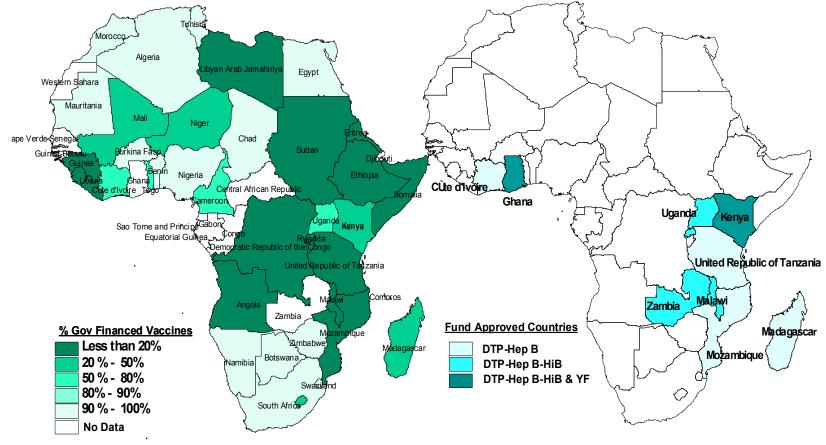
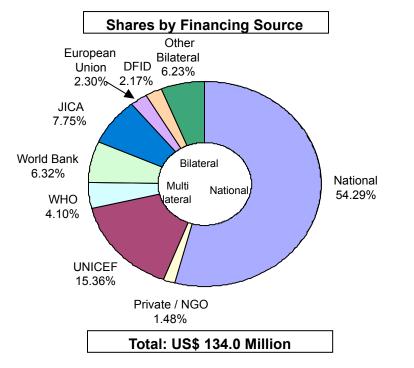
WHO PAID FOR VACCINES? GAVI EARLY DAYS

Government financing of vaccines and Vaccine Fund recipient countries in Africa

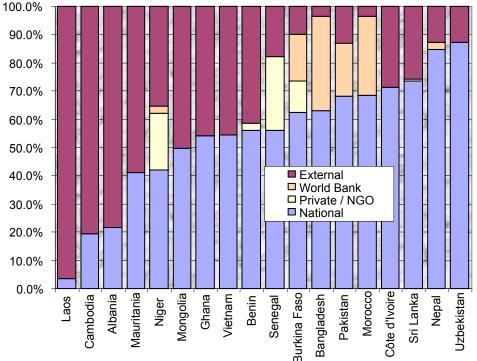


For Illustration only. Do not quote From 2002

Financing of routine immunization services by source

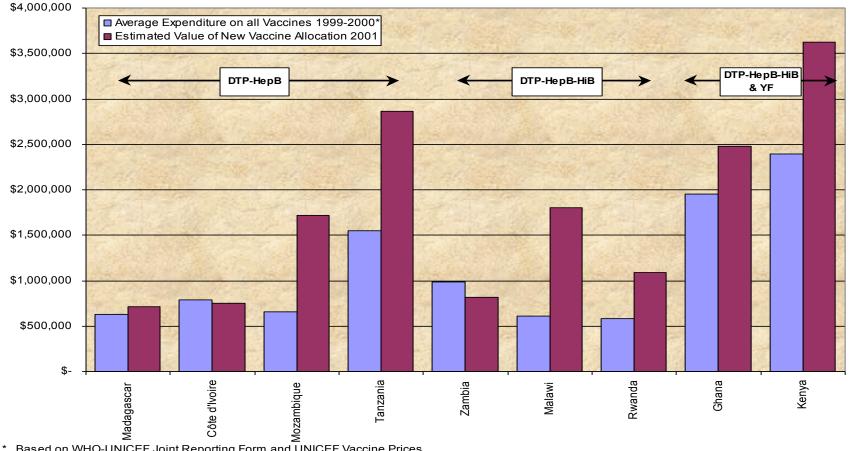


Based on 18 recent in-depth costing studies and financing assessments *Source:* Abt-Associates, PHR, ARIVAS-CATR, World Bank and WHO.



