[1] Medical equipment technology is a field in which 'real world' problems have to be addressed and as such developments are strongly influenced by socio cultural factors. The 'real' world encompasses both developed and developing countries - with massive social, political, environmental, economic and cultural differences between potential user groups.

In the process of technological development – wherever it occurs, and whatever the need or opportunity identified, socio cultural factors will be constantly interacting and the result will be a complexity of competing priorities which have to be addressed and somehow resolved as the development process progresses.

This complexity is illustrated in the consideration of three different examples of medical equipment development:

- The M8 Intensive Care bed
- The Acuset IV Flow Controller
- The 'car parts' incubator

In each case a need or opportunity has been identified, design innovation produced and prototype or end product implementation taken place.

[2] In the case of the IV flow controller and the 'car parts' incubator the innovation was to address pressing third world social issues:

- World wide over four million infants die every year within a month of birth
- In developing countries huge numbers of patients die unnecessarily due to inaccurate administering of medicine and drugs intravenously

The M8 Intensive care bed was designed to complement the changing intensive care environment in modern hospitals.

In all three social, cultural, economic and environmental considerations were critical drivers but the interaction of these factors during the development produced differing sets of competing priorities which had to be managed during the process.

[3] In the case of the IV flow controller economic considerations necessitated a cooperative development process. *Design That Matters* and Medicine *Mondiale*, two not-for-profit organisations with limited 'in-house' technical expertise, collaborated to develop a cheap, reliable device which could be easily used by non trained people to accurately administer life saving medicines and drugs in a non-hospital environment. In the design and development process technical expertise had to be identified and engaged within an environment in which costs had to be kept to a minimum. This was managed by initially working with design teams of professional volunteers and university students participating as part of their coursework. Plans for an initial prototype were developed and the challenge of producing a manufacturing prototype accepted without charge by a socially responsible and experienced industrial designer. He was faced by a range of competing priorities – the device would have to be able to deliver the fluid not only accurately but reliably over a period of time and be able to be used in non sterile conditions by people in communities where the was limited access to medical supplies and expertise. It would also have to be able to be cheaply and efficiently manufactured in bulk to be cost-competitive when matched against the cheap but inaccurate and unreliable roller clamp device extensively used in developing countries. The final product turned out to be a skilful combination of improved functionality and user friendly design. Plastic was selected as the construction material to enable production in bulk. However the type of plastic used not only had to be able to be machined accurately but also had to be strong enough to resist 'creep' – gradual movement away from its set delivery position. The device also had to be designed in a way that inexperienced users would be able to handle easily and operate intuitively and efficiently. With the absolute necessity for accuracy and reliability the manufacturing costs for the final prototype ended up to be greater than the roller clamp it was designed to replace. However as the device was more robust and able to be attached to the outside of the IV line it was re-useable and so this made the product more cost effective to the end users. In a climate of economic restraint the challenge of finding funding for the tooling required for commercial production and distribution to the target developing world market remained. This task was managed by developing further links with a like minded individual within the social entrepreneur network and the identification of additional marketing opportunities for the device. These included targeting rest homes and home swimming pool manufacturers in developed countries globally. The profits made from these sales could be used to subsidise the development of a sustainable distribution model to meet the differing needs of the developing world countries.

[4] The *Design That Matters* organisation has also been closely involved in the development of a range of low cost infant incubators. These are designed to be cheap enough to be able to be more readily available for regular use in remote geographical areas – particularly in developing countries - and in situations of urgent need in times of social and political unrest or where natural disasters have occurred and medical facilities are restricted. Currently about half of the worldwide total, or 1.8 million babies each year, die for lack of a consistent source of heat until they have the body fat and metabolic rate to stay warm. The recommended method of providing infant temperature regulation in resource-constrained settings is placing newborns directly onto the mother's chest. However If the mother either dies in childbirth , or is ill after delivery, or if she has other family obligations required in her economic and cultural setting she is often unable to provide this care. Other adults are not able to take the mothers place in some countries because skin-to-skin contact is considered a culturally inappropriate violation of privacy.

In the design phase the brief was to develop a device that would not only assist at-risk babies with temperature regulation and breathing but which would also allow for air filtration to reduce incidence of cross infection which can often occur in hospital environments. In doing this the design would also have to allow parents and caregivers to have easy access to the baby being treated. So where and how the incubator would be required to operate were critical considerations. It could be required to be used in rural situations where power may be problematic - with frequent variations being the norm in many places, causing damaging voltage spikes. In many places when malfunctions do occur there will be limited access to spare parts or repair expertise and even where this exists there will often be no budget for repairs. To be affordable for the agencies that would be using the incubators the cost was to be kept at around US$200 – about one tenth of the cost of the equivalent product used in hospitals in developed countries.

