Exploring medical device management strategies

The recent EBME Seminar explored some of the challenges facing the electro-biomedical engineering profession – including ensuring patient safety through effective medical device management, while delivering efficiency and productivity gains. **Louise Frampton** reports.

Electro-biomedical engineering (EBME) departments will have a key role in delivering the objectives of improving productivity, tackling variation, reducing waste and eliminating inefficiency, through the effective management of innovative medical devices. The recent EBME Seminar explored some of the topical issues facing the profession in the wake of the Carter report, as well as strategies for ensuring the role keeps pace with advancing, connected technologies.

The EBME Seminar is an independent educational event bringing together healthcare professionals that are responsible for the management of medical equipment – including procurement, maintenance, user training and managing inventories. Taking place at the Milton Keynes DoubleTree Hilton, alongside the stadium of the MK Dons, the event was attended by over 300 delegates.

In his opening presentation, EBME Seminar chair, Dr John Sandham, focused on 'Technology as an enabler for productivity in the NHS', highlighting the role of connected technology in facilitating cost-efficient models of care, such as 'step down care' – an interim step that bridges the gap between hospital discharge and returning home, which has been adopted in Scandinavia.

Dr Sandham warned that poorly implemented technology projects can lead to higher risks and higher costs. However, if managed effectively, technology can assist the NHS to deliver better care at a lower cost. (The themes of his presentation are further explored in a separate article in this edition of *CSJ see p56*.)

The EBME Seminar covered a diverse range of topical issues – from debate on 'taking equipment off contract' and alternative strategies for medical device management; to key insights into innovations in healthcare connectivity and the role of clinical engineers in supporting pathology devices.

Risk and reliability based maintenance strategies

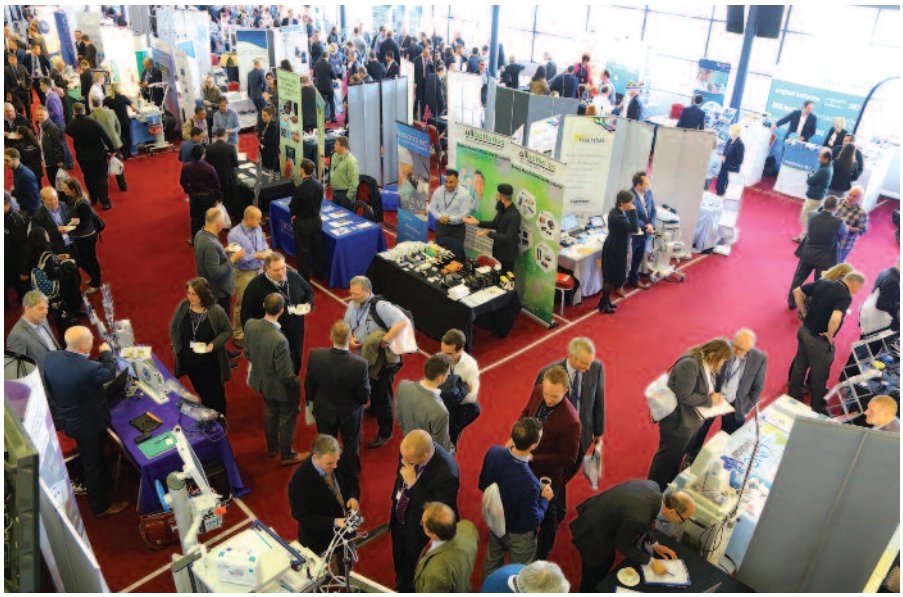
Ted Mullen, head of service, medical equipment management, NHS Greater Glasgow and Clyde, explained how the Trust has moved away from a traditional model of maintenance. He drew on a comparison of the TV repair man, who became increasingly obsolete as television sets became more reliable – although the technicians that worked in this sector were highly skilled, the technology became semi-disposable and a whole career also went "to landfill".

Ted Mullen pointed out that medical equipment is less costly today; technologies such as pulse oximeters are now more widely accessible, as costs have come down, and they are also much more reliable – requiring less maintenance.

He explained that the NHS Greater Glasgow and Clyde's clinical engineering department has now moved to a 'risk and reliability based maintenance strategy', while still ensuring a safe environment, for patients and staff.

He advised that the document, ANSI/AAMI EQ89: 2015, provides some useful guidance on medical maintenance strategies. The development of EQ89 started several years ago after the US Centers for Medicare & Medicaid Services announced in December 2011 that hospitals should adhere to the manufacturer's recommendations on planned maintenance activities for medical equipment in almost all instances. This prompted uproar in the health technology management community, with many professionals saying it would be impractical, expensive and failed to recognise the value of some alternative strategies with a proven history of safety and success. Two years later, a more flexible posture was adopted, giving healthcare technology management departments some latitude in setting their maintenance activities. (Source: www.aami.org)

"This is a sensible and pragmatic document," said Ted Mullen, pointing out that the EQ89 document acknowledges that: "a maintenance strategy is not a one-size-fits-all approach." It also states that healthcare technology management departments should



The EBME seminar showcased the latest innovations to support effective medical device management.

develop a plan that will keep the devices functioning and available "without expending resources unnecessarily."

In addition, the guidance identifies factors to consider when there is a potential change to a maintenance strategy, including the consequences of a device failure, the clinical environment in which the device will operate, and the impact of the physical environment on the device (e.g. temperature and humidity; portable *vs* fixed location.) Some of the various strategy options outlined in the document include: corrective maintenance, planned maintenance, preventative maintenance, predictive maintenance, diagnostic or detective maintenance.

