

# Standards for Sterile Supply in low-income countries:

## In search for an appropriate concept

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Sterilization of medical supplies plays a key role in the battle against the advance of many infectious diseases. In order to improve the quality of sterile supply, international standards have been developed which provide the requirements for the, equipment and procedures in the sterilization departments in health facilities. These guidelines have been conceived in the industrialized world, and assume a strong economy as a background for implementation of these standards. However simply transferring such standards to low-income countries is bound to fail and may even work against improvement of quality. There is a need for a concept for high-quality sterile supply, which is sustainable in low-income countries, with however minimal concessions to safety of patients and staff.

### High-tech or trouble-tech

In the past years the author has been visiting many health facilities in the African continent and in several of them the sterilization department was arranged and equipped according to the latest standards of sterilization. Advanced and expensive steam sterilizers (autoclaves) were found broken down for years due to lack of spare parts, unreliable electricity supply, problems with the steam supply or lacking know-how. Because of the breakdowns, the machines quickly become a great financial burden and drain the already so limited hospital budget. In the end, usually the high-tech machines are abandoned and replaced by basic hand-operated or semi-automatic autoclaves. The hospital would have saved great amounts of money, disappointment and frustration, when from the start it directly had been equipped with a technology feasible in the context of the country.

### The financial gap

The per capita expenditures on health care greatly varies throughout the countries of the world. The average for high-income countries, such as Western Europe and North America are in the order of USD 1300, whereas the average in Sub-Saharan Africa is below USD 10. A difference of a factor of more than 130! An example illustrates this gap:

Equipping a sterilization department for a moderate size hospital (200-300 beds), according to the latest international standards requires an investment which can also finance all medical equipment and furniture for the essential services of a complete similar size district hospital in a low-income country according to guidelines as formulated by the World Bank.

At the same time, when observing the world population, the picture looks different: Of the total expenditures for health care, 90% is spent in the high-income countries.

Whereas almost 80% of the earth population lives in low-income countries! The standards as formulated are developed by the industrialized nations and designed to the living standards and socio-economic standard prevailing in these countries. Knowing that a majority of the world's population is concerned, it is of utmost importance to consider what the consequences are, when implementing such standards in low-income countries. How feasible is it that they are implemented successfully and are they sustainable on the long term?

It therefore is necessary to reconsider the implementation of international standards. The essential issues, which are the core requirements, should be taken over but implementation of certain technological solutions, which are recommended need careful reconsideration taking the local situation into account.

### Towards a new concept

A number of basic principles of the international standards for sterile supply should remain in place such as:

- The standard definition of what is considered as sterile
- Quality assurance of all steps in the chain of sterile supply

In order to meet these basic principles, technological requirements for sterilizers have been defined; such as the need for an automatic control system of the sterilizers. Based on state-of-the-art technology, this results in sterilizers with computer controlled processes, with advanced electronics, electro-magnetic/pneumatic valves and control systems, etc. Moreover this technology requires a complete infra structure to support it such as high-quality water and electricity supply, trained technical personnel, manufacturer support with spares and supplies etc. Not to speak of an adequate telecommunications network and good access roads for safe and quick delivery of all the supplies and services.

Thus implementation of the standards implies investment in expensive equipment and services. However it is not feasible to impose such requirements in counties, which have no means to finance the implementation and long term enforcement of such standards. It is even dangerous, as it may drain the meager resources required in other essential fields within the health system. It is necessary to find a balance between what is desirable and which is feasible within the financial constraints of a country.

The following example shows that there are possibilities for improving prevailing procedures and standards considerably even with basic technology and still keeping costs down.

## Hand operated sterilizers: Drastic improvement is possible

In many rural health facilities manually operated or semi-automatic steam sterilizers are commonly used. With the limited resources available, only the use of such models has proven to be sustainable.

