Promoting Research and Development: Lessons from the Meningitis Vaccine Project

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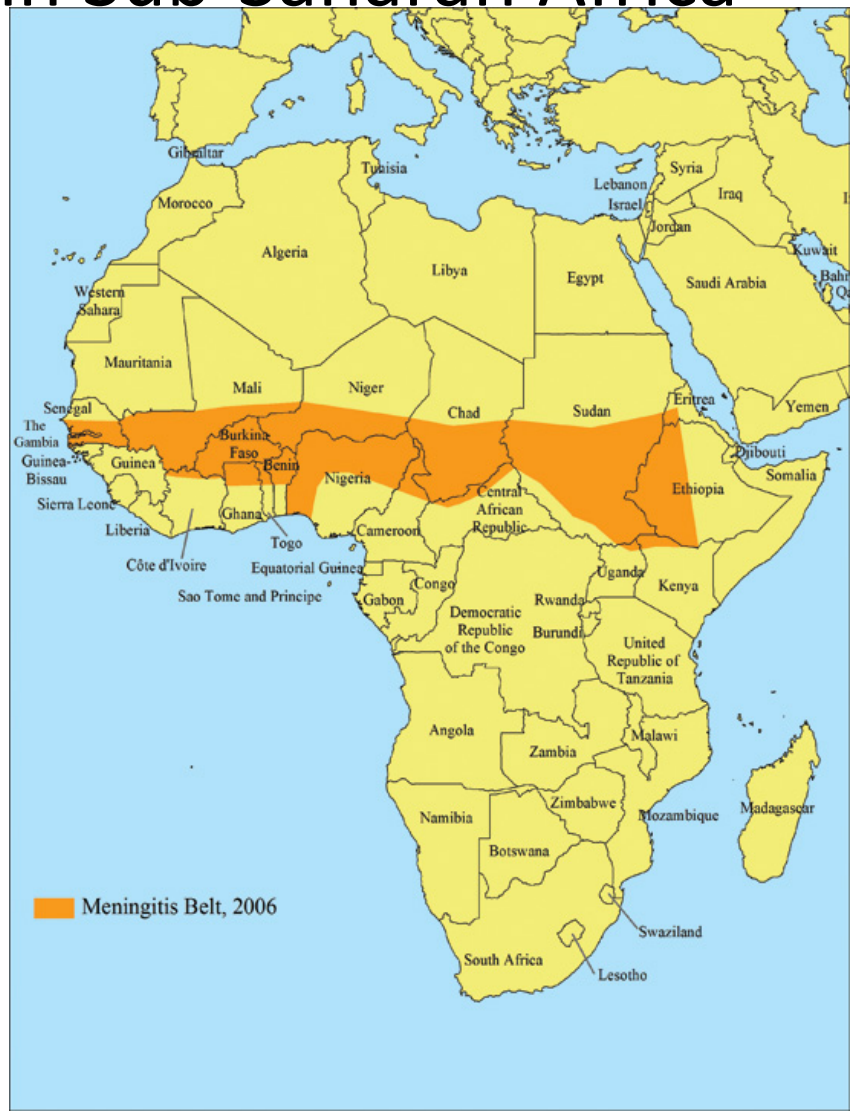
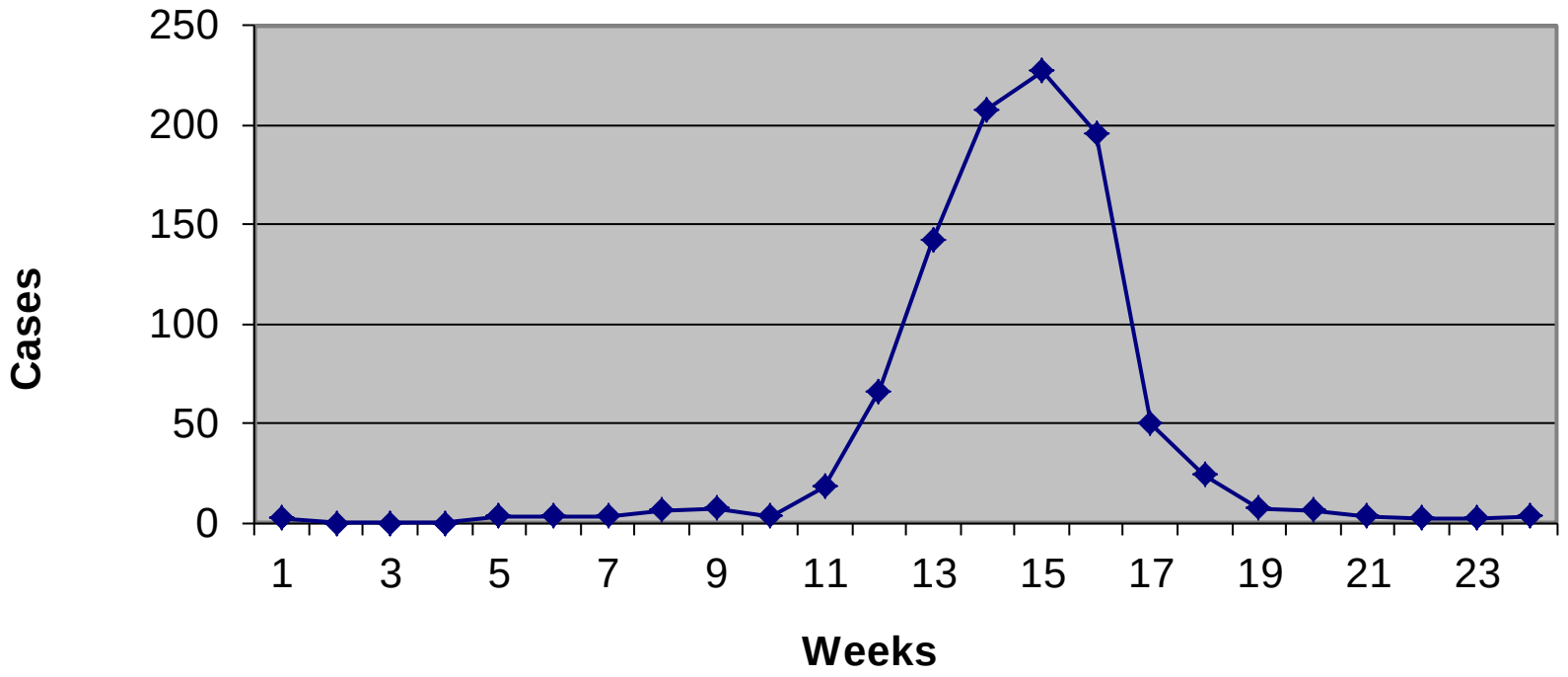
Meningitis belt in Sub-Saharan Africa

