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Technical note

Medical Device Guidebook: A browser information resource for medical device users

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ABSTRACT

A web based information resource – the 'Medical Device Guidebook' – for the enabling of safe use of medical devices is described. Medical devices are described within a 'catalogue' of specific models and information on a specific model is provided within a consistent set of information 'keys'. These include 'user manuals', 'points of caution', 'clinical use framework', 'training/assessment material', 'frequently asked questions', 'authorised user comments' and 'consumables'. The system allows identification of known risk/hazards associated with specific devices, triggered, for example, by national alerts or locally raised safety observations. This provides a mechanism for more effective briefing of equipment users on the associated hazards of equipment. A feature of the system is the inclusion of a specific 'Operational Procedure' for each device, where the lack of this focus is shown in the literature to often be a key factor in equipment misuse and associated patient injury. The 'Guidebook' provides a mechanism for the development of an information resource developed within local clinical networks and encourages a consistent approach to medical device use.

1. Introduction

1.1. Challenges of safe medical device use

There is an increasing dependence on the use of medical devices in the processes of patient diagnosis, monitoring and treatment. This requires clinical staff to acquire and maintain an appropriate level of competence and skill in the use of these devices. While the term 'medical devices' is normally associated with items of medical equipment such as patient monitors, defibrillators and syringe drivers, often the correct use of medical devices such as wound dressings, surgical sutures and medical gloves etc. can also be of importance to ensure safe and appropriate patient care. This implies that the scope of training in the use of medical devices is probably more extensive than generally appreciated.

Health organisations typically ensure that the training of staff in the use of medical devices is identified as a key organisational goal as indicated, for example, in national UK frameworks for safe equipment use and management [1]. This requires policies to be co-ordinated within an appropriate procurement process and user training programme to ensure that competency levels of users are appropriate for the specific medical devices utilised. There are, however, a number of factors, summarised in Table 1, which impact negatively on the ability of clinical staff to attain the necessary levels of competency to operate equipment safely. This indicates that systems for safe device use require co-ordination of a range of factors

1.2. Communication of shared experience

One of the strands of governance issues relating to medical device use at a global level is that of shared experience of adverse clinical events relating to their use [3]. This is primarily to prevent the recurrence of identified patterns of device use which could adversely affect patients. In England, for example, the processes of Central Alerting System [4] provides a mechanism for alerting health organisations of such risks. The development of an active system to identify, communicate details and manage identified risk has also been outlined in detail [5]. A range of actions can be indicated – such as the removal of specific units from clinical use or the requirement to communicate information relating to specific types of medical device where the corrective action relates to user awareness/training to overcome device shortcomings. In the context of nutrition feed pumps, for example, there is the requirement to implement safe practice to ensure the correct placement of nasogastric tubes [6] and which can be considered as an ongoing responsibility of a healthcare organisation to maintain appropriate vigilance.

The availability of information relating to the risk of use of medical equipment presents a challenge to a healthcare

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Table 1
Summary of factors which tend to degrade the effectiveness of staff training programmes for medical device use.

Factor	Impact on patient safety
Diversity of numbers of equipment types	Large numbers of models of a specific general function of device (e.g. syringe driver) can adversely impact on the training compliance of users [2].
Staff turnover	High staff turnover requires higher than 'baseline' training activity to maintain competence levels.
Migration of staff between specific clinical areas	Staff may not initially have competence to operate specific equipment when moving between clinical areas.
Infrequent use of items of equipment	Tendency will be to reduce competency levels, especially for complex equipment.
Lack of available training resources	Levels of delivered competency among staff in use of medical devices may be below set targets.
Lack of system to track/document/manage training status of staff	Training resources may be poorly targeted and also poorly managed as an organisational risk.
Staffing pressures – difficulty in releasing operational clinical staff for device training	Levels of competency among staff in use of medical devices may be below set targets.
Challenge to communicate details of device risks relating to medical devices among clinical users	Staff may not be informed or receive specific training to overcome known risks in the use of specific medical devices based on information received through external or locally based clinical alert mechanisms.
Increasing complexity of equipment function and operation	Training resources available my not keep pace with organisational requirements to use such systems safely and effectively.
Equipment may be purchased which is prone to errors in use due to inadequate human interface design factors	Such devices may require high levels of training input and which may not be sufficient to reduce risks of use to acceptable levels.

