

**[1]** Medical equipment technology is a field in which innovation is most often impacted on significantly by socio cultural factors. These include things like economic, social, environmental, political, cultural and even spiritual influences.

Economics is the driving force in many new developments. The cost of medical equipment is closely tied to the way it is used and often limits who can benefit from its use. Some equipment is prohibitively costly and so has a very small niche market. If production costs can be reduced, without affecting the performance of the equipment, prices can be reduced and the market potential for the product significantly increased. With some equipment, like heart rate monitors, use of new electronics technology has allowed costs to be reduced to a low enough point for the device to be able to be bought for individual everyday use.

Where the medical equipment is going to be used and who is going to operate the device is also critical in the way products are developed. Equipment like the critical care bed is only designed for hospital use by trained staff whereas the Acuset IV flow controller was designed to be used by non-trained people in any environment.



Political decisions can also influence the way equipment is developed. Codes of practice and equipment standards are introduced by governments as a protection for consumers. This can impose limitations which will put some companies off investing in new equipment research and development. Governments can also impose import restrictions and duties which penalise potential importers of equipment. This can make new product development less attractive and restrict improvements in technology.



Social issues will also impact significantly on developments in medical equipment technology. Low cost infant incubators are now more readily available in developing countries to try to lower the unacceptably high death rate of newly born babies.

In an international market place cultural differences will invariably impact on the way a medical product is viewed and used. If a product is to be effectively used in the way that is intended then cultural influences need to be clearly identified and addressed in the development process.

**[2]** In medical equipment technology as in all technological development there will be competing priorities which can come into play in all aspects of the development work.

This competition often surfaces at the point of fixing on the specific need or opportunity to be addressed. The driving force for the initial development may be a social one such as addressing the problem of over four million infant deaths annually within a month of birth, but if this is being addressed by a large commercial organisation then the interests of the shareholders will be a significant consideration with the project usually having to not only cover costs but end up making money for the company. This can stall some potential developments right at the beginning but even if they go ahead then competing priorities will force decisions to be made throughout the development process.

The drive for new development like the critical care bed may be the need to improve the performance of a particular device where the views of a range of stakeholders may have to be taken into consideration and the improvements required may be seen differently. In the case of a product to be used in a hospital situation the patients, doctors, nursing staff and relatives will all agree on the overall purpose of using the equipment – improved patient care in a way that makes things easier for everyone else, however their prioritising of desired attributes in the new product may well be different.

In the design process both form and function will be important - however their eventual weighting will have to be determined in the specifications developed. The equipment has to be able to do what it is intended to do but ideally this has to be able to be done in the most user friendly way. In the case of the infant incubator the equipment had to be able to effectively address the immediate needs of at risk babies and also to reduce the risk of cross infection but equally importantly be able to allow easy access to the babies by both staff and caregivers. The M8 Intensive care bed was developed to allow the wide range of medical procedures needed during critical care to be carried out without having to transfer the patient from the bed. By lowering the handling required by staff the discomfort felt by patients would be significantly reduced. In developing a solution that met the needs of the diverse range of stakeholders in a practical, innovative and intuitive manner, social factors such as the increasing average age of nurses, and higher patient weights interacted with regulatory issues such as more demanding occupational health and safety legislation and institutional priorities including the need to work towards greater workplace productivity.

The selection of resources to be used can also raise issues. Material choices will most often be made to match material properties and costs to the desired performance requirements of the equipment being developed. In the hospital environment this choice often hinges on sterility and durability issues. However when the equipment is designed to be used in more remote requirement the ability to be easily transported, assembled and serviced may be equally important. In this environment lifecycle issues may also be a strong consideration with the ability of parts or all of the equipment to be reused or recycled a desirable attribute.

How the product is ultimately manufactured may also be influenced by competing priorities. Some products such as artificial limbs may require significant individual customisation whereas devices such as the Acuset IV flow controller has the potential to be manufactured cheaply in bulk. Where bulk manufacturing is selected issues around selection of the manufacturing site, efficient use of resources, material sustainability and ensuring the health and safety of workers will require efficient management and inevitably involve resolving competing economic, social and environmental priorities.

[3] The need for the development of the Acuset Intravenous (IV) Flow Controller was established from observing that in developing countries medicines were still being administered intravenously (IV) using nineteenth century medical technology. Because present day drugs are delivered in a more concentrated form the need for accuracy is even more vital now. In a hospital situation in developed countries this medical procedure is most often carried out using microprocessor controlled syringe pumps by trained medical staff. In under developed counties this procedure often has to be carried out in the field by non-trained staff or by the patients themselves or close family members using roller clamp devices. Although these roller clamps are cheap to manufacture they can be inaccurate and difficult to control with the result that many patients end up not surviving when they should have.



The Acuset IV infusion controller is a device developed to administer medicines and rehydration fluids safely and accurately to patients in developing countries. Over two million IV drip sets are used every year in the developing world alone so the total cost of administering this procedure world-wide is significant. The not-for-profit organisation *Design that Matters* saw the need to develop a cheap, reliable device which could be easily used by non trained people and their initial design was picked up for further development by the not-for-profit *Medicine Mondiale* organisation

Ray Avery, principal of *Medicine Mondiale*, had the immediate problem of identifying and engaging the technical expertise which would be required to develop the initial design while keeping the costs within the limited budget available. In accordance with his organisational ethos he would also have to manage and finance the manufacturing and distribution processes both ethically and responsibly.

During development work industrial designer Murray Fenton had the task of matching the existing relatively inexpensive but inaccurate and difficult to operate in-line roller clamp system against the new design which would have to be more accurate and reliable but may ultimately turn out to be more expensive to produce.

In tackling this issue Murray focused on the dual demand of enhancing the functionality of the device while also addressing the need for a design that would be 'attractive' to an inexperienced user often working in an uncomfortable setting – fitting neatly into the hand and being intuitive to use. A design would also be required that would meet the need for the product to be manufactured cheaply and efficiently. These competing priorities were resolved through adapting the initial design to ensure that the final device would be not only accurate and reliable but could also be reusable. This multi-use capability would produce cost benefits that could be easily justified to potential funding partners and target user groups.

The prototype manufactured for field testing overseas had to be simple to use but robust enough to deliver the fluids accurately over the period it operates for. This was initially managed through careful selection of materials. Because of the need to manufacture in bulk the construction material had to be relatively inexpensive, so plastic was the obvious choice. However the plastic chosen would have to be able to be machined accurately and also be strong enough to resist any movement from the pre-set flow rate while in use. In selecting the material Murray made good use of his prior experience but admitted that in coming up with their final solution they 'stepped out on a limb'.

With a workable prototype now developed, additional funding had to be found to make the dies required for commercial manufacture, and for developing an economically sound distribution model for the final product. Ray was helped in the task of finding the required funding by his identification of both a like minded financial partner and an unforeseen alternative market for the device. Although originally designed as a life saving piece of equipment for use in developing countries it was recognised that it could also provide a relatively inexpensive but easy to use and accurate way of adding chemicals to home swimming pools in more developed countries. With this dual marketing strategy *Medicine Mondiale* would have an income stream from first world sales which would allow them to tailor a sustainable distribution model to meet the needs of the developing world countries.