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Letter from the Editor

Welcome to the third edition of the medical devices newsletter for 2005.

One of the issues which we focus on in this edition is counterfeit medical devices. This article highlights how counterfeiting of medical devices can pose a significant risk to public health and how manufacturers can combat counterfeiting by taking proactive steps to protect their brands. We also feature an article on infusion devices and how one hospital improved their infusion device management system using an established quality management approach.

Over the last few months, we have had a number of queries in relation to post market surveillance audits of Irish manufacturers. In response to these queries, a guidance note has been drafted by the IMB to answer manufacturers frequently asked questions. An article giving a brief overview of this new guidance note has been included in this edition of the medical devices newsletter.

This newsletter also contains our regular articles including a regulatory update, staff update and upcoming events.

As always we welcome feedback or suggestions for specific topics you would like to see addressed in future newsletters.

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Infusion Devices

Treating the Patient on Time

How one hospital improved their infusion device management system using an established quality management approach.

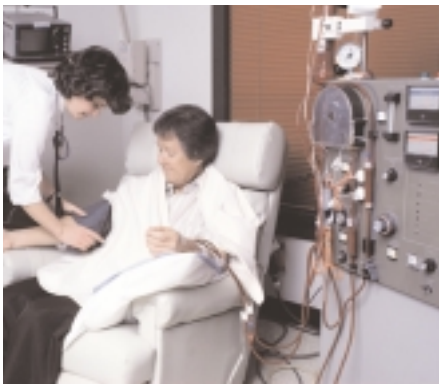
INTRODUCTION

Within recent times the role of the nurse in a modern healthcare system has diversified significantly. Over the past twenty years nursing has embraced a multitude of additional responsibilities. One such responsibility is ensuring that the vast array of medical equipment currently available to the healthcare professional is available and safe to use. Anecdotal evidence however suggests that many hours could be spent locating equipment, which when found was often damaged, unfamiliar, incomplete or contaminated.

At Adelaide and Meath incorporating the National Children's Hospital (AMNCH) the time spent looking for infusion pumps alone amounted to at least one hour every day in eighteen different clinical locations. Consider an hourly rate of €10 per hour, for example this could relate to a care assistance or ward attendants pay, which when applied hospital wide produces an indicative annual cost of €65,700. This situation highlights a compelling financial cost and it also contributes to outcomes that are not so easily quantified such as stress which can lead to low morale, sickness and more importantly, delays occurring in patient treatment.

Offering nursing staff a way to avoid wasting time performing non-nursing duties was an issue that clearly needed to be addressed. This need for an improved system of medical equipment management formed the basis for a hospital quality improvement project that not only saved time but also secured huge capital and revenue savings. It was projected that a €1 million saving could be made over three years.

The need for a speedy, accurate and efficient equipment loan system coupled with an ongoing equipment educational programme for nursing staff was identified. This article looks at the method, steps taken and the short-term results that have occurred within the first year, which has amounted to



nearly €500k savings since the hospital sanctioned the opening of a Medical Equipment Library (MEL).

PROJECT OVERVIEW

In 2003 the hospital became a leading organisation in 'Continuous Improvement' (CI) projects aimed at raising the quality of services within and where possible show how value for money would be achieved. This project reviewed ways of reducing the non-clinical duty time spent searching for infusion devices for clinical use.

Three distinct phases were used for the project.

(a) A nursing questionnaire was devised to assess the real situation that needed to be improved.
(b) An audit of current practice collected data to find how many infusion devices were in use throughout the hospital and equally important how many were not in use.
(c) A pilot study was introduced in selected wards. This allowed staff to borrow infusion pumps from one location, returning them when finished.

In the past five years since the hospital was first opened the distribution and management of infusion devices at ward ownership level was uncoordinated and poorly managed. Specialities that often needed pumps had few, whereas areas that rarely used pumps had large stocks. This imbalance needed correcting.