For Illustration only. Do not quote

Average vaccine expenditure & estimated fund allocation of vaccines

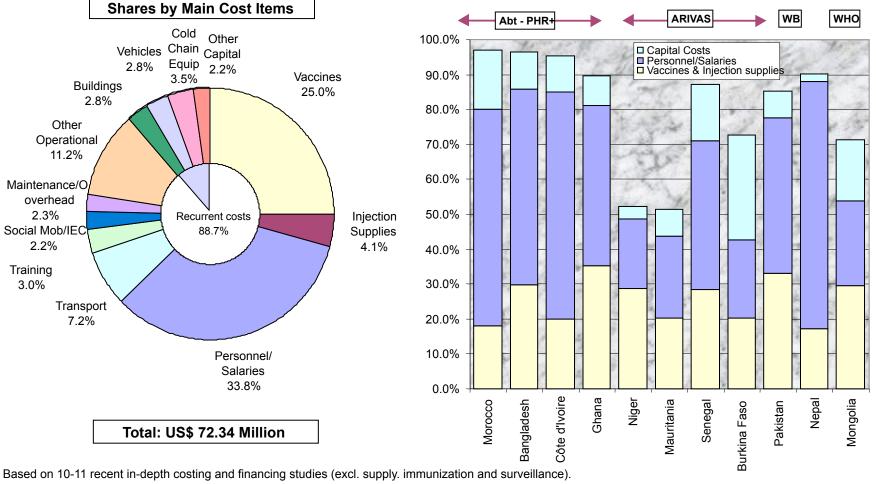


Based on WHO-UNICEF Joint Reporting Form and UNICEF Vaccine Prices

** Based on data from the GAVI Secretariat

For Illustration only. Do not quote

Shares of main cost items in routine immunization services

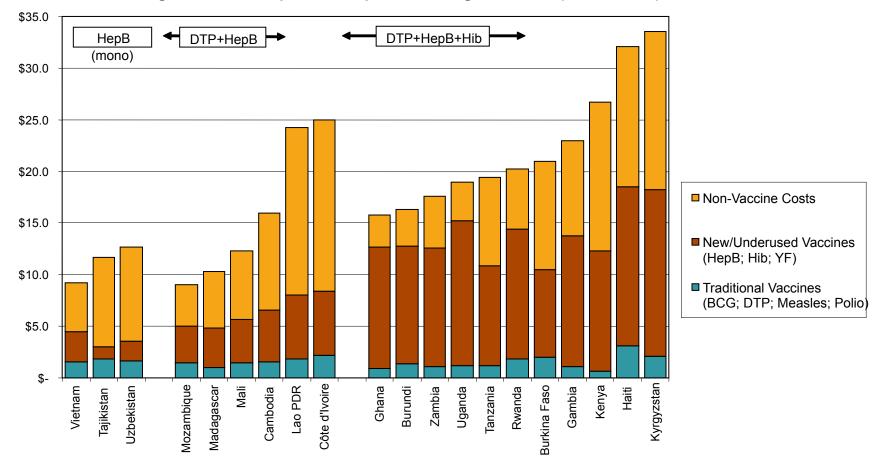


Source: WHO-VAM based on Abt-Associates, ADB, PHR, ARIVAS-CATR, World Bank and WHO.

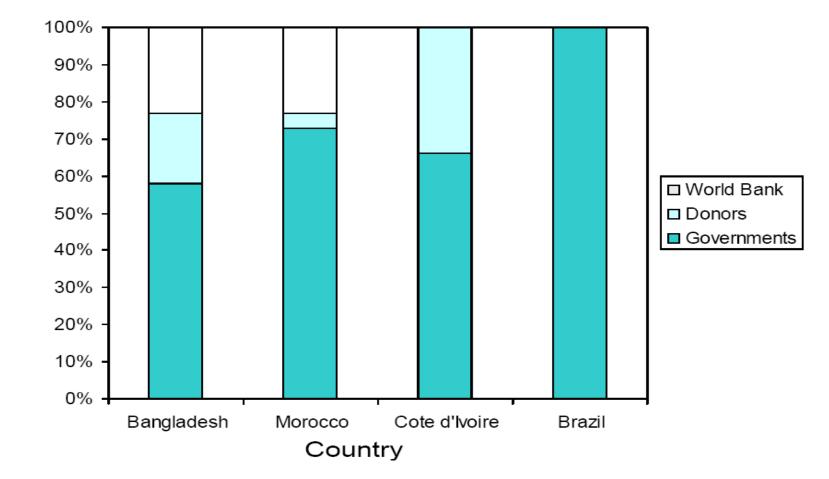
For Illustration only. Do not quote

Cost per fully-immunized child varies

Avg. Resource Requirements per DTP3 Targeted Child (Total Period)

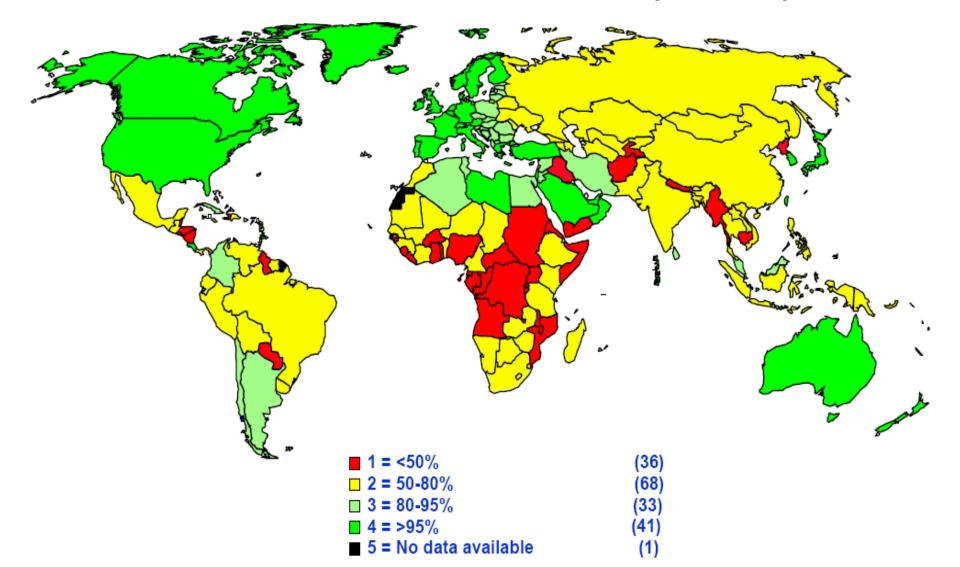


Who typically funded and now funds it all (2002 figures)

