A FUNDER'S PERSPECTIVE: THE BILL AND MELINDA GATES FOUNDATION

Beyond Efficacy: The full public health impact of vaccines in addition to efficacy measures in trials

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At the Bill & Melinda Gates Foundation, we believe that all lives have equal value.

HOW WE WORK: OUR GLOBAL REACH AND PRESENCE

1,500+
2013 active grantees

$3.6B
2013 grant payments

1,300
2013 employees worldwide

WHAT WE DO

GLOBAL HEALTH

GLOBAL DEVELOPMENT

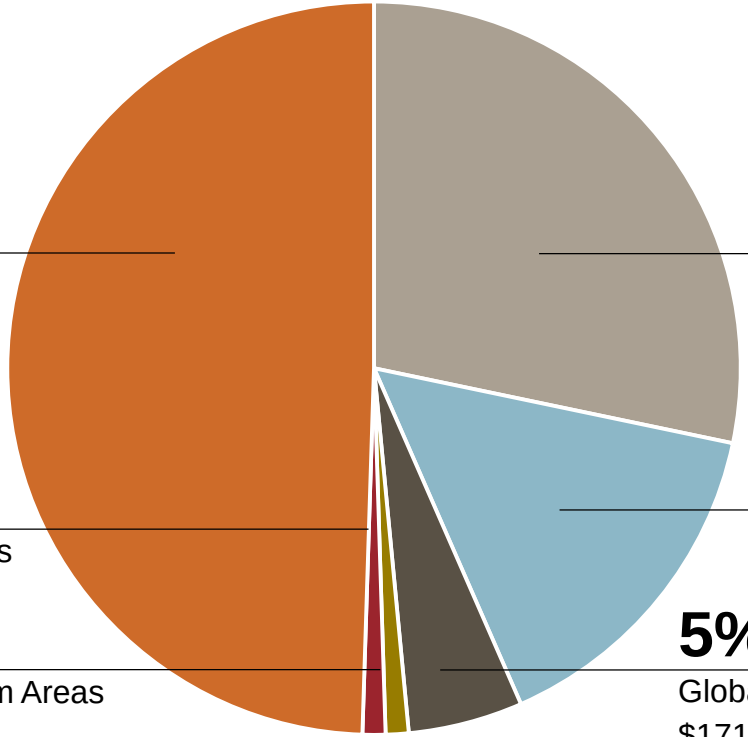
UNITED STATES PROGRAM

GLOBAL POLICY & ADVOCACY

COMMUNICATIONS

FOUNDATION GRANTS SUMMARY

In 2013, the foundation invested US$3.6 billion in these areas.



