Corollaries of vaccine introduction: Benefits beyond vaccine efficacy

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Conflict of interest

- January 2011- present: no COI
- < 2011: Sanofi Pasteur, GSK, Novartis







Bulletin of the World Health Organization

Vaccination greatly reduces disease, disability, death and inequity worldwide

FE Andre a, R Booy b, HL Bock c, J Clemens d, SK Datta c, TJ John e, BW Lee f, S Lolekha g, H Peltola h, TA Ruff i, M Santosham i, HJ Schmitt

- Mortality
- Morbidity
- Mitigation of severe disease
- Elimination/Eradication
- Herd protection
- Source drying

- Protection against related diseases
- Cancer prevention
- Preventing development of antibiotic resistance
- Reducing all cause mortality

Societal benefits beyond efficacy

- Health-care and other savings for society
- Strengthening of primary health care services
- Promoting economic growth
- Enhancing equity
- Peace



Equity in immunisation

GAVI's mission – to save children's lives and protect people's health by increasing access to immunisation in poor countries – is underpinned by the basic tenet of equity. Access to the benefits of vaccines should not depend on where in the world a child is born.

Oslo Ministerial Declaration—global health: a pressing foreign policy issue of our time



Ministers of Foreign Affairs of Brazil, France, Indonesia, Norway, Senegal, South Africa, and Thailand*

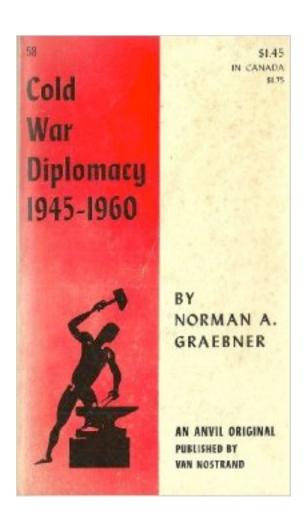
Under their initiative on Global Health and Foreign Policy, launched in September, 2006, in New York, the Ministers of Foreign Affairs of Brazil, France, Indonesia, Norway, Senegal, South Africa, and Thailand issued the following statement in Oslo on March 20, 2007—In today's era of globalisation and interdependence there is an urgent need to broaden the scope of foreign policy. Together, we face a number of pressing challenges that require concerted responses and

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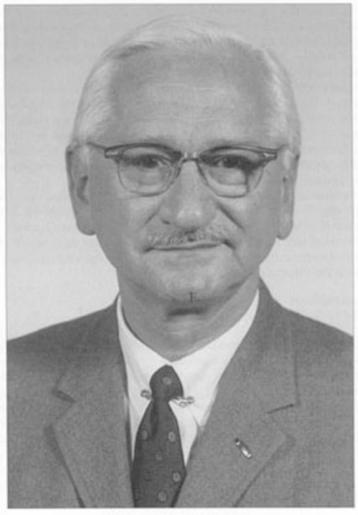
*Celso Amorim (Brazil);



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Benefits of vaccines beyond efficacy

- Vaccines may have unanticipated uses beyond efficacy
- Vaccines as instruments of foreign policy
- Vaccine diplomacy
- "There are no better grounds on which we can meet other nations and demonstrate our own concern for peace and the betterment of mankind than in a common battle against disease" (Secretary of Health John Gardner 1966)



Table II. UNICEF vaccine-mediated cease-fires during civil conflicts

Date	Location
June 1996	Liberia
July 1998	Sudan
June 1999	Afghanistan
May 2000	Afghanistan
August 2000	DR Congo
October 2000	Afghanistan
October 2000	Sudan



Sources: www.unicef.org and www.bbc.co.uk.

Peace Through Vaccine Diplomacy

Vaccines as instruments of foreign policy

The new vaccines for tropical infectious diseases may have unanticipated uses beyond fighting diseases • by Peter J. Hotez

EMBO reports vol. 2 | no. 10 | 2001



Table 1. Historical milestones in vaccine diplomacy.