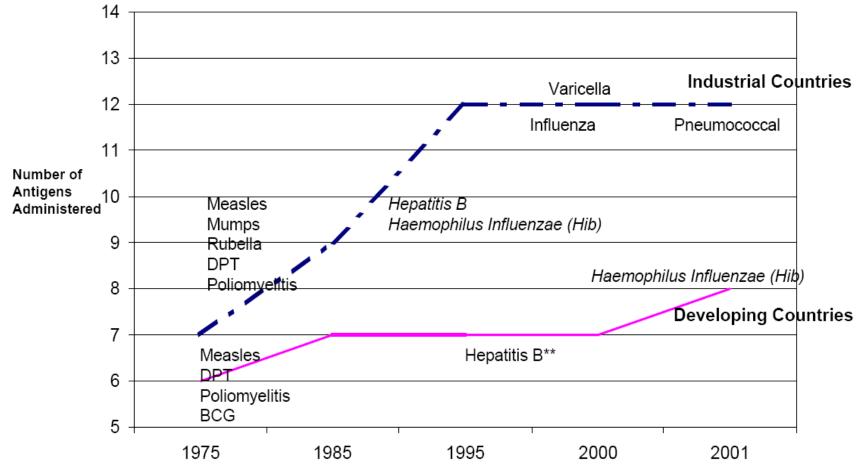


% immunization expenditures

Population with regular access to essential medicines (1997)

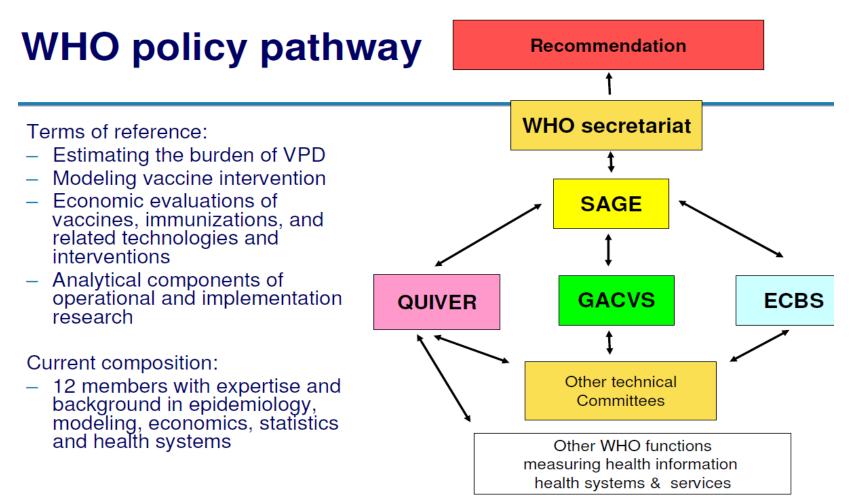


Early in the decade, 12 antigens to developed world and 8 to developing

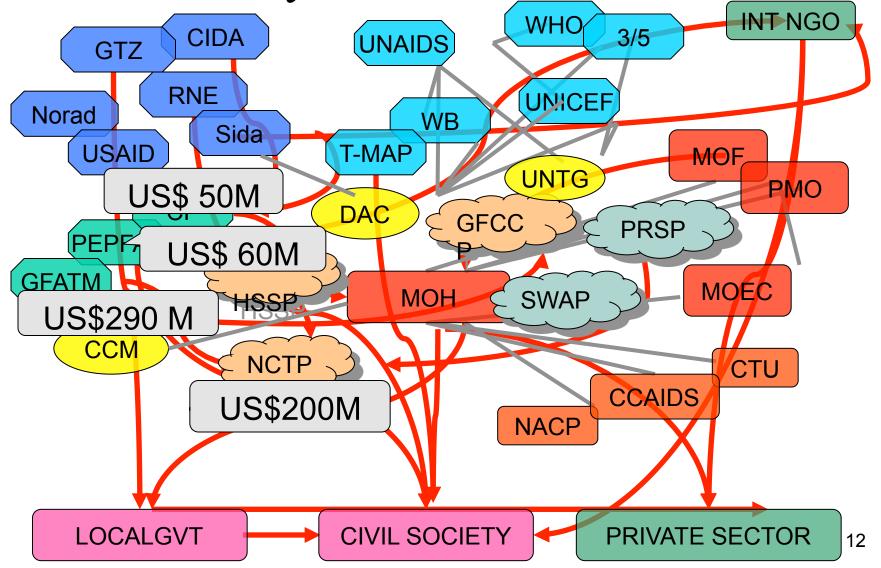


HOW POLICY IS MADE

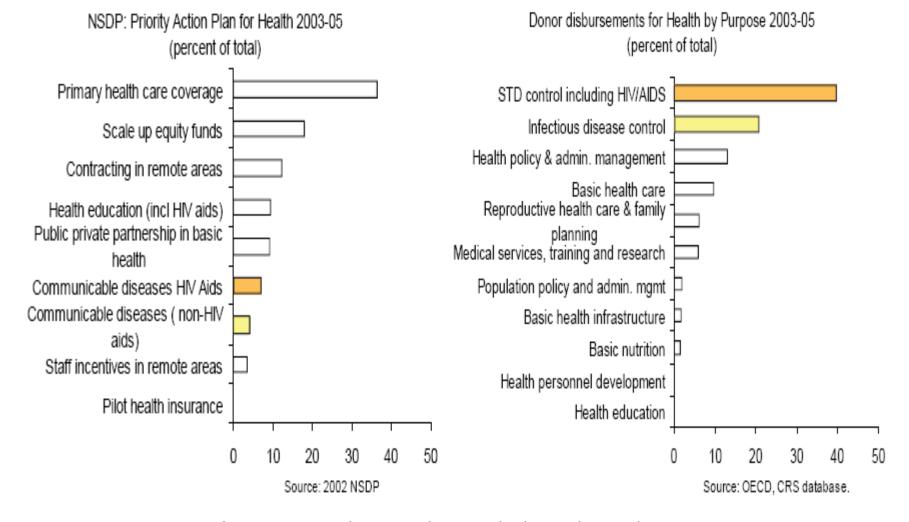
How WHO makes policy



AIDS stakeholders and donors in one African country (World Bank AIDS Campaign Team for Africa)



