

A Very Brief History of Global Hepatitis B Immunization

Musings of a delivery boy

Disclaimer

- This will be a biased personal view of the history of Hepatitis B immunization. There are as many points of view as there are people who participated in this history.
- The opinions expressed herein do not necessarily represent the opinions of any organizations with which I have been associated.
- I have no financial conflict of interest. Or very many finances at all for that matter.

History

- “History is an account, mostly false, of events, mostly unimportant, which are brought about by rulers, mostly knaves, and soldiers, mostly fools.”
- Ambrose Bierce
- Later in the meeting we will break up into discussion groups of knaves and fools.

Hepatitis B in EURO Region

- Excellent job in controlling hepatitis B with vaccine
- Very diverse in pre-vaccine prevalence, disease burden, public health systems, socioeconomic level, epidemiology
- Breakup of Soviet Union left many countries with dire economic and social problems
- Some countries had high burden of chronic hepatitis, delta
- EURO understaffed and underfunded
- However, most countries had high immunization coverage
- 50/53 countries universal HB immunization high coverage
- All countries have either a birth dose or selective HBsAg screening of mothers + Rx (or both)
- Chronic carrier prevalence <0.5% in immunized cohorts

Origins of Global Immunization

- 1950s campaigns to control/eliminate yaws, trachoma, leprosy, Tb
- 1955 Malaria Eradication failed
- 1959 First attempt at Smallpox eradication
- Smallpox Eradication Program 1967-1980
 - Everyone on earth could be reached with campaigns
 - Saved 2-5 million lives per year, eradication possible
 - First successful large scale global partnership
 - Seed planted for developing global programs on immunization, malaria, blindness, diarrheal diseases

Origins of Global Immunization

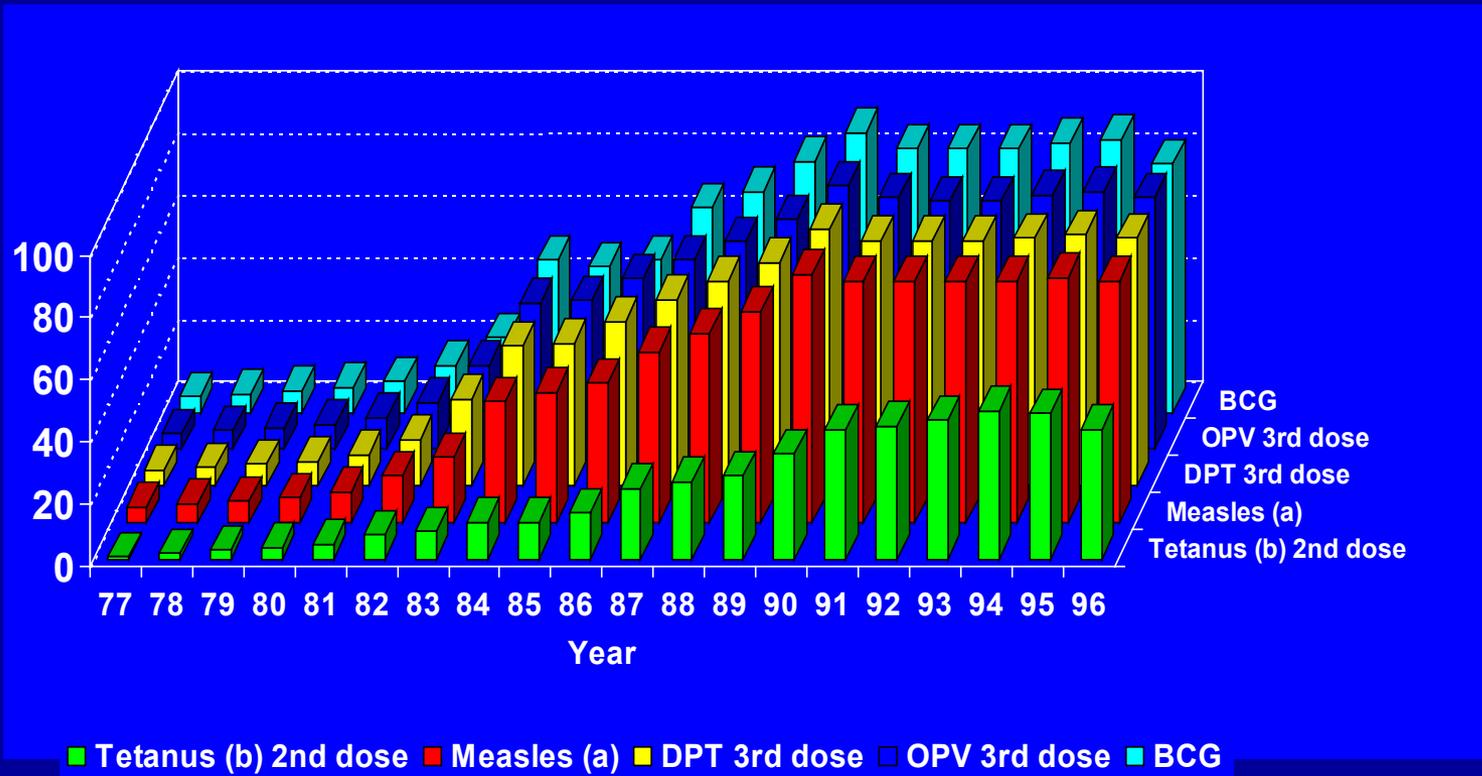
- The birth of the EPI 1974
 - 5% global coverage in early 1970's primarily benefitting children in high income countries
 - Encouraged development of NIP in all countries
 - Developed global cold chain, surveillance systems, training materials, advocacy
 - Immunization posts became the wedge bringing modern HC to much of the world

