Specifications of steam sterilizers for health facilities with limited resources

Jan Huys

presented by: Dr. med. Andreas Mueller
Medical Mission Institute, Wuerzburg, Germany
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health facilities with

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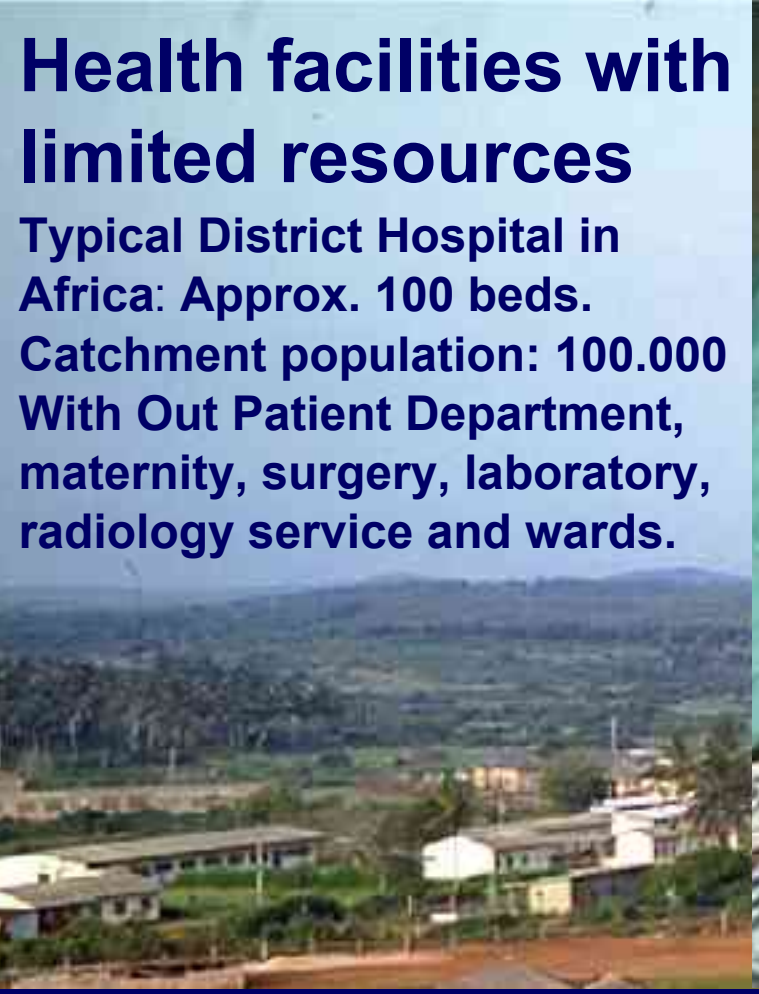
Modern healthcare has become dependent from advanced technology

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

Diesel power plant

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.

Solar power for a clinic

Water storage tanks

Water supply

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

Water from well

Long distances

Access roads

- Poor road network
- Long distances
- High transportation costs

Poor road net work

Local context: Operational constraints

Operating Staff

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

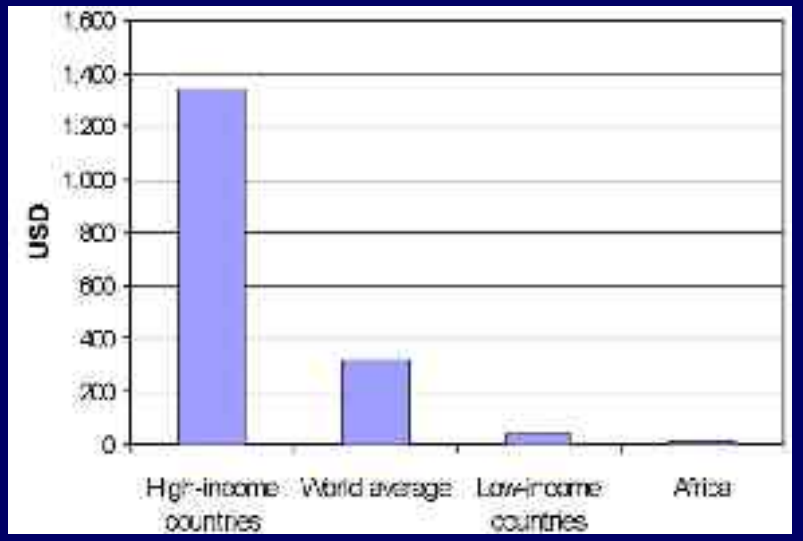
Technical Support

- 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 equiment
- 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