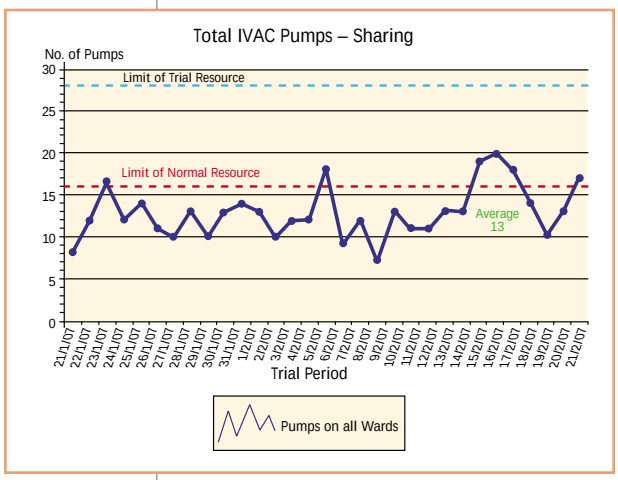
In a one month survey that compared pumps connected to patients, and pumps not in use the following results were noted:

- 66 volumetric pumps; and,
- 80 syringe drivers

were not being used, their combined capital value exceeded €300,000.

The third phase was a trial carried out in one section of the hospital, comprising four wards all sharing ownership of the infusion pump stock for one month via a central store.

At the end of the trial it was established that the overall usage from the four participating wards was less than was planned for. Originally all four wards collectively owned sixteen devices yet over the trial period the average use was only thirteen. (See chart number e.g. fig.1; table 1)



A number of infusion pumps use a dedicated administration set. This same set in some areas was also being used for gravity treatments instead of a cheaper dedicated gravity set. Financial projections suggest that if a 'dedicated' gravity administration set

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was used only where indicated then the savings over one year could be as much as €73,000. These findings have recently become the subject of another 'Continuous Improvement' project.

The outcome from the pilot work findings was the recommendation to develop and establish a central point to lend equipment,

i.e. store room for managing medical infusion devices.

A Medical Equipment Library would be the answer.

The concept of a MEL is not new to hospital trusts in the UK. One of the first hospitals to open an equipment library was The John Radcliffe in Oxford (1992). A survey in 1999 showed that 22% of UK trust hospitals had medical equipment libraries and their establishment had led to benefits such as:

- reductions in rental costs
- helping to standardise medical equipment and optimise use
- improve access to medical equipment for maintenance
- provide safe storage and therefore reducing breakage's
- ensuring that medical equipment is complete with accessories
- facilitate training in the use of medical equipment as it is loaned

NHS Executive (1999)

The opportunity for AMNCH was to open the first Medical Equipment Library in Ireland, not only as a borrowing location within the hospital for medical devices but also as a place for teaching staff how to use infusion pumps and how to operate other medical devices.

A business plan was presented to the CEO and the hospital management team. Approval was given with the provision that accommodation could be found, easily modified and overheads kept to a minimum. The hospital accreditation department sought help from the Department of Health for funding assistance. This was duly provided which allowed for a room (60 sq.metres) to be modified. The MEL was fitted out with 96 electrical sockets and shelving for storing pumps. Office furniture along with desktop PC's for two staff and laptop computer/projector/screen for nurse training was also provided. Two new staff positions were introduced to manage the MEL services and will last for an initial duration of three years.

The next step in developing the MEL was to get acceptance of the concept by staff throughout the hospital. An amnesty was introduced encouraging all infusion devices to be given-up to the MEL. The only exemptions to this were ICU, CCU and the Operating Theatre complex where devices were instantly required. These pumps would be registered to the MEL but labelled 'long term loan', always kept on stand-by permanently with the original owner. The remaining majority of pumps were passed into the MEL and labelled 'short term loan' available for any area to borrow.

In July 2004 the MEL at AMNCH opened, an operational policy was put in place and commencement of 'short term loans' of infusion devices began. The first six months of the MEL's activities has been summarised and is shown below by way of this paper's conclusions.

CONCLUSIONS

Medical Equipment Library (MEL) Executive Summary (July 2004 - December 2004)

The MEL opened in July 2004 and for the first six months has been successful, meeting all project expectations.

The daytime commitment to deliver pumps in less than 15 minutes has been achieved for all day time deliveries.

The out of hours service provided by the portering department has also done well, maintaining an excellent delivery service, achieving a 15 minute delivery of 95%.

