Equipping the Supply Chain

Update on the WHO PQS Prequalification of Equipment and Devices for Immunization
Outline

- Update on process
- Prequalified products
- Equipping the cold chain
  Supporting projects
Scope of PQS

A three step cycle ...

1. Standards & Innovation
   - Identify requirements.
   - Develop and maintain performance specs and verification protocols

2. Pre-qualify products and accredit test laboratories

3. Field validation
   - Generic protocol

3. Monitor products post-market and inform new requirements

Specifications working group
WHO GAVI UNICEF-SD PATH SELF CHAI

Dossier Review Committee

4. TPPs
   Timeline
TPPs for Enhanced SDD Refrigerators

- TPP process to signal new needs and get inputs.
- Existing PQS specs can be upgraded or enhanced,
- New categories can be communicated and then specified.
- It can inform procurers and funding agencies on new proposed devices attributes
Field Validation

• Only for new technologies
• Definition in protocol, but at discretion of PQS group
• Objective: get a minimum of experience before complete prequalification
• Min one month study
• Protocol to be adapted for each technology with PQS agreement.
• Implementation: facilitated by PQS and partners
Prequalified Products

264 products prequalified
From 54 manufacturers,
50% from China and India
Number of Products: x 5 since 2008

Repartition by category

- 32.5% RUPS syringes
- 20% refrigerators/freezers
E003 Repartition by Sub-categories

- 47 products from 8 Manufacturers; Solar 44.7%
PQS Partners' Supporting Projects

- Interest of the BMGF and other funding agencies
- Supply chain initiative with CCE working group
- WHO/UNICEF hub – work in line with country programmes
1. International transport

International shipping guidelines to be revised through VPPAG incorporating the work on barcoding and on packaging harmonization.
2. In-country transport: large distribution

- Initiated the establishment of a list of refrigerated truck qualified suppliers (GAVI)
- Revision of the protocol on temperature studies for route validation started WHO/UNICEF Hub and multi-partners' effort
3. In-country transport
   To provinces or large districts

- DRAFT Vaccine cold box freeze-prevention:
  WHO/PQS/E004/CB05.1

- Large capacity vaccine cold box:
  PQS performance specifications, 
  WHO/PQS/E004/ CB02.1

- No device prequalified as yet
4. In-country Transport: District & Health Facilities

- DRAFT Vaccine carrier freeze-prevention: WHO/PQS/E004/VC02.1
- No device prequalified as yet
- Various projects from UNICEF SD, CHAI and PATH are in progress
- Look at various options such as the use of gel-packs, protective sleeves and integrated protective layer.
- Will lead to a revision of specifications
Improved Freeze-Safe Vaccine Carriers

Technology solution in development by PATH

• Redesigning existing vaccine carriers to be freeze safe
• Even when used with non-conditioned ice packs, the freeze-safe carriers will protect vaccines from temperatures below 0°C
• Advantages of freeze-safe designs could include longer holdover times than carriers that use cool water packs
• Reduced training burden.
• Exploring the potential for the redesigned carriers to maintain competitive costs to current carriers.
Current status and results

• First lab results very promising
• PATH is now collaborating with equipment manufacturers to:
  – helping meet the latest WHO PQS freeze-protection specifications and
  – Further optimize the design of vaccine carriers that are low cost, durable, and freeze-safe.
  – process of transferring the technology to manufacturing partners to bring new freeze-safe vaccine carriers to market.
1. National stores

E001 category:
• Specifications and protocols extended to large capacity cold rooms and freezer rooms
• UNICEF SD project on field evaluation
• WHO/IVB/EPI guideline on temperature mapping
2. District Stores

- Use of ILRs and risk of vaccine freezing
- Use of inadequate AVR

- WHO/CHAI project
  - TPP and grading system
  - Conduct performance evaluation of selected refrigerators (Pennsylvania State University)
    - Propose (when relevant) any improvement to appliances

- Other CHAI project is looking at AVR's causes of failure to lead to revision of specifications
Equipping the Supply Chain

3. Health facility Vaccine Storage

- Learning experience from project from SELF in Columbia & other countries on SDDs
- Enhanced equipment through TPPs – drafts published on SDD & solar system
- First draft on SDD freezer to be released
- Guidelines on solar systems introduction at finalization stage in support to VMHB
- PATH/SELF Solar energy harvesting project

Add standalone freezing for SDD & Passive cooling
Selection of equipment

In average how many hours a day is power available?

0 to 3

- Use ice-lined refrigerator\(^*\) rated 4 hours electricity a day, or consider solar

Is solar service provider available or can one be established?

- Yes
  - Is solar direct-drive technology suitable?
    - Yes: Use solar direct-drive refrigerator
    - No: Use battery-powered solar refrigerator or refrigerator-freezer

- No: Use standard ice-lined refrigerator with/without freezing compartment\(^*\)

Is passive refrigeration technology suitable?

- Yes: Use long-term passive refrigeration device
- No: Consider liquid petroleum gas solutions

4 to 7

- Do power cuts of more than 20 hours occur?
  - Yes:
  - Do power cuts of more than 4 hours occur?
    - Yes: Use electric compressor refrigerator/freezer\(^\dagger\)
    - No: Use standard ice-lined refrigerator with/without freezing compartment\(^*\)
  - No: Use ice-lined refrigerator\(^*\) rated 4 hours electricity a day, or consider solar

8 to 20

21 to 24

\(^*\) With voltage regulator

\(^\dagger\) Do not use domestic refrigerators unless lab tested to PQS standards
4. Health Posts Vaccine Storage

- Arktek first long-term passive container prequalified
- Eventual solution for small health posts
- Need more field experience and field study underway by PATH in India
- Need recharge of conditioned waterpacks every month

This model not recommended for transport
4. **Temperature monitoring in the CC**

- Part of the WHO/UNICEF hub agenda
- CHAI leading that work for PQS

She had only one vapour thermometer
RTMS specifications and verification protocol

4. Temperature monitoring in the CC
   Remote vs locally centralized systems

Progress:
• Providing countries and manufacturers with greater guidance, e.g., segmentation for cold chain, hardware vs. software requirements.
• Non-restrictive to any particular kind of technology, i.e., encouraging innovation.
• Increasing the speed and decreasing the burden of PQS certification.

UNICEF workshop in Zanzibar:
• PQS Working Group at the workshop adopted a product design approach to identify usage conditions and product requirements.
• A segmentation approach was proposed, with some requirements varying across segments.
• Requirements were grouped into hardware and software categories.
TO ALL OF THOSE SUPPORTING THE PQS WORK

COUNTRY PROGRAMMES

PARTNERS & MANUFACTURERS

The first rule of any technology used in a business is that automation applied to an efficient operation will magnify the efficiency. The second is that automation applied to an inefficient operation will magnify the inefficiency.

Bill Gates