Donor priorities versus country priorities



Source: National Strategic Development Plan, Cambodia, and OECD/CRS

The vaccine procurement process (for poor countries) WHO BMGF UNICEF WB OTHER BMGF Countries Suppliers (GNP/Capita <\$1K) А 1 в 2 TheVaccineFund Proposals Recommendation Every child, Everywhere, С 3 VACCINES AIMMUNIZATION Partnering with The Vaccine Fund D 4 Е 5 Negotiation F unicef 🌚

" Tarmac to Tarmac

6

7

8

9

...

- 1 Qualifying countries submit proposals to be considered for funding
- 2 GAVI evaluates and submits recommendation to the Vaccine Fund
- 3 The Vaccine Fund approves purchase recommendation and provides funding through UNICEF

Vaccine Vial Monitor

- 4 UNICEF supply division procures all vaccines after negotiating directly with suppliers
- 5 Suppliers ship directly to recipient countries or via UNICEF

Supplies

Shipped

G

...

KEY: WHO - World Health Organization, BMGF - Bill & Melinda Gates Foundation, WB - World Bank, GAVI - The Global Alliance for Vaccines and Immunization Source: GAVI, UNICEF, Vaccine Fund websites; BVGH/BCG interviews

Vaccine Annual Report

GAVI

The GAVI Alliance

GAVI Alliance: An Innovative Public-Private Partnership



GAVI / GAVI Fund

- GAVI is an alliance of the various actors involved in immunization programs
- Goals
 - -Increase global access to basic vaccines
 - Shorten time before available vaccines are widely used in the developing world
 - Accelerate the development and introduction of future vaccines.

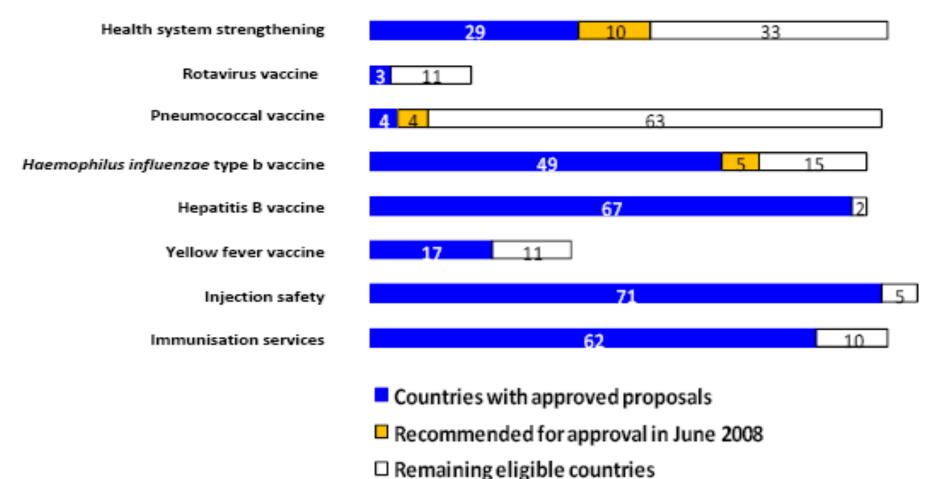
GAVI / GAVI Fund

- GAVI Fund is the financing & resource mobilization arm
 - Finances procurement of new vaccines & injection supplies
 - Rewards performance to strengthen health systems and increase coverage
 - Engages in strategic research and negotiation with the pharmaceutical and public health sectors through ADIPs

How GAVI financing is used

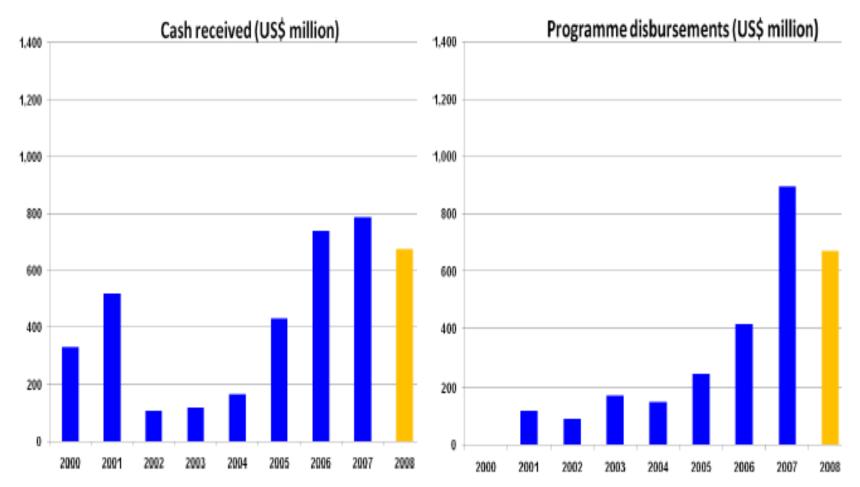
- Focus on the poorest 72 countries, where disease burden is greatest
- Two windows of support:
 - 1) Providing new and underused vaccines
 - 2) Building capacity in national health systems for the delivery of immunisation, maternal and child health services