49%
Global Development Program
$1.8B

28%
Global Health Program
$1.1B

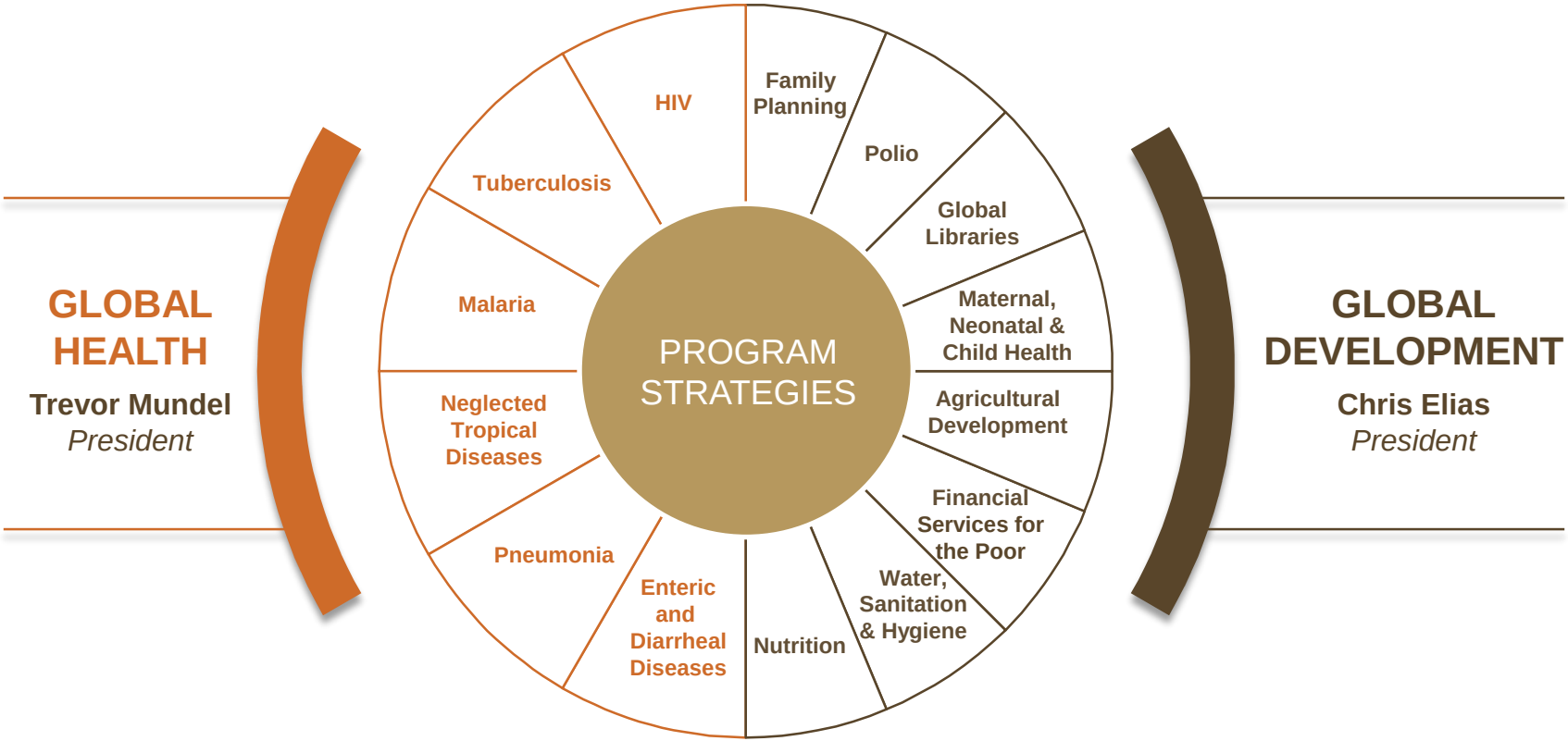
15%
United States Program
$510M

5%
Global Policy & Advocacy
$171M

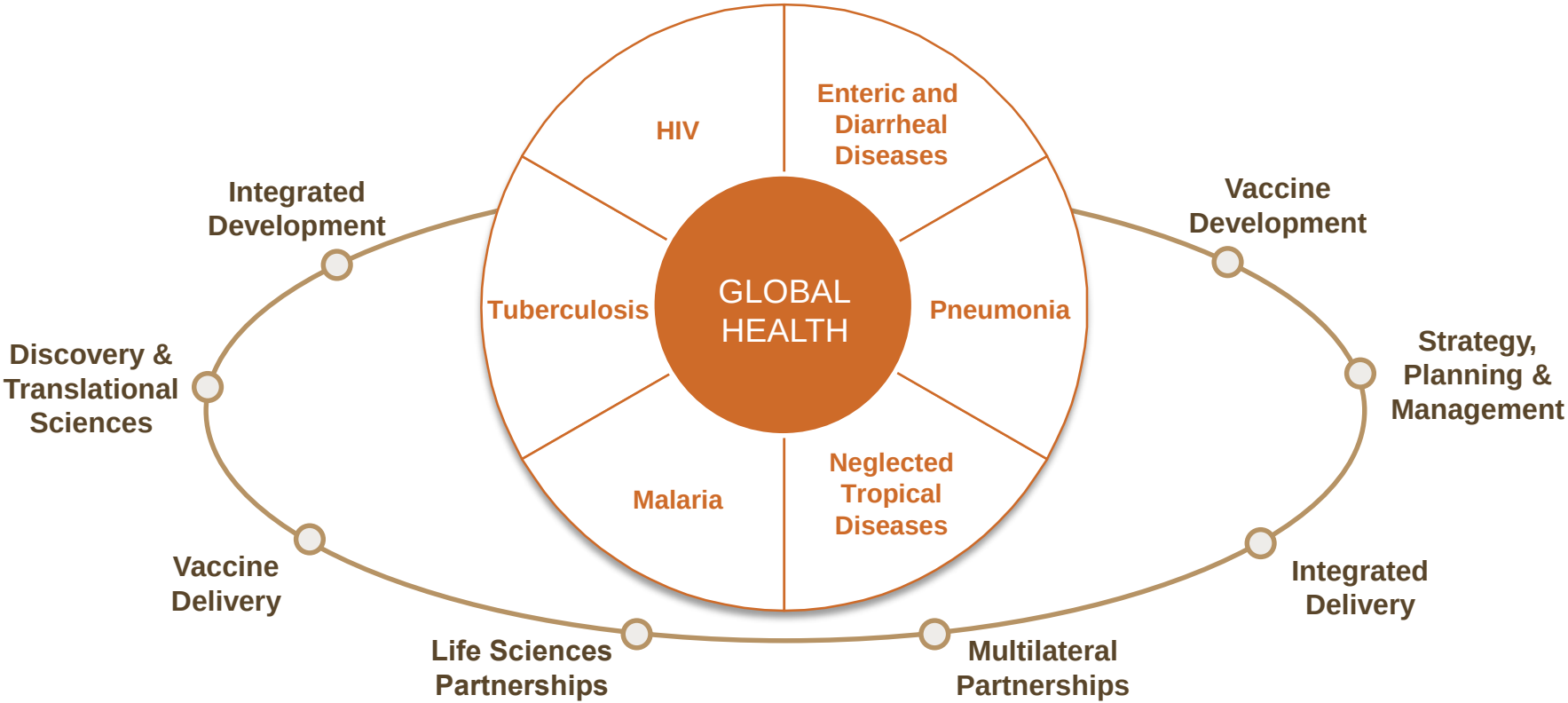
2%
