

Opportunities and challenges with introduction of newer vaccines: What is needed from the next generation of vaccines

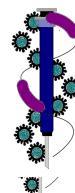
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1. Lessons learned from Hib and penta introduction: Mali experience



Lessons learned from Hib and penta introduction: The Mali experience

- Estimation of local disease burden:
 - Routine surveillance data
 - Research data
- Impact measure
 - Critical
 - Convince decision makers and donors
 - Better prepare for future vaccines



Local disease burden

- **Clinical Bacteriology Laboratory** established by CVD
- Blood cultures or body fluid cultures (e.g., CSF) systematically (7 days/week) obtained from hospital admissions with:
 - ✓ Age: 0-15 years
 - ✓ Fever: $\geq 39^{\circ}\text{C}$ and/or
 - ✓ Clinical syndrome compatible with invasive bacterial disease (e.g., sepsis, meningitis, septic arthritis, etc.)

Surveillance at
l'Hôpital Gabriel
Touré (HGT),
Bamako, Mali



Local disease burden

Incidence of invasive Hib disease per 100,000 7/2002 - 6/2005
(S Sow et al, Pediatr Infect Dis J 2005)

Age group	Year 1	Year 2	Year 3	Mean Annual
0-1 m	21.9	10.6	10.3	14.2
2-3 m	22.3	43.4	63.4	43.4
4-5 m	133.1	270.7	263.3	223.6
6-7 m	411.5	341.4	377.8	376.6
8-9 m	175.2	275.2	446.1	301.3
10-11 m	134.7	117.9	127.5	126.6
0-11 m	145.5	171.0	206.5	174.9



Local disease burden

Among infants age 4-11 months admitted to hospital:

- 12% of all hospital admissions were due to invasive Hib disease
- 19.3% of deaths were due to Hib

S Sow et al, *Pediatr Infect Dis J* 2005



Political will led to a public health decision

- A very high burden of bacteriologically-confirmed Hib disease was revealed
- Mali government successfully applied for GAVI support to introduce Hib vaccine into the EPI
- 3-step introduction
- Hib vaccine introduced in Bamako in July 2005



↑
President Amadou
Toumani Toure



Impact measure is critical

- Hospital-based surveillance monitored impact : 88% reduction on Hib disease incidence in 23 months
- Prevalence of serum Hib PRP antibodies in Malian infants 6-7 months of age before and 18 & 30 months after the introduction of Hib conjugate into the EPI for Malian infants: 80 to >90% high serum antibody levels



Impact measure is critical

- Lack of impact of Hib vaccine introduction on invasive pneumococcal hospitalizations
- Impact on hospitalization:
 - 29.2% reduction in all-cause hospitalizations
 - 75.0% reduction in confirmed Hib disease



Several opportunities

- Pneumococcal vaccine
- Rotavirus vaccine
- Meningococcal A conjugate vaccine
- Flu vaccine
- HPV
- ...etc



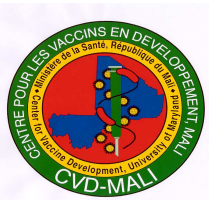
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But, challenges!



Timing

- Delays :
 - Funding
 - Logistics
 - Training
 - Vaccine arrival and use



Vaccine supply

- Assuring in advance :
 - Adequate vaccine supply
 - Sufficient quantities
 - Sustainable pricing



Vaccine supply

- Penta case :
 - Single supplier
 - Insufficient quantity 1st year
 - Price up after GAVI until competition
 - In 2001: penta~\$3.10
 - By 2005: close to \$3.75
 - Now competition: \$1.90



Vaccine transition

- DTP-HepB and Penta in the same country at the same time when step-wise introduction
 - Risk of giving the same child current and new vaccine
 - Confusion in calculating coverage



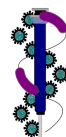
Vaccine transition

- Thus we recommend:
 - Provide new vaccine
 - Switch in a given date
 - Change all at once
 - Withdraw old vaccine



Training and supervision

- The complexities of adding a new vaccine are such:
 - Even with good training
 - Practice does not follow immediately
 - In Bamako, Mali, 2 years after penta introduction issues with vaccine :
 - Route
 - Dose
 - Storage
 - Vaccination site
 - Mastery of AD syringes
 - Filling out immunization cards and registers



Training and supervision

- Supervise, monitor vaccination activities
- Inform, sensitize community about new vaccine, name, administration (injection site, oral, what diseases/infections are prevented by the vaccine, doses, side effects,...etc)



Cold chain

- Assess in advance:
 - Cold chain impact of new vaccines
 - Capacity, delivery frequencies
 - Storage temperatures
 - Expiration dates
 - Syringes
 - Mali: 5 ml syringes are very much in demand by people, so, measles reconstitution with 2 ml



2. Anticipated challenges with pneumo, rota and menA conjugate vaccines introduction:

All the challenges in previous slides plus



Challenges for pneumo, rota and menA

- Specific challenges for pneumo vaccine:
 - Understanding serotypes
 - Monitoring serotypes
 - Issue of price



Challenges for pneumo, rota and menA

- Specific challenges for rota vaccine:
 - Not for all diarrheas
 - Issue of communication
 - Monitoring serotypes



Challenges for pneumo, rota and menA

- Specific challenges for menA vaccine:
 - Catch up vaccination vs routine
 - Many ongoing campaigns:
 - In the past 5 years in Mali : several campaigns on polio, measles, tetanus, YF and MenAC



Challenges for pneumo, rota and menA

- Choice of new vaccines
 - How can a country handle all priority vaccines at once?
 - How can a country with lack of local burden data make priority decision?

