

Developing Countries' Vaccine Manufacturers' Network International

Improving vaccination for all people



Developing Countries Vaccine
Manufacturers Network

Our Mission

- To **protect all people** against known and emerging infectious diseases, by **improving the availability of high-quality vaccines** globally.

DCVMN International

- It is a **voluntary, non-governmental, non-partisan, not-for-profit**, public health driven alliance of vaccine manufacturers, research and policy organizations from all over the world.
- **Operates based on principles of international scientific, technical and economic cooperation.**
- Legal entity established in Switzerland, according to articles 60 and ff. of Swiss Civil Code, with liaison offices in India.

OUR VALUES

EQUITY

Maximize access to vaccines making them affordable to all people, and provide information and opportunities to all members

RESPONSIBILITY

Each and all our activities aim to achieve our common mission

TRANSPARENCY

Foster a culture of good governance based on collegial decision making processes

ACCOUNTABILITY

Provide accurate reports and financial statements to all members

RESPECT

Different views and opinions are welcome and respected

Developing Countries Economies



- developing economies according to the IMF
- graduated to [developed economy](#)

The World Bank classifies countries into four income groups. These are set each year on July 1. Economies were divided according to 2011 GNI per capita using the following ranges of income:^[11]

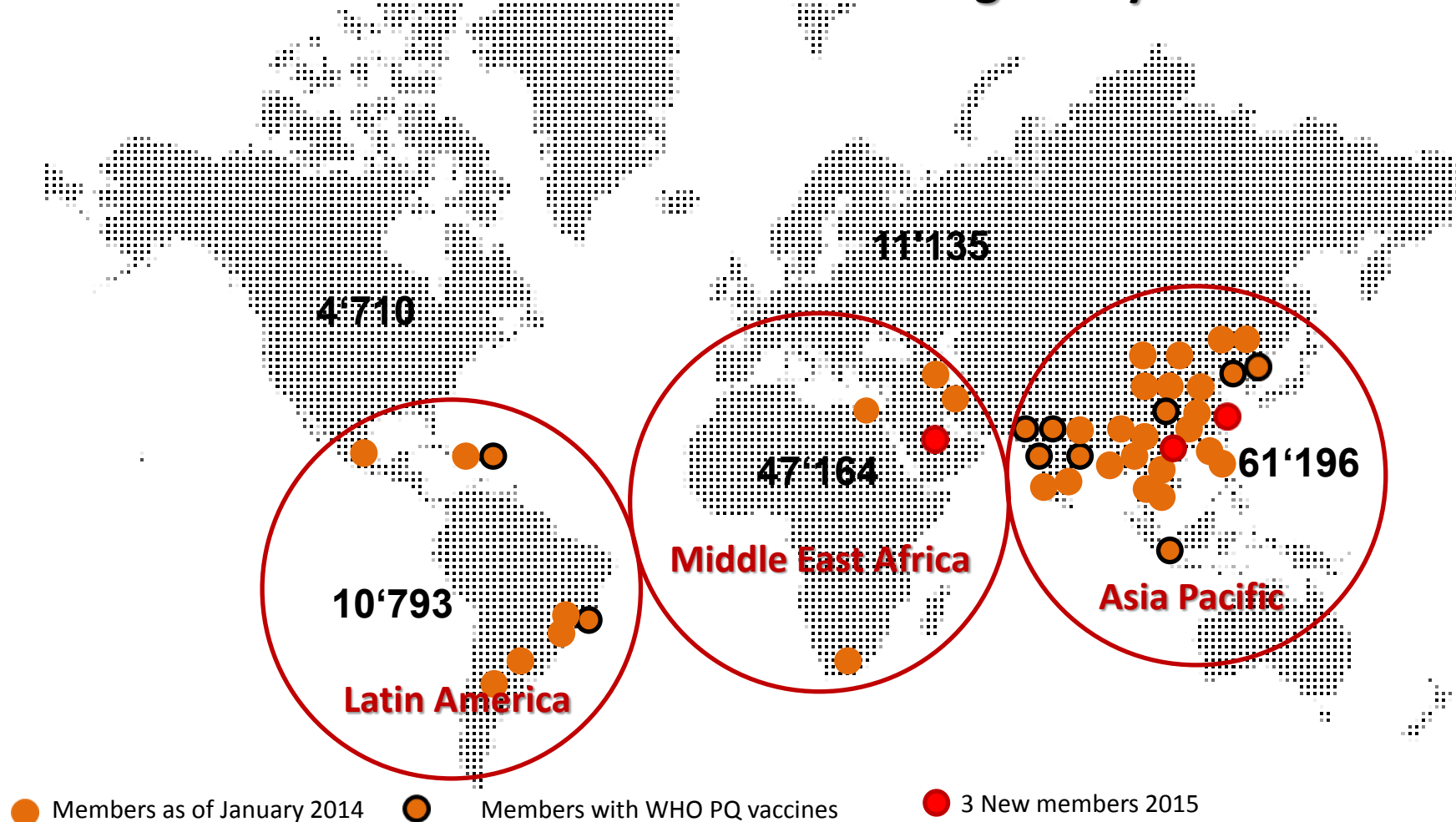
Low income countries had GNI per capita of US\$1,026 or less.

Lower middle income countries had GNI per capita between US\$1,026 and US\$4,036.

Upper middle income countries had GNI per capita between US\$4,036 and US\$12,476.