Because of budget restrictions the need for comprehensive initial research became critical. This would help avoid costly redesign situations occurring. The research carried out by the volunteer development teams proved that ongoing maintenance would the most critical factor – both in terms of spare part supply and availability of expertise to carry out repairs. It was established that even in the most isolated of environments car parts and technical support are usually close at hand. With there being in the order of 40,000 parts in a standard SUV, and with the global automotive industry having efficient distribution channels to deliver those parts to even the most remote communities it was decided to make use of many of these car parts in the incubator design in order to take advantage of economies of scale and have access to spares and skilled expertise.

The final incubator design featured a bassinette which would be detachable from the base and be light enough to allow two people to easily carry the newborn baby up and down stairs and over uneven ground — important features in the context of a rural hospital in a third world country where infants often need to be carried long distances between the delivery room and the newborn intensive care unit.

[5] In the case of the development of the M8 Intensive Care Bed the need focused on the intensive care department of a modern hospital and the particular needs of the critically ill patients and the team of specialist medical professionals responsible for their care. Here the focus was on designing a bed which would 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. The project reinforced the importance of extensive end user research, human factors and ergonomics in the field of medical equipment technology which have been emphasised in the first two developments.

In this hi-tech and emotionally intense environment seemingly innocuous social factors such as the increasing average age of nurses, and higher patient weights interact with regulatory issues such as more demanding occupational health and safety legislation and institutional priorities including the need to work towards greater workplace productivity. This is the complex environment that the in-house development team had to negotiate their way through as they worked to develop a solution that met the needs of the diverse range of stakeholders in a practical, innovative and intuitive manner.

[6] The development process was heavily shaped by the company's movement towards a design centred approach to product development. This was stimulated by taking part in the government – led *Better-by-Design* project with industrial design innovation complementing the existing strong mechanical engineering skill set in the company.

[7] The project built from a comprehensive initial research phase which successfully engaged the wide range of people that would interact with the bed in a critical care situation. The initial focus was on the needs of the patients – of differing ages, sizes and weights and from differing cultural backgrounds - and staff involved in the critical care process. Anthropomorphic and ergonomic data was gathered and analysed in relation to the specific requirements of each of the specialist tasks carried out. Data was also gathered from other groups such as maintenance staff, cleaners, hospital management and the families and friends of patients. This helped to broaden the understanding of differing needs and address issues of competing priorities. Functional modelling within a specialist facility allowed potential solutions to be tested and evaluated to find creative solutions to meet the user-needs. Safety was an important consideration in all aspects of the design. Features incorporated included additions such as a fifth wheel to allow not only flexible manoeuvring but also rapid breaking if required during movement of the patient. Sustainability of resources was also a major design consideration with material choices such as steel and leather being made to suit not only functionality within the operating environment but to meet changing public attitudes towards reuse and recycling of componentry. The developers had to work within the constraints of existing operating codes and regulatory standards relating to the manufacture and use of medical equipment. Differing global requirements would have to be factored into the decision making process in a way that maximised the export potential of the design without unduly extending the period or costs of development. The end result was the timely delivery of a product well suited for efficient use in critical care facilities in hospitals in a broad international market.

[8] The above three examples highlight in particular the complexity of interactions between economic, social and environmental factors in product development and the implications for innovation in medical equipment technology. In this field product development can be targeted at both narrow niche markets and broad global marketing opportunities. In all cases costs and returns will be carefully calculated before development begins with returns often being measured not only in economic terms but in terms of social, environmental and cultural gains achieved. The examples shown illustrate the influence that the targeted gains can have across all aspects of the technological practice undertaken by the developers.

Political influences in this field can also produce competing priorities. This can be evidenced in the evolving internationalisation of manufacturing standards and codes of practice in this field of development. Innovation is often driven by a need to simplify standard procedures undertaken to provide patient care and so benefit the medical professionals involved. Here a development focus on the needs of the user may produce competing priorities in terms of the protection of the rights of the patients. Legal protections and ethical codes of practice introduce the possibility of litigation and significant financial penalties for practice which is shown to be expedient rather than ethically and legally acceptable. This issue is illustrated by the focus on patient safety and quality of care in each of the above examples. Governments can also influence the direction of innovation in products such as the low cost incubator and the IV flow controller designed for use in developing world countries. Here the availability or non availability of subsidies, aid money and a reliable distribution infrastructure can have both positive and negative influences on decisions on whether a desired innovation is undertaken and how that development proceeds.