

Lessons Learned from Technology Transfer Programme for Influenza Vaccines

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Pandemic Response

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REVIEW ARTICLE

GLOBAL HEALTH

Pandemic Preparedness and Response —

The most serious operational shortcoming was the failure to distribute enough vaccine in a timely way. Ultimately, 78 million doses of vaccine were sent to 77 countries, but mainly long after they would have done the most good.

At its root, this reflected a shortfall in global vaccine-production capacity and technical delays due to production, as well as distributional problems.

Among the latter were variation among wealthier countries and manufacturers in their willingness to donate vaccine, concerns about liability, complex negotiations over legal agreements with both manufactures and recipient countries and limited national and local capacities to transport, store, and administer vaccines.

The Problem - Insufficient Global Vaccine Manufacturing Capacity to Respond to an Influenza Pandemic

Flu vaccine shortage a worldwide crisis

December 13, 2004 | By Michael Coren CNN

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Concerned about the flu vaccine shortage at home, U.S. public health officials are examining the defenses against a global flu outbreak -- and they don't like what they see.

"We're very unprepared," said Ira Longini, a professor at Emory University's Rollins School of Public Health. "We haven't made influenza a high priority in this country, or anywhere else that I know of."

The World Health Organization, based in Geneva, Switzerland, recently warned that a global flu outbreak will happen in a matter of time and urged nations to strengthen their health infrastructures before it hits.

Immediate and sustained action required to sharply increase pandemic influenza vaccine supply

23 OCTOBER 2006 | GENEVA - A set of activities identified in the World Health Organization's (WHO's) new *Global pandemic influenza action plan to increase vaccine supply* requires immediate and sustained action and funding, if the world is to be prepared for an influenza pandemic to which there would be almost universal susceptibility.

The global swine flu vaccine shortage

Category: Big Pharma • Swine flu • Vaccines • WHO

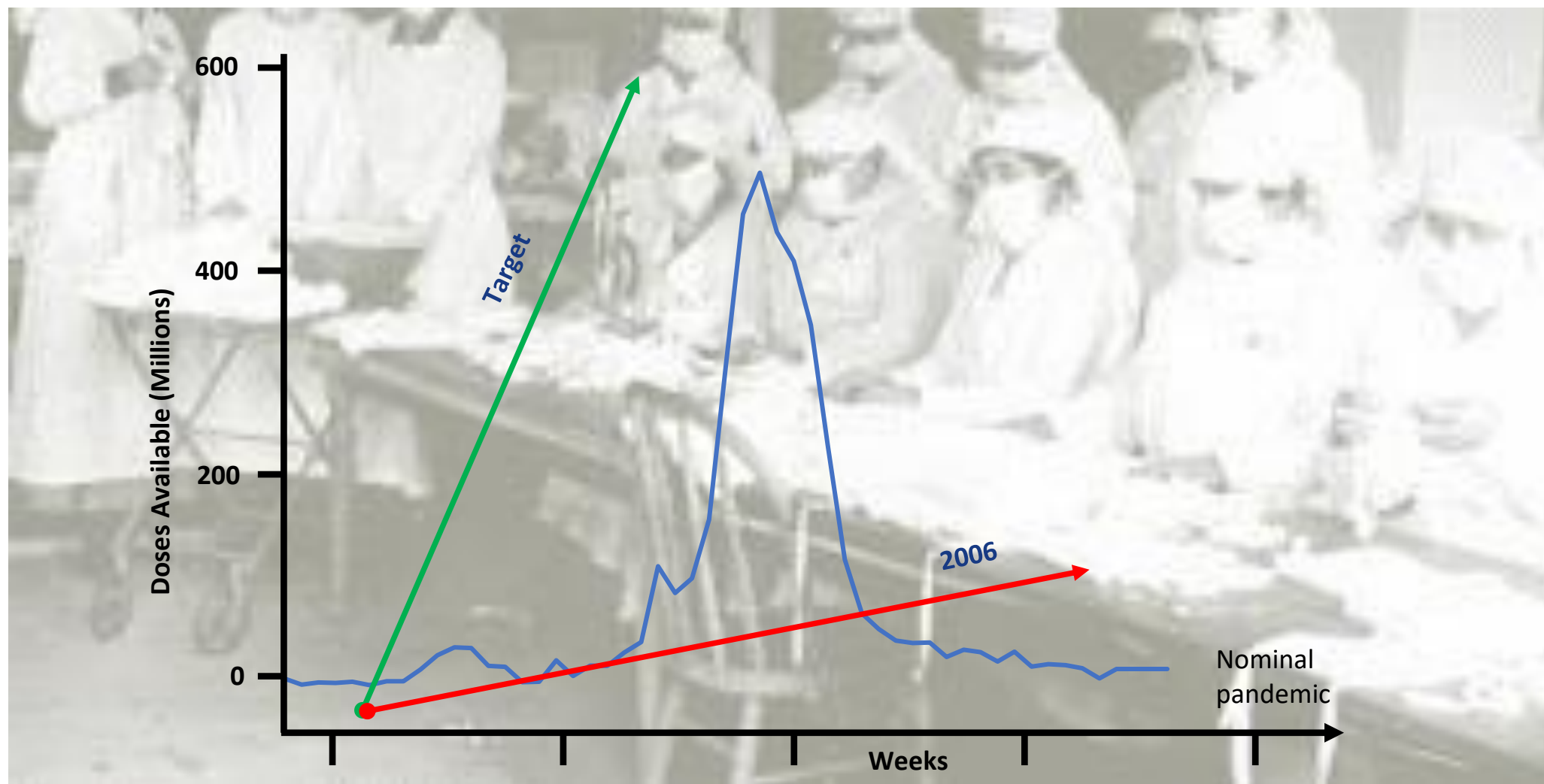
Posted on: November 23, 2009 6:45 AM, by reverse