Global Immunization 1980's

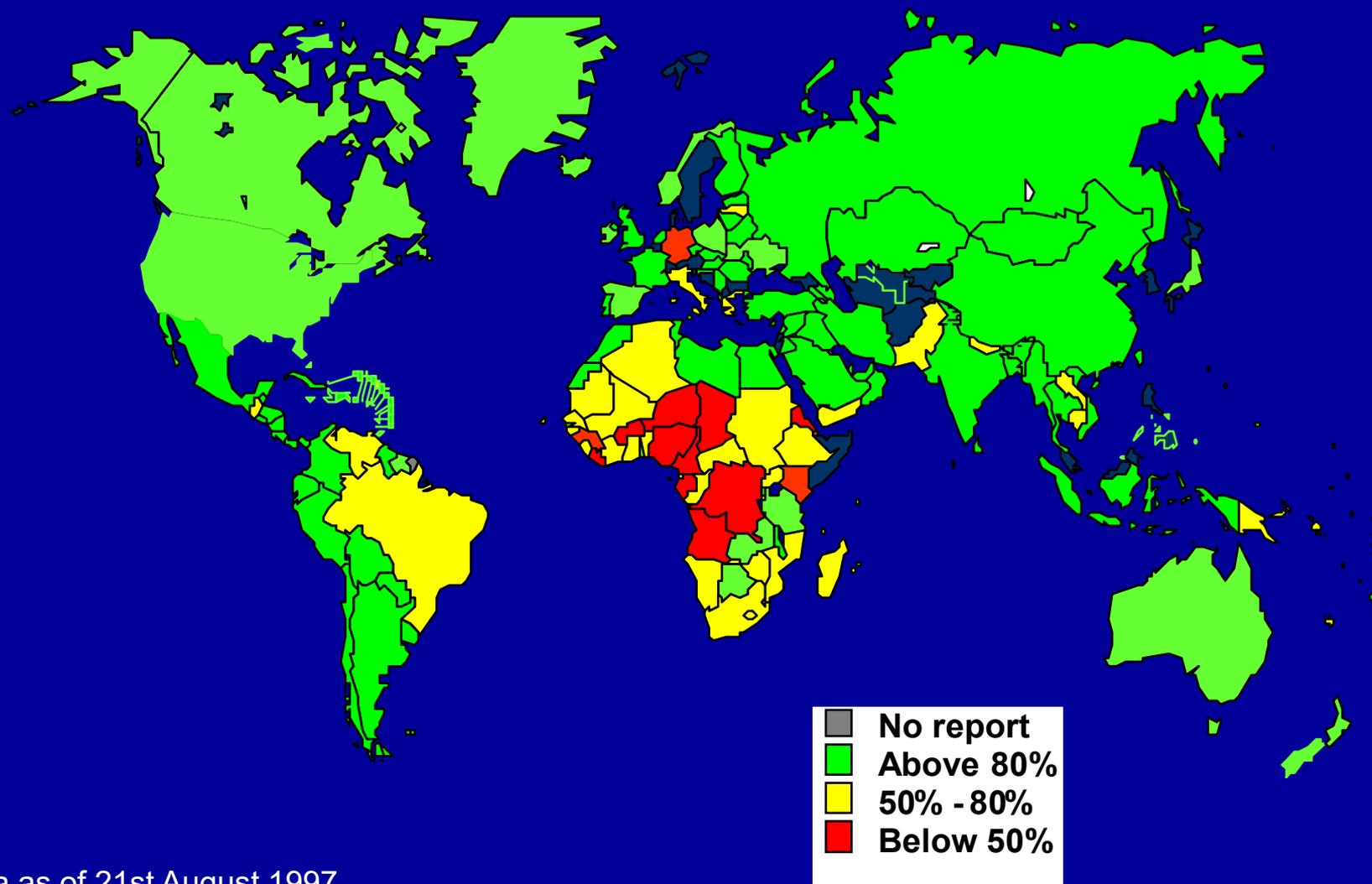
Universal Childhood Immunization (UCI)