Eligible countries, approved proposals by support window



Source: GAVI Executive Secretary / CEO Report to the Board June 2008

GAVI cash received and programme disbursements, 2000-2008



Source: GAVI Executive Secretary / CEO Report to the Board June 2008 21 (2008 figures are projections)

GAVI cash, breakdown

| | 1999-2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 | 2007 | 2008 Q1 |
|---|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|-------------|
| Australia | 0 | 0 | 0 | 0 | 0 | 0 | 5,000,000 | 5,000,000 | |
| Canada | 0 | 0 | 1,880,356 | 4,755,421 | 6,032,835 | 130,868,641 | 5,190,311 | 0 | - |
| Denmark | 0 | 1,147,407 | 0 | 0 | 3,338,879 | 3,416,107 | 4,411,262 | 4,737,540 | - |
| European Commission (EC) | 0 | 0 | 0 | 1,260,000 | 0 | 0 | 0 | 4,849,640 | - |
| France | 0 | 0 | 0 | 0 | 6,029,114 | 0 | 12,630,000 | 0 | - |
| Germany | 0 | 0 | 0 | 0 | 0 | 0 | 5,260,400 | 5,948,000 | - |
| Ireland | 0 | 0 | 510,750 | 623,750 | 650,000 | 831,460 | 7,902,000 | 8,311,200 | - |
| Luxembourg | 0 | 0 | 0 | 0 | 0 | 645,150 | 1,318,775 | 811,840 | 1,422,900 |
| Netherlands | 0 | 24,060,335 | 13,375,172 | 16,492,642 | 17,329,866 | 15,859,414 | 0 | 33,547,469 | 38,885,301 |
| Norway | 0 | 17,894,690 | 21,325,656 | 21,791,087 | 40,924,593 | 39,534,594 | 64,979,314 | 86,156,761 | - |
| Sweden | 0 | 1,892,133 | 1,114,800 | 2,385,182 | 4,931,430 | 12,663,401 | 14,593,975 | 15,514,976 | - |
| United Kingdom | 4,463,400 | 0 | 15,048,250 | 5,605,950 | 18,491,535 | 6,625,149 | 23,214,072 | 48,113,952 | - |
| United States | 0 | 48,092,000 | 53,000,000 | 58,000,000 | 59,640,000 | 64,480,000 | 69,300,000 | 69,300,000 | - |
| Direct contributions from government Donors + EC | 4,463,400 | 93,086,564 | 106,254,984 | 110,914,032 | 157,368,252 | 274,923,916 | 213,800,109 | 282,291,378 | 40,308,201 |
| IFFIm* | 0 | 0 | 0 | 0 | 0 | 0 | 524,749,285 | 428,268,866 | |
| The Bill & Melinda Gates Foundation | 325,000,000 | 425,000,000 | 0 | 3,500,000 | 5,000,000 | 154,338,000 | 0 | 75,000,000 | 75,000,000 |
| Other Private" | 20,000 | 0 | 1,630,361 | 2,580,847 | 1,805,051 | 473,480 | 1,904,352 | 1,335,180 | 6,212,838 |
| Private and institutions | 325,020,000 | 425,000,000 | 1,630,361 | 6,080,847 | 6,805,051 | 154,811,480 | 1,904,352 | 76,335,180 | 81,212,838 |
| Total Contributions | 329,483,400 | 518,086,564 | 107,885,345 | 116,994,879 | 164,173,303 | 429,735,396 | 740,453,746 | 786,895,424 | 121,521,039 |

*IFFIm funds available to support GAVI programmes. IFFIm donors: United Kingdom, France, Italy, Spain, Norway, Sweden and South Africa.

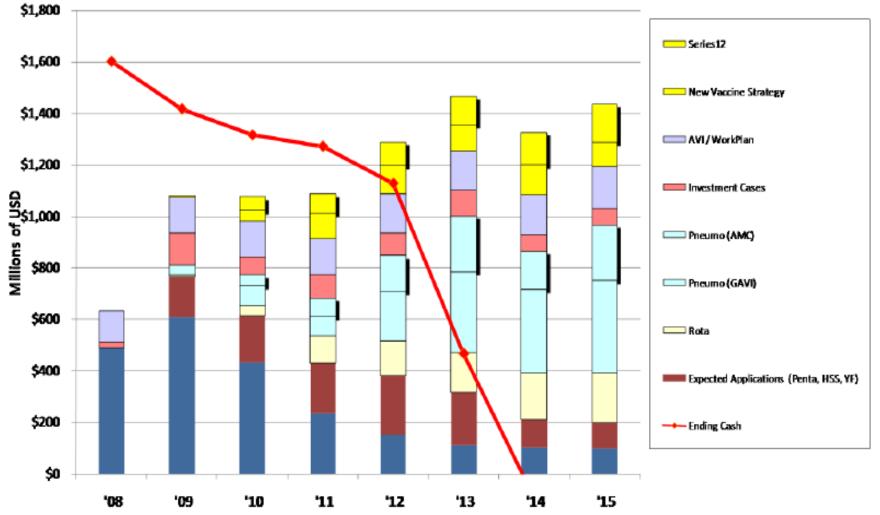
** Including funds received from the Immunize Every Child Campaign