Thursday, April 29, 2010

Vaccine Shortage Threatens 2009 H1N1 Control in Nigeria

Despite the recent outbreak of the pandemic 2009 H1N1 virus in Ghana, Nigeria is yet to receive stocks of vaccine to prepare for a possible outbreak in the country.

Influenza Vaccine Response Timeline



The Problem - Insufficient Global Vaccine Manufacturing Capacity to Respond to an Influenza Pandemic

- Global Shortage of vaccines in the event of a pandemic
- Inequitable access to available vaccines
 - Countries refuse to share virus
 - Lack of distribution agreements
 - Limited regulatory harmonization
- No supply at probable origins to aid early containment



WHO Global Action Plan for Influenza Vaccines

2006 - 2016

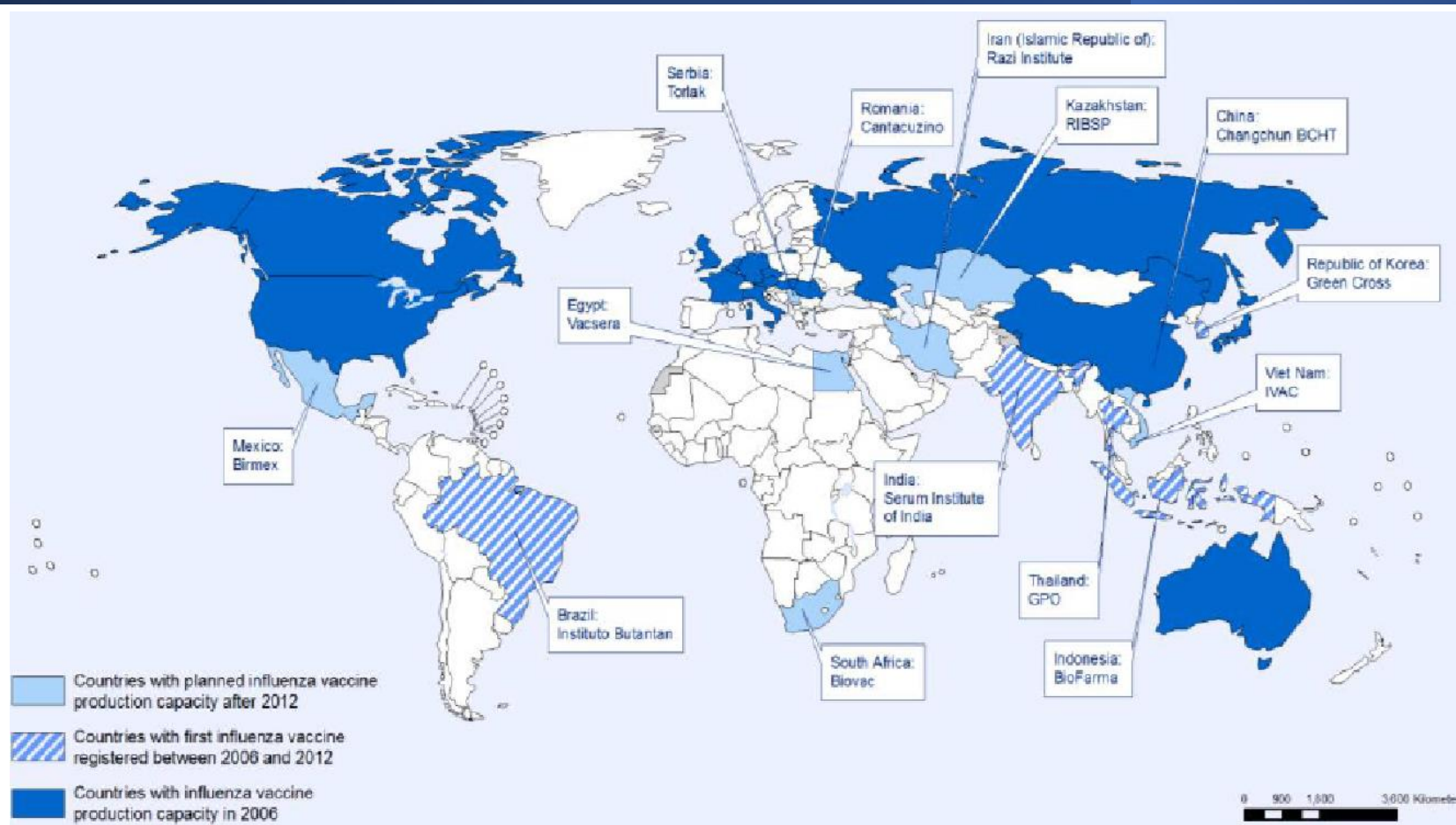


Goal - To create sustainable capacity for the development and production of influenza vaccine for self reliance and pandemic response