High income countries had GNI above US\$12,476. http://en.wikipedia.org/wiki/Developing_country (2012-10-09)

DCVMN: 44 manufacturers from 16 countries/territories are well placed to supply vaccines where needed :
number of birth cohorts regionally

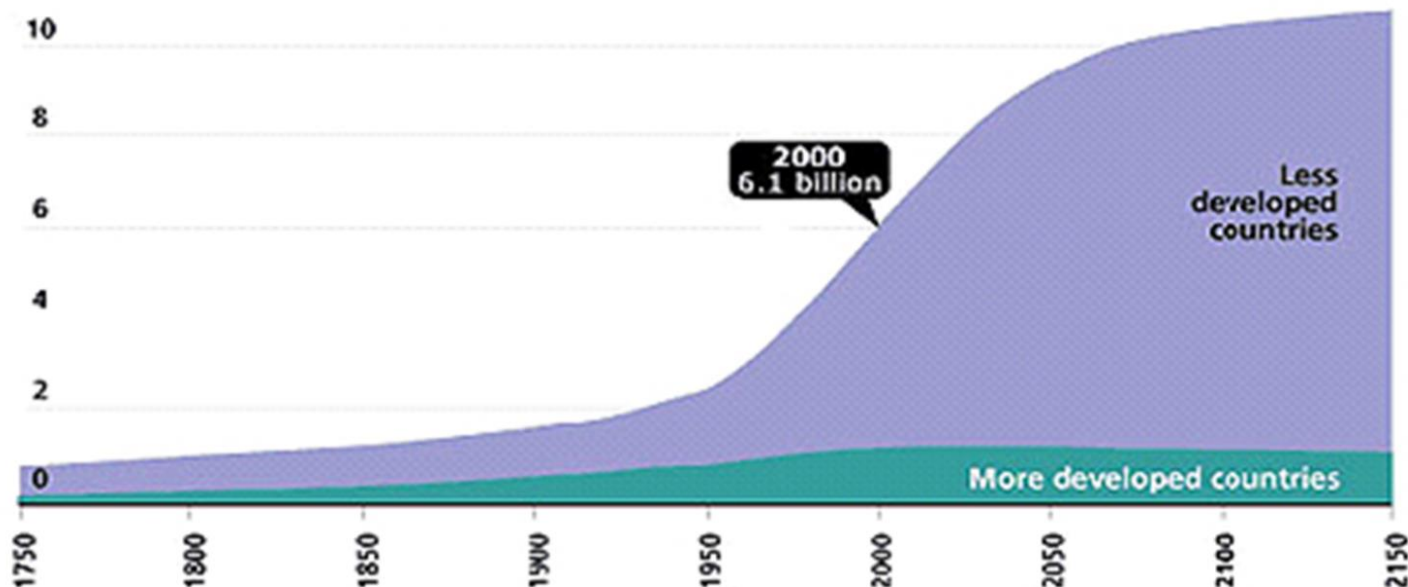


Our Challenge : vaccination to all people

The developing world needs vaccines

World Population Growth, 1750–2150

Population (in billions)



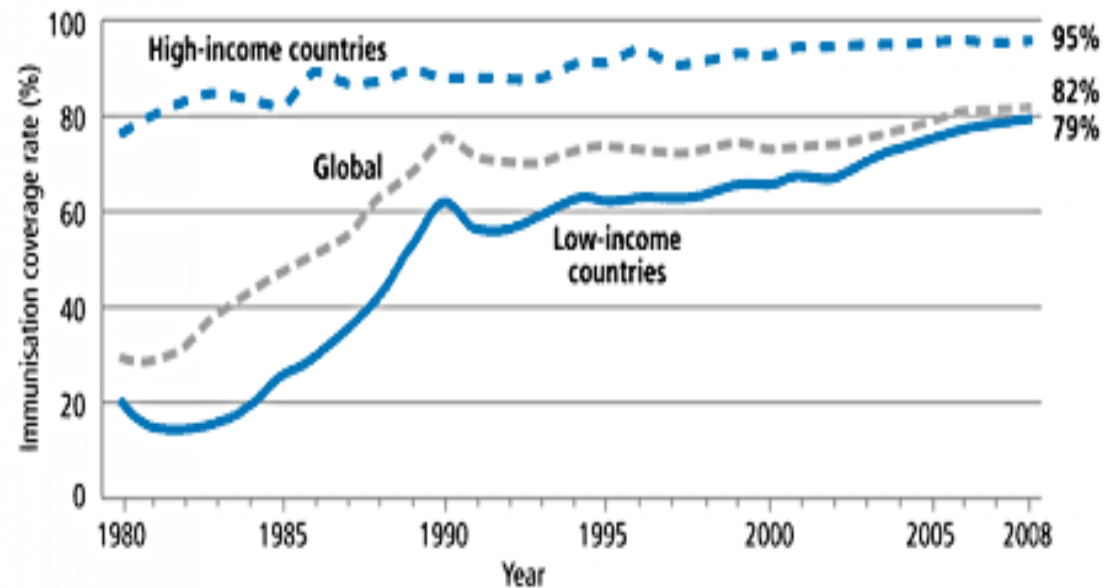
Source: United Nations, *World Population Prospects, The 1998 Revision*; and estimates by the Population Reference Bureau.

Expanded Global Programme on Immunization*

The Expanded Programme on Immunization (EPI) was established in 1974 through a World Health Assembly resolution (resolution WHA27.57) to build on the success of smallpox eradication programme, ensuring that all children in all countries benefit from life-saving vaccines.