Non-Program Areas
$52M

1%
Strategic Media Partnerships
$35M

HOW WE WORK: GLOBAL PROGRAMS



HOW WE WORK: CROSS-CUTTING FUNCTIONS



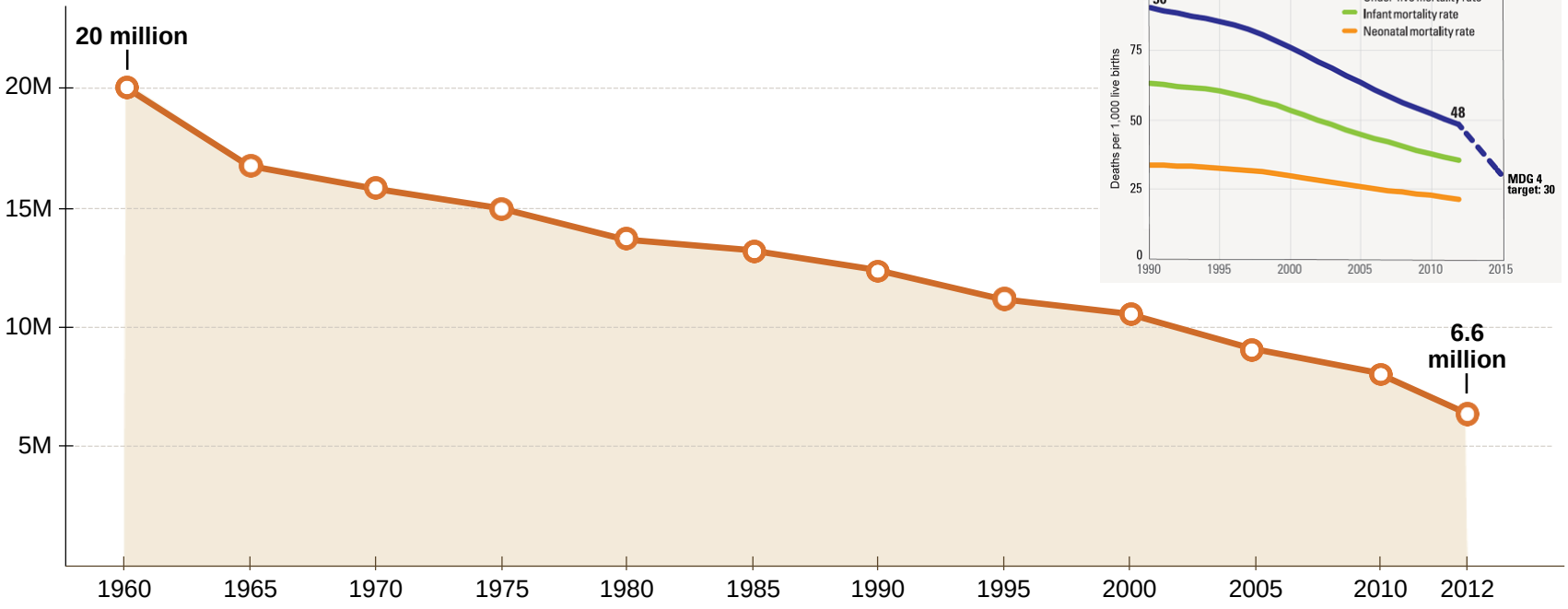
WHAT WE FOCUS ON

What are the areas of greatest need?

