

THE DESIGN OF MEDICAL EQUIPMENT FOR LOW INCOME COUNTRIES (*Dual Standards or Common Sense*)

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Keywords: International standards, Medical Devices, Low income countries.

Abstract

Medical equipment is usually designed to operate in a relatively constant environment, with stable, controlled temperatures and humidity, dust and insect free conditions, uninterrupted electrical supply and unlimited medical consumables. This ideal environment also includes expert users, advanced technical support and reserve equipment capacity. Change these basic fundamental conditions, for example as in low income countries, and the design process does not need modification – it needs to be turned upside down. In addition to the engineering challenges, equipment design needs to take account of international standards. One complication is that the requirements of international legislative and regulatory authorities invariably insist on standards written for an ivory tower medical environment, but which are far removed from what is actually needed in the average low income country. This paper deliberately leaves open a number of important questions in order to provoke debate.

1. Introduction

Over the last decade there have been numerous reports identifying the mismatch between the medical equipment needs in low income countries and the medical equipment being provided for those areas. One of the more recent reports published by the World Health Organisation is entitled *Medical Devices - Managing the Mismatch*¹. This report states that up to 75% of medical equipment supplied to these areas fails to function, citing inappropriate design as a major contributing factor. These statistics will come as no surprise to those who have travelled to, and worked in, hospitals in low income countries and it is a statistic that has been repeated in reports over several years. The only surprising factor is that it never improves. If appropriate equipment was provided to the same value as the non-functioning equipment, then the progress towards meeting many of the health targets set by the Millennium Development Goals would take a huge leap forward.

Why has this scandalous issue not been resolved?
What are the constraining factors to resolving this issue?

The ‘Managing the Mismatch’ report highlighted a number of barriers to choosing appropriate medical devices including

fascination with technology, aggressive marketing, and inadequate information about the device. This last point is often circumvented by those in aid organisations tasked with providing technical specifications, relying on the latest international standards as a misplaced guide to appropriate equipment. In addition the international tendering process for medical equipment itself does not always provide value for money. Some years ago a paper by Dr P Hougbo² from Benin was presented at this conference stating that the cost of medical equipment increased up to six times when purchased through these processes.

2. The Cry of Double Standards

Surely the goal should be to provide the same technologically advanced equipment to low income countries as the more developed countries use. I would agree, as soon as those low income countries have the same transport conditions and infrastructure, stable electrical supplies, compatible levels of medical and technical support, access to consumables and available funds as more developed countries. They will of course also require environmentally controlled hospitals maintaining appropriate levels of temperature and humidity. These are not conditions that will exist for many decades for the majority of the world’s population.

In the interim these countries do not just require equipment as good as that used in more developed countries, they require something better, in that it not only needs to function safely, it needs to do so in the challenging conditions frequently found in these less developed countries, and it needs to do so in an economically sustainable way.

How many of those who object to situation specific standards have a vested interest in maintaining the status quo?

3. Regulation: Help or Constraint

If we look at the tender requirements issued by the same bodies that identify the supply of inappropriate medical equipment we find that insistence on equipment that is CE marked is the most common. So let us examine what this means, as it is often misunderstood. Many claim the CE mark as recognition of the safety or quality of a product. The European Commission specifically states that it is not. ‘CE marking is not a European safety mark or quality symbol. Its purpose is to indicate to enforcement authorities that the

product is intended for sale in the European Economic Area’.

Is a product designed for use in the EEA suitable for an environment unlikely to be experienced in Sub Saharan Africa?

For anaesthetic equipment a new international standard specifically written for environments such as those found in many low income countries was published last year (ISO 8835-7). Whilst it is very encouraging that these ‘special circumstance’ issues have been considered, there is now the slightly bizarre situation where a manufacturer can CE mark a product for use in the EEA to a standard specifically aimed at situations that do not exist in that area. This provides manufacturers of anaesthetic equipment developed for low income and emergency situations with a dilemma; do they design products to meet the parameters of a standard that does not apply or do they apply a more loose interpretation of the standards in order to supply more appropriate products for the environment? The result is often an unsatisfactory compromise resulting in a hybrid that claims to meet the requirements of both worlds but does not quite satisfy either situation.

4. Environmental conditions and Standards Provision

The environment in many areas of the world would be classed as extreme by those in America and Europe, but temperatures above 40°C and humidity above 95% are often the norm in low income countries, yet how many international standards refer to those parameters in the testing regimes that they lay down. One of the few standards that does refer to such environmental conditions is ISO 8359:2009 ‘Oxygen Concentrators for Medical Use’. These machines are now common in many areas such as Sub Saharan Africa and all show a CE mark claiming compliance to the appropriate standard. However when independently tested few oxygen concentrators actually meet the requirements laid down in ISO 8359. The international standard for anaesthetic workstations ISO 80601-2-13 does provide wider voltage parameters for ‘Emergency Anaesthetic Workstations’ (+15% - 20% from nominal voltage) and increased frequency variation ($\leq 5\text{Hz}$).

