

Developing a Meningitis Vaccine Program to Prevent Epidemics in Africa

Outline

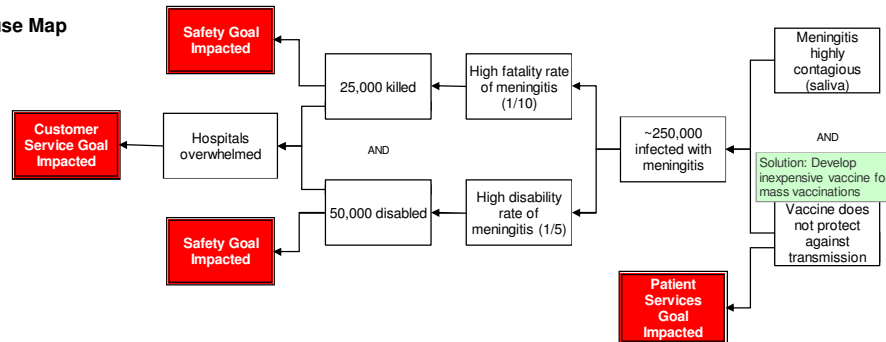
What	Problem(s)	Meningitis epidemic
	Date	1996-1997
When	Different, unusual, unique	?
Where	Countries	"Meningitis belt" - Senegal to Ethiopia
	Task being performed	Meningitis transferred by transfer of saliva, coughing

Impact to the Goals

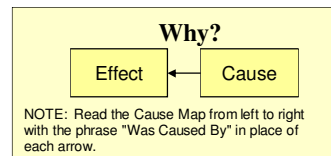
Safety	25,000 killed (1 of 10 infected)
	50,000 disabled (1 of 5 infected)
Environmental	?
Cust. Service	Hospitals overwhelmed
Patient Services	Vaccine does not protect against transmission

Frequency >88,000 cases of meningitis in 2009

Cause Map



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Timeline

Date	Description
1966	Polysaccharide vaccines are developed in response to epidemics of meningitis in industrialized countries
1996	More than 25,000 people die during the largest meningococcal meningitis epidemic ever recorded in history - more than 250,000 cases are reported to the WHO
2000	Plans are drawn for the creation of the Meningitis Vaccine Project (MVP)
2001	The Gates Foundation awards PATH and WHO US\$70 million for the development of meningitis vaccines in Africa African public health officials make it clear that a cost of more than US\$0.50 per dose would be unsustainable
2002	It becomes clear that no manufacturer in the developed world can produce a MenA conjugate vaccine at less than US\$0.50 per dose MVP starts exploring alternative strategies for the development of such a vaccine
2003	MVP and scientific consultants define a timeline for pharmaceutical operations
2004	PATH enters into a long-term sublicense and supply agreement with SILL to develop, test, and produce clinical and commercial lots of MenA conjugate vaccine at a target price of US\$0.40 per dose INTOXPRM Ltd. conducts toxicology and local tolerance testing of the candidate vaccine that shows that the product has no deleterious effects in animals SILL prepares test lots and the first batches of the MenA conjugate vaccine
2005	The first clinical trial, PsA-TT-001, is launched. This Phase 1 trial evaluates the safety and immunogenicity of the MenA conjugate vaccine in 74 healthy adults in India
2006	One-year follow-up data from PsA-TT-001 show the vaccine to be safe and immunogenic The MVP pivotal Phase 2 trial, PsA-TT-002, is launched. The study looks at safety and immunogenicity of the MenA conjugate vaccine in the younger age-group targeted by the mass vaccination campaigns
2007	Week 4 results from PsA-TT-002 show that the MenA conjugate vaccine is safe and highly immunogenic Phase 2/3 studies PsA-TT-003 and PsA-TT-003a are launched
2008	The Phase 2 infant study PsA-TT-004 is launched in Ghana
2009	78,890 suspected cases and 4,243 deaths are reported during the epidemic season; Médecins Sans Frontières (MSF) launches its largest mass vaccination campaign ever, deploying up to 400 emergency vaccination teams to vaccinate 7.5 million people in Chad, Niger, and Nigeria SILL submits the MenA vaccine regulatory file to the Drugs Controller General of India (DCGI) for Indian licensure and to the World Health Organization (WHO) for prequalification
2010	The World Health Organization prequalifies MenAfriVac™, the new meningococcal A (MenA) conjugate vaccine developed through the Meningitis Vaccine Project PsA-TT-005 (Phase 3 lot-to-lot consistency study) is launched in India PsA-TT-006 (Phase 3 safety study) is launched in Mali