Specifications of steam sterilizers for health facilities with limited resources

Jan Huys

presented by: Dr. med. Andreas Mueller
Medical Mission Institute, Wuerzburg, Germany
„Appropriate Technology in the Health Sector“
Specifications of steam sterilizers for health facilities with limited resources

Modern healthcare has become dependent from advanced technology
Health facilities with limited resources

Typical District Hospital in Africa: Approx. 100 beds.
Catchment population: 100,000
With Out Patient Department, maternity, surgery, laboratory, radiology service and wards.

Reliable sterile supply is indispensable!
In industrialized world: Sterilization performed by advanced steam sterilizers

Sterilizers for medical use should meet functional, safety and technical standards resulting in high-tech equipment with stringent operational requirements:

- High quality supplies: Electricity, steam, water
- Adequate installation / commissioning
- Network of technical service and support
- Adequate infrastructure
- Adequately trained staff
- Financial resources

*Used technology embedded in industrialized societies*
Local context: Supplies / Infrastructure

**Electricity supply**
- Town supply; fluctuations (>20%); regular brown outs and black-outs
- Often: own (Diesel) generators: limited capacity; only few hours per day; high operational cost.
- Solar systems: limited power, high investment cost. Battery problems.

**Water supply**
- Town supply: regular cut off
- Often: only own borehole or well
- Poor quality: sediments, minerals
- Limited quantities; low pressure

**Access roads**
- Poor road network
- Long distances
- High transportation costs
Local context: Operational constraints

Operating Staff
- Limited Know-How due to limited training, brain drain, etc.
- No / limited budgets for training

Technical Support
- Virtual no technical support by suppliers due to too limited installed quantities
- High-tech components need to be imported, leading to long down-time
- Extremely high repair cost, especially in remote areas

Limited budgets
- Budgets available are a fraction of what is available in industrialized world
- Thus: influx of low cost, sub-standard, poorly performing equipment
- Donated equipment often does not function due to inappropriate technology, missing parts, consumables, high operational costs

Well trained operating staff and technicians is essential, but scarce!

Annual per capita expenditure on health care
Local context: Sterilizer acquisition

- Driven by new (western) standards: → procurement of high-tech equipment.
  - High-tech is embedded in high-income economies with all required resources.
  - Transfer of high-tech to low-income economies without considering the context is bound to fail.
  - Donor/procurement community tends to supply equipment meeting the standards, Often they have very limited know-how about actual conditions in the field.

- Driven by low cost: → procurement of cheap, substandard equipment
  - Poor performance
  - Poor safety

Both options result in poorly or non-performing equipment, frustration and waste of resources!

- Currently no adequate appropriate equipment available for this market

- Need for appropriate equipment. Introduction on market requires binding specifications for production and procurement.

Broken down high-tech sterilizers in regional hospitals.

Cheap, but poorly performing and poor quality sterilizers.
General objectives of the Specifications

- Improved patient care in target countries through better sterile supply and thus reduction of nosocomial diseases
- Satisfaction of users and management
- Improved use of funds in the health service. (Donors / MoH / Private)

Specific objectives in relation to sterile supply

- Ensure minimum performance and safety of sterilizers
- Provide approved specifications for manufacturing and procurement
- Facilitate fair competition among manufactures in this market segment
- Putting sustainable, appropriate equipment onto the market

Current status of implementation

- Text of concept Specifications available
- Gain support and then submit specifications to WHO and other stakeholders for approval and subsequent enforcement

Target area: low- lower middle income countries. A huge market!

Figures: GNI 1999; World Bank

Population per country

Figures: 2000 (millions); World Bank
Specifications: Key requirements

- Suitable for common hospital loads
- Processed load should meet international standards for sterility (EN556) and load dryness (EN285)
- Safe for operator according to international standards (pressure vessel; electrical systems)
- Manual control shall be possible, thus allowing for appropriate technology and designs independent of electricity
- Automatic systems should allow for manual control in case of breakdown of automatic controller or power failure
- Easy to repair and maintain. Majority of components can be produced / repaired locally
- Minimized consumption of water and energy
- Affordable

Processes shall be validated

Modern design methods and materials will result in optimized technology

Lid of a (US-built/UNICEF supplied!) steam sterilizer

Poor performance, poor construction and poor safety shall be eliminated
Prototype of sterilizer based on Specifications

- Validated process for instruments and porous loads
- Vacuum system by air-cooled external condensation vessel
  - Adequate drying
  - No moving parts
  - No cooling water
  - No electricity
- Cam disk control unit
  - Simple, single-knob operation
  - Mechanically operated valves by cam - disks
  - Manual control; possibility for automatic control
- Modular design:
  - For new sterilizers
  - Modules for reconditioning broken down sterilizers
- **Manufactures are invited!**
Conclusion

- Bringing sterilization equipment on the market suitable for countries of our colleagues overseas will make a great difference to the quality of sterile supply!
- Adequate, binding sterilizer specifications are a crucial tool to facilitate this.
- This can be realized by your support!