Is this electrical power variation adequate for Low income countries?

Figure 1 and Figure 2 below show mains electricity in Afghanistan and generator electrical power in Uganda.



Figure 1.

These examples are not unique or at the extreme of situations found in the majority of low income settings. If equipment cannot cope with these situations it is morally wrong to specify it or supply it, yet few standards even recognise it. Those that do often require the equipment to shut down when it is encountered, the so called ‘fail safe’ position. This may be acceptable when an alternative piece of equipment is available but this is unlikely to be the case in areas that are resource poor.

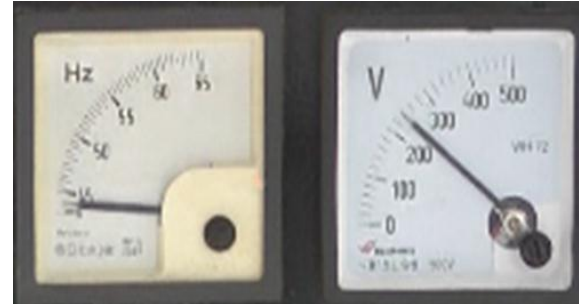


Figure 2. 250 volts at 43Hz

The above assumes that electrical power is available at all times, but in many areas power outages are not only common but often prolonged. Figure 3 shows Outages and reconnection delay averages by country³. Is this situation considered by those drafting international standards or by those specifying international standards and legislative requirements when issuing tenders for medical equipment?

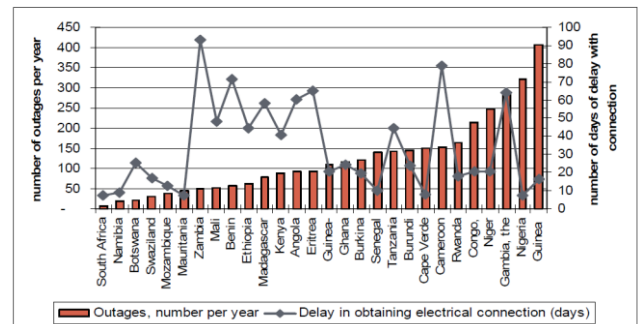


Figure 3. Outages and reconnection delays by country

Medical electrical equipment that does not incorporate voltage stabilisation and battery back up support should not be considered for low income settings.

5. Initial Cost and Running Costs

Over the last decade ‘reuse’ and ‘recycling’ have become watchwords for design engineers in every field with the exception of the medical sector. In that sector the opposite has prevailed and those words have been supplanted with ‘single use’ and ‘disposable’ under the major drive for patient safety. This has taken the sector away from any culture of thrift even where it would not impact on patient safety issues.

In a low income setting, single use and disposable items are repeatedly used as replacement costs are beyond the available budgets. Repair and reuse of components and

consumables will, by necessity, be the norm for many years to come (Figure 4).

Obviously in these situations cross contamination is a concern sometimes compounded by the lack of available facilities for adequate cleaning and sterilisation. Again, it is important to a) understand the situation on the ground, and b) only provide equipment that can be adequately cleaned with the facilities available (figure 5).



Figure 4. Repair and Reuse



Fig 5. Pressure steriliser

6. Case Example

The majority of anaesthetic workstations and ventilators require large quantities of compressed gases to function. Compressed medical oxygen, nitrous oxide and air, delivered in bulk and supplied through hospital pipeline systems, are hardly acknowledged in many developed countries as being a cost. However in a low income country hospital they may be the largest single cost⁴, with the exception of salaries. The majority of medical gases supplied to these areas are in cylinders that are transported great distances. Their supply may be intermittent or often not available at all. Nitrous Oxide, the use of which in western hospitals has been in decline is in particular beyond the budget of most locations even when it is available.

n = 91	Always	Sometimes	Never	Don't know
Adrenaline	68 (74%)	17 (18%)	3 (3%)	3
Ephedrine / metaraminol / phenylephrine	41 (45%)	20 (21%)	26 (28%)	4
Spinal local anaesthetic	36 (39%)	26 (28%)	28 (30%)	1
Local anaesthetics for blocks	64 (70%)	17 (18%)	7 (7%)	3
Magnesium	18 (19%)	35 (38%)	36 (39%)	2
Hydralazine	28 (30%)	31 (34%)	28 (30%)	4
Diazepam	74 (81%)	16 (17%)	0 (0%)	1
Labetalol	27 (29%)	27 (29%)	28 (30%)	9
Oxytocin	52 (57%)	29 (31%)	7 (7%)	3
Ergometrine	74 (81%)	13 (14%)	1 (1%)	3
Oxygen	58 (63%)	23 (25%)	10 (10%)	0
Intravenous fluid	62 (68%)	25 (27%)	2 (2%)	0
Nitrous oxide	0 (0%)	3 (3%)	84 (92%)	4
Blood for transfusion	21 (23%)	54 (59%)	15 (16%)	1

Fig 6 Medical gas availability in 91 Hospitals in Uganda⁵

Oxygen always available in less than 60% of hospitals and Nitrous Oxide available sometimes in only 3% of hospitals.