- Underlying paradigm “Child Survival”
- Widespread international cooperation among donors, UN agencies and Partners
- 6 EPI vaccines <\$1.00 per child
- Countries paid for most delivery costs
- By 1990 75-80% global coverage
- Financial Infrastructure underlying global immunization was incapable of supporting new vaccines
- ? Greatest achievement of UN

Expanded Programme on Immunization Coverage



Global reported immunization coverage with three doses of DTP in infants, 1996



Data as of 21st August 1997

The designation employed and the presentation of material on this map do not imply the expression of any opinion whatsoever on the part of the secretariat of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted lines on maps represent approximate border lines for which there may not yet be full agreement.

HIC and Hepatitis B

- Hepatitis B vaccine licensed in 1981
- First of “new” vaccines: Plasma derived then DNA recombinant in 1986
- Cost >\$100 for 3 doses, no use in developing world public sector
- Strategy to reach “high risk groups” protected individuals but no impact on transmission.
- 1991 US recommended Universal Immunization of children-Hal Margolis
- Barcelona and Italy

A long decade's journey into night: 1990s

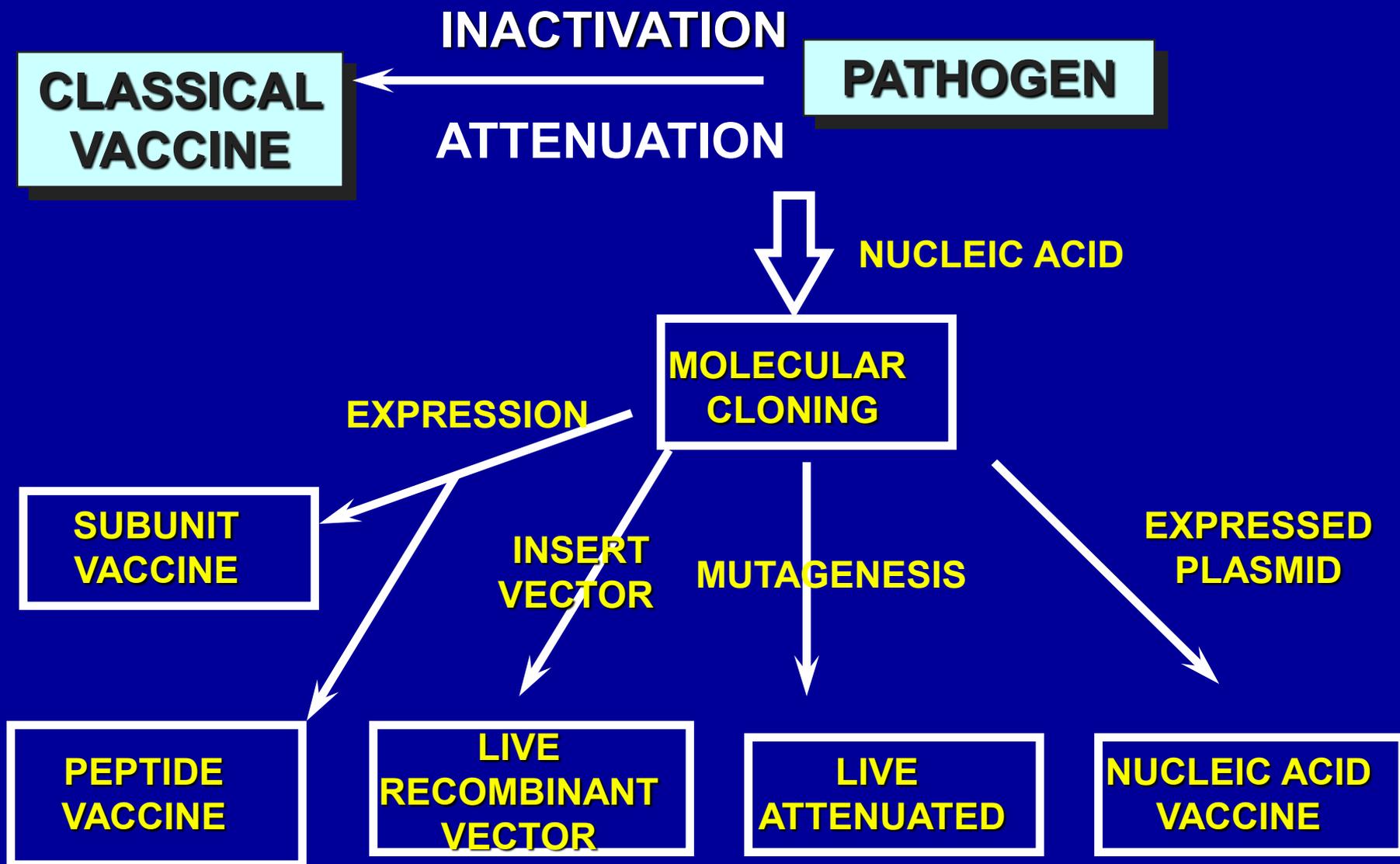
- Underlying paradigm changed to “health reform” and “decentralization”
- Donor attention shifted
- Immunization coverage plateaued
- Immunization became the poster child of “the bad old vertical programs”
- Health reform ignored EPI managers and other “vertical programs”
- Schizophrenic message to countries