Recommended vaccinations include:

- **BCG**
 - **DTP**
 - **HepB**
 - **Hib (conjugate)**
 - **Polio**
 - **Measles/rubella**
 - **Yellow Fever**
 - **HPV**
 - **ROTA**
 - **PCV**
- Meninge**
Typhoid
JE



Increasing global immunization coverage. DTP3

Source: Country income categories (World Bank) as of July 2009 (2008 GNI per capita); annual coverage estimates (WHO/UNICEF) weighted by annual number of surviving infants (UNDP).

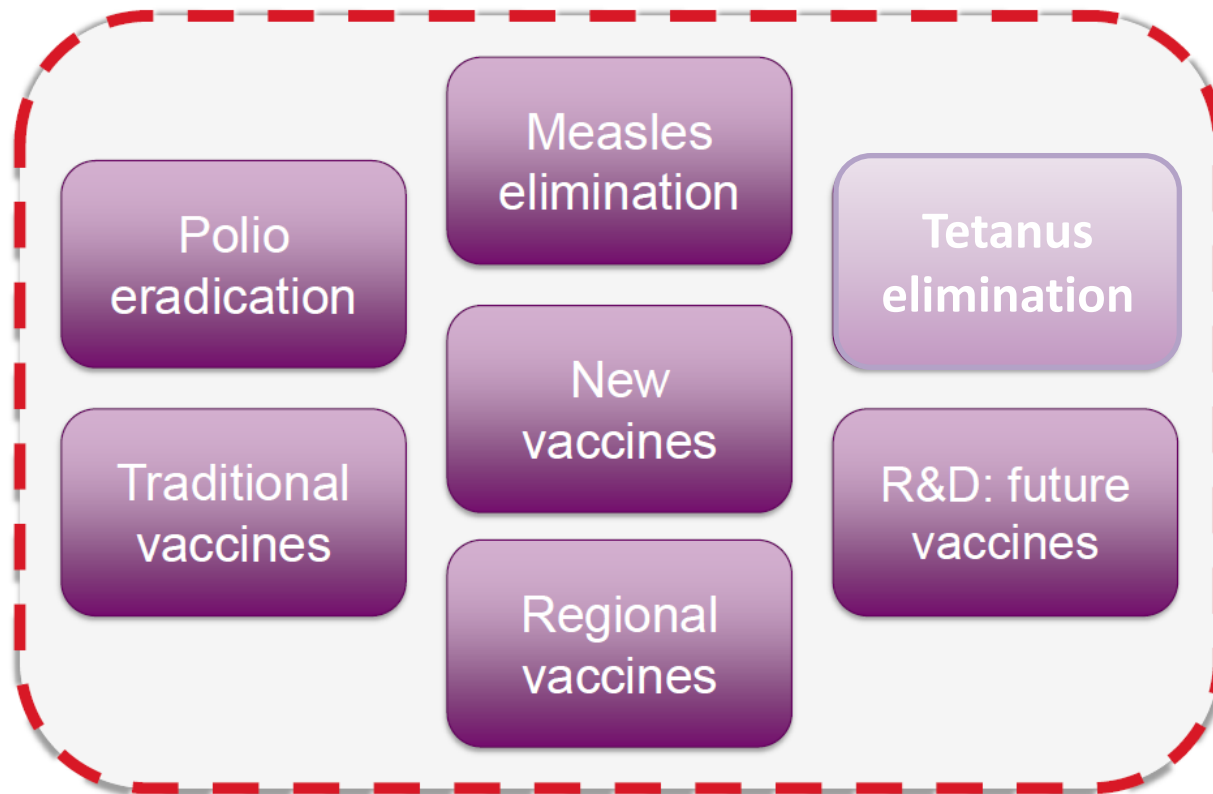
Matrix of vaccines portfolio by DCVMN

	BHARAT	BIOFARMA	BIOLOGICAL E	BIOMANGUI	NHOS	BIONET	BIRMEX	BUTANTAN	CADILA	CIGB	CNCG	CDBIO	FINLAY	GPO	HAFKINE	INDIAN	IMMUNOL	INNOVAX	IVAC	LGLS	PANACEA	PASTEUR	INST. IRAN	QSMI	RAZI	SERUM	INST.INDIA	SINOVAC	MINHAI	VABIOTECH	VACSERA	WALVAX
VACCINES																																
BCG																																
Rabies																																
Typhoid																																
Pertusis a																																
OPV 3																																
OPV 1																																
OPV 1/3																																
OPV tri																																
IPV																																
Tetanus Toxoid																																
DT or Td																																
DTPacelular																																
DTPwhole cell																																
DTPwHepB																																
PENTAVALENT																																
Haemophilus i. b																																
DTPhib																																
Hepatitis A																																
Hepatitis B																																
Hepatitis E																																
Yellow Fever																																
Meninge A																																
MeningeA/C																																
MeningeB/C																																
Measles (M)																																
Rubella (R)																																
MR																																
MMR																																
Japan. Encephal.																																
Rotavirus																																
Pneumo 10																																
Pneumo 23																																
Flu seasonal																																
Flu H1N1																																
Cholera																																
Hemoragic fever																																
Leptospirosis																																
Varicella																																
Anthrax																																
Tick encephalitis																																
Brucella																																