Where can we have the greatest impact?

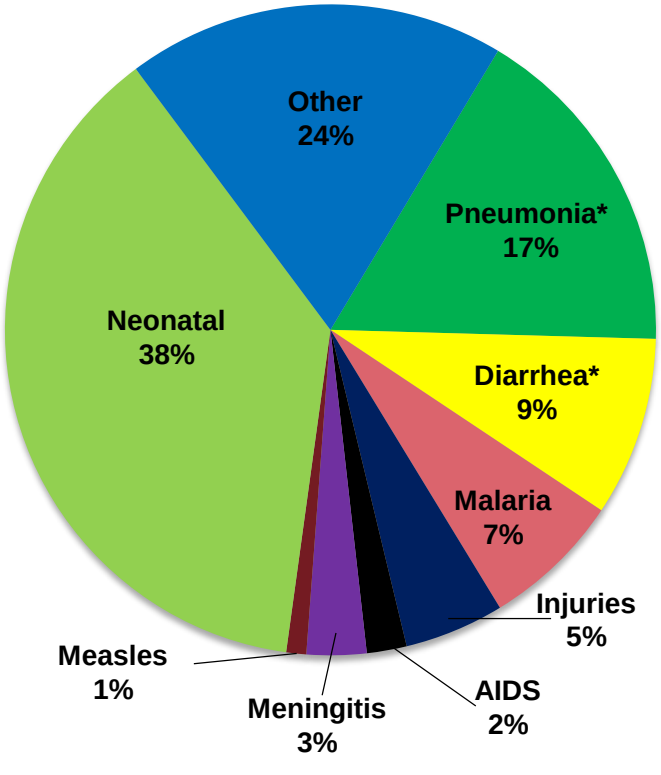
CHILDHOOD DEATHS DECLINING WORLDWIDE

A combination of vaccines, malaria prevention, and improved newborn health care has helped reduce under-five child mortality globally since 1960.



Source: The World Bank

LEADING CAUSES OF MORTALITY IN CHILDREN UNDER FIVE



Vaccine Development Priorities

Near-term

- Poliovirus vaccines
- Pneumococcal conjugate vaccines
- Rotavirus vaccines

Mid- and long-term

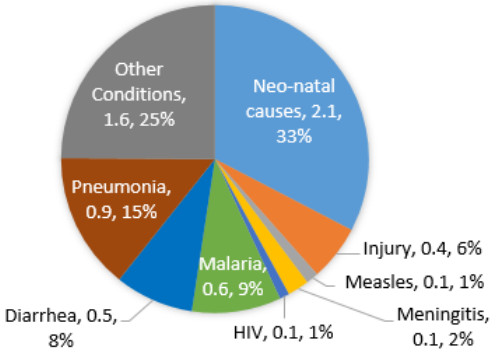
- Maternal immunization platform
- Malaria
- HIV
- TB
- Enteric disease (Shigella, ETEC and others)

Source: CHERG 2013; *=includes neonatal deaths

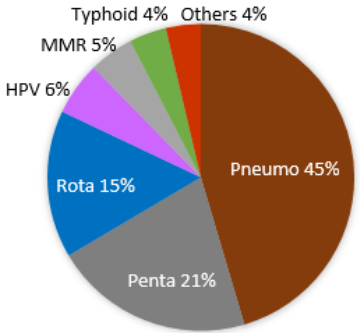
VACCINE DEVELOPMENT TEAM PURPOSE: CATALYZE DEVELOPMENT OF AFFORDABLE, APPROPRIATE VACCINES TO REDUCE MORTALITY

Problem

6.3M deaths under 5 / yr (2013)



GAVI budget $6.5B (2016-2020) (1)