A long decade's journey

- Decade of 1990s
- Immunization split into “routine” and “supplemental campaigns”
- Polio eradication got ~ 90% of operational funding
- Immunization seen as a zero sum game, routine or campaigns or new vaccines.
- Meanwhile the biotech revolution was underway...the ability to manipulate DNA and RNA
- Progress was made in integrating hepatitis B

WHO and Hep B

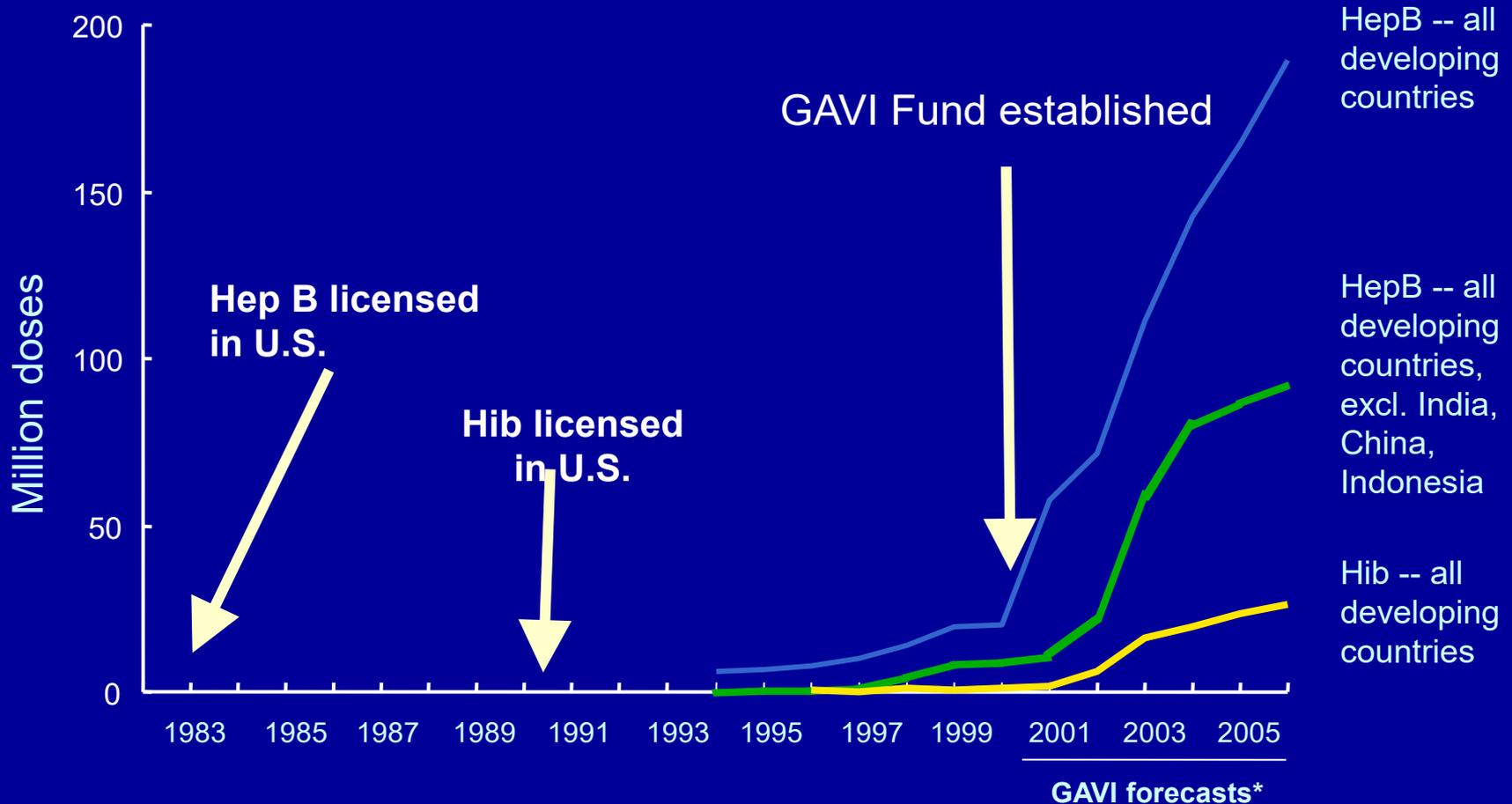
- 1991 GAG EPI resolution for Universal Immunization with Hep B by 1997
- 1992 World Health Assembly Resolution
- 1994 Hep B became an EPI vaccine
- First “new” vaccine into global immunization since measles
- By 1999, 110 countries introduced Hep B into routine immunization
- Poorest countries did not have access to Hep B vaccine