=PQ

DCVMN Contributions to the Global Vaccination Landscape

Synergies and shared learnings



*GAVI Alliance Board meeting
Dhaka, 16–17 November 2011*

DCVMs preventing regional infectious diseases

New conjugate vaccines to Typhoid Fever



Jevax™, Japanese encephalitis



MenAfriVac™



Hepatitis E vaccine, Hecolin™



Geographic distribution of hepatitis E

Expert Reviews in Molecular Medicine © 1999 Cambridge University Press

Yellow Fever Vaccines



New Initiatives to Support DCVMN Members to improve vaccine supply globally

Proposal 2014-2017

BILL & MELINDA
GATES *foundation*

Four Initiatives to Support Members



Our goals are to:

- a. Increase and maintain the number of vaccines available for international procurement, particularly for GAVI-eligible countries
- b. Reduce the time from filing a complete dossier to obtaining WHO PQ
- b. Broaden the basis of manufacturers, to secure sustainable vaccines supply

Interviews and extensive discussions were conducted by McKinsey & Co. with the support of BMGF, and four initiatives were **recommended**:

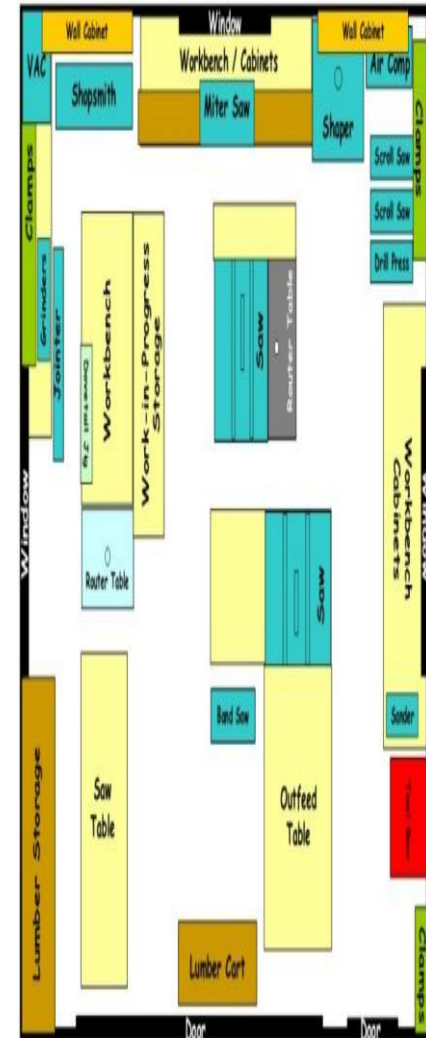
- **Initiative 1: review the design of manufacturing plants and systems**
- **Initiative 2: Train-the-trainers one week workshops, on GMP and PQ**
- **Initiative 3: Forum to discuss regulatory challenges with experts**
- **Initiative 4: create a database of expert consultants for members to hire**

Initiative 1:

Review concept design of manufacturing plants and systems for priority vaccines

- Priority to GAVI vaccines including: IPV, PCV, TCV, Rota, HPV, MR, Penta and Hexavalent.
- up to 100 thousand dollars for consulting services, depending on vaccine type and needs, to design GMP facilities for clean rooms, filling suites, water systems, HVAC, etc.
- Service partners to have records of being reliable, responsive, and responsible.
- Members of priority vaccines apply for grants if they:
 - plan to, or presently make a priority vaccine
 - agree to pay 20% of review design project costs
 - commit to implement recommendations and apply for PQ

Call for applications issued in August, audits in Q1 2015



Initiative 2:

Train-the-trainer workshops, including GMP, QMS and PQ

- One week training workshops for all corporate members to send **3 professionals** to benefit, plus follow up support through webinars, phone and email will be provided.
- Same curriculum delivered in three regional workshops annually (LA, IN, CH) for average 42 participants per workshop plus 6 faculty and 2 secretariat).
- Curriculum to include:
 - Risk assessment, aseptic process, hygiene, change control, change & variations management, OOS, GMP, CAPA analysis, etc.
- Participants commit to take responsibility for corporate training program and cascade down the knowledge in the respective company, through similar internal workshops within 6 months.
- Additional participants would cover own travel expenses as co-share



Initiative 3:

Forum to discuss common regulatory challenges with experts

Forum for industry and regulatory experts to have informal discussions on topics that will accelerate vaccine access in developing countries



- A DCVMN regulatory working group to select discussion topics, to be developed and researched by independent consultants, then reported to the group
- Results, and evidence to be presented at forum
- Discussions will run under Chatam House rule (no names), and options for solutions to be captured in a report or white paper and made available publicly

Initiative 4:

create an expert consultants database for members to hire

- Create a **database** of expert consultants on several vaccine areas important for PQ dossiers, members can contribute.
- Consultants reputed to be reliable, responsive and responsible.
- Database will be available online for DCVMN members only, with feedback information.
- Database to be updated and grow every year with new names.