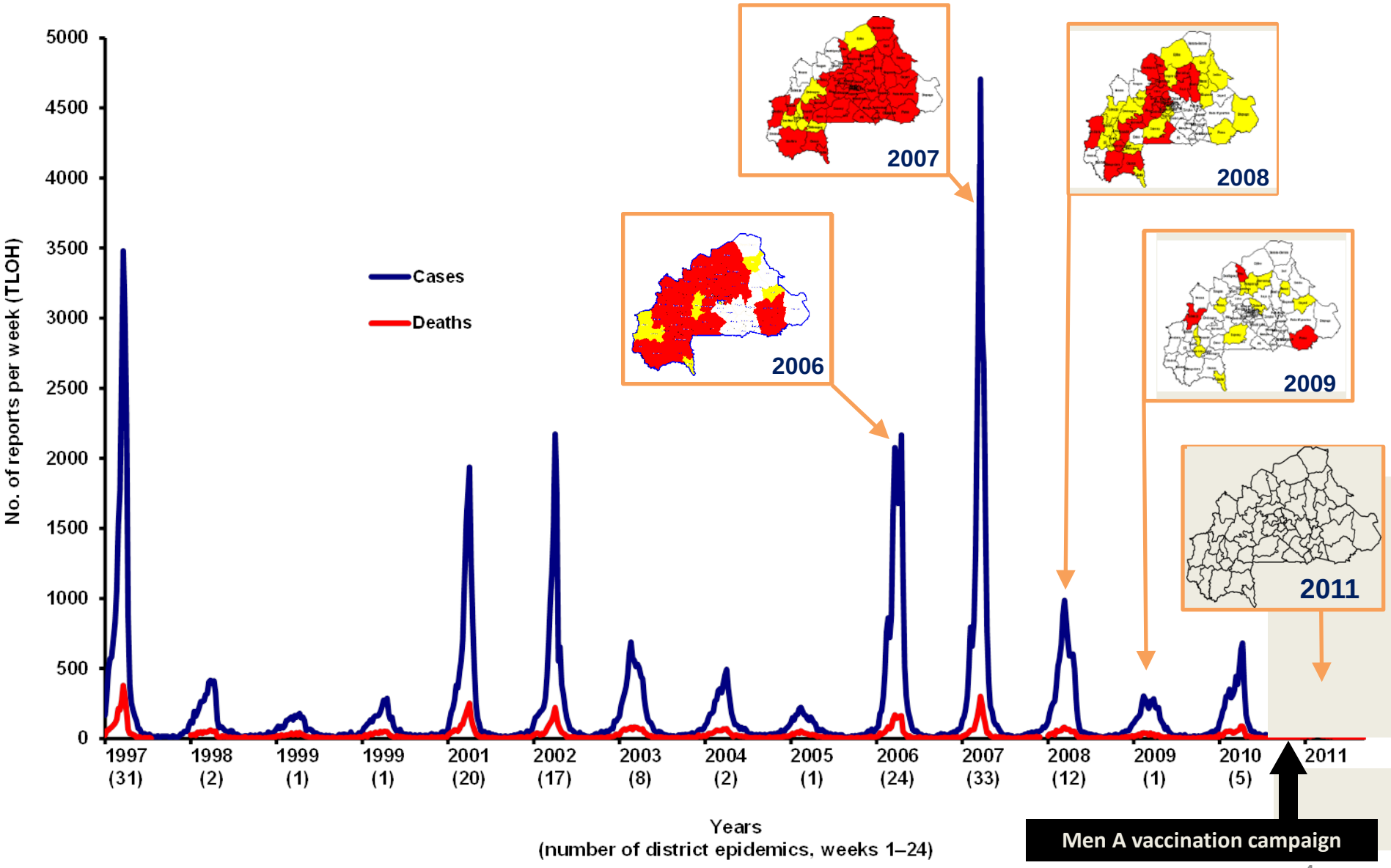
- Over 90 percent of global meningococcal disease occurs in the African meningitis belt
- One strain (Group A Nm) accounts for estimated 80% of all meningococcal cases.
- Focal epidemics occur every year.
- Major epidemics occur every 7-14 years.