INTRODUCTION OF NEW VACCINES

- New Vaccines more expensive
- Protected IP TRIPS
- Cost to licensure could approach one billion dollars
- Belief that only Big Pharma could do this
- Vaccines developed if profitable in wealthy countries
- Long gap until available in LMIC
- Hepatitis B implementation needed competition from developing country manufacturers to lower prices before vaccine became available in LMIC

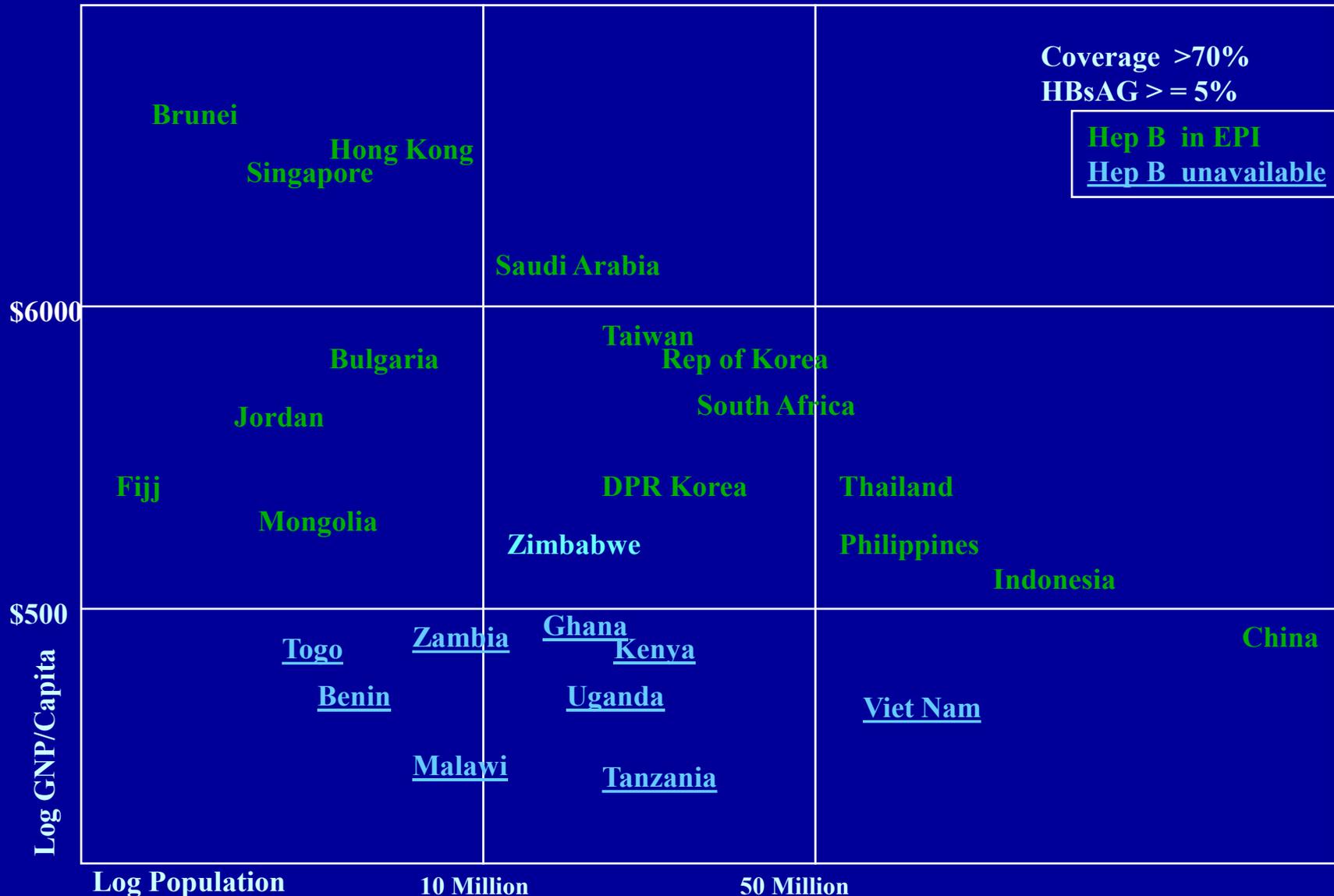
Slow introduction of Hep B and Hib vaccines into developing countries