Why is medical gas availability often not considered when specifying anaesthetic equipment for a remote location?

Why is the cost of medical gas provision not included when evaluating the sustainability of equipment? Why do the procurement departments of aid organisations and of international donors still persist in specifying equipment that

is reliant on expensive and often unavailable gases when alternatives have been available for over ten years⁶?

7. Operator Skills and Maintenance

Under section one of the General Requirements of the Essential Requirements (Annex 1) of the European Medical Devices Directive there is the following statement:

The device must be manufactured in such a way that, when used under the conditions and for the purposes intended, it will not compromise the clinical condition or the safety of patients. This shall include:

- i. reducing, as far as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and
- ii. consideration of the technical knowledge, experience, education and training and where applicable the medical and physical conditions of intended users, (design for lay, professional, or other users).

Is it possible for equipment not designed to function in the prevailing conditions found in a low income country setting to comply with this statement?

There is some recent good news, the World Federation of Societies of Anaesthesiologists (WFSA) has recently published a performance standard for anaesthetic equipment suitable for provision to low income countries.

WFSA Performance standard requirements:

Electrical supply

1. The equipment must function normally in spite of mains fluctuations of 15% above or 20% below nominal mains rating.
2. The equipment must remain safe and usable in face of a complete power outage of at least 90 minutes

Oxygen supply

1. Where a cylinder or pipeline system is in use, the equipment must detect and signal impending failure, using a system not dependent on mains electricity.
2. When the oxygen supply fails, it must be possible to continue a safe anaesthetic, including IPPV.
3. Must be able to supply room air to the patient in the event of failure of compressed gas supply.
4. If any gases other than oxygen and are supplied, there must be a monitor of inspired oxygen.
5. There must be the means of supplying high oxygen flows (flush) in emergency.
6. It must be possible to ventilate the lungs manually; if a mechanical lung ventilator is fitted, it must have disconnect and high pressure alarms.

Physical environment

1. The equipment must function normally between temperatures of 10° and 45° Celsius, and Relative Humidity of 0-100%.

All of which is technically feasible but unless the funding bodies specifying the technical requirements of anaesthetic

equipment for aid organisations refer to this new standard, there is a danger that most manufacturers may ignore it.

Perhaps this could lead the way for other professional bodies to take the initiative in specifying equipment requirements, rather than leaving those requirements to be specified by large equipment manufacturers, who form the majority membership of international standards committees.

The numbers of skilled medical professionals in many countries results in less qualified personnel operating medical equipment. With more complex equipment it is not until the device is in widespread use by less trained practitioners and on a broader population of patients that adverse effects not apparent prior to supply can show up.

Maintenance of medical equipment is also of great concern in these settings, biomedical engineers and technicians are very few and are generally under resourced. In addition because of the variety of equipment supplied by uncoordinated agencies they have a much wider range of equipment to deal with when compared to an average western hospital. There will also be less support from manufacturers and they are unlikely to have access to budgets for spare parts, in short if something fails they are unlikely to be able to repair it.

8. Conclusions

Low income countries have the least resources, both financial and human, and the greatest need for reliable medical equipment. In addition Low income countries often have the harshest physical environments, and least infrastructure.

International standards do not always reflect the requirements of the less developed areas of the world and providing high technology solutions to areas with limited infrastructure has been shown not to work.

There needs to be a much greater understanding of the medical equipment needs and constraints of Low income countries amongst international bodies. Engineering solutions must take account of operating condition, available operator skills and cost constraints of medical product needs in low income settings.

In the poorer countries of the developing world standard anaesthetic equipment may be unsatisfactory as it is unable to cope with the additional difficulties encountered there. These include the lack of medical gases, electricity, engineering support and lack of funds for maintenance, repair and running costs.

More robust equipment such as the Glostavent[®] has over the last decade proven to overcome these problems and a safe anaesthesia to be delivered at a fraction of the cost.

It is no longer satisfactory for safety regulations designed for wealthy countries to be applied to poorer countries where higher performances are required and it is certainly not acceptable for conditions to be laid down by those with vested interests in maintaining the status quo.

The WFSA has taken on the role to 'make available the highest standards of anaesthesia for all peoples of the world'. The time was surely due for an independent and authoritative body such as the WFSA to make its view known and issue the guidelines on minimum standards of anaesthetic equipment.

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