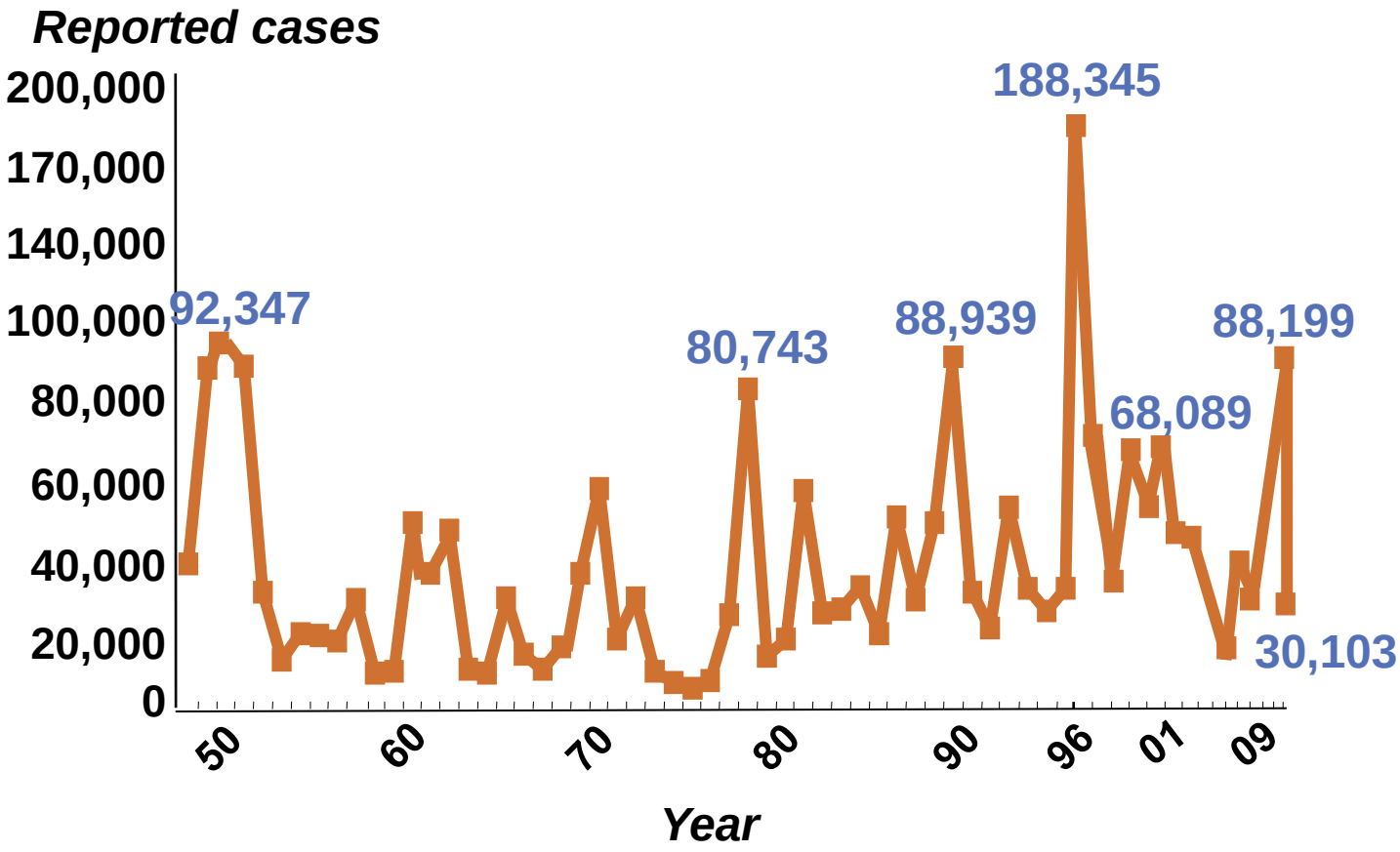
Acute Group A Nm meningitis in Bousse District (pop 134,000) - Burkina Faso Weeks 1-24, 2006



