



 **Facing the standards gap**

Focus on sterilization of medical supplies in developing world

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 **Facing the standards gap**

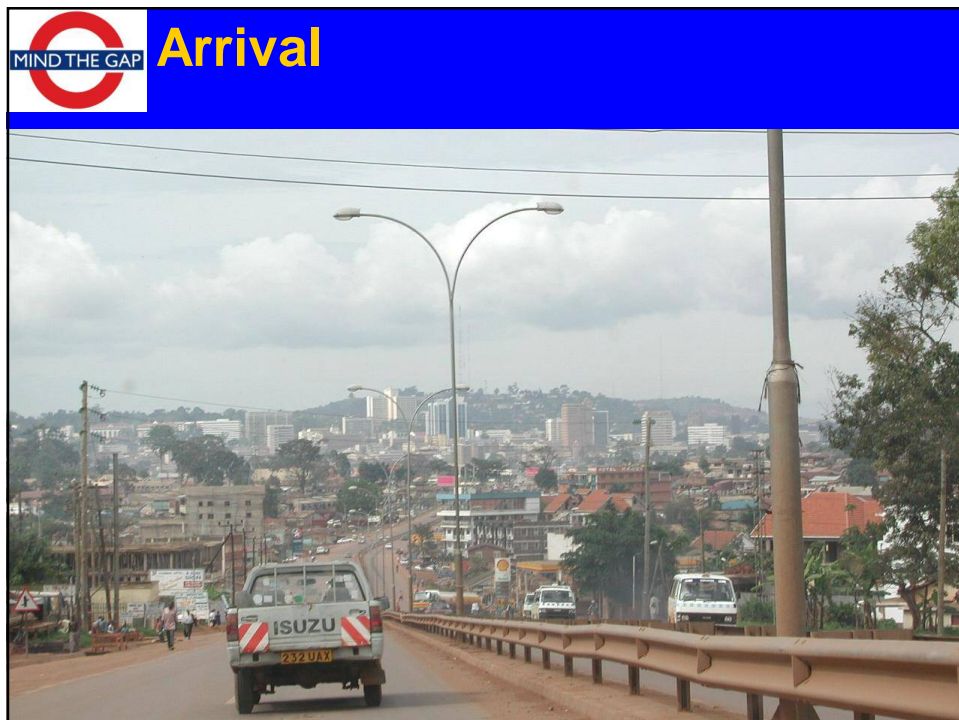
- Technology in health care
- Focus on sterile supply
- Local reality/constraints
- Situation analysis: sample cases
- Objectives of standards
- Problems caused by standards
- Bridging the gap:
Toward a solution
- Concept for sterile supply

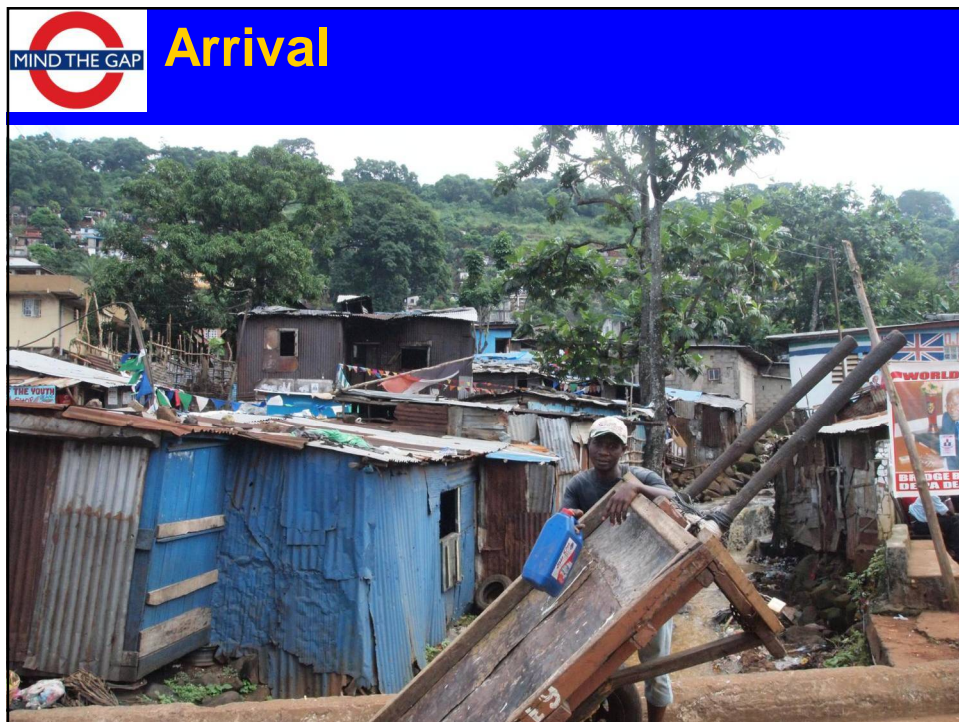














MIND THE GAP

Local context: Constraints of Supplies/Infrastructure

Electricity supply

Water supply

Access roads

The collage consists of four photographs. Top left: A green generator with a 'Lister' logo. Top right: A person standing next to a blue water pump. Bottom left: A white van with 'MOTHERS BLESS' on the side, stuck in a muddy, rutted road. Bottom right: A person holding a blue bucket next to a water pump.