Deliveries have been totalling nearly 500 per month to all parts of the hospital. This gives an annual projection of 6,000 loans per year.

The expenditure savings by the end of 2004 was over €200k. This was shown as two main parts, Hard savings and soft savings

Hard savings are:

1. Capital Expenditure saving amounted to > €200,000 for pumps;

   (i) Obsolete devices and devices removed from service (over one hundred pumps retired).
   (ii) Missing devices
   (iii) Avoidable new device purchases that could be supplied from MEL.

2. Revenue saving of annual servicing of the above €12,000

Soft savings are:

(i) Nursing time €65,700
(ii) Care of equipment - clean, charged and serviceable
(iii) 'On-site' repair turnaround

- The MEL has also now taken responsibility for infusion device maintenance and service repair. Pumps requiring repair has reduced by 80% from 10 per week to 2. This equates to repair savings of €2,400 per week, an annual projected saving of €125,000.
- The total projected savings in all categories in one year was > €400,000.
- Infusion device training is now available through the hospital intranet. It allows nurses to pre book places on a monthly training session lasting one hour. It involves the teaching of volumetric and syringe driver infusion stock. To date 51 nurses have received training. Nurses are requested to give training feedback by completing an evaluation form.
- An outcome of a Nurse Practice Development hospital audit has resulted in additional pumps being added to the MEL. The Graseby Ambulatory syringe drivers (MS16A) have now been added to the MEL stock.
- A nursing survey of the new hospital wide service has reflected an overall acceptance and realisation of widespread quality improvement for everybody.
- Finally the results recognised good access for pumps, more direct nursing time to patients and various local ward improvements.

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NOTE: Please be advised this is shortened version of the complete paper. The full article is available from the above e-mail address.

MANUFACTURING ISSUES

Counterfeit Medical Devices

In recent times counterfeiting has become an attractive crime. This is due to extremely high levels of profitability and low risk of prosecution, and even if prosecution occurs, penalties can be very light.

Just about every product imaginable has been counterfeited, from the obvious examples such as banknotes, Rolex watches and brand name denim jeans to the less obvious such as medicines, spirits, tea, software and medical devices. These less obvious examples can present serious risks to public health, especially where medical devices and medicines are concerned.

A counterfeit is an imitation that is made with the intent to deceptively represent its content or origins. The word counterfeit most frequently describes forged money or documents, but can also apply to any other manufactured item including medical devices. Counterfeiting is big business and accounts for approximately 5 - 7% of world trade, or 250 billion euro per annum. In 2003 across the EU there was a 77% increase in the seizure of foodstuffs and medicines and a 996% increase in the seizure of child's games and toys. Overall the number of items seized by EU customs in 2003 increased by 9%, to a total number of approximately 100 million items, compared to a 2002 figure of 85 million. Statistics for 2004 and 2005, while not yet finalised indicate that this trend is set to continue. Counterfeiting occurs worldwide but, presently, the majority of counterfeit goods are coming from Asia, with 60% of goods confiscated by EU customs in 2003 coming from China.

A counterfeit medical device may be a product that is made without the licensed owners approval, or a deliberately and fraudulently mislabelled device. They may contain the same materials and elements as the original device or may be made from cheaper, lower quality or even toxic materials. Functionality may be maintained or may be compromised. No matter what the type of counterfeit medical device or how it is actually counterfeited, all pose a significant risk to public health. This risk can take the form of under-specified materials, poor quality controls, hazardous materials; devices not meeting design specifications or simply the lack of traceability that is always associated with counterfeit products.

The devices most at risk of falling prey to the counterfeiters are those devices that are large volume, well-distributed brands. Also at risk are low volume high value brands, and low value brands that are very recognisable. Devices, packaging and instructions for use (IFU's) that are easy to replicate or imitate are also at risk. Due to the fact that medical devices are usually either high value products or have huge distribution the vast majority are at risk.

Counterfeiters are constantly changing the products they copy in order to reduce the chances of getting caught by flooding a market. Therefore all manufacturers, even those whose products have not been targeted before, are at risk.

