PATH'S EXPERIENCES IN VIETNAM ON VACCINE CLINICAL TRIALS

The Sustainable Influenza Vaccine Production Capacity Stakeholders' Workshop

PATH
A catalyst for global health

Presentation outline

- An overview of PATH Vietnam and PATH experience with vaccine clinical trials in Vietnam
- Current status of clinical trial regulations and vaccine registration in Vietnam
- Current status of vaccine production in Vietnam
- Some thoughts about the needs of support

Conducting serology survey in the field
Photo credit: Huong Vu - PATH

PATH Vietnam: An Overview

- PATH has been working in Vietnam since the early 1980's.
- In 1997 a project office was established in Hanoi with a staff of 5. It is now a country program with a staff of 27.
- From 1980 until present, 55 projects have been implemented covering a broad range of health issues
- PATH partners with both public and private sector, and works from national to community level to provide technical support for health interventions.

Clinical trial experience in Vietnam

- Immunogenicity of local produced Hepatitis B plasma derived vaccine with total sample size of 570 subjects (completed)
- Immunogenicity and safety of local produced Hep B vaccine with the first dose kept outside the cold chain with total sample size of 1106 subjects (completed)
- Efficacy, Safety, and Immunogenicity of RotaTeq™ with total sample size of 900 subjects (completed)
- Immunogenicity and reactogenicity of alternative schedules of Gardasil vaccine to prevent HPV infection with total sample size of 903 subjects (on going)

All of these trials conducted in collaboration with National Institute of Hygiene and Epidemiology (NIHE) and provincial department of health.

Current status of clinical trial regulations in Vietnam

- First issued in 1975 as a guideline, the latest regulation issued in 2008.
- The regulation defines:

- The rights/roles and responsibilities of the Ethics Committee of MOH, investigators, sponsors, implementing agencies (implementers), study subjects
- The approval process for clinical protocols:
  - clinical protocol should be reviewed by Ethics Committee and Science Committee.
  - MOH must respond within 60 working days of receipt of complete protocol documents
- The guidance for conducting clinical trials including implementation, recording, reporting, inspection and monitoring, finalization, dissemination and financing of clinical trials

Some key points

- Ethics committee must review the protocol, supervise the implementation
- Only Health institutes at the central level are allowed to implement a clinical trial.
- Protocols must follow MOH format and be in either English or Vietnamese.
- MOH responds within 60 working days of receipt of complete protocol documents.
- 2 steps of reviewing/approval clinical trial (product dossiers and protocol)
- PI should report to MOH/sponsor quarterly on AEFI, safety
- Result should only be disseminated or published after being approved by the MOH review committee.
- Sponsor is responsible for monitoring, supervision, regular (quarterly)/ad hoc report to MOH, paying compensation to study subject if serious adverse event happened due to study

Regulation on drug registration (including vaccines)

The current regulation issued in 2009 by Drug Administration of Vietnam (DAV). The regulation regulates:

- Eligibility, right, requirement and responsibility of manufacturers/distributors for product registration
- Requirement of dossiers, specifically for local produced products and imported products, requirement of product labeling
- Types of license, effective period of drug licensed, suspension of the licensed product
- Intellectual property and confidentiality of information related to licensed product
- Roles of review experts and advisory committee of drug registration

Some key points related to vaccine registration

- Manufacture should get GMP certificate (issued by MOH)
- The vaccine should get quality testing certificate from National Institute for Control of Vaccine and Biologicals
- The vaccine needs to follow regulations on clinical trial of MOH
- It takes about 6 months for MOH to issue the license or provide reasons if vaccine is not licensed.
- In general, once a vaccine gets registered, the license takes effect for 5 years.
- Requirement of dossiers for vaccine registration composed of 4 types of document including Admin data and product document, quality document, pre/non-clinical trial, safety document, clinical/efficacy document.

Overview of vaccine production in Vietnam

- There are currently 4 vaccine manufactures in Vietnam (VABIOTECH, IVAC, POLYVAC and Da Lat Pasteur Vaccine Company), all of them are state owned company/institute
- At this moment, all vaccines being used in EPI (polio, measles, DPT, BCG, Hep. B, TT, JE, typhoid, cholera) and some others (Hep. A, td, rabies, etc) are being produced by these local company/institute
- Capacity of local companies/institute fully meets the need of Vietnam EPI program (~ 5-6 million doses of each vaccine type/year) and could be able to export.
- So far, there are no local products with WHO pre-qualification

Needs of support

- Strengthening capacity of manufactures in flu vaccine production (covered by Rick Bright)
- Strengthening capacity of local institutions in conducting/managing standard clinical trials
- Strengthening capacity of National Regulatory Authority (MOH) to exercise 6 functions for ensuring vaccine quality

Giving Hep B birthdose to a child
Photo credit: Huong Vu, PATH

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