



**World Health  
Organization**

# **Pandemic Preparedness and Vaccine Success**

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Dr. Martin Friede

Vaccine Product and Delivery Research

# Recent history on vaccine preparedness and response to outbreaks – a story of inequity and delays

- 1976 Swine influenza H1N1 in USA – no supply to Canada
- 2005 Avian H5N1 – LMICs note they lack to technology and threaten to withhold virus sharing
- 2009 H1N1 pandemic – LMICs last in line to receive vaccine, arriving after end of pandemic
- 2014 Ebola – vaccine candidate available but no human data leads to delay
- 2019 Sars-CoV-2 – LMICs without vaccine manufacturing capacity last in line to receive vaccine

# Pragmatically what does it take to be ready /respond to an outbreak ?

## What are we doing to be ready ?

- A vaccine candidate that can be tested for efficacy rapidly
  - Ideally animal efficacy and human immunogenicity and safety completed before outbreak, clinical protocols ready
    - WHO R&D blueprint priority list, clinical trial networks, clinical trial capacity in all regions of world
    - CEPI portfolio of pre-outbreak product development to human safety/immunogenicity
    - Academic/Biotech research on new technologies, pathogens etc.
- Manufacturing capacity in ALL regions of the world
  - Urgently need vaccine manufacturing capacity in AFRO, EMRO and expand in other regions
  - Human resources with know-how, technology, skills and experience
  - Regulatory agency at maturity level III or above to approve products
    - Vaccine technology transfer hubs (influenza, adjuvants, mRNA, tbd..)
    - Biomanufacturing workforce training hub and network
    - Regulatory strengthening
  - **SUSTAINABLE Infrastructure and know-how for rapid-response**: the elephant in the room.....



# Sustainable vaccine preparedness...



- The problem with outbreaks is that they are unpredictable

"It's tough to make predictions, especially about the future."

– Yogi Berra



- How do you sustain a technology /know-how / facility that is designed to respond to outbreaks ?
  - Annual procurement of some batches by government (eg USA H5N1)
  - Make a routine vaccine with the same technology, staff, equipment
    - Apply dose-sparing technologies for outbreak eg adjuvants
    - Which technologies can respond to outbreaks AND routine needs ?
  - Make another product eg biotherapeutics to sustain staff, facility – but facility size/scale inadequate for outbreak
- How do you sustain a global supply chain for reagents / equipment that can respond to an outbreak ?
  - No point having local production if reagents not available during outbreak

## IP, technology, know-how, and access:

- Were patents a barrier to responding to Covid in LMICs ?
  - Inactivated virus – no. But confidence and Biosafety level II facilities possibly
  - Adenovirus – not in most LMICs, but access to proprietary proven and tested cells and strains yes. Lengthy to start from scratch making these reagents.
  - mRNA – in some LMICs yes, but Moderna covenant of non-enforcement did not result in new manufacturing in LMICs. Know-how in LMIC was a key barrier (and some mRNA technologies had failed)
  - Recombinant proteins – not in most LMICs – but know-how on which technology to use, and access to adjuvants was a barrier.
- Will patents be a barrier to LMIC outbreak-response vaccines in the future ?
  - Very likely: seeing increased territorial scope in patenting of improvements
  - Will impact sustainability of local production plans.

# The future

- **The next outbreak may be much, much worse than Covid**
- **Investments are needed to ensure that vaccine and drug technologies are developed and shared with manufacturers in all regions of the world**
  - **Need best practices in licensing of innovations from academia to ensure access to LMICs**
- **Investments are needed to ensure that LMICs expand their capacity to undertake R&D, absorb technology, and produce and approve biological products**