Years	Specific Vaccine(s)	Actions	Reference
1800-1805	Smallpox	Edward Jenner promotes vaccine use in Russia, Turkey, and Spain and with Native Americans in the Spanish colonies of Mexico, the Five Nations of Canada, and the United States.	[31,32]
1801	Smallpox	The chaplain of Congress, Dr. Edward Gantt, vaccinates Native American diplomats visiting Washington, D.C.	[32]
1803	Smallpox	The Lewis and Clark Expedition provides vaccine intended for Native Americans, but it is unclear if successful vaccinations were performed.	[32]
1803-1815	Smallpox	During the Napoleonic Wars, Jenner calls for prisoner release and other diplomatic functions. In a letter to the National Institute of France, he writes that "the sciences are never at war."	[31]
1851		The First International Sanitary Conference is held in Europe.	[3]
1888		In a speech on the inauguration of the Pasteur Institute, Louis Pasteur states, "Science knows no country, because knowledge belongs to humanity and is the torch which illuminates the world."	[31,33]
1891-present		International network of Pasteur Institutes begins, initially in Saigon, for purposes of fundamental research and research on vaccines for rabies and other infectious diseases.	[34]
1892-1897	Cholera and plague	After first testing the vaccines on himself, Dr. Waldemar Haffkine travels to India to inoculate tens of thousands of people with his prototype cholera and plague vaccines.	[35]
1902		Formation of the International Sanitary Bureau (present-day Pan American Health Organization)	[4]
1946-48		Formation of the World Health Organization	[3]
1956-1959	Polio	Dr. Albert Sabin travels to the USSR and collaborates with Dr. Mikhail Chumakov, ultimately testing an oral vaccine on 10 million children and then on 100 million people under the age of 20.	[36]
1962-1966	Smallpox	The USSR provides 450 million doses of vaccine for an eradication campaign, while the US provides financial support.	[37]
1968		Formation of the Fogarty International Center of the NIH	
Mid-1970s		Formation of PATH	
1980s and 1990s	Polio and other vaccines	"Days of tranquility" for immunizations are held in more than a dozen war-torn countries.	[25]
1987		Indo-US Vaccine Action Program (VAP) is administered under the auspices of NIAID, NIH.	[38]
1990-91		Children's Vaccine Initiative (CVI)	
1993		Formation of the Sabin Vaccine Institute	[58]
		Formation of the Infectious Diseases Research Institute	
1997		Formation of the International Vaccine Institute	
1997		Formation of the Bill & Melinda Gates Foundation	
2000		GAVI Alliance is established, ultimately providing vaccines for North Korea.	[39,41]
2001		"Vaccine diplomacy" enters the literature.	[19]
2007		Formation of program in Sustainable Immunization Financing at Sabin Vaccine Institute	[65]
2007	Influenza	Under the auspices of the WHO, Brazil, India, Indonesia, Mexico, Thailand, and Vietnam receive US and Japanese grants for influenza vaccine manufacturing capacity and technology transfer.	[52]
2008	Yellow Fever	Outbreak of urban yellow fever—the neighboring countries of Paraguay mobilize to ensure access to yellow fever vaccine.	[45]
2009	H1N1 Influenza A	Intergovernmental Meeting (IGM) on Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits	[43]
2010	Cholera	Call for international cholera vaccine stockpile as a humanitarian and diplomatic resource	[44]
2011		Decade of Vaccines Collaboration	[46]
2012	•	The Global Vaccine Action Plan (GVAP)—endorsed by the 194 Member States of the World Health Assembly in May 2012	[47,48]
2013	Leishmaniasis and other neglected tropical diseases	Joint statement on vaccine diplomacy between US and Iran	[54]
2013		State Department forms new Office of Global Health Diplomacy.	

Hotez PJ (2014) "Vaccine Diplomacy": Historical Perspectives and Future Directions. PLoS Negl Trop Dis 8(6): e2808. doi:10.1371/journal.pntd.0002808

http://127.0.0.1:8081/plosntds/article?id=info:doi/10.1371/journal.pntd.0002808

FIGHTING CRITICAL DISEASES

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By Peter Hotez

A Handful Of 'Antipoverty' Vaccines Exist For Neglected Diseases, But The World's Poorest Billion People Need More