Total of 1003 cases of acute meningitis in 2006; incidence rate of 740 per 100,000


No. of reports per week (TLOH)
5000
4500
4000
3500
3000
2500
2000
1500
1000
500
0
Cases
Deaths
2007
2008
2006
2009
2011
1997 (31)
1998 (2)
1999 (1)
1999 (1)
2001 (20)
2002 (17)
2003 (8)
2004 (2)
2005 (1)
2006 (24)
2007 (33)
2008 (12)
2009 (1)
2010 (5)
2011
Years
(number of district epidemics, weeks 1–24)
Men A vaccination campaign

Epidemic meningitis in Africa



Availability of Meningococcal Vaccines for Sub-Saharan Africa in 2001

- Only older polysaccharide A vaccines were available and were used in reactive campaigns.
- The reactive campaigns were expensive, largely ineffective, but politically necessary.
- There were no plans from multinationals to develop newer, more effective meningococcal A conjugate vaccines for Africa.

Problems for vaccines aimed at developing country problems

- Development of new vaccines are largely controlled by multinationals and aimed at products with market potential

- Very slow introduction of new products to developing countries (15-20 years)
  - Hepatitis B vaccine
  - HiB conjugate vaccine

Creation of the Meningitis Vaccine Project

- The terrible meningitis epidemic in 1996 led African public health officials to ask WHO to help them address this problem.