Source: GAVI Executive Secretary / CEO Report to the Board June 2008

GAVI AND PNEUMO VACCINE

The next slides discuss a recent decision involving about \$5.5bn of funds, a large proportion of which still needs to be raised The point is to show how difficult it is to enact policy in an efficient way regardless of what the 'models' says should be done The spirit in which it is written is that 'we can do things better' Most of the text was added after the talk

GAVI Spending Projections and Cash Balance 2008-2015



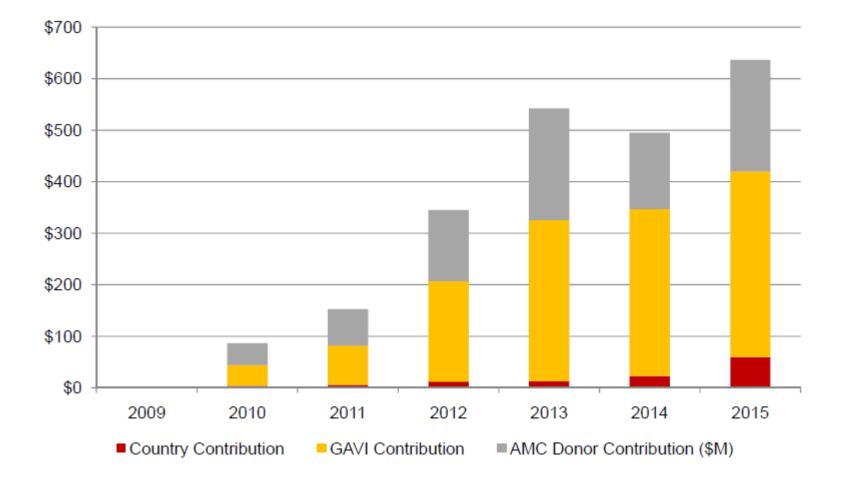
Costs: Maximum contributions

| Years | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 | 2015 Cumulative (\$ | |
|---|------|------|------|------|------|------|---------------------|-------|
| AMC Donor Contribution (\$M) | 42 | 70 | 138 | 216 | 148 | 216 | 831 | 1,500 |
| GAVI Contribution (\$M) (no inflation) | 40 | 76 | 195 | 313 | 324 | 360 | 1,308 | 3,381 |
| Country contribution (\$M) | 4 | 6 | 12 | 13 | 23 | 60 | 118 | 667 |
| Total | 86 | 153 | 345 | 542 | 495 | 637 | 2,257 | 5,548 |

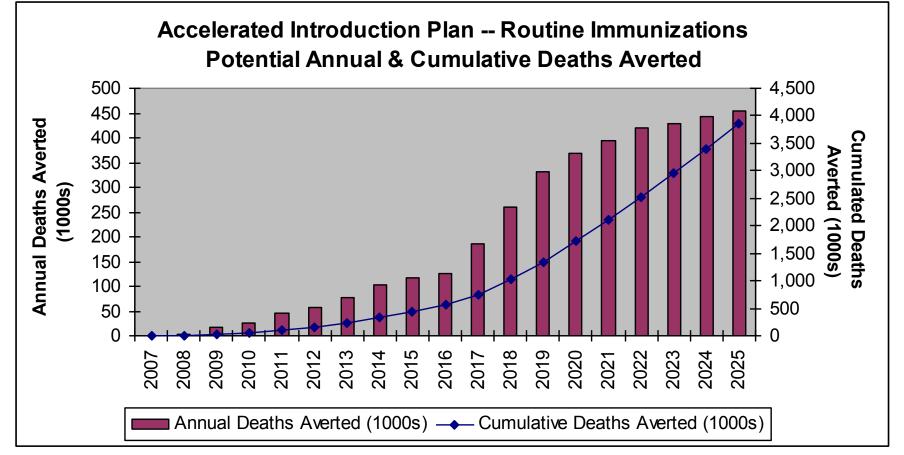
Source: GAVI Alliance & Fund Board meetings 25 & 26 June 2008

- Total costs (bottom right-hand corner) of \$5.5bn+
 - AMC \$1.5bn
 - GAVI own funds \$3.4bn
 - Country contributions (mostly from donor sources) just under \$700m

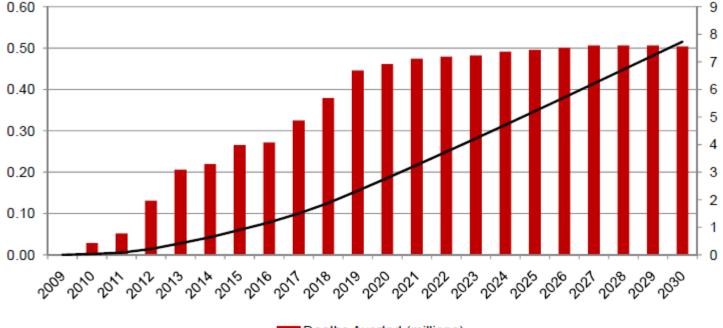
Costs: Maximum contributions cont...