Manufacturers can combat counterfeiting by taking proactive steps to protect their brands. Products should carry overt and covert recognition features that are difficult to copy. Design of packaging components and control of components design and distribution should be carefully protected. The market place should be monitored for:

- Increases in the amount of product on the market without a corresponding increase in production and distribution.
- A normal supply of product on the market place during circumstances of short legitimate supply.
- Presence of product in unusual supply / distribution outlets.
- Large purchases of raw materials, components, or finished product in abnormal circumstances, e.g. purchasers not known in business, consumer market too small to absorb level purchased etc.
- Lot numbers, batch codes, CE mark, expiry dates, etc.
- Quality of packaging print, packaging language and wording, method of wrapping packets etc.

Consumers and distributors of medical devices can also help to:

- Reduce the risk of harm to the end user and
- Protect themselves and / or their business

by being vigilant and being aware of

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Counterfeit Medical Devices

the presence of counterfeit goods on the market. Distributors and consumers should be cautious if approached by people with offers of goods that are much cheaper than the normal cost of authentic product. They should ensure that products purchased are genuine. End users should always look for the CE mark (although this too can be easily copied) and distributors can ask for proof of conformity to the relevant legislation. Distributors of medical devices should ensure that they purchase from authorised channels or be satisfied that the source of the medical device is genuine. Finally product from an unlikely source should always be avoided, unless the manufacturer confirms the product as genuine. If you suspect that a source of product is not genuine, please ensure that you report your concerns to the Medical Devices Department of the IMB.

Counterfeiting is big business and is on the rise in the medical device industry. Everything from surgical instruments to syringes, from catheters to condoms and from dental restorative to dressings can be counterfeited. Companies and end users can help to combat this crime and its associated risk to public health by being vigilant and cautious.

Upcoming Events

The Irish Medicines Board (IMB) will be holding an information day on Tuesday 6th September 2005 at 9.30am in the Robert Smith Lecture Theatre, Trinity Centre for Health Sciences, St. James's Hospital Campus, James's Street, Dublin 8 to launch our new guidance document on "Manufacturing of Medical Devices within Healthcare Institutions".

The information day is targeted at healthcare professionals who manufacture medical devices for patients in the healthcare setting including:

- Central Sterile Services Departments
- Clinical Engineers
- Physiotherapists
- Theatre Staff
- Occupational Therapists
- Laboratory Staff

It is envisaged that the day would be split into three sessions. The first session will provide information on the Medical Devices Department of the IMB and who can be defined as a manufacturer under the legislation. The second session will give details on how to meet the legislative requirements and what type of surveillance is carried out after the medical device is placed on the market. The afternoon session will give details on the vigilance system including the DATH's pilot, which is underway in Dublin. The afternoon session will also include two case studies – one on splints and the other on theatre packs. A question and answer session will take place after each session.

If you would like to attend this event, a copy of the registration form should be filled in for each attendee and returned by Friday 2nd September 2005 to Sinead Carty in the Medical Devices Department. A booking fee of 50.00 is being charged for this conference. Refreshments, lunch and conference documentation is included in this fee. Registration applications should be made as soon as possible as there is a limit on the number of places available. A copy of the agenda and registration form can be downloaded from the IMB medical devices website at www.medicaldevices.ie under the events section. Alternatively, please contact the IMB Medical Devices Department and a copy of this documentation can be sent to you.

If you have any queries relating to this conference, please contact Sinead Carty at 01-6764971 or medicaldevices@imb.ie.

New Draft Guidance Note for Medical Device Manufacturers regarding Auditing by the Irish Medicines Board (IMB) to the Medical Devices Regulations

The IMB is preparing a new guidance note for medical device manufacturers regarding auditing to the Medical Devices Regulations. The purpose of this document is to provide information to manufacturers on how the IMB conducts post market surveillance audits of Irish based medical device manufacturers.

As the Competent Authority for medical devices in the Republic of Ireland, the IMB may conduct post market surveillance in relation to Irish based medical device manufacturers and their products. This post market surveillance activity forms part of the review of manufacturers' compliance to the EU Directives and related Irish legislation by the IMB.