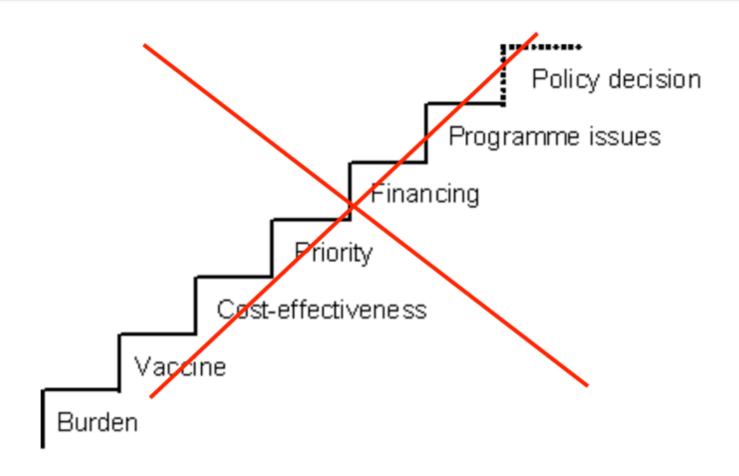
ABSTRACT So-called neglected tropical diseases are the most common infections of the world's poor. Almost all of the "bottom billion"—the 1.4 billion people who live below the poverty level defined by the World Bank—suffer from one or more neglected diseases including hookworm infection, sleeping sickness, or Chagas disease. These diseases are actually a cause of poverty because of their adverse effects on child growth and development and worker productivity. Vaccines to combat such diseases have come to be known as "antipoverty vaccines." Unfortunately, the

The antipoverty vaccines present the greatest economic hurdles and disincentives.

New era of vaccinology

- "Global health conscience" for novel vaccines for developing countries
- Appreciation of public health benefits of vaccines, philanthropy, partnerships GAVI
- "Easy" vaccines have already been implemented
- Newer vaccines are more complex, often only partially effective, and more expensive

Dengue vaccine introduction













Accelerate vaccine introduction

Dengue vaccine introduction: Points for consideration

- 1. Regulatory
- 2. Evidence for Decision-making
- 3. Impact Modeling
- 4. Immunization Systems
- 5. Demand and Financing
- 6. Post-Licensure/Demonstration Projects.



REGULATORY

Countries considering introducing a dengue vaccine should consider:

- Capacity of the National Regulatory Authority (NRA)⁴⁻⁹
- Countries considering dengue vaccine introduction should also consider:
 - Involving WHO Recognized Regulators to Discuss Needs for a Licensing Decision
 - A Gap Analysis of the NRA
 - The NRA's Willingness to Accord Priority Review
 - The NRA's Ability to Assess Manufacturers' Risk Management Plans
 - The NRA's Ability to Assess Country Specific Issues (GMOs, etc)
 - Coordination between the National Immunization Technical Advisory Group (NITAG) and NRA

EVIDENCE FOR DECISION-MAKING

Countries considering dengue vaccine introduction should have the ability to undertake or participate in:

- Epidemiological Surveillance
- Economic Studies
- Policy Studies
- Social Studies
- Modeling
- Impact Assessments



DEMAND AND FINANCING

Demand

Countries considering dengue vaccine introduction should consider:

- Historical Rollout Data
- Previous Experience with Mass Immunization Campaigns or with a Vaccine Outside of the EPI schedule
- The Functioning of Management and Delivery Systems

Financing

Countries considering dengue vaccine introduction should consider:

- The Budget Line-Item for a Dengue Vaccine
- The Fiscal Space to Increase the Immunization Budget
- The Budget for Implementation and Delivery of a Dengue Immunization Program
- The Fiscal Space for Monitoring and Evaluation
- The Fiscal Space to Maintain Financing for Existing Vector Control
- Experience in the Coordination of Budgets across Ministries
- Experience with Price Negotiations

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Advocacy – Creating a Sense of Urgency



Creating opportunities for discussion

Asking key stakeholders for a plan





Learning from other champions

Spin-offs just for planning dengue vaccine introduction

- Consortium: DVI
- Capacity building for NRA
- Generation of evidence
- Demand forecasting
- Engagement with policy-makers
- Advocacy
- Move to more integrated vector controlvaccine approach (PDC)

Benefits beyond efficacy in LMIC

All cause

mortality

Vaccine diplomacy

Enhancing equity

Economic growth

Protection of un-vaccinated

Efficacy



Lee Kong Chian School of Medicine

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Thank you!