Projected mortality impact from accelerated pneumococcal vaccination



Projected mortality impact from accelerated pneumococcal vaccination



Deaths Averted (millions)

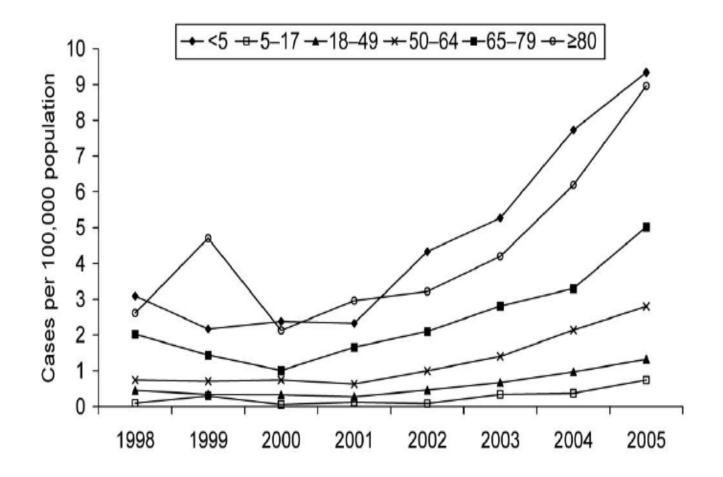
But it is still tough going

- [The following uses only the GAVI financing and mortality figures given above without further comment. Like the GAVI figures, there is no discounting. Base-line mortality taken to be 700,000-1m, most recent WHO figure]
- First \$2.25bn associated with about 4.75%-6.8% reduction in pneumococcal mortality 2009-2030
- Next \$3.25bn associated with about 28.75%-41.2% reduction in pneumococcal mortality 2009-2030
- Still need to work out how to prevent the other 52%-66% or so of pneumococcal mortality 2009-2030
- The above heavily dependent on long-term low prices: peak years fall after the \$5.5 billion has gone
 - 2.8 million lives saved in the period the money is spent (at about [undiscounted] \$2000 per life saved)
 - 5.2 million after the \$5.5bn spent, out to 2020. Prices must of necessity be a great deal lower in the latter period

But it is still tough going

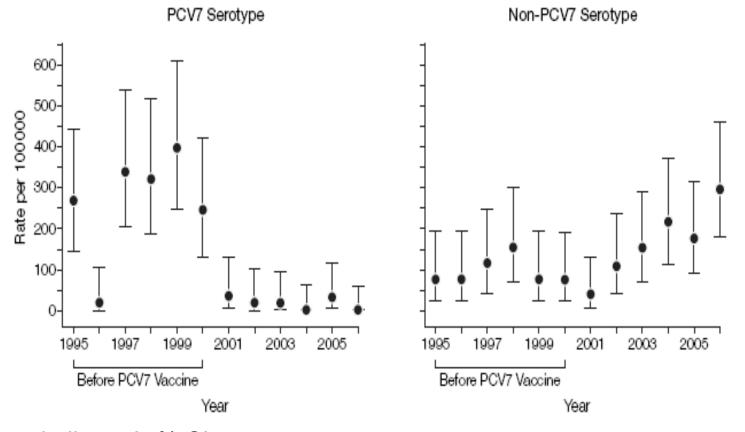
- Follow on vaccines because of serotype issues?
 - Capacity issues?
 - Cost of goods?
 - Long-term success hugely dependent on what happens ten or so year out
 - Protein-based vaccines for example. What is the incentive and funding for them?
- US will need (and buy at good prices) follow-on moreserotype vaccines (see next two slides)
- Costs of sustaining first round GAVI countries?
- Packaging issues in first round GAVI countries
- Needs for big investment in cold chain
- Three-dose schedule (4 in developed economies but evidence coming in is that 3 is OK) and timing of dose matters
- It is still a hugely tough problem

Age-specific incidence of serotype 19A replacement disease in the USA



Moore et al, J Infect Dis 2008;197:1016

Invasive pneumococcal disease among Alaskan Native children <2 yrs of age



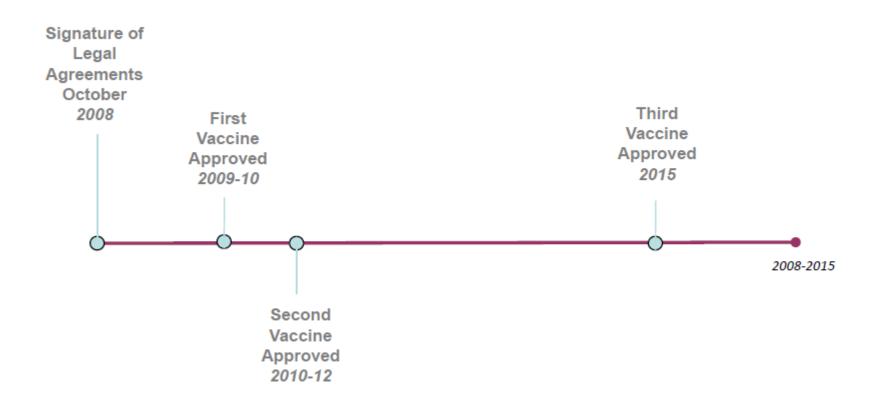
Error bars indicate 95% CI

Singleton et al, JAMA 2007;297:1784 32

GAVI financing issues

- GAVI and countries putting in about \$4bn on top of the pneumococcal AMC up to 2020 (probably more because some of the other budget lines also support this program)
 - This has to come from sponsors too
- Note that not much of the AMC payment is particularly front loaded
 - A lot is in the 2015-2020
 - The payments would be heavily discounted if used as an R&D incentive
- GAVI funding shortfall of \$2.5bn out to 2020 on the pneumo program (according to figures above and presuming AMC fully pays out)
- GAVI needs to heavily top up its funding starting 2014
- GAVI also needs all other programs refunding of about \$1bn per year
- About \$16bn if 2015 levels are sustained during the pneumo program
- There are lots of other potentially competing vaccines on the horizon and a need to think critically how to raise and spend money in this area as efficiently as possible to have as big an impact as possible.
- Affordability? Long-term sustainability?
- Main problems in this case were
 - Not to develop a more universally applicable vaccine in the first place
 - Profit motive drove a string of lower-number serotype vaccines and now we need funding to make up for this
 - Not enough attention to technology to make it cheaper in the long-run
 - Not sufficiently exploit the value of rich-world markets (including for follow-on moreserotype vaccines)
 33

