An essential 'health check' for all medical devices

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ABSTRACT – In order to safeguard patient safety, all new or modified medical devices must be assessed for their safety and performance before they are used routinely in clinical practice. Most devices will carry a CE (Confirmity European) mark to demonstrate their safety, but many devices will require an alternative method of assessment. In this article, we discuss the procedures already in place, the significant gaps that exist in the system and the risk management issues. We consider the impact on research and clinical practice, and describe our comprehensive risk management system for objectively assessing the safety of any medical device.

KEY WORDS: CE mark, clinical governance, medical device, research governance, risk assessment

Safety of medical devices

From tongue depressors to magnetic resonance scanners, medical devices are essential tools in clinical practice and medical research. A degree of risk is inherent in the use of any medical device and may sometimes result in serious adverse incidents.[1] So, when new technology must be introduced to improve medical care, doctors, researchers and others in the medical setting have to ensure that any equipment they use is safe and used in an appropriate manner.

CE marking

The CE (Conformity European) mark on a medical device affirms that its manufacturer is satisfied that it conforms with the relevant 'Essential Requirements' for safety and performance, as laid out in the European Medical Devices Directive.[2] First, the health and safety of the patient, user or any other person must not be compromised as a result of using the device. Secondly, any risks associated with the device must be compatible with patient health and protection. Thirdly, the intended performance of the device must outweigh any potential side effects.[3] It can only be affixed to a product once the manufacturer has produced a 'declaration of conformity' stating that the product meets the requirements of the relevant directive(s). This does not give any guarantee of quality, but does give the purchaser and user assurance that the device is fit for the purpose for which it is intended and can be used without risk of patient or user harm. The CE mark allows free marketing of the device anywhere within the European Economic Area (EEA) without further control.

Medical Devices Directive

Before the introduction of the CE mark, different methods of controlling the safety and marketing of medical devices were applied in each country. In the UK, the system used by the NHS was one of voluntary manufacturer registration and product approval. The Medical Devices Directive[4] is one of three European Directives which apply to medical devices anywhere in the European Union. The other two are the Active Implantable Medical Devices Directive and the *In Vitro* Diagnostic Medical Devices Directive. The Medical Devices Directive was implemented in the UK in 1994, in the form of the Medical Device Regulations, and has been in full force since 1998. Compliant devices will carry a CE mark, but custom-made devices and those undergoing clinical investigation (as defined by the Medical Devices Agency (MDA)) will not be eligible to do so. Additionally, in the same way that drugs used outside the terms of their licence are not endorsed by the manufacturer,[5] the CE mark is invalidated if any part of a device is modified or used in a way that was not intended by the manufacturer. This leaves a sizeable void in the user's ability to demonstrate equipment safety. Any device, whether simple or complex, with no CE mark or an invalidated CE mark must be indemnified by the host organisation

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Key Points

A CE mark on medical equipment provides assurance that the equipment is safe and fit for its purpose

The CE mark is invalidated if the equipment is modified or used outside its intended purpose

Equipment built in-house or with an invalidated CE mark requires a risk assessment to demonstrate safety

Ethics committees require principal researchers to demonstrate safety of equipment used for research

A risk assessment tool and its application is described

(normally the hospital) before it can be used for clinical or research purposes. In these circumstances, the host organisation effectively takes on the responsibilities of a manufacturer and, before agreeing to provide indemnity and sanctioning the use of the device, has to assure itself that the following criteria are met:

- The risks of using the device are within acceptable limits.
- All potential risks have been minimised (ie there are no unnecessary risks).
- The benefits of using the device outweigh any risks.