- Under WHO leadership international meetings in 2000 and 2001 recommended that new and more potent conjugate meningococcal vaccines be developed for Africa.

- In June 2001 MVP was created with Gates Foundation support as a 10 year partnership between WHO and PATH.

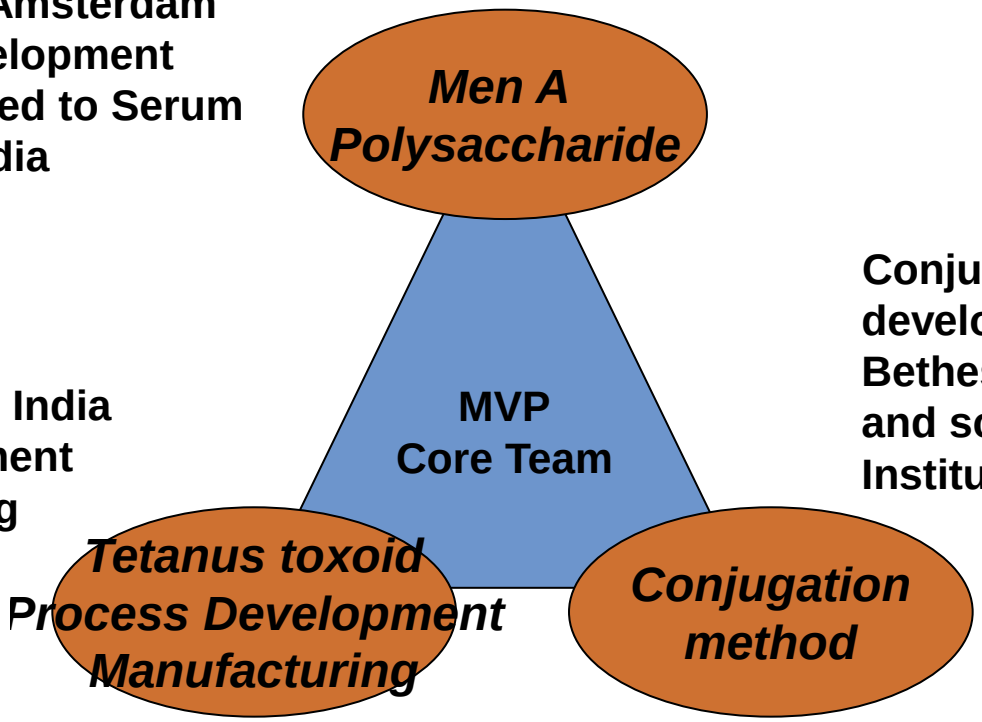
Goal: to eliminate epidemic meningitis in Africa as a public health problem through the development, testing, licensure, and widespread use of ***conjugate*** *meningococcal vaccines*

Understanding the problem: Key discussions with African public health officials & WHO/AFRO, Fall 01-Spring 02

- Epidemics of Group A meningitis were still occurring
- Reactive vaccination campaigns were expensive and logistically difficult
- Dire need for a new and more potent preventive vaccines
- Conditions that would define any new meningitis vaccine:
  - *Cost of vaccine was the most important limiting factor to the introduction of new vaccines in Africa*
  - *Widespread use of a new conjugate meningococcal vaccine in mass campaigns would not be sustainable unless vaccines were priced less than $US 0.50 per dose*
  - *(US prices for meningococcal vaccines at > $100/dose)*

Men A Vaccine development

A PS produced by SynCo BioPartners, Amsterdam for initial development then transferred to Serum Institute of India



Conjugation method developed at CBER/FDA, Bethesda, USA, transferred and scaled-up at Serum Institute of India

Serum Institute of India process development and manufacturing

Lyophylization and stabilization tech transfer from Aerial in France to Serum Institute