organisation to communicate this information to equipment users to ensure that the risk is subsequently managed for the lifetime of use of the equipment. Such risks, however, do not necessarily relate to the immediate operation of the specific device but rather to the 'clinical environment' within which the device is used. In addition, within an active governance framework scrutinised by external auditing agencies, such as that implemented by the Care Quality Commission in NHS England, there is the requirement to be able to demonstrate that such processes are actively managed and that information to ensure safe device use can readily be accessed by equipment users. Healthcare organisations may be able to demonstrate lines of communication relating to the management of such incidents but to a lesser extent how a device user is made aware of specific issues relating to the safe use of a specific device.

In the USA, the FDA has established the MedSun reporting system [7] as part of its Medical Product Safety Network, where specific reported incidents relating to medical device use are searchable and provide a mechanism for clinical users to access the experience of a wider group of equipment users. In addition the FDA also supports the MAUDE facility (Manufacturer and User Facility Device Experience). In this context, the concept of an 'aware community' can be considered as an outworking of such initiatives.

1.3. Focus of medical device training

Zhang et al. [8] describe the increasing importance of medical devices in the context of nursing care and where an important consideration identified is the increased stress experienced by clinical staff where medical devices are used without adequate training. Williams and Lefever [9] describe how the details of adverse medical device reporting confirm the high importance of appropriate device training in the context of infusion pumps. Newton et al. [9] also references the specific failings in medical device training as a key challenge in the safe update of medical device technology and especially in the developing world. An additional element identified by Newton et al. [10] relates to the advantage of an 'open' culture of adverse event recording where it is more likely that higher 'quality' feedback will more readily prompt safer device use. Fouladinejad and Roberts [11] describe in a survey of adult and neonatal intensive care departments in the United Kingdom that only around 1% of staff time was actively taken up by training in the use of medical equipment. In addition, analysis of data indicated that equipment could be more safely and effectively used if formal training processes were implemented.

The World Health Organisation [12] outlines a review of the challenges of the development of medical technology within the framework of utilisation of this technology by healthcare professionals. In particular the scenario is identified of the medical device which provides poor performance even after extensive training and where the underlying problem relates to inadequate device design. This identifies the increasing importance of adequate device evaluation prior to the stage of procurement [13,14].

2. Materials and methods

2.1. Development and scope of the medical device guidebook

It was identified that there was a requirement for a web based information resource to facilitate the safe and effective use of medical devices. The development of the 'Medical Device Guidebook' (subsequently referred as the 'Guidebook') has allowed specific departments to develop an equipment induction training modality for new staff members. In addition, nurse practitioners within various disciplines have been able to assimilate device use material which is of relevance across broad clinical groups. This resource would essentially provide a mechanism to access information which had been given an approved 'status' by a controlling group of healthcare professionals and with a significant contribution from Clinical Engineers.

Fig. 1 indicates the screen view of a specific 'catalogue' entry. The 'Device Name' provides a description of the device incorporating manufacturer/model/type details. The 'model code' is a unique local identifier used within the medical equipment management database used by the local Clinical Engineering Department (MEBS). The status of the equipment with respect to availability in the Trust's Equipment Library is also indicated as 'available' or 'unavailable'. In the structure of definitions of the device entries, use is made of specific coded entries of equipment category, manufacturer and keywords where in the latter a range of these can be 'tagged' to a specific device. Such keywords can in turn be used as 'tags' in searches of the device catalogue.

Reference is made to 'Operational procedure' within the 'Clinical Use Framework' option where standard sections of 'Clinical Applications', 'Device Checks', 'Storage/Device Charge', 'Management of Leads/Consumables' and 'Training Contacts/Details' are included.

Users of the 'Guidebook' can send e-mails to the 'Guidebook' administrator mail box to communicate comments/queries relating to its content. Such e-mail enquiries sent from a specific device screen (as in Fig. 1) are tagged with the details of the specific medical device item. Entries can only be updated within specific