In his closing comments, he re-emphasised that the management of medical devices shouldn't be a one-size-fits-all approach: "It should be about what we can do with the resources that we have. We need to think about the future; to consider the technological advances and the impact they will have on reliability…There is no doubt that risk needs to be managed, but we need to think about what we do, how often we do it, and what skill levels are required to perform the work." He went on to warn delegates: "do not become like the TV repair man"; there is a need to adapt and evolve, to ensure value for money.

"Don't over maintain the equipment. Don't do something because 'this is the way it has always been done'. We need to use our resources much more wisely," he concluded.

The EBME seminar was attended by over 300 delegates.

Modernising technology management

David Cook, head of clinical engineering at University College London Hospitals (UCLH) NHS Foundation Trust, has been at the forefront of driving innovation while working in medical equipment management since 1988. He believes that we are facing an enormous challenge: "not of what technology can do, but of what we want to do with the capabilities at our disposal." Discussing the theme of 'modernising technology management', his presentation considered the relationship between clinical engineering and IT departments and how this is key to achieving the best overall outcomes. ▶

He explained that UCLH has over £100 million worth of medical assets, across eight major sites, and strives to be at the cutting-edge of innovation. Identifying some of the challenges ahead, he referred to the Carter report (published earlier this year), which proposed personalised healthcare by 2020, using data and technology to transform outcomes for patients.

Lord Carter commented that "All Trusts should grasp the use of their resources more effectively" in order to deliver a target of £5bn of efficiency savings. David Cook pointed out that Trusts that are 'not performing' will face consequences, which he believes will be similar to being placed on 'special measures'. He pointed out that some of the changes to procurement must be implemented in 2016/17 – which is a very short time scale indeed. However, one of the key areas for transformation, in his view, is 'Recommendation 9', which states that: "All Trusts should have the key digital information systems in place, fully integrated and utilised by October 2018..."

David Cook explained that this involves Trusts having: fully integrated and utilised e-rostering systems, e-prescribing systems, patient-level costing and accounting systems, e-catalogue and inventory systems for procurement, RFID systems where appropriate, and electronic health records.

"There is a lack of understanding of where medical devices fit into this. There is talk of 'technology' and 'systems' and how this is going to improve personalised healthcare, but not much talk of 'medical devices'. The question is 'how are we going to manage this technology?'" he commented. Clinical engineering leadership will be crucial across many areas – such as medical device design, human factors, networking and medical service contracts. "Who will be responsible for all the technology in the Trust?" he questioned. "What about theatre lights, wheel chairs, bed accessories, blood fridges, and consumables?" he continued.

He highlighted the need for an 'Equipment Responsibility Matrix', which outlines who is responsible for the replacement of equipment, the writing of the specification, maintenance and ordering of consumables etc. However, there are emerging areas of technology increasingly used by clinicians that raise key questions of responsibility and present significant challenges. For example, when is a mobile app considered a medical device? He argued that the medical devices regulation definition makes reference to software that is 'used for monitoring' or 'the alleviation of disease' as a being a medical device. An app should be considered a medical device in his view, therefore, but the question arises: how should they be controlled?

Ted Mullen.

David Cook.

Dr John Sandham.

Another area of medical devices management that needs to be addressed relates to the control of devices once the patient is discharged to home. Failure to understand instructions is a significant issue in this setting, as well as what happens when medical devices go wrong. There are many problems associated with the use of devices in the home setting, therefore, which clinical engineering departments will need to manage as care is moved away from the acute setting to care at home.

He further explored the issue of clinical human factors, medical devices management and the potential role for clinical engineers in improving patient safety. In particular, he focused on poor device design, which increases the risk of human errors. "It is not surprising that clinical staff make mistakes with devices when they push the button on one device and it does one thing, and press the same button on another device and it does something different," he warned. Clinical engineers need to think about the risks of device design and understand human factors, therefore. To address this issue, he recommended the development of a flow chart that outlines the processes for the procurement of medical devices which considers the specification of the device and the potential risks.

Networking of medical devices is another challenge facing clinical engineering departments. He pointed out that equipment such as weighing scales, infusion pumps and monitoring devices all have the potential to be entered into the Trust's network, so the case for standardisation is 'overwhelming', in his view. He argued that the need for standardisation is a strong driver for clinical engineering to be involved in the specification of medical devices and emphasised that there must be a clear understanding of which equipment needs to be networked. A strong working relationship with the IT department will be required.

"If there is a proliferation of medical devices it is going to become very expensive to ensure they are all networked," he commented.

Artificial intelligence is another area that will need to be considered, according to David Cook – clinical decision-making software for CT scanning is just one area under development that raises questions of responsibility and prompts discussion of what exactly is defined as a 'medical device'.

There needs to be a better model to deal with these issues, he argued: "There are many important decisions being driven by technology and we need to get these messages understood, otherwise devices won't be networked and we will be making decisions that 'happen to us', rather than us being in control of them," he warned.

He recommended the formation of a number of sub-committees including a medical technology planning sub-committee; a network integration sub-committee; an incident review sub-commitee; a human factors and training sub-committee; and a maintenance provider sub-committee.

"For too long we have been seen as a profession that 'fixes things'," asserted David Cook. Ultimately, there is an increasing need for clinical engineers to perform a crucial role in educating and informing the boardroom on "the changes that are happening with technology", he concluded. CSJ