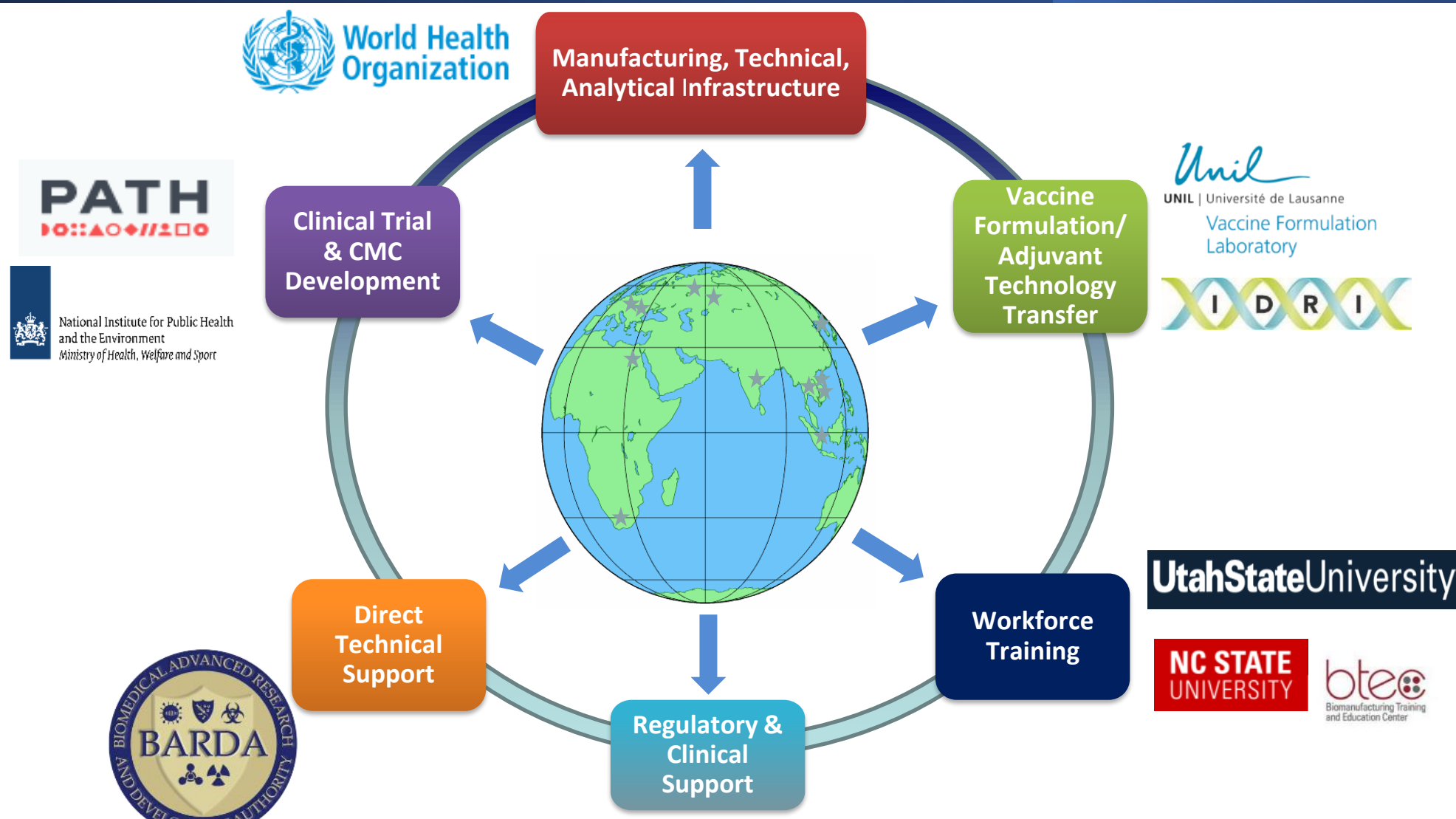
- Three objectives:
 - Increase in seasonal vaccine use
 - Increase in vaccine production capacity
 - support new manufacturers; support development of adjuvants that increase vaccine capacity
 - Goal was to increase production capacity from <1 M to 500 M doses within the program
 - Research and development for next generation vaccines