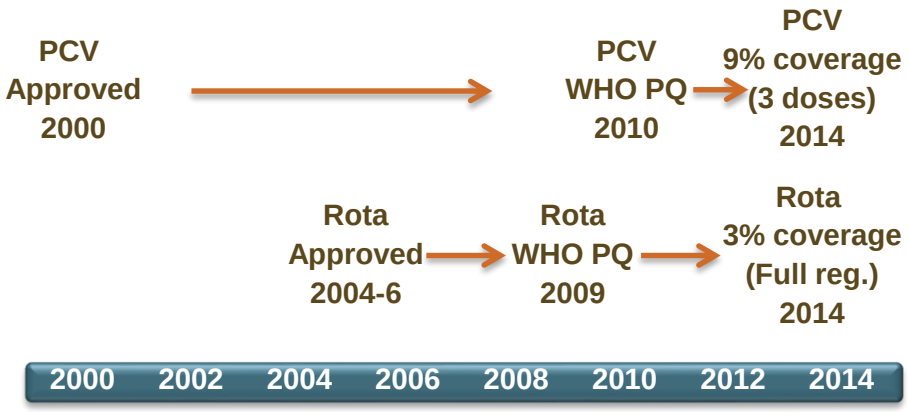
Goals

1. Achieve 25-50% cost of goods reduction of key vaccines (pneumo, rota, IPV, HPV, penta) by 2020, while ensuring reliable, sustainable supply
2. Accelerate development of novel vaccines with 3 achieving WHO prequalification by 2020 (e.g., RSV, new enteric vaccines, malaria)
3. Establish surveillance system in Sub-Saharan Africa and Asia that is used as reference standard to guide reductions in under-5 mortality by 2020

1) Vaccine spend only. Excludes GAVI spend tied to VIS (e.g., Cholera Stockpile, YF Campaigns) as well as cash programs and business plan. Source: Under 5 mortality from GBD 2013 IHME; GAVI budget source: GAVI Investment Opportunity 2015

CHALLENGES OF VACCINE DEVELOPMENT FOR GAVI-ELIGIBLE/LOWER MIDDLE INCOME COUNTRIES

Timing gaps between initial approvals and uptake in low income countries



Challenges that have led to gaps

Inadequate supply

Product profiles not optimal

- Large cold-chain footprint
- High costs
- Inadequate strain-coverage
- Immunity/efficacy lower than desired (lower than in high income countries)

Clinical and manufacturing data necessary for WHO prequalification not available with initial regulatory approval

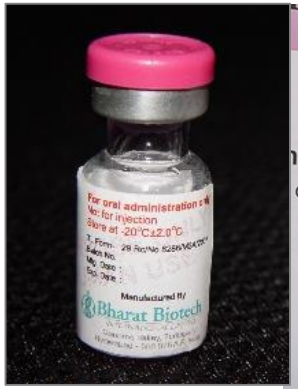
FIVE OPTIONS TO LOWER COSTS AND IMPROVE SEROTYPE COVERAGE OF PNEUMOCOCCAL VACCINES

1. Multi-dose vials
2. More low-cost conjugate vaccine suppliers
3. Dose reduction – trade off for lower efficacy (?or not)
4. Alternate conjugation strategies to lower cost-of-goods
5. Moving beyond conjugate vaccines
   - Whole cell vaccine
   - Conjugate plus proteins

HIGHLIGHT: ROTAVAC® LICENSURE IN INDIA

ROTAVAC® licensure in India

- Shown to be safe and efficacious in Phase III trial in India
  - 54% efficacy against severe rotavirus gastroenteritis
  - Nearly 56% protection in the first year of life
- ROTAVAC products could achieve major impact in India and in Gavi countries
- First-generation product to be priced at ~$1 per dose



Bharat Biotech
Lead Innovation

A THIRD OF CHILDHOOD DEATHS DUE TO INFECTION CAN BE PREVENTED WITH EXISTING VACCINES…

Retrofit existing rotavirus and PCV vaccines to meet the needs of children in low income countries

For future vaccines, get early and better alignment between industry and public health partners on desired vaccine characteristics

Implementation of industry standard practices for vaccine development adapted for public health partners and developing country manufacturers

Advance new technologies to solve problems unique to vaccines for low income countries i.e., technologies that drive down costs and simplify delivery

…AND EVEN GREATER REDUCTIONS CAN BE ACHIEVED WITH ADVANCES IN HIV, MALARIA, AND MATERNAL VACCINES

CONCLUSIONS

- The Bill and Melinda Gates Foundation has unique role at intersection of public health, industry, academics and international partners
- Existing vaccines have great potential for impact, but some still need targeted development to facilitate uptake
- “Easy” vaccines are done. Novel vaccines are likely more difficult with additional challenges on both safety and efficacy requiring early engagement with stakeholders
- End-to-end product development mindset is important
- Full (and best current) understanding of potential vaccine impact should be utilized


THE WORK IS
COMPLICATED.
WHY WE DO IT IS NOT.

OUR EVOLVING PRODUCT DEVELOPMENT NETWORK