15

MIND THE GAP

Local context: Operational constraints

Operating Staff

Technical Support

Limited budgets

Medical technology is embedded in industrialized societies

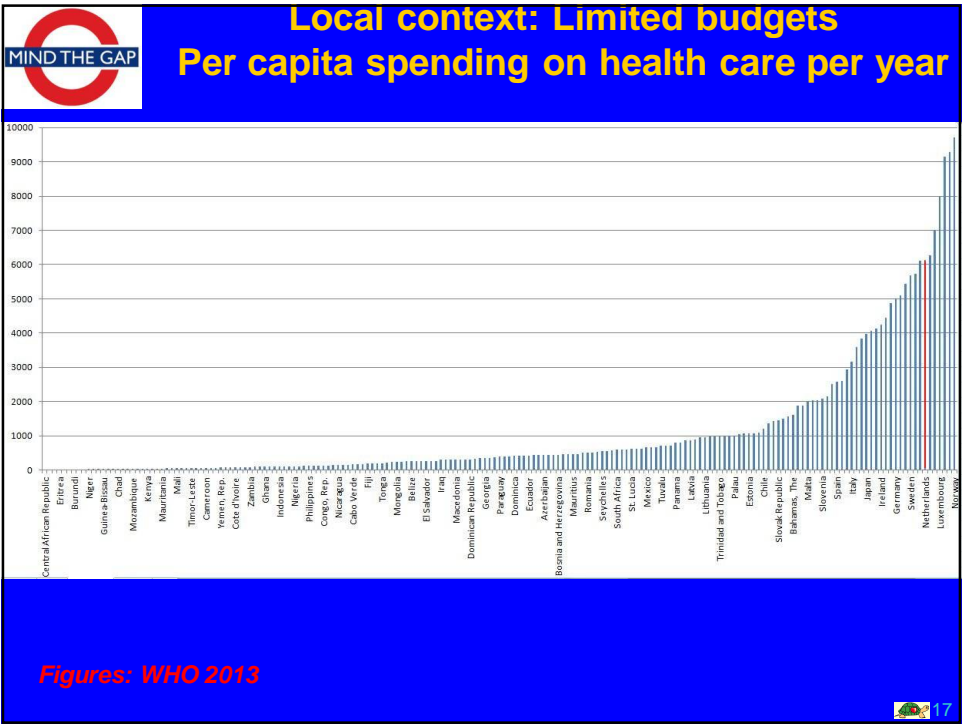
Well trained operating staff and technicians is essential, but scarce!

The bar chart displays the annual per capita expenditure on health care in USD. The y-axis ranges from 0 to 1,600 USD. The x-axis categories are High-income countries, World average, Low-income countries, and Africa. The bars show that high-income countries have the highest expenditure, followed by the world average, low-income countries, and Africa.

Category	Annual per capita expenditure on health care (USD)
High-income countries	~1,300
World average	~350
Low-income countries	~100
Africa	~50