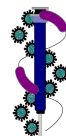


3. Balancing opportunities from new vaccines and possible disturbance of current vaccine activities



Balancing of opportunities vs possible disturbances

- Ongoing campaigns : polio, measles and tetanus interfere with training and immunization activities
- Training issues still outstanding with penta
- Surveillance issues: disease burden and impact for all different antigens

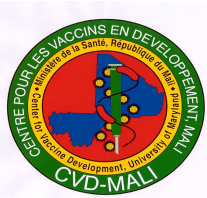


Balancing of opportunities vs possible disturbances

- Cold chain issues: space, logistics
- Sustainability: immunization activities, so fragile infrastructure, so many new interventions even if high priority
- GAVI payments require co-payments by country, thus:
 - Much higher costs for each new vaccine added
 - Increased proportion of immunization cost on health budget



4. Essential requirements for new vaccines in terms of epidemiology & presentation



Epidemiology

- Effective vaccines needed:
 - Direct effect on disease burden (Morbidity and mortality)
 - Indirect effect on carriage (reduce transmission)
- Surveillance needed to monitor changes in epidemiology and to adapt the vaccine
 - Serotypes replacements



Presentation

- Reasonable cold chain storage volume
- Not freeze sensitive
- With VVM
- Not freeze dried
- As thermostable as HepB ideally
- Oral if possible (avoid syringes with cost and disposal issues)
- Prepackaged in AD syringes if possible to do for same price



Conclusions

- Infrastructures critical for new vaccine introduction
- Assuming the right presentation and sustainable pricing will make this introduction easier
- Countries need mechanisms and processes for prioritization based on epidemiology and laboratory support
- Training & logistics issues are different and not trivial for each new vaccine introduction



Conclusions

- Challenges **MUST NOT** keep us away from taking advantage of good opportunities
- We **MUST** reduce the time it takes to introduce new vaccines into developing countries
- Together, we will overcome these challenges and get new vaccines promptly to where they are the needed most

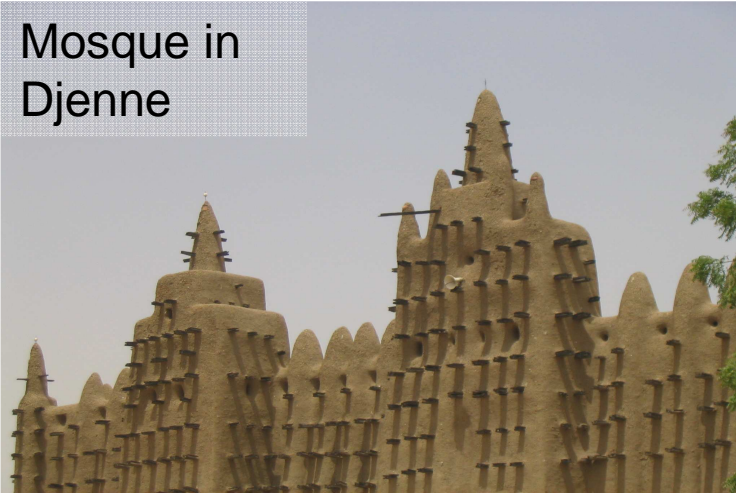


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- Myron M Levine



Mosque in Djenne

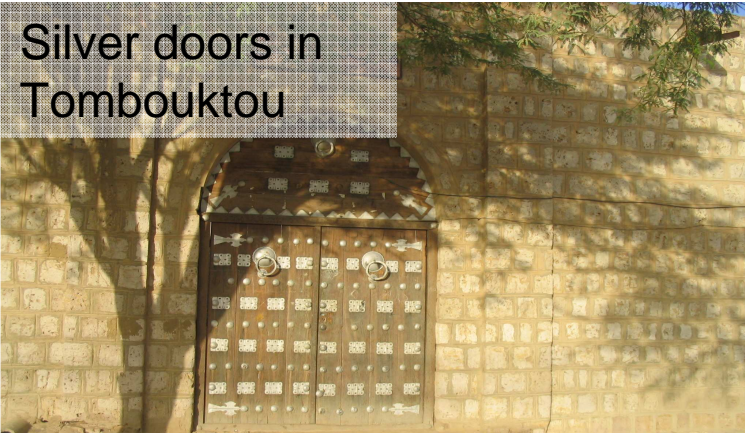


Nomads in Tombouktou

Oral vaccine



Silver doors in Tombouktou



Niger River

Village life



Cliff dwellings in Bandiagara



Locally designed transport for polio victims



Music