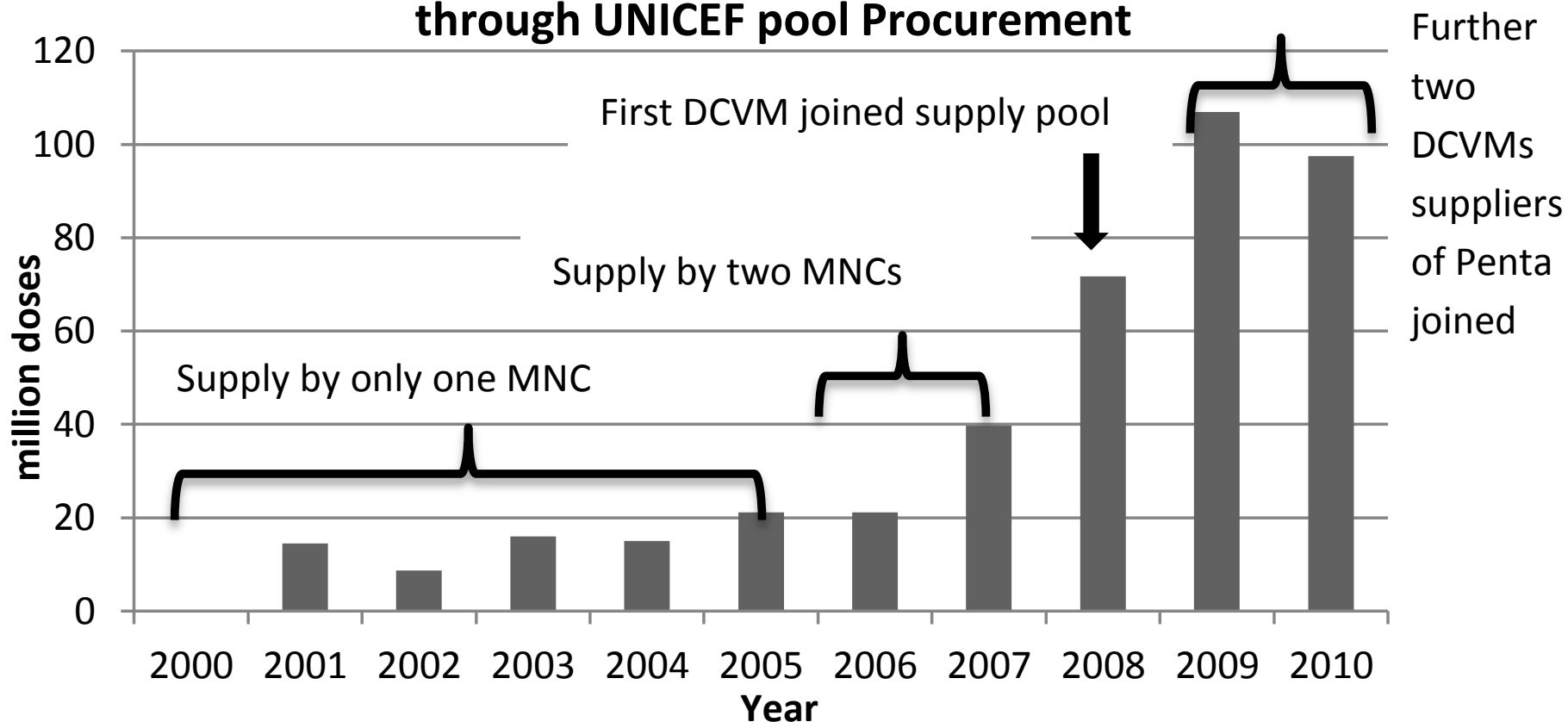


New Initiatives Expected Impact in three years

1. Several (3-8) upgraded GMP facilities for priority vaccines
2. Consistent information disseminated and knowledge sharing on GMP, QC/QA, QMS and PQ among DCVMN members, serving as “harmonization” effort:
 1. Quality policy statement
 2. Governance-organigram available
 3. Site master file and validation master plan available
 4. Seeds and cell banks certified
 5. Water and HVAC systems certified
3. New cost effective regulatory approaches to improve access to needed vaccines and benefit people on a regional or global basis
4. Consulting expertise “at hand” for members to advance with clinical development, GMP, regulatory dossiers, PQ, investments, and partnerships

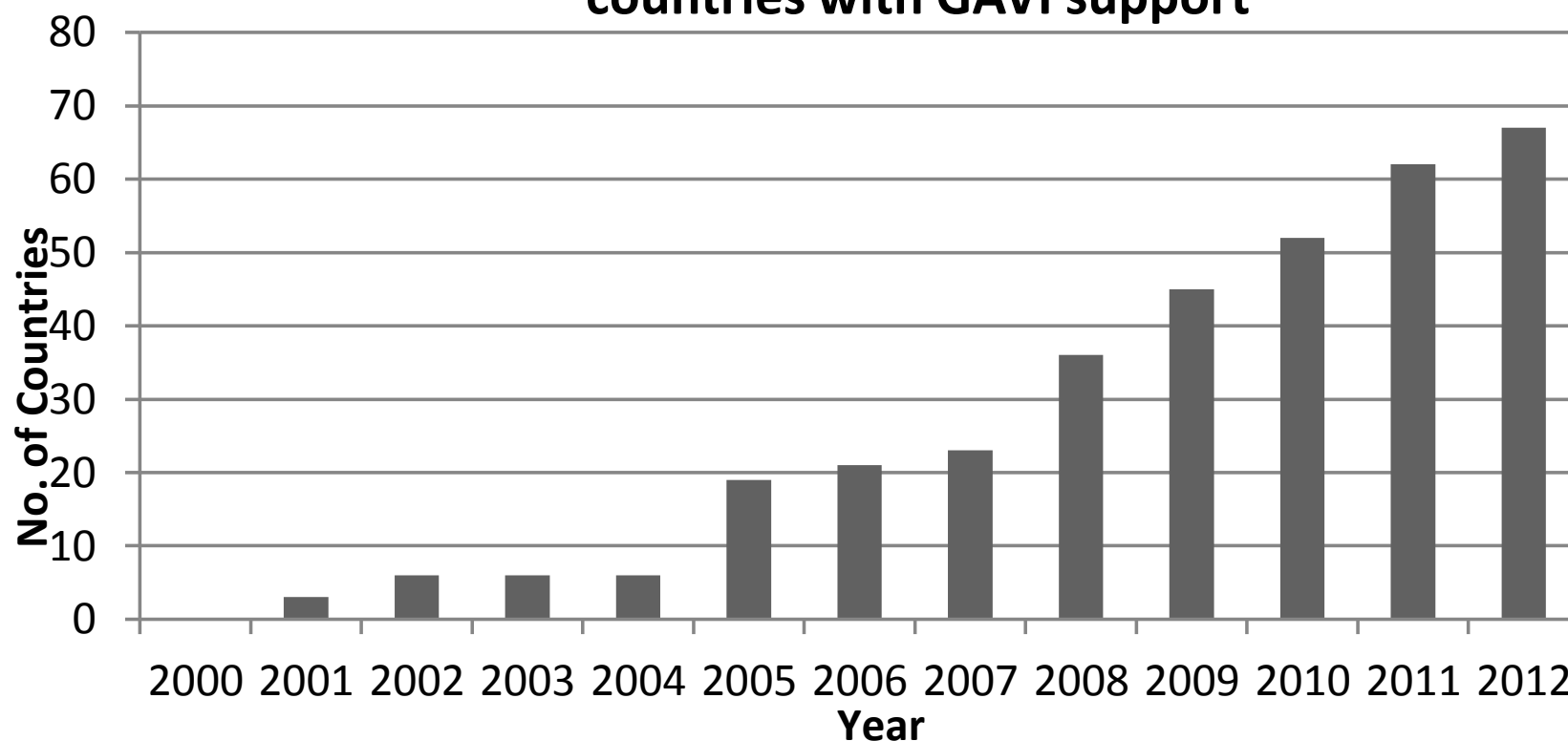
The growing supply for 5 vaccines in developing countries