Geographical Distribution of Influenza Vaccine Production



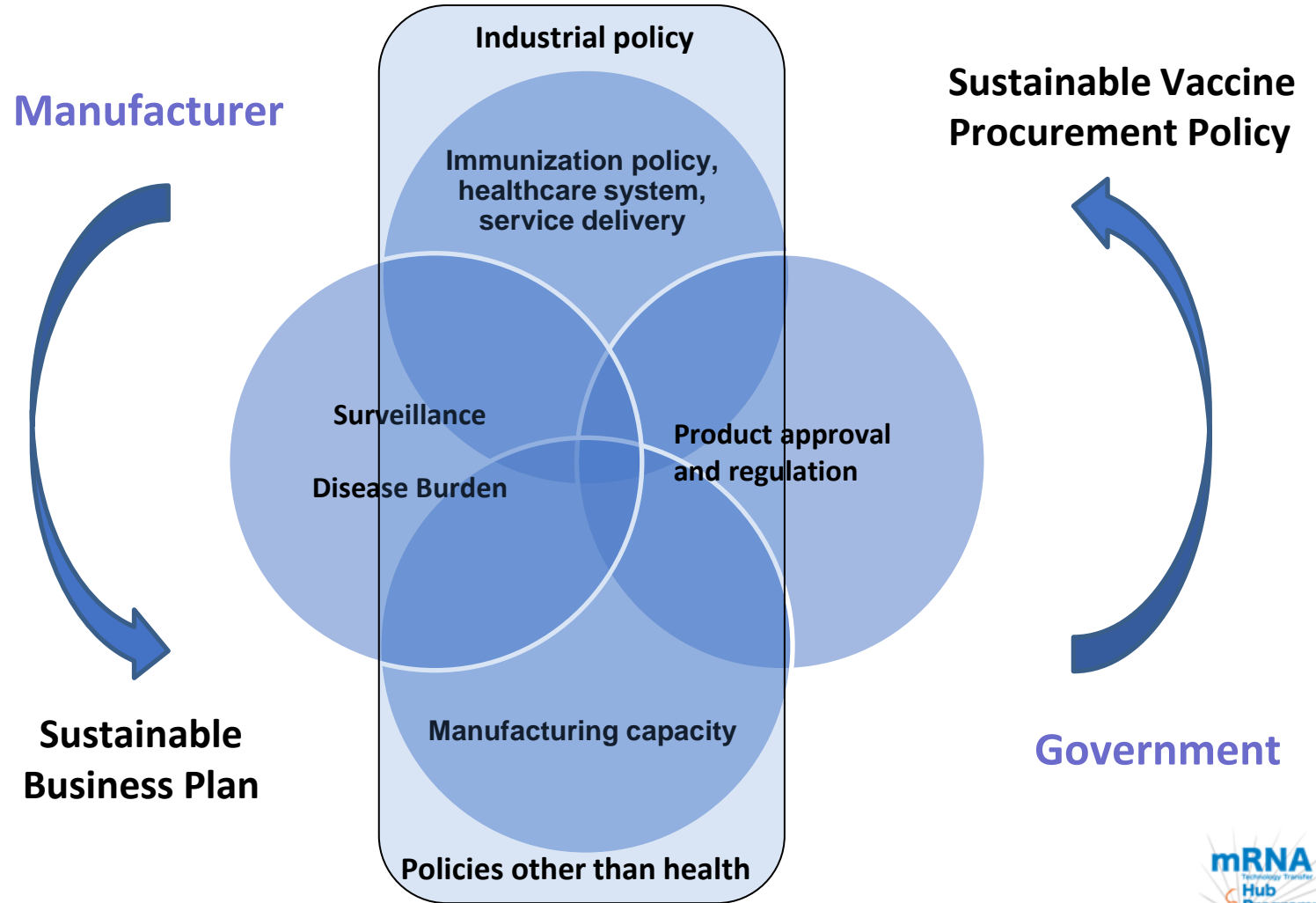
Tailored Multifaceted Approach



Conducive Environment to Sustainability

Technology Transfer: Necessary but insufficient by itself to ensure pandemic production when it's needed

Business Plans, Policies, and Market forces that Facilitate Sustainability



Program Accomplishments (2006 – 2018)

Vaccine Production

>1M doses (2005)

10 international partners

15 manufacturers in 14 countries

\$108.3M USG Invested (\$30M to countries - \$495M leveraged)

12 International Workshops/Partner Meetings

>250 scientists trained in advanced biomanufacturing skills

14 publications in 2016, 2 in 2018, and 4 publications in 2019

4 countries have adjuvant production capability

3 countries (4 vaccines) in late stage human clinical development

9 countries (15 vaccines) have licensed seasonal and/or pandemic vaccine for human use

~1 Billion doses pandemic vaccine projected from companies in the GAP program (2018) (with adjuvant use)



Every dollar invested by the USG leveraged \$17 of additional local investment (government and/or manufacturers)