Timeline



Assessments of GAVI

- <u>http://www.gavialliance.org/resources/</u>
 <u>6._GAVI_Phase_1_Evaluation___Secretariat_Response.PDF</u>
- "GAVI's vaccine strategy in Phase 1, based on the assumption that creating and demonstrating a market for vaccines in developing countries would attract new suppliers, create competition, and lower prices, did not come to fruition. While GAVI has taken various studies of the vaccine market and the procurement agent function, more should be done to investigate new approaches, since this is a critical component of GAVI's long term mission. More analysis of the economics of vaccine production and vaccine markets, and development of strategies to create competitive and sustainable vaccine markets is needed."
- "GAVI should focus more attention on improving performance in underperforming countries, working with in-country partners to provide additional support."
- "The Accelerated Development and Introduction of Priority New Vaccines (ADIPs) were effective in compiling data to support new vaccine introduction, and advocating for their use. However, the key weakness of the ADIP model was that it did **not adequately** prepare countries for vaccine introduction."

Assessments of GAVI

- GAVI allowed countries to set their own priorities for use of ISS funding, but its overall policies governing support to countries strongly promoted adoption of new vaccines. GAVI did not always have strong scientific evidence, or universal support for all of its strategic policies - such as Hib introduction. As a result, there was a perception that GAVI pushes new vaccines inappropriately. GAVI must ensure that its positions and policies have strong scientific foundations and widespread support throughout its partner organizations, and must seek additional ways to allow countries to set priorities for themselves regarding how to improve its immunization programs, particularly as it embarks on new activities."
- "There has also been criticism that GAVI has not increased total funding for immunization, merely redirected it to GAVI."
- "GAVI should reassess its sustainability definition and approach to ensure there is broad partner agreement on the importance of sustainability relative to adding new vaccines, and to develop a long term financing plan for all vaccines.

GAVI programme spending projections, 2008–2015

| | 2008 | 2009 | 2010 | 2011 | 2012 | 2013 | 2014 | 2015 |
|---|---------------|------------|-------------|-------------|---------------|--------------|--------------|--------------|
| Approved Country Applications | \$491 | \$608 | \$430 | \$236 | \$152 | \$108 | \$101 | \$98 |
| Expected Applications (Penta, HSS, YF) | \$0 | \$158 | \$184 | \$194 | \$229 | \$208 | \$109 | \$100 |
| Rota | \$0 | \$7 | \$39 | \$105 | \$ 133 | \$156 | \$183 | \$193 |
| Pneumo (GAVI Purchases) | \$0 | \$40 | \$79 | \$76 | \$ 195 | \$313 | \$324 | \$360 |
| Pneumo (AMC Purchases) | \$0 | \$0 | \$42 | \$70 | \$ 138 | \$216 | \$148 | \$216 |
| Investment Cases | \$21 | \$124 | \$70 | \$90 | \$90 | \$99 | \$62 | \$64 |
| AVI / WorkPlan / Admin expenses | \$120 | \$137 | \$137 | \$140 | \$148 | \$152 | \$156 | \$161 |
| New Vaccine Strategy - Child mortality | \$0 | \$6 | \$42 | \$101 | \$112 | \$104 | \$117 | \$96 |
| New Vaccine Strategy - Reduced Disease Burden * | <u>\$0</u> | <u>\$0</u> | <u>\$52</u> | <u>\$72</u> | <u>\$90</u> | <u>\$109</u> | <u>\$127</u> | <u>\$147</u> |
| Total | \$ 632 | \$1,079 | \$1,074 | \$1,085 | \$1,288 | \$1,466 | \$1,327 | \$1,436 |

Source: GAVI Executive Secretary / CEO Report to the Board June 2008

GAVI: New sources of funds

| IFFIm Commitments | In local currencies | AMC commitments | US\$ | |
|-------------------|---------------------------|-------------------------------------|---------------|--|
| United Kingdom | £1,380 million | Italy | 635 million | |
| France | €1,239.9 million | United Kingdom | 485 million | |
| Italy | €473.45 million | Canada | 200 million | |
| Spain | € 189.5 million | Russian Federation | 80 million | |
| Norway | US \$ 27 million | The Bill & Melinda Gates Foundation | 50 million | |
| Sweden | SEK 276.15 million | Norway | 50 million | |
| | | Total | \$1.5 billion | |
| South Africa | US \$20 million | | | |
| Brazil | US \$20 million* | | | |
| Total | approx US\$ 5.5 billion** | | | |

*In 2006, Brazil announced its intention to join IFFIm with a commitment of US\$ 20 million over 20 years.

Formalisation of this commitment is pending.

**subject to currency fluctuations

Source: GAVI Executive Secretary / CEO Report to the Board June 2008