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

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DCVMN Annual General Meeting
21 October 2022
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

10 proposals to build a safer world together – Strengthening the Global Architecture for Health Emergency Preparedness, Response and Resilience: white paper for consultation, June 2022 [who.int]
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
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:
### Problem

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<th>Problem</th>
<th>Solution</th>
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<td>Vx production goes beyond just increasing supply</td>
<td>Political will, whole-of-government &amp; multisectoral coordination &amp; collaboration is necessary</td>
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<td>Tech transfer is not a quick fix for increasing access to Vx during a pandemic</td>
<td>Long-term planning, support, trust, &amp; vision are required</td>
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<td>Sustainability can't be driven by global priorities alone</td>
<td>Sustainability during the inter-pandemic period should be driven by national/regional priorities &amp; disease burden</td>
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**Sustainability should be considered throughout the entirety of the project**
Sustainable production for pandemic preparedness: Role of governments & manufacturers

- Intersectoral dialogue and coordination
- Involvement of relevant national stakeholders
- Manufacturing capacity and development
- Procurement mechanisms, pricing and access policies
- National financing and private investments
- Product regulation and approval for use
- Industrial, trade, S&T, public health policies and coordination
### 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 | • 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 | • 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 | • Vx manufacture from other tech platforms provides income stream, generating economic viability |
Considerations for sustainability: Role of government policy and strategy coordination

- National Plan for Vaccine Manufacturing Capacity
- Intersectoral Dialogue & Multi-Partner Commitments
- National & Regional Strategy Alignment
- Mutually Agreed Sustainability Workplan