Target price US$ <0.50/dose

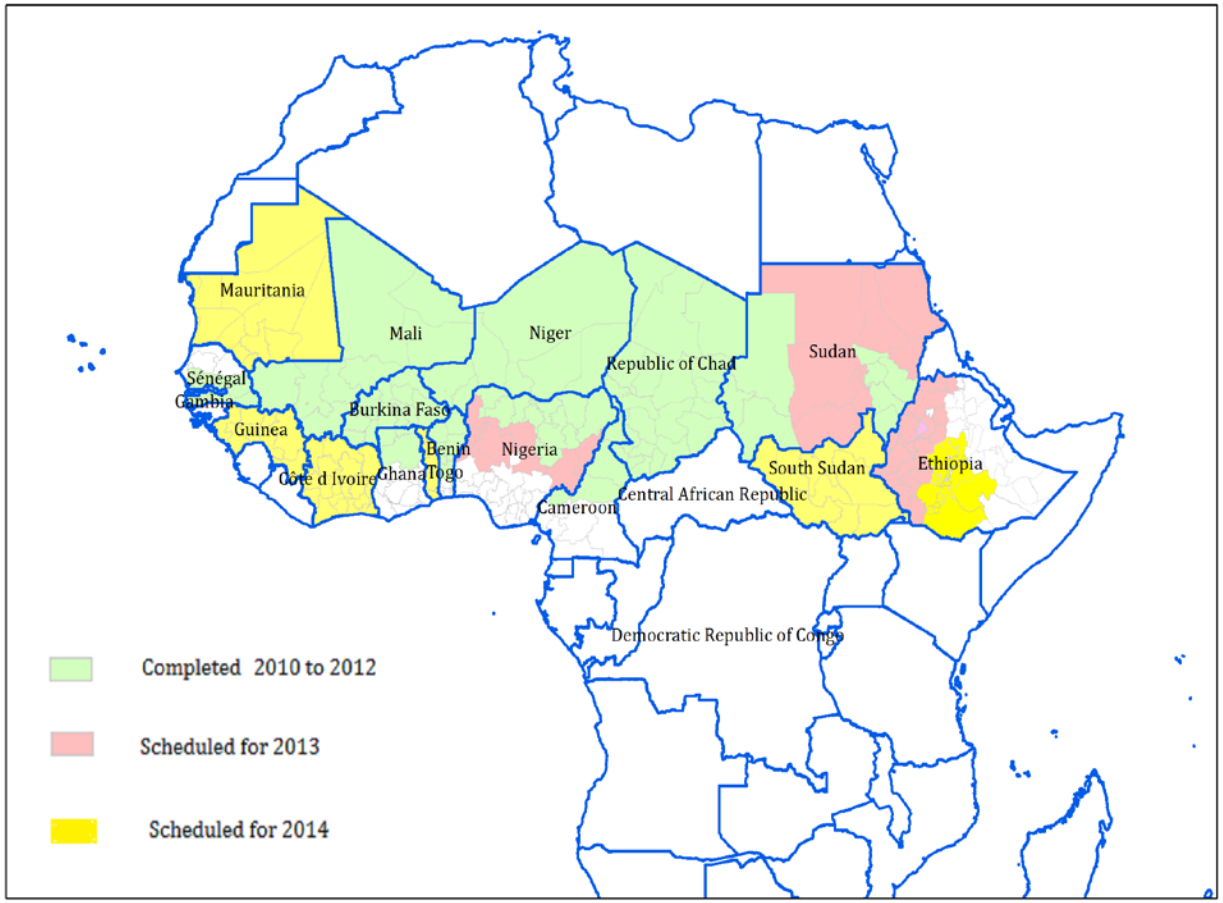

MenAfriVac
10 mcg
10 to 33 mcg
SHAKE WELL BEFORE
Meets W.H.O. requ
MFG. LIC. No.
INSTITUTE OF INDIA LTD.
Pune 411 028, INDIA
5 ml
Diluent for
Meningococcal A
Conjugate Vaccine
0.5ml for 1 dose
INSTITUTE OF INDIA LTD

