



TB is a significant problem, does not get attention needed

Study captures opinions of developing country decision makers on TB vaccines

Eight High Burden Countries Surveyed

- ◇ Brazil
- ◇ Russia
- ◇ India
- ◇ China
- ◇ South Africa
- ◇ Romania
- ◇ Cambodia
- ◇ Mozambique

Scenarios

Scenario 1.

A BCG replacement that was as effective as, but safer than current BCGs and that would prime for a second booster vaccine

Scenario 2.

A prime boost regimen starting with either current or replacement BCG followed by infant and later boosts with a different vaccine that would reduce TB disease by 60%

Scenario 3.

The regimen described in Scenario 2 delivered by aerosol rather than needle injection

TB Does Not Get the Attention It Needs

In 2010, in-depth interviews were held with 86 public health workers, government officials, and journalists across eight high-burden countries. The results indicated that top health priorities include better primary care, improved vaccine coverage, as well as infant health and mother and child health. The overall view of TB is that it is a significant problem that does not get the attention needed. The incidence of TB is seen to be rising and prevention is viewed as extremely difficult due to an ineffective BCG vaccine and congested living conditions that help spread TB.

Positive Responses on TB Vaccines - Mixed with Concerns

The participants were asked to respond to various new TB vaccine scenarios. There was a mixture of responses within and between countries. However, overall responses were positive to the introduction of a new TB vaccine, with some scenarios more positive than others, yet some concerns with respect to new vaccine introduction were encountered across the board. Respondents highlighted strong efficacy data, including in-country data, as an important success factor in the adoption of a new TB vaccine. Other challenges to adoption included regulatory requirements; information, education and communication (IEC) among the public; training of health workers; and logistics. The low cost presented in the scenarios was a lesser concern. (Scenarios listed in sidebar.)

Groundwork Needed to Prepare for Success

Despite the fact that 75 percent of the respondents had personal knowledge of or experience dealing with TB, with one fifth of those having contracted it themselves, the survey clearly demonstrated that while the need is high, the challenges associated with introducing a new TB vaccine are likely to be significant. Laying the groundwork early in collaboration with key constituents and raising awareness will be important to successful vaccine introduction, but raising expectations too high needs to be avoided.

Background

Tuberculosis is estimated by WHO to have caused over 9 million new cases and killed nearly 2 million men, women and children in 2009, despite global efforts to stop it. The current vaccine -- *Bacille Calmette-Guérin* (BCG) -- is widely administered to infants in TB endemic countries yet its use has not had a significant impact on the global TB burden. Developed nearly a century ago, BCG given to newborns has been shown to be effective in children for the prevention of more serious forms of tuberculosis, such as tuberculosis meningitis and miliary tuberculosis. However, infant vaccination does not prevent pulmonary TB in adults, the most common form of the disease.

Recently, the WHO recommended against the use of BCG in HIV-infected infants due to concern over an increased risk of disseminated BCG.



Current TB Vaccine Research

New TB vaccines are undergoing research today. Approaches include:

- the development of an improved BCG that is more effective than those currently available;
- a new BCG that is safer in HIV-infected infants; and
- a booster vaccine, to be given sometime after BCG vaccination at birth, that will increase protection against the disease.

Study Gauges Opinions on TB vaccines

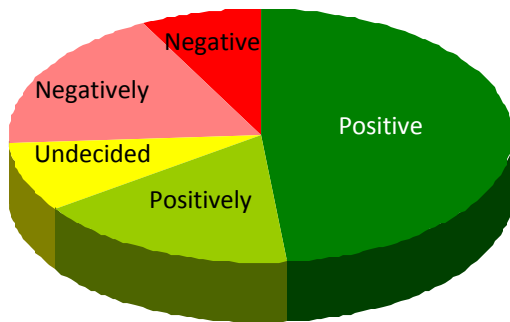
The study of barriers and drivers to the introduction of new TB vaccines was commissioned by Aeras in 2009* that would:

- inform the strategies of Aeras as related to the opinions of country level decision makers as they would approach decisions regarding adoption of a new TB vaccine
- provide information that would drive dialogue and collaboration between Aeras and its international partners
- create the first step in the body of knowledge that Aeras will build with respect to future activities in this area

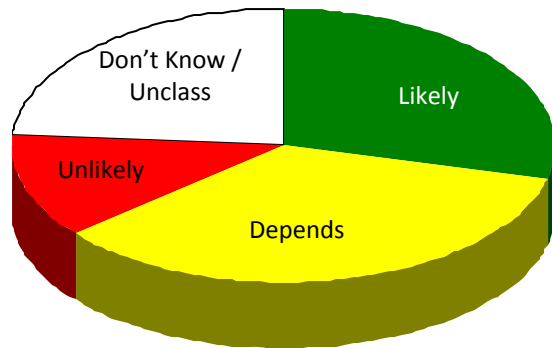
Sample of overall responses

SCENARIO 1 - A BCG replacement that was as effective as, but safer than current BCGs and that would prime for a second booster vaccine

First Reactions

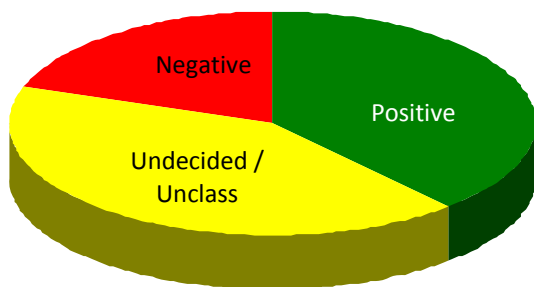


How likely to adopt

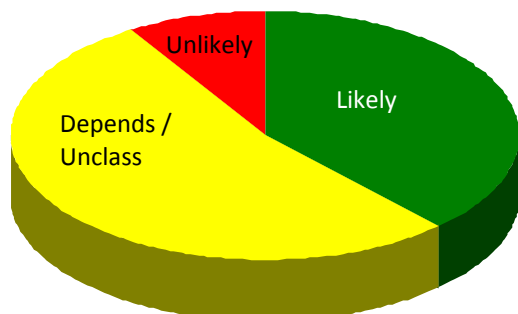


SCENARIO 2 - A prime boost regimen starting with either current or replacement BCG followed by infant and later boosts with a different vaccine that would reduce TB disease by 60%

First Reactions



How likely to adopt



*Baird's CMC, a global strategy consulting firm, conducted the study described.