Annual per capita expenditure on health care

16



MIND THE GAP

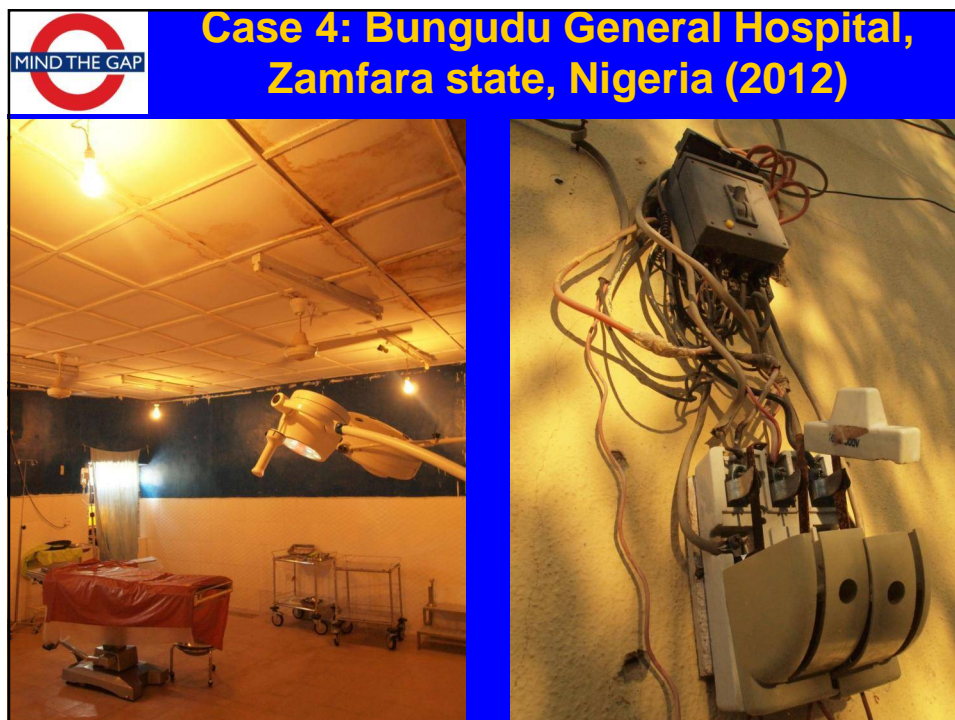
Case 1: CMA de Kossodo, Ouagadougou, Burkina Faso. (2005)

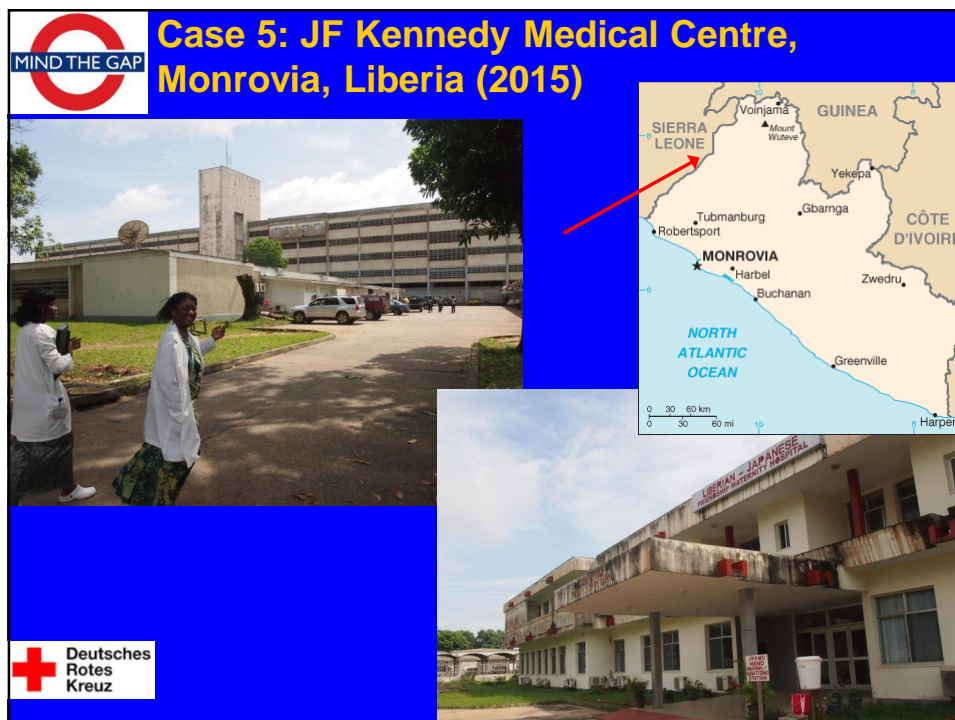
The collage consists of four main images: a map of Burkina Faso in the top right corner showing the location of Ouagadougou; a photograph of the hospital entrance in the middle left; a photograph of a group of people, including a man in a white shirt, in the bottom left; and a photograph of a motorcycle parked outside the hospital in the bottom right.

















MIND THE GAP

Local context: Sterilizer acquisition

☐ Driven by low cost: → procurement of cheap, substandard equipment

- Poor performance
- Poor safety



Cheap, but poorly performing and poor quality sterilizers

34

MIND THE GAP

Local context: Sterilizer acquisition

- ❑ Driven by (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. Very limited know-how about actual conditions in the field
- ❑ **Standards thus may lead to non functioning equipment**





Broken down high-tech sterilizers in regional hospitals.

