



Sustainable vaccine production and pandemic preparedness: Lessons learned and future perspectives

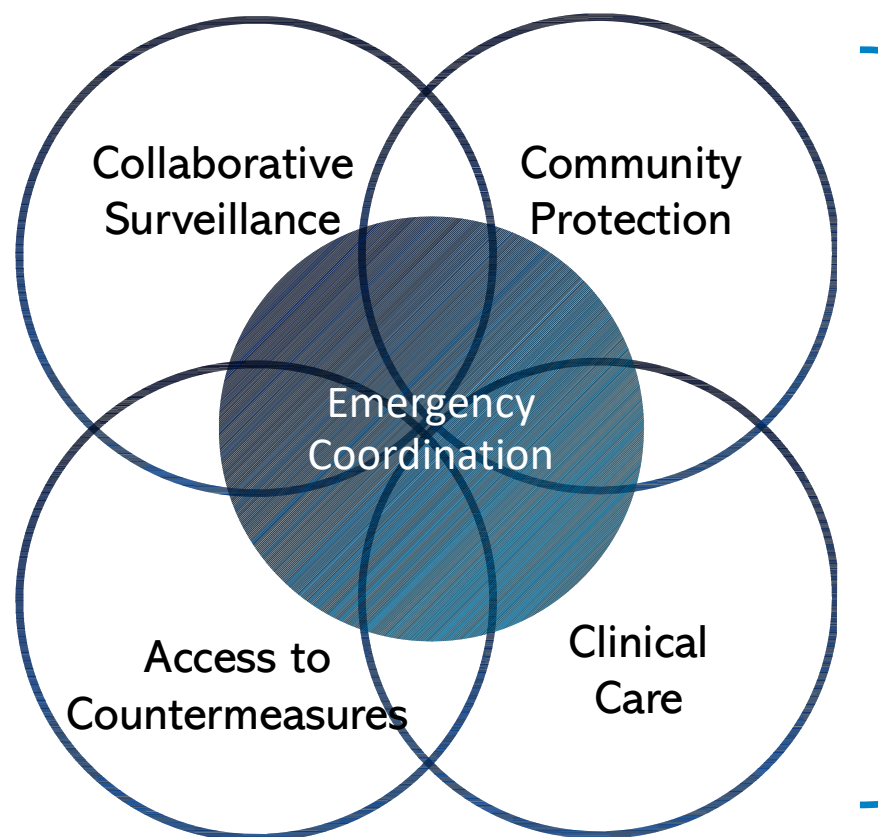
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Expanding access to pandemic products



Fast track **R&D** with pre-negotiated benefit sharing agreements

Scalable **manufacturing platforms** & agreements for technology transfer

Coordinated procurement & **emergency supply chains** to ensure equitable access

Embedded in health systems & multi-sectoral capacities & action

Underpinned by:

- ☐ Governance
- ☐ Financing
- ☐ Equity, inclusivity, & coherence



mRNA Tech Transfer Hub Programme vision and objectives

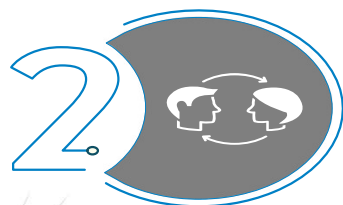
Vision

Improve health security in LMIC through sustainable, regional production of mRNA vaccines



Objective 1

Establish or enhance **sustainable mRNA vaccine manufacturing capacity** in regions with no or limited capacity



Objective 2

Build human capital for regulation and biomanufacturing in LMICs



Sustainable Vx manufacturing: Lessons learned from influenza

- **WHO Global Action Plan for Influenza Vaccines (2006-2016): Technology transfer to expand influenza vaccine manufacturing capacity in LMICs for pandemic preparedness:**
 - 14 manufacturers identified as recipients of egg-based inactivated or live attenuated influenza vaccine production technologies
 - 9/14 obtained approval of at least one seasonal or pandemic influenza vaccine
 - 6/14 currently produce a seasonal influenza vaccine
 - Capacity equates to 675 million doses of pandemic influenza vaccine in 12 months
- **Multiple areas impact sustainability:**

Policy & Political
Landscape

Product Development
& Manufacturing

Product Approval &
Regulation

Acceptance, Demand,
& Delivery of Vaccine



Key sustainability drivers relevant across other Vx products

Problem

Vx production goes beyond just increasing supply

Tech transfer is not a quick fix for increasing access to Vx during a pandemic

Sustainability can't be driven by global priorities alone

Solution

Political will, whole-of-government & multisectoral coordination & collaboration is necessary

Long-term planning, support, trust, & vision are required

Sustainability during the inter-pandemic period should be driven by national/regional priorities & disease burden

Sustainability should be considered throughout the entirety of the project



Sustainable production for pandemic preparedness: Role of governments & manufacturers





Considerations for sustainability: Business models

Three basic business models are currently under consideration for the mRNA tech transfer hub programme, but they're more broadly applicable as well

Option 1	Small scale mRNA facility for response in outbreak situation, operating limited production runs annually; scale up in emergencies	<ul style="list-style-type: none">• Small footprint, low running costs• Annual OPEX investment to fund initial production runs to keep facility 'warm'• Potential for revenue streams from mRNA production for R&D purposes
Option 2	Flexible biologics and mRNA Vx facility which manufactures product continuously on a commercial, sustainable basis; switch to Vx response in outbreak situation	<ul style="list-style-type: none">• Biologics manufacture provides income stream, generating economic viability• Potential for revenue streams from mRNA production for R&D purposes
Option 3	Vaccine-focused facility with mRNA and other Vx production platforms, manufacturing continuously on a commercial, sustainable basis; switch to Vx response in outbreak situation	<ul style="list-style-type: none">• Vx manufacture from other tech platforms provides income stream, generating economic viability



Considerations for sustainability: Role of government policy and strategy coordination

