-annualreport-en.pdf?sfvrsn=bd1b8933_36

The Report highlights the need for determined political leadership to prepare for health threats at national and global levels and outlines seven urgent actions to prepare the world for health emergencies; i. Commitment and Investment from Government Heads: Heads of government in every country must commit to preparedness by implementing their binding obligations under the International Health Regulations (IHR (2005); ii. Countries and regional organizations must lead by example: G7, G20 and G77 Member States, and regional intergovernmental organizations must follow through on their political and funding commitments for preparedness and agree to routinely monitor progress during their annual meetings; iii. All countries must build strong systems: Heads of government must appoint a national high-level coordinator with authority and political accountability to lead whole-of-government and whole-of-society approaches, and routinely conduct multisectoral simulation exercises to establish and maintain effective preparedness; iv. Countries, donors and multilateral institutions must be prepared for the worst: Donors and multilateral institutions must ensure adequate investment in developing innovative vaccines and therapeutics, surge manufacturing capacity, broad-spectrum antivirals and appropriate non-pharmaceutical interventions; v. Financing institutions must link preparedness with financial risk planning: Funding replenishments of the IDA, Global Fund to Fight AIDS, TB and Malaria (Global Fund), and GAVI should include explicit commitments regarding preparedness; vi. Development assistance funders must create incentives and increase funding for preparedness; Donors, international

financing institutions, global funds and philanthropies must increase funding for the poorest and most vulnerable countries through development assistance for health and greater/earlier access to the United Nations Central Emergency Response Fund to close financing gaps for their national actions plans for health security as a joint responsibility and a global public good; vii. The United Nations must strengthen coordination mechanisms: The Secretary General of the United Nations, with WHO and United Nations Office for the Coordination of Humanitarian Affairs (OCHA), must strengthen coordination in different country, health and humanitarian emergency contexts, by ensuring clear United Nations systemwide roles and responsibilities; rapidly resetting preparedness and response strategies during health emergencies; and, enhancing United Nations system leadership for preparedness, including through routine simulation exercises.

iii. **A Fragile State of Preparedness 2023 Report On The State Of The World's Preparedness;** https: // www. gpmb. org / reports / m / item / a- fragile- state - of-preparedness-2023-report-on-the-state-of-the-worlds-preparedness

The GPMB Monitoring Framework for Preparedness, 2023, provides a robust, evidence-based methodology to assess global preparedness. It has been applied for the first time in this Report, reporting on 30 of its full 90 indicators most pertinent to equity, leadership and accountability, and coherence. Across the indicators reviewed, the assessment shows that capacities are inadequate. There are particular weaknesses in global R&D coordination, addressing the impact of misinformation, providing financing and including all actors in governance. Some improvements following COVID-19 have been seen in relation to global information platforms, community engagement, independent monitoring and regional laboratory capacity. Weaknesses in the global financing system for Pandemic Prevention, Preparedness and Response (PPPR) and the failure of international commitment to strengthening independent monitoring will weaken future prospects for effective PPPR.

iv. **COVID-19: Make it the Last Pandemic by The Independent Panel for Pandemic Preparedness & Response;** https://theindependentpanel.org/wp-content/uploads/2021/05/COVID-19-Make-it-the-Last-Pandemic_final.pdf

The Panel has examined the state of pandemic preparedness prior to COVID-19, the circumstances of the identification of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the disease it causes, coronavirus disease (COVID-19), and responses globally, regionally and nationally, particularly in the pandemic's early months. It has also analysed the wide-ranging impact of the pandemic and the ongoing social and economic crisis that it has precipitated. This report presents the Panel's findings on what happened, the lessons to be learned from that, and our recommendations for strategic action now to end this pandemic and to ensure that any future infectious disease outbreak does not become a catastrophic pandemic. Complementing this report, the Panel presents a companion report describing thirteen defining moments which have been pivotal in shaping the course of the pandemic. In addition, the Panel is publishing a series of background papers representing in-depth research including a chronology of the early response.

v. **100 Days Mission Implementation Report by International Pandemic Preparedness Secretariat (IPPS);** https://d7npznmd5zvwd.cloudfront.net/prod/uploads/2023/01/100-Days-Mission-2nd-Implementation-Report-1.pdf

The 100DM offers a framework for implementers at all levels to take forward and apply, whether at the global, regional or national level. The essence of the 100DM is to significantly reduce the time to develop diagnostics, therapeutics, and vaccines (DTVs), maximising the health impact and saving lives.

This year's report maintains a rigorous focus on the overarching end goals of the 100DM which gives a more quantifiable sense of our state of readiness. Within each section, overarching goals, critical bottlenecks to achieving these goals and the proposed inputs needed in 2024 to maintain satisfactory progress have been reiterated. The chapters provide high-level analysis, and a summary of 2024 milestones those already planned by implementation partners, and more aspirational goals set by the IPPS.

For this year, while significant progress has been made, analysis from implementation partner feedback and the 100DM scorecard data highlights key areas needing urgent attention in 2024: 1. Therapeutics Pipeline Enhancement; 2. Diagnostics Framework Funding, 3. Regulatory Alignment And Preparatory Regulatory Approaches; 4. Sustain And Strengthen Regional And Global Clinical Trial Infrastructure.

Designed by:

सत्यमेव जयते

NITI Aayog