A) Number of doses of Pentavalent - DTPHepBHib - supplied through UNICEF pool Procurement

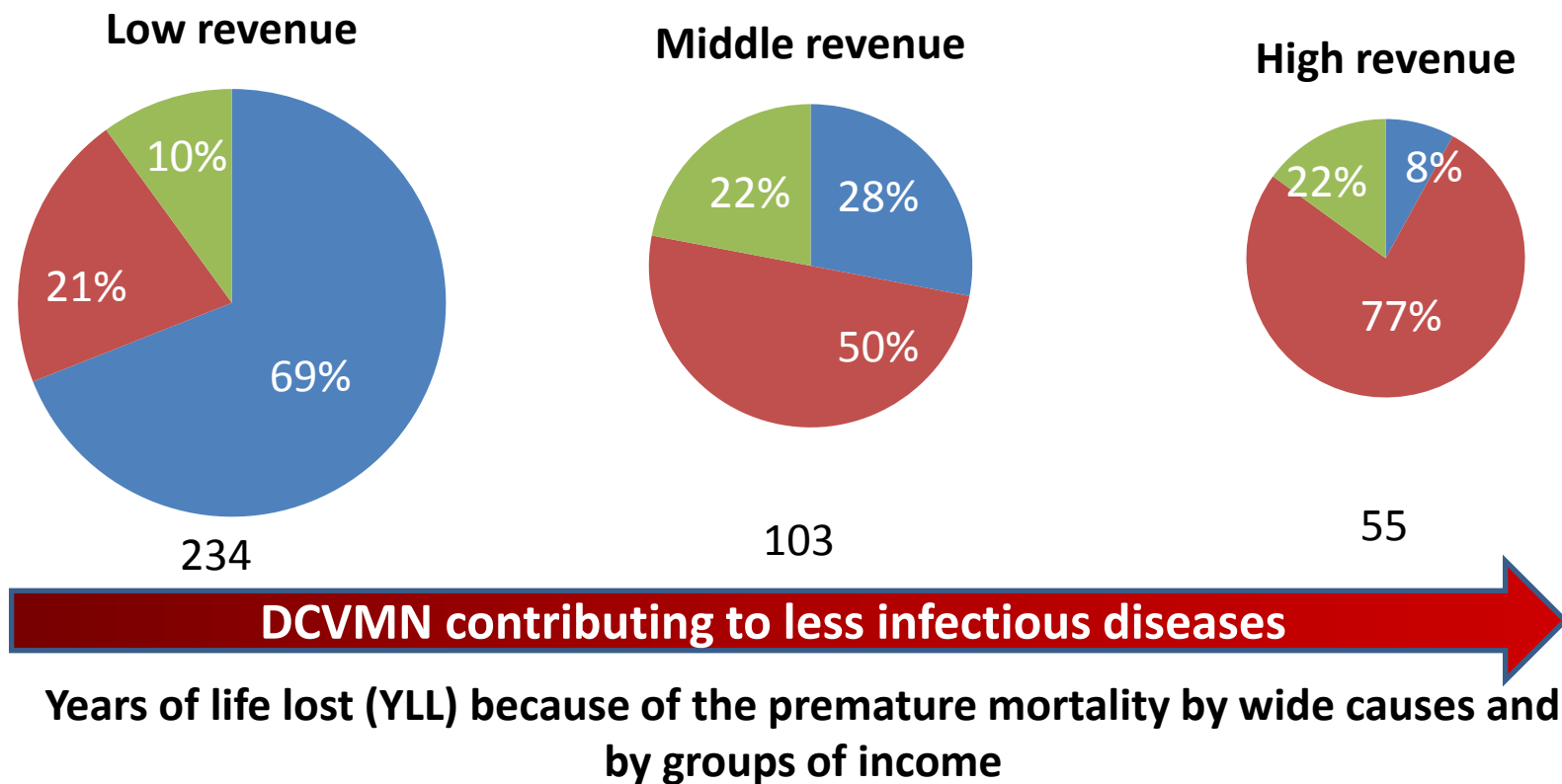


Growing Demand by countries to introduce Pentavalent vaccines, over the last decade with GAVI support