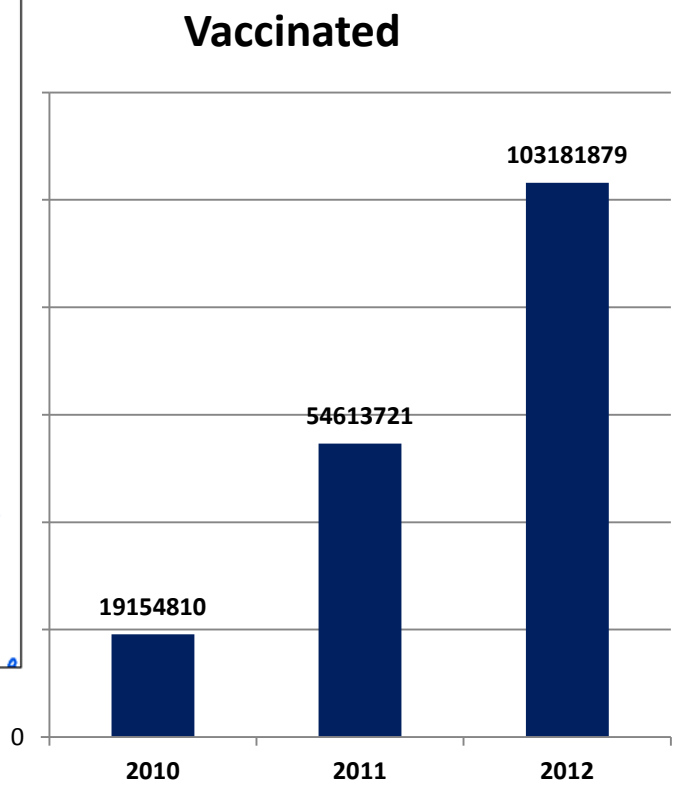
Reported meningitis cases with percent distribution of serogroup A meningococci—Burkina Faso, 2005-2012

Year	Meningitis Cases	% Men A
2005	3,626	11.6
2006	19,134	84.6
2007	26,878	91.1
2008	10,401	79.2
2009	4,723	30.1
2010	6,732	24.9
Introduction of *MenAfriVac* in December 2010		
2011	3,875	0.1
2012	6,957	0.0
2013 (wk 25)	2,124	0.0