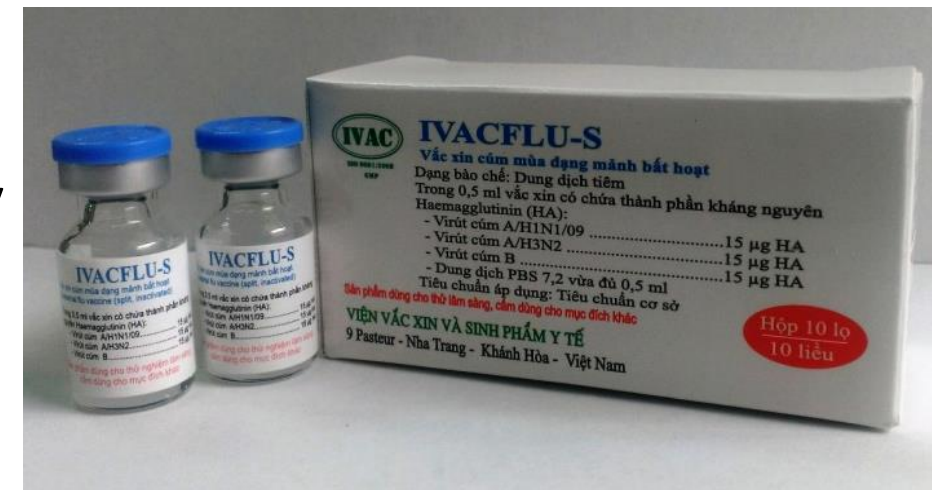
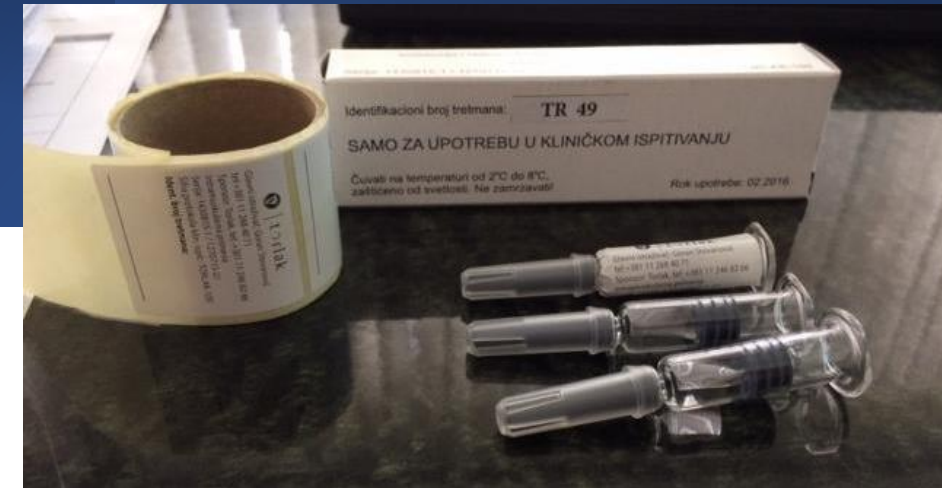
Lesson's Learned

- Manufacturing capacity building cannot happen in a vacuum
 - Technical training (group & on-site)
 - Regulatory strengthening & harmonization
 - Clinical trial capacity
 - Policy (pandemic and seasonal vaccine use)
 - Business models for sustainability
 - Data (disease burden, vaccine effectiveness)
 - Supply chain challenges (eggs)
- Local government support (financial, policy, regulatory)
- Close collaboration and communication with partners
- Need for flexibility in approach, models, pace, funding
- Need for broad international support, collaboration and alignment
- Need for multiple and diverse funding sources (Fundors/schedules vary)



Benefits to the World

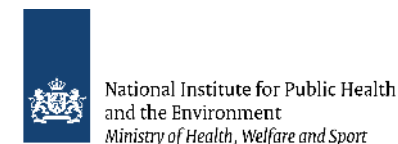
- Enhanced global capability to respond to an influenza pandemic (and other pandemics)
 - More equitable and geographical distribution of vaccine
- Reduced burden on a few countries to produce and distribute limited vaccine
 - More efficient to produce vaccine locally/regionally
- Strengthened International/biological diplomacy
- Minimal investment has yielded significant ROI
 - Virus/Sample sharing benefits
 - Rapid notification of emerging threats
 - Enhanced surveillance and disease burden data



Global Partners



ИЭМ



UtahStateUniversity



With Gratitude









Great things in the world have never been
accomplished by one person; they have been
accomplished by great teams of people. --
Unknown