B) Introduction of Pentavalent - DTPHepBHib - Vaccines in countries with GAVI support



The control of infectious diseases as element of acceleration of the economic transition



- Infectious, maternal or neonatal diseases and nutrition deficiencies
- Non-transmissible diseases
- Traumatisms

DCVMN Collaborating organizations and Partners

Center for Vaccine
Ethics and Policy
UPenn | Wistar Institute | CHOP

SABIN
VACCINE INSTITUTE



**BILL & MELINDA
GATES foundation**

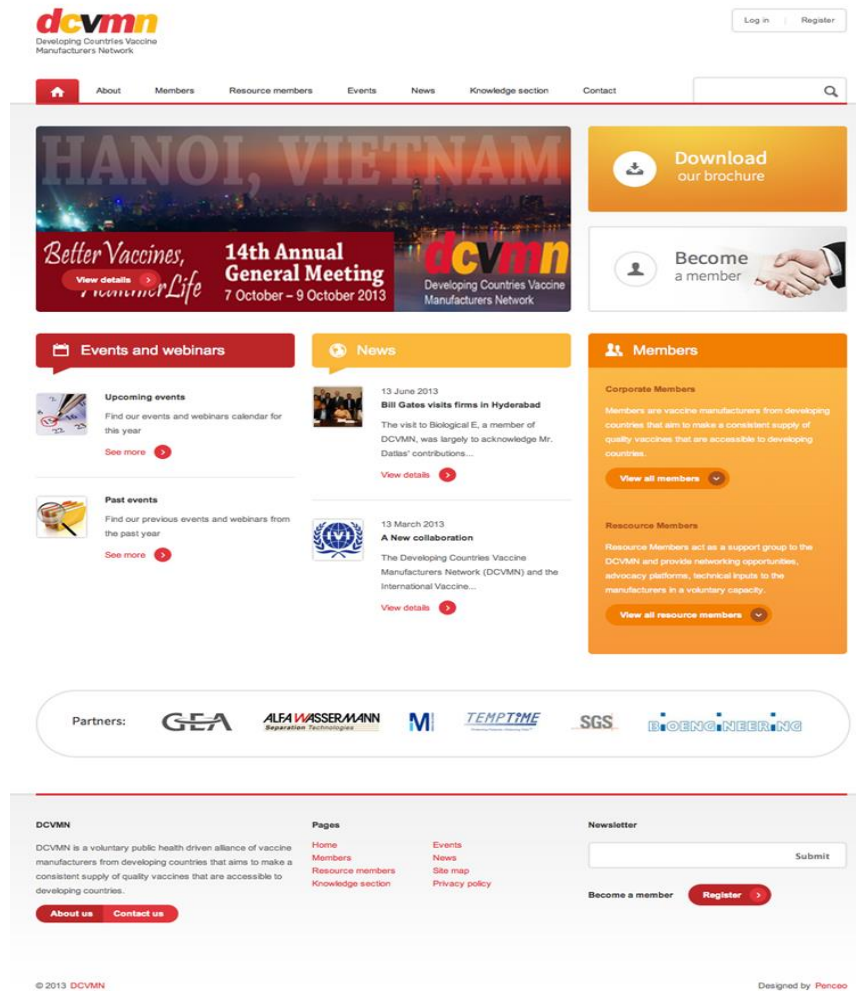
AERAS



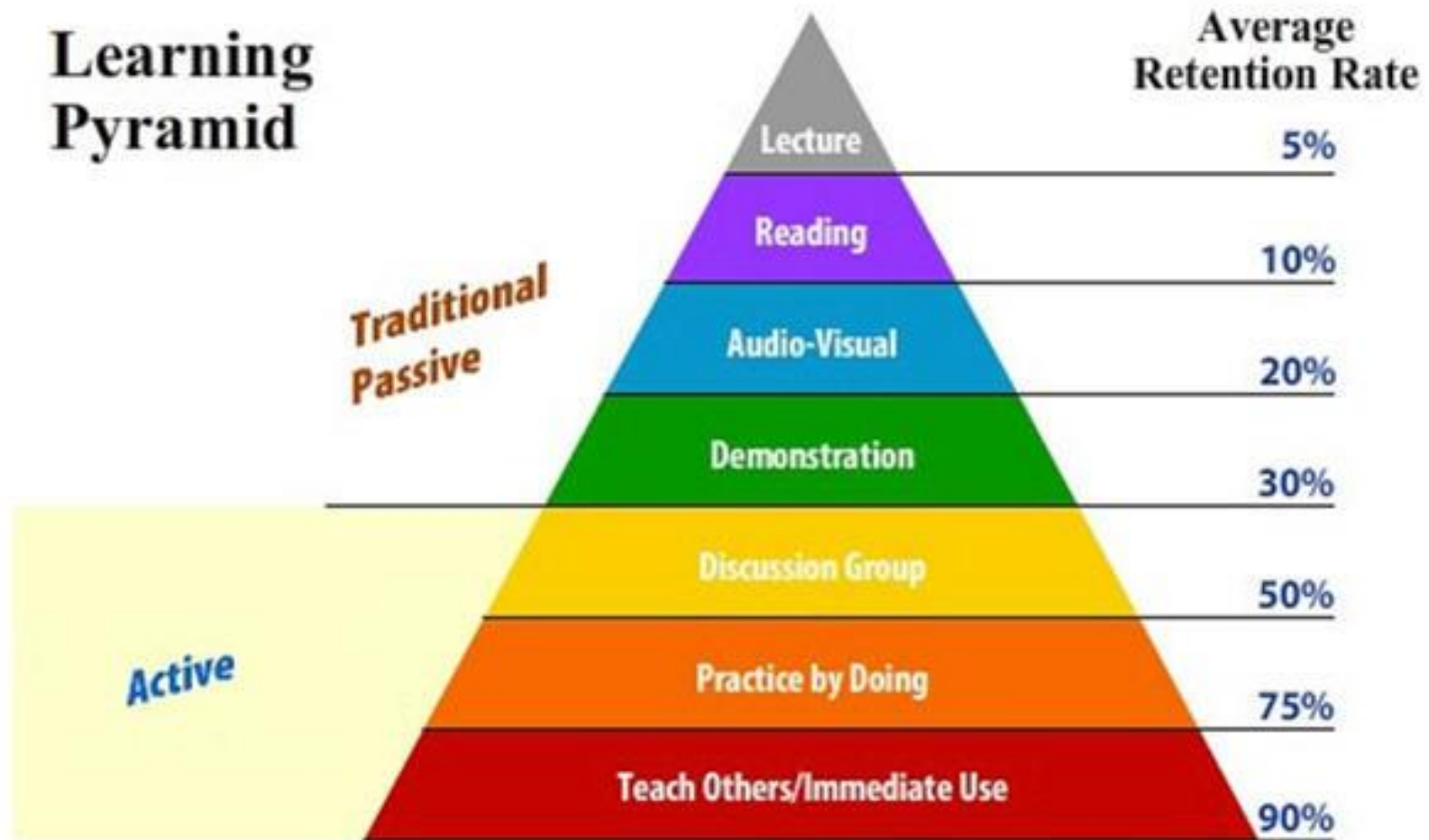
EUROPEAN VACCINE INITIATIVE



New Website



Train the trainers

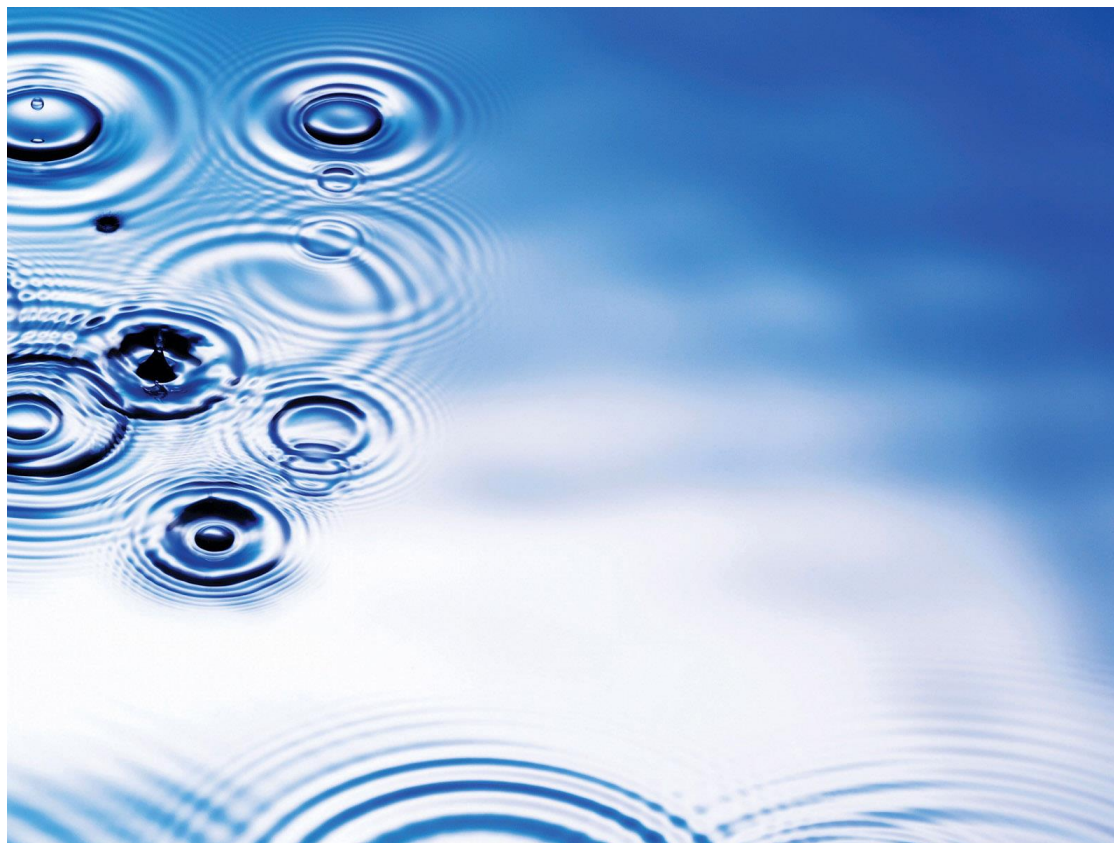


Source: National Training Laboratories, Bethel, Maine



DCVMN International

www.dcvmn.org



Thank you