HB vaccine: Universal Immunization Policy 1999



Impact of income on programme implementation: Hepatitis B



Coalitions Supporting EPI

- Several coalitions were formed to encourage EPI to adopt new vaccines, provide technical support, conduct demonstration projects, country advocacy
- Task Force for Child Survival- Coalition for Hepatitis Elimination
- International Task Force for Hepatitis B Immunization (ITFHBI) 1986
- Children's Vaccine Initiative (CVI) 1990
- Viral Hepatitis Prevention Board 1991-2
- Childrens Vaccine Program at PATH 1999
- GAVI 2000

Viral Hepatitis Prevention Board 1991-Today

- Provides important support to EURO
- Technical support and recommendations
- Regional and country meetings
 - Unbiased information
 - Country programs rarely communicated
 - High level attention by decision makers
- Advisors important advocates
- Support during anti-vaccine crises
- Still here!

International Task Force on Hepatitis B Immunization

- Vision that hep B vaccine could reach all children in the developing world through EPI
- High Level Advocacy Group (Secretariat PATH)
- Transferred vaccine technology to Asia
- Dropped price from \$40 ~ \$0.50/dose making global immunization possible
- Demonstration Projects in Indonesia, Thailand, China, Kenya, Cameroon
- Major influence on WHO and UNICEF to introduce Hep B vaccine into EPI

Children's Vaccine Initiative (CVI)

- Began in 1990 because of concern with WHO and UNICEF's limited activities on new vaccines
- UNICEF, WHO, UNDP, World Bank, Rockefeller
- Did some very valuable work eg Batson, Evans, Milstein work on developing country producers
- Never had projects in developing countries, insufficient funding, mostly meetings of experts
- Incorporated into WHO 1994 following failed coup attempt on EPI
- Died during extremely contentious mtg in Bellagio 1997
- Advocates for new vaccines formed "Working Group" to plan for a new organization and fund

GAVI

- Formed at “Protoboard” Meeting held at CVP PATH 1999
- CVP submitted proposal to Gates Foundation on behalf of Working Group to establish Children’s Vaccine Fund
- Gates approved \$750 million, later gave billions more
- Donor Governments contributed billions
- Now major source of routine and new vaccines to children in 75 lowest income countries. 21 have “graduated”
- Provided HepB vaccine and safe injections. Now provides pentavalent
- 11 EURO countries initial support. 5 have “graduated”
- Great contribution to EURO Region

Hepatitis B in EURO Region

- Much work needed to achieve WHO Elimination goals
- WHO is calling for HBsAg screening of all pregnant women and anti-viral treatment
- Region must decide on Triple Elimination
- Elimination goals call for 90% identification of chronic carriers and 80% on Rx if appropriate
- How will these goals be accomplished?

Thank You!

GAVI

- Provided HepB vaccine and AD syringes to 72 poorest countries
- Now provides pentavalent and many new vaccines
- China, Indonesia, India special programs
- China Project major global impact
- 11 Euro countries originally supported
- 5 graduated