A risk assessment tool

Devices without a valid CE mark must still conform to the relevant 'Essential Requirements' and every precaution must be taken to protect the health and safety of patients.[6] A reliable method for analysing the risks of such devices is essential for the introduction of new technology into both the clinical and research environment. The Department of Clinical Technology at North Staffordshire Hospital (NHS) Trust has recently developed a risk assessment tool (available in PDF format on request)[7] for the purpose of assessing non CE-marked (or modified) medical devices. This has been applied successfully to various pieces of equipment, leading to the identification of risks and subsequently to these risks being minimised. The tool is based upon current legislation produced by the International Organisation for Standardisation (ISO)[8] and can be applied to any medical device. Using this tool, risk assessment of a device is carried out by a team of three people. The team should consist of the lead clinician supervising the use of the device, an independent person who takes the role of principal risk assessor, and a second risk assessor who has been involved in the development or modification of the device. The whole process is likely to take around 1–2 hours. The risk assessment tool requires a full description of the device and its intended use, and includes questions designed to elicit factors which are known to increase the potential for human error, such as connecting parts or control interfaces. This is followed by a series of questions asking the team to consider all possible hazards relating to a number of different domains. These include energy and incorrect output, biological hazards, environmental hazards, hazards arising from the use of the device or the user interface and the consequences of ageing and/or failure of the device. Each area of risk is assessed individually for probability and severity of risk relating to both the patient and the user, taking into consideration any risk reduction methods that are already in place. For example, in an electrical device the energy hazard may be dealt with by means of a low voltage battery. This would normally obviate the need for further consideration of this hazard.

Should the risk assessment identify any avoidable or serious risks, then the equipment should be modified. In some cases risks can be reduced by an improvement in documentation or by formalising a training programme for all users of the device. An example of this is a gas collection system that was designed for the purpose of collecting exhaled air from newborn babies for laboratory analysis. The gas collection system has to be assembled prior to each use, and consists of both re-usable and disposable parts. The risk assessment highlighted a potential risk in that it was possible to assemble the gas collection system incorrectly. A slight modification to the fabrication together with a user instruction leaflet reduced the risk to an acceptable level.

Once changes have been implemented, the risk assessment is repeated as often as is necessary to reduce all risks to an acceptable level. When this is not possible, then the device should not be used. In this way, it is possible to be confident that any device can be rigorously assessed in line with legislative requirements and that all risks will be addressed.

Risk management structures

NHS trusts need to have effective structures and systems for managing risk.[9] The NHS Controls Assurance Standard for Medical Devices Management includes the requirement that 'all medical device developments, modifications and trials are conducted in accordance with relevant legislation and guidance'.[10] Evidence of this can be in the form of policy documentation, risk assessments, committee minutes and technical files. Organisational policy should clarify responsibilities, including approval, monitoring and review mechanisms, and crucially, the policy should encourage an enabling environment. North Staffordshire NHS Trust is currently developing such a policy, which is at advanced draft stage and has the medical device risk assessment at its centre.

Implications for research

Research undertaken within the NHS must now adhere to the principles outlined in *Research governance framework for health and social care*, which was established in 2001.[11] In addition, the requirements of relevant regulatory agencies and applicable laws must be observed. The framework states that the dignity, rights, safety and well-being of participants must be the primary consideration in any research study and all parties involved in a research study have a duty to ensure that this is the case. The framework indicated the need for a review of the workings of ethics committees and this has led to the new *Governance arrangements for NHS research ethics committees*,[12] which have been fully implemented since April 2003. These arrangements require researchers to provide ethics committees with evidence that a project is scientifically meritorious. This will usually be provided by the sponsoring organisation.

In parallel with the ethical review, the host's research and development department has to take a view as to whether the host wishes the research to proceed within its organisation. Under the new arrangements for research governance, research cannot go ahead without both ethical and host organisation approval. One of the host's considerations will be the degree of risk involved in managing the project. When a project involves the use of a medical device, the host organisation must be able to satisfy itself that the equipment is safe and will be used in an appropriate way. The ethics committee also requires evidence of

device safety. When the device is not CE marked, or the methodology falls outside the confines of the device's intended use, so rendering the CE mark invalid, a decision on device safety can be achieved using the system described above. These risk assessment and risk management procedures have been used successfully in North Staffordshire. Without such a system in place, principal research investigators will be unable to provide local ethics committees with the assurances they require.

In conclusion, whilst recognising that this is a challenging area, we suggest that it would be prudent for all trusts involved in any type of equipment development or modification to set up a system of risk management similar to the one described above.

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