Q. What is tuberculosis and why is it a problem?

- Tuberculosis (TB) is a disease caused by infection with the germ *Mycobacterium tuberculosis* (*Mtb*). TB is spread from person to person through the air. Many people who are exposed to TB become infected, but not everyone who becomes infected gets sick with TB.
- If someone is infected with TB but does not become sick, they have what is called latent TB. An estimated one third of the world’s population has latent TB and is at risk of developing active TB disease.
- Active TB disease usually attacks the lungs. Symptoms include coughing blood, night sweats, fever and weight loss. TB can also infect other parts of the body. Each year, almost 9 million people become sick with TB, and 1.4 million people die from the disease.
- Because TB preys on weakened immune systems, people infected with HIV are at much higher risk of becoming sick with TB, and TB causes HIV to progress to AIDS much more rapidly. This is known as TB/HIV co-infection, and it is an urgent problem in countries with high rates of HIV. One in four HIV deaths is TB related.
- New forms of TB have emerged, and in some cases the most common drugs to treat TB no longer work. This is known as drug-resistant TB. Drug-resistant TB is much more difficult and much more expensive to treat than regular TB, and the drugs have toxic side effects.

Q. Why do we need a new TB vaccine?

- Current TB treatment is long and difficult, lasting 6 months or more. Treatment for drug-resistant TB can be up to 24 months and the drugs can have severe side effects, such as hearing loss and psychosis.
- TB/HIV coinfection makes it even more difficult to diagnose and treat TB. The most commonly used diagnostics only detect TB in 20% of patients co-infected with HIV, and common antiretroviral therapies have negative interactions with current TB treatments.
- Vaccines are one of the world’s most effective public health tools, saving millions of lives each year from infectious diseases like measles, mumps, influenza, rotavirus and certain types of meningitis.
- The only available TB vaccine, Bacille Calmette Guerin (BCG), was developed over 90 years ago, and protects against severe forms of TB in children. However, it is unreliable in protecting against pulmonary TB, which is the most infectious form of TB. Therefore, despite being one of the most widely used vaccines in the world, it does not seem to have any impact on the global TB epidemic.
- The global plan to eliminate TB as a public health threat cannot be achieved without new TB vaccines that effectively prevent all forms of TB in all age groups—infants, adolescents and adults—and that are safe in all populations, including people living with HIV.
Q. What is being done to develop new TB vaccines?

- In the last decade much progress has been made in the global effort to develop new, more effective TB vaccines. Multiple new vaccine candidates are now being studied in humans, a process known as clinical trials, and many more are in earlier stages of research.

- Vaccines are being developed that would prevent infection with TB and/or prevent TB disease. These are known as preventive vaccines. Vaccines are also being developed that could be used with TB drugs to more effectively treat active disease. These are called immunotherapeutic vaccines.

- Because researchers do not yet understand how the human body protects against TB, it is very difficult to develop a vaccine that will mimic that protection. Research is currently underway to better understand how the TB germ causes disease and how vaccines can fight infection and disease.

Q. Will it take a long time to develop a new TB vaccine?

- Developing a new vaccines is almost always a long and complex process. A coordinated research effort to develop new, more effective TB vaccines only began just over a decade ago.

- Novel vaccine candidates have to go through many stages of research and testing in laboratories and in animals before they can be tested in humans. This process can span several years.

- Once new TB vaccine candidates enter human trials, they have to go through multiple small, early clinical trials to demonstrate that they are safe before they enter trials that show that they prevent TB disease.

- Because of the gaps in knowledge about TB and particularly about how humans respond to TB infection, trials to show that vaccines work against TB are lengthy and very large. These late stage trials may involve tens of thousands of participants and last 3-5 years.

Q. How can I be involved?

- Learn more about TB vaccine research and development. Resources are available through:
  - Working Group on New Vaccines www.stoptb.org/wg/new_vaccines/
  - Aeras www.aeras.org
  - TBVI www.tbvi.eu

- Review *Tuberculosis Vaccines: A Strategic Blueprint* to understand the key challenges in TB vaccine R&D and how the field is working together to overcome those challenges. The Blueprint and a summary brochure are available at www.stoptb.org/wg/new_vaccines/

- View the film series EXPOSED and share it with others. www.aeras.org/exposed

- Find out if TB vaccine research is happening in your country and which organizations are involved. This information is available through product development organizations like Aeras and TBVI, and through the Working Group on New Vaccines.

- Join the listserv dedicated to TB vaccine R&D advocacy to learn about news and progress, and to identify and share information with other advocates. To join, send an email to: newtbvaccines+subscribe@googlegroups.com

- Join a network of TB, TB/HIV, or other health advocates in your community or country and find out if they are supporting TB vaccine R&D. If they are not, encourage them to learn more.

For more information about tuberculosis, visit www.stoptb.org

To join the listserv dedicated to TB vaccine R&D advocacy send an email to: newtbvaccines+subscribe@googlegroups.com