Post market surveillance is carried out by either:

(i) Proactive surveillance
(ii) Reactive surveillance

Proactive surveillance is carried out depending on what the IMB deems appropriate e.g. targeted audits in relation to a specific category of medical devices. This is a planned activity and manufacturers are advised well in advance of such an audit. Reactive surveillance is as a result of a specific market issue which requires prompt follow up in the interest of public health.

Post market surveillance can take place by way of audit. The aim of the audit is to ensure that the medical device manufacturer is complying with the essential requirements and schedules of the medical devices legislation.

The first draft of this guidance note has been issued to the Irish Medical Device Association (IMDA) for comments by its members. Any other parties interested in reviewing this document should contact medicaldevices@imb.ie. The IMB will take into account any feedback on the guidance note prior to its publication later in the year.

Regulatory Update

A public consultation in relation to the proposed changes to the Medical Devices Directive 93/42/EEC took place in May / June 2005. The EU Commission received a significant response. Comments were received in relation to the proposals to amend Annex IX on clinical investigations, re-use of single use devices, classification, etc. All comments received are under consideration by the EU Commission. It is expected that inter-services consultation at the EU Commission will take place in early autumn and that the first reading of the proposals will take place in Council during the UK Presidency.

A workshop took place in Brussels in July 2005 relating to emerging technologies. A working group is to be formed by the Commission to look at emerging technologies, their impact and whether the legislation currently in existence will be sufficient to handle these innovative products. The EU Commission has asked that the working group initially consider the area of nanotechnology.

A fifth workshop for new Member States took place in Prague, Czech Republic in June 2005. This workshop aimed at assisting the new countries with specific aspects of the implementation of medical devices legislation. Particular focus was placed on the handling of pre-market and post market surveillance issues. Ireland provided a workshop in relation to proposed changes to the medical devices legislation that is currently under review.

At the Market Surveillance Operations Group (MSOG) meeting in June 2005 the role of MSOG in the review of the Medical Devices Directive was discussed. Guidance documents on the roles and responsibilities of authorised representatives and class I medical device manufacturers were almost finalised and it is anticipated that these documents will be issued in late 2005. As well as discussing specific compliance communications from individual Member States, the Competent Authorities also reviewed the first set of data in relation to a market surveillance programme by Competent Authorities for compliance to the Commission Directive 2003/32/EC for medical devices utilising materials from transmissable spongiform encephalopathies (TSE) related species.

The *In-vitro* Diagnostic (IVD) Technical Working Group meeting considered terms of reference for the group. It is expected that these will be discussed by the MDEG in the autumn. The revision of the Common Technical Specifications (CTS) for Annex II, List A IVD medical devices was discussed and a number of Member States and industry put forward proposed changes for inclusion. The need to develop a CTS for Annex II, List B products, for example cytomegalovirus and chlamydia, was considered. It was agreed that the working group would review the draft proposals put forward by the original CTS Committee and discuss this issue further at the next meeting.

A MED.DEV in relation to labelling of *in-vitro* diagnostic medical devices is currently under preparation. This guidance will address the issue of electronic labeling for IVDs specifically for use by professional users. Ireland is leading the drafting group in relation to this guidance and it is envisaged that a draft paper will be presented to the Medical Devices Expert Group (MDEG) at its October 2005 meeting.

The study on Medical Devices Competitiveness and impact on public health expenditure commissioned by the EU Commission following the review of Directive 93/42/EEC has now been finalised. This study provides up-to-date data in relation to the medical devices sector in Europe. The study is available on the EU Commission website at: **http://europa.eu.int/comm/enterprise/medical_devices/compet_fact_en.htm.**

Staff Update

The Medical Devices Department is delighted to announce that DR. NIALL MACALEENAN has joined the medical devices team. Niall is a medical doctor and has extensive experience of the Irish healthcare sector including general medical professional training, clinical microbiology and serology and broad research experience. He recently completed a MBA degree in the Michael Smurfit Graduate School of Business. He will be working primarily in the area of clinical investigations and providing support to the vigilance section.

In July MARSHA NALLY, Medical Devices Administrator and MARY ATKINSON, Medical Devices Administrator, left the medical devices team. In their absence, any issues should be addressed to SINEAD CARTY or the medical devices general email address medicaldevices@imb.ie.