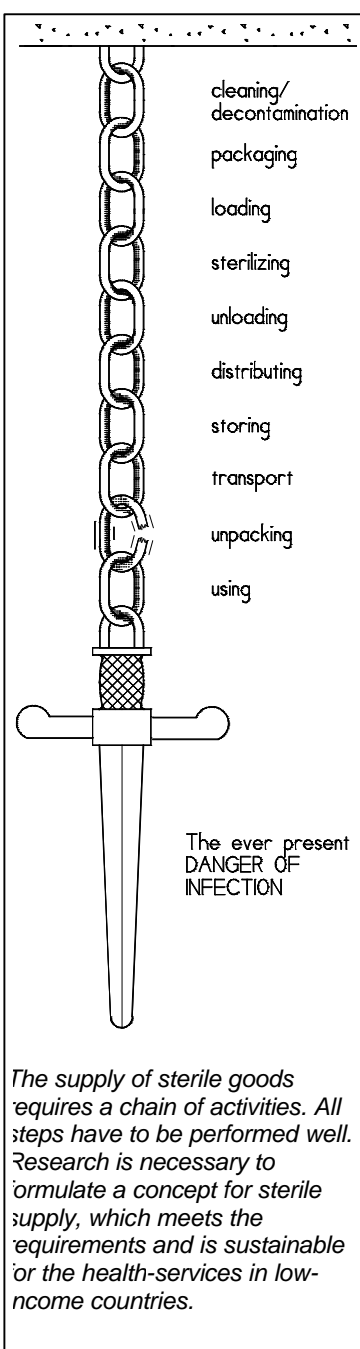
Measurements in autoclaves as used in local hospitals were conducted during a course for hospital technicians at the end of 1997 at the Mombasa Polytechnic in Kenya. The measurements proved that especially for porous loads such as drapes and gowns, the performance of the processes used is not sufficient for producing safe sterile products. Temperatures of only 70-80°C were measured in the centre of textile packs, where 121°C-134°C is required.

Poor sterilization practices may be one of the hidden causes for many hospital-acquired infections, which

could not be traced.

Poor air-removal and thus poor steam penetration is the reason of the bad performance.

For porous loads the air-removal, and thus the performance of the sterilization process, can be considerably improved by performing steam pulses before the actual sterilization phase starts. Steam pulsing, a technique where steam is released and admitted again by short pulses, is a well-known method of stimulating air-removal. It is a standard procedure in processes of automatic sterilizers for porous loads. It however is a procedure, forgotten to be applied in the operation of hand-operated autoclaves. The pulses can be easily performed by opening and closing of the appropriate valve(s) of the sterilizer and result in drastically improved performance. Thus, by simply changing the operating procedures, significant improvement of the



performance of sterilization processes can be realized, also in very basic, pressure cooker-type autoclaves.

## Research needed

In the same way as the performance of the sterilization process can be improved, also the other steps in the sterile supply cycle may be apt for cost-effective improvements. The steps to be looked into should comprise all links of sterile supply: from instrument transport systems, cleaning, disinfection, packaging, loading, sterilizing upto sterile storage and distribution. Research in each of the steps can result in an appropriate overall concept. Such research should follow a number of guidelines:

- Any measures to improve sterile supply should be compatible with the socio-economic background of the country where the concept is to be implemented
- The quality of each step in the reprocessing cycle of sterile goods should be ensured through an adequate Quality Assurance system.
- A people-oriented rather than technology oriented approach: standards developed in the industrialized world, tend to solve problems through technology. However through protocols and adequate training programmes, good results could be achieved with a technology level, sustainable in low-income country.
- Products should be developed which meet the specific needs of this market. The equipment should be designed to withstand the tropical climate, consider presence of poor quality of water and electricity supply; should survive rough handling and shipping over poor roads etc. Also the use of solar energy for sterilization should get more attention.
- Priority on training. Through the more people oriented approach, an adequate training programme is essential at all levels: management, users and technical personnel.

## A new research programme

In order to make a start to the formulation of this concept, a research programme is starting in the first quarter of this year and initially is planned for a period of half a year. Anybody interested or wanting to participate or contribute to the programme is invited to contact the author.

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Further Reading:

Huys JFMM. *Sterilization of Medical Supplies by Steam*

Vol. 1: *General theory*. HEART Consultancy, Wageningen, The Netherlands (1996)