35

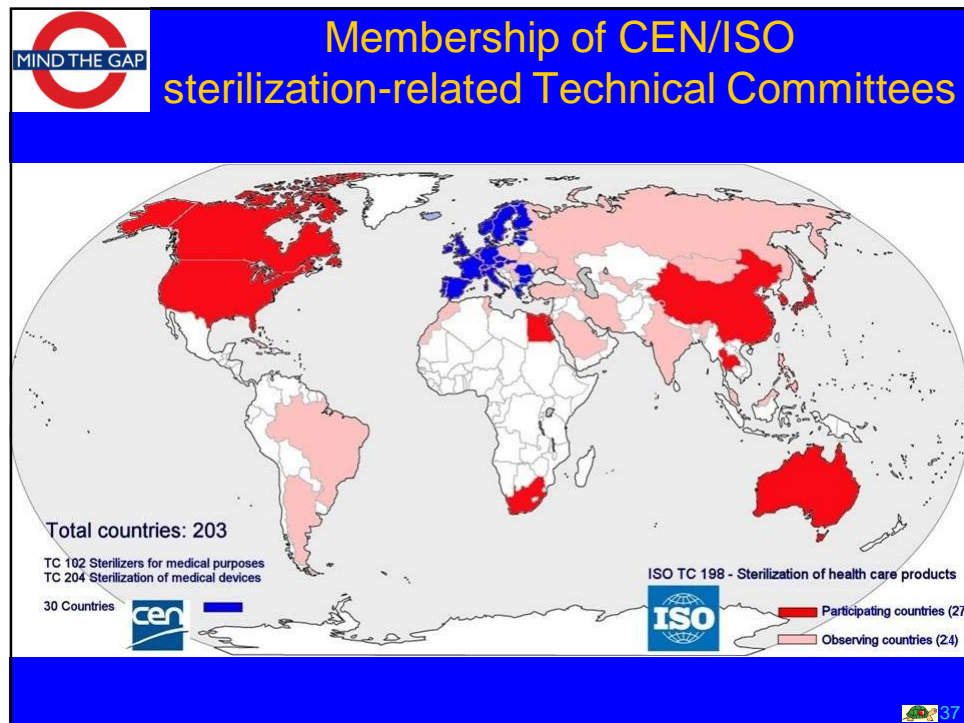
MIND THE GAP

International standards for sterilization Objectives




- Ensure safety and health of the users and patients
- Ensure minimum standards of quality
- Facilitate interchangeability of products and services between nations: reduce trade-barriers
- Legal requirements: responsibility: traceability


36



MIND THE GAP

The current standards result in

- High performance automatic sterilizers; human intervention is ruled out
- Require advanced technology
- Requires advanced infrastructure, support and thus: money.



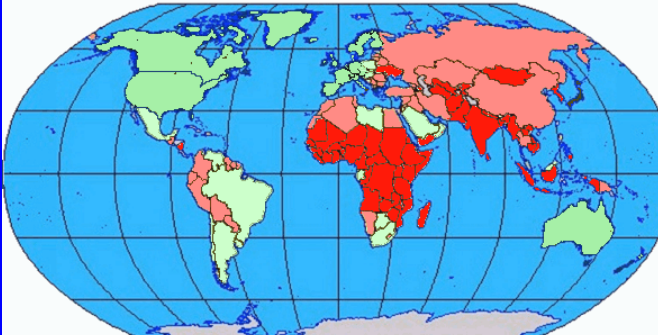
MIND THE GAP

Situation in developing countries

- Majority of world population (6.9 billion) lives in low/middle income countries (approx 4 billion)
- Health authorities seek to follow developments
- Eager to improve situation
- Want guidance to improve
- Want to use of international standards as reference

Total: 6.9 billion
Low/medium income:
4 billion

Low (\$755 or less)
Lower middle (\$756-2,995)
Upper middle (\$2,995-9,265)
High (\$9,265 or more)
No data





MIND THE GAP

Bridging the standards gap

Case: sterilization of medical supplies



FILL THE GAP

- Consider local economy:
Compatible with socio-economic background
- Facilitate that developing countries become members of standards committees
- Identify relevant standards:
e.g. No concessions to ISO/CEN standard for sterility of products (CEN/ISO 554)
- Interim solution: Provide binding guidelines for emerging markets through authoritative bodies such as WHO, Red Cross, MSF





Total countries: 203

TC 152 Sterilizers for medical purposes
TC 204 Sterilization of medical devices

ISO TC 158 - Sterilization of health care products

30 Countries

Participating countries (2)

Observing countries (2)



Bridging the standards gap


Case: sterilization of medical supplies

- Validation of all steps of reprocessing cycle
- Introduce quality assurance
- Development of products appropriate for this (huge) market based on guidelines
- Education/Training at all levels







Conclusions/observations

- ☐ World wide standards should be world wide!
- ☐ Developing countries want to develop!
- ☐ Need of appropriate equipment that meets essential functional requirements and local conditions
- ☐ Role for standards organizations ISO and CEN; WHO
- ☐ Instability in many regions increases demands for appropriate equipment