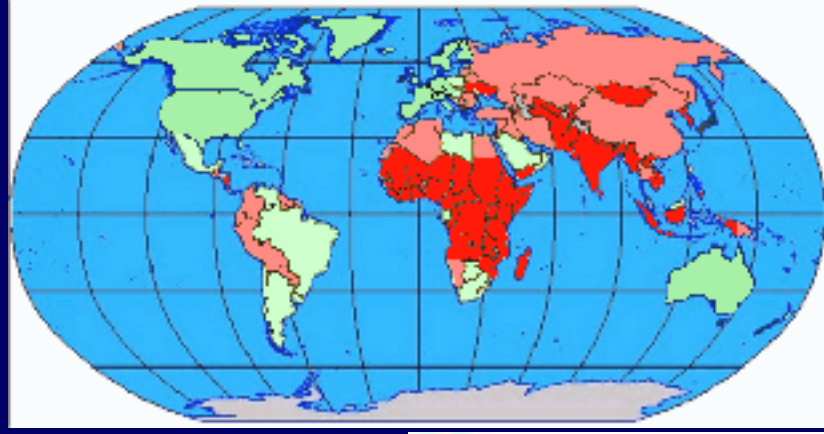
- Improved patient care in target countries through better sterile supply and thus reduction of nosocomial diseases
- Satisfaction of users and management
- Improved use of funds in the health service. (Donors / MoH / Private)

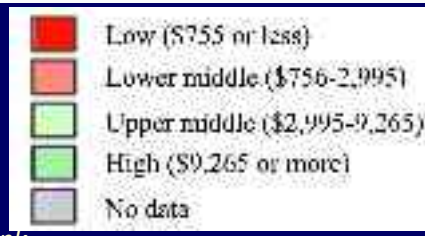
Specific objectives in relation to sterile supply

- 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

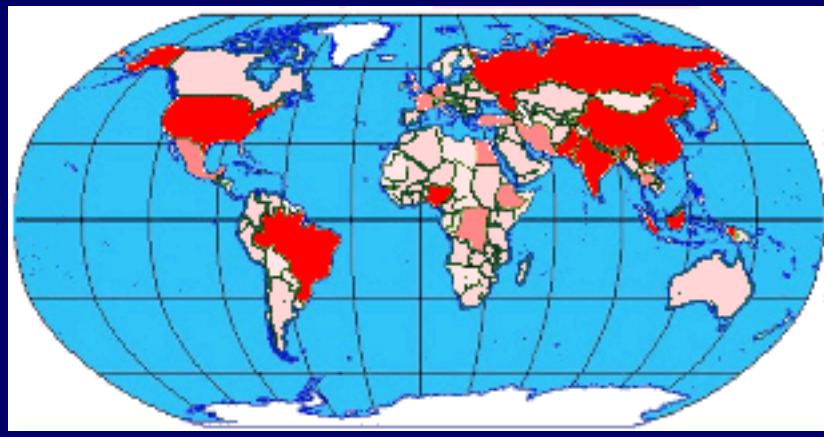
- Text of concept Specifications available
- Gain support and then submit specifications to WHO and other steakholders for approval and subsequent enforcement





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

Figures: GNI 1999; World Bank

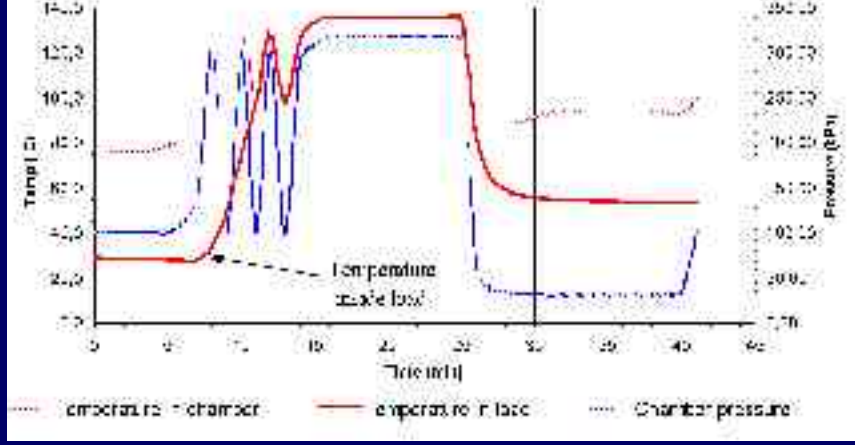


Population per country

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 inter-national 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

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

Poor performance, poor construction and poor safety shall be eliminated

Modern design methods and materials will result in optimized technology

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 by cam - disks
  - Manual control; possibility for automatic control
- Modular design:
  - For new sterilizers
  - Modules for reconditioning broken down sterilizers
- **Manufactures are invited!**

Prototype of sterilizer based on Specifications

Cam - disk operated control unit

Conclusion

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