MenAfriVac roll-out 2010 – 2014

Early achievements 2010-2012



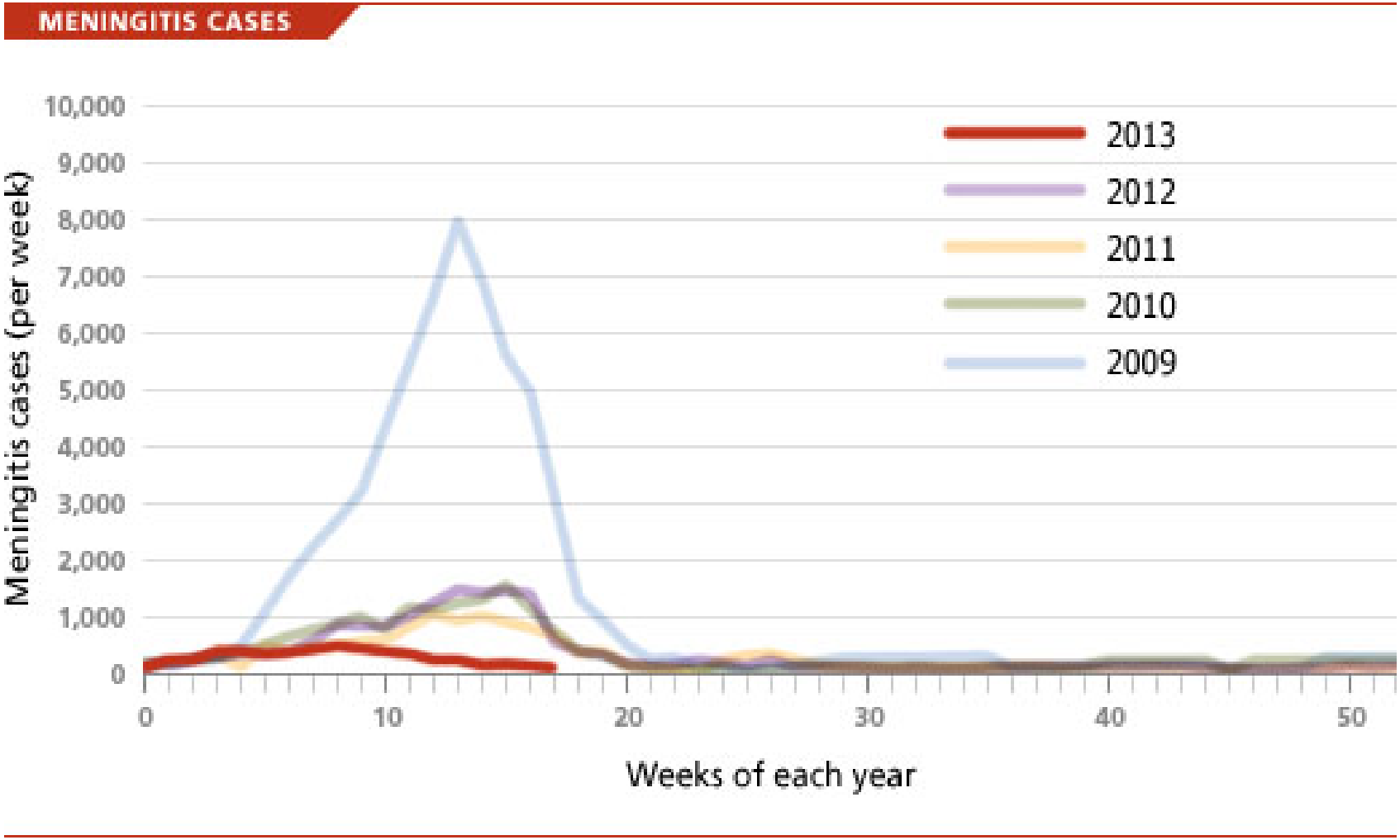


100M milestone celebrated in Cotonou Nov2012

No reported case of NmA among the vaccinated

Experience of CTC in Benin to be used by other countries

Meningitis cases 2009-2013 across the African meningitis belt (WHO data through week 17 2013)



Funders for MVP vaccine development and introduction

- Bill and Melinda Gates Foundation
- WHO and PATH/Seattle
- Global Alliance for Vaccines and Immunization
- Serum Institute of India, Ltd
- Michael and Susan Dell Foundation
- US Agency for International Development
- Centers for Disease Control, Atlanta
- Agence Medecine Preventive, Paris
- Medecins sans Frontieres
- Individual donors ($US 100 to $US 10,000)

Lessons learned

- First, listen to the customer (make sure the product is right)
- Align partners to make sure that all are “winning”
- Make sure to understand what everyone wants
- Use funding to leverage more funding; the task is never over
- Actively work with all funders
- A sound communication strategy is a must

Listening to the customer

- Unanimity among African public health officials that the meningitis problem had to be solved
- Affordability and quantity of vaccine were critical factors
- Defining “affordability”

Obligations to partners

- All donors have goals they want to achieve (think of these as “deliverables”)
  - Publicity and recognition
  - New markets
  - Making money
  - New findings (chemistry, immunology, public health, etc…)

Meeting their needs is critical to success

Leveraging funding

- The task of identifying and accessing new funds never ends
  - Interesting projects need money
  - There are always gaps in funding
  - New problems require new funds

Be alert to these opportunities knowing that new resources will have to be identified

Communication

- A comprehensive communication strategy is a must
- Invest in communication
- Expertise is essential (amateurs do not do a very good job)

A strong communication platform is the backbone of an effective funding strategy

Other observations

- Face to face meetings are always better
- Communication, communication, communication…
- Expect to be disappointed, sometimes from surprising sites and partners
- Expect to succeed, good ideas that are soundly managed get funded
- Always pay attention to WHO and UNICEF

In collaboration with Health Authorities of 26 countries in Sub-Saharan Africa and of India