This e-solution is a novel approach for dealing with vigilance issues in hospitals and one that should be commended. Arising from the many queries we receive in relation to medical devices manufactured within the healthcare setting and the need for formal approval for the commencement of a clinical investigation, we have included an article that hopefully will address the concerns raised by professionals on a regular basis. We are also delighted to announce the completion of phase II of our online registration system for medical devices. The upgrades include the provision of more functionality to the user and also allow the manufacturer two way viewing of his registered low risk medical devices. It is hoped over the coming months that we will be in a position to commence the pilot testing of a similar online vigilance reporting system for medical devices.

As with all newsletters, we appreciate any feedback or suggestions for future articles.
The Medical Devices Department of the Irish Medicines Board (IMB) upgraded the online registration system for medical devices in June 2003. The reason for this upgrade was to increase functionality and to allow two-way viewing for users. Users can now also follow the progress of their registration as well as viewing and printing their organisation’s device reports. At a later date, the user will also be able to submit vigilance reports to the IMB through the IMB Medical Devices Extranet.

Current users of the medical device on-line registration system will have received a username and password when they first registered their organisation. These user names and passwords are still valid and will allow the user to access the new upgraded system. To access the IMB Medical Devices Extranet, these users must cut and paste the following address into their web browser: https://access.medicaldevices.ie/home/login.asp. The user will be prompted to enter their username and password before entering the site.

New users who wish to register their organisation using the online system may do so at the Registration section of the IMB Medical Devices website at www.imb.ie. Once the application has been approved, a username and password will be issued to the organisation.

Use of the On-Line Registration System for Medical Devices, provides further guidance on the online registration system. These instructions for use and other Guidance Notes may be downloaded from the IMB Medical Devices Website under the Publications section.

Frequently Asked Questions

**What is a custom made device?**

When manufacturing is carried out in accordance with a duly qualified medical practitioner’s or professional user’s written prescription for sole use of a particular patient, then the product is considered to be a "custom-made medical device".

Individual therapists do not have to be named.

The same therapist can be prescriber and manufacturer in current practice. Does this meet with the requirements of the Directives?

Yes. In the manufacturing cycle of a "custom-made" medical device, it is considered that it is the prescriber who undertakes the design of the product and the manufacturer who manufactures it to a predefined specification. The Therapist may undertake both of these roles.

Do current guidelines with regard to the Health and Safety Act satisfy the Medical Devices legislative requirements?

Both the Medical Devices legislation and the Health and Safety Act should be applied during the manufacture of medical devices. However both pieces of legislation are independent of each other. The Health and Safety Act is used to protect personnel at work. Statutory Instrument No. 252 of 1994 applies to the manufacturing and post market surveillance of medical devices. Manufacturers of medical devices must meet the legislative requirements of the medical devices legislation and in doing so the device in question “…..must not compromise the clinical condition or safety of patients, or the safety and health of users or where applicable other persons...” (S.I.252 of 1994 Schedule 1). In ensuring the safety of personnel it would be good practice for manufacturers to apply the provisions of the Health and Safety Act.
### Status of Guidance Notes

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HOSPITAL ISSUES

Hazard Notification - An E-solution developed by the North Eastern Health Board

All Health Boards receive notifications, both internally and from external agencies of potential hazards in equipment, consumables (including drugs and medical appliances) and food. The responsibility then rests with the Health Board to ascertain whether the hazard exists in any or all of the locations under its control, and, if it is found to exist, to take whatever action is appropriate. Within the NEHB as with most Health Boards there was no designated route for these notifications either for entry into or distribution internally. Though in recent years the NEHB have made efforts to rationalise their entry and hence their distribution, there remained no clearly mapped route.

The manner in which hazard notifications (internal and external) were dealt with was therefore uncoordinated and provided no assurance that the notifications either reached the appropriate person for action or that action was taken. This posed a risk to patients, staff, and the organisation.

In order to attempt to reduce this risk and simplify the system a project within the NEHB was undertaken which had four objectives.

1. To develop a system that distributes notifications appropriately.
2. To track the various stages and processes through which notifications must pass.
3. To report on completion of actions before they can be regarded as “closed”.
4. To, insofar as is practicable, be electronic.

A multidisciplinary committee was convened to include all internal stakeholders. External agencies were also consulted. The current processes were mapped and an integrated process agreed upon which could achieve assurance, with regard to distribution and feedback, using an electronic format. A project manager and a member of the Management Services Department were appointed to oversee the development of the distribution system. The system and database are Lotus Notes based and are managed by a Database Administrator. This ensures accurate distribution of notifications to, and collation of responses from, operational locations throughout the Health Board.

The Regional Materials Management Service was identified as being best placed to act as the conduit for the receipt, distribution and tracking of these notices. The Corporate Risk Management Office would receive monthly monitoring reports.

Solution

Upon receipt of a notification, either internal or external, an electronic alert is generated by the Database Administrator and sent to the appropriate “Designated Persons” for action in their particular locations. There will be a timescale within which the action must be reported to the Database Administrator as being “Not Applicable”, “Laid” or “Completed” detailing the action taken and the date of such action. This timescale varies in accordance with the priority assigned to the notice by external agencies. The report must be routed to the Database Administrator through the General Manager or such other person who may be in charge of the location.

The system will provide an audit trail, showing the status of all alerts for follow up of outstanding actions and periodic reports for Corporate Risk Management.

The finalised system has been tested and is due to go live on a phased basis. Phase one implementation is to take account of the Board’s Acute Hospitals.

The issue of coordination of hazard notification is one that poses a challenge to all healthcare agencies nationally and thus, there exists the potential for national application.

The outcome of this project was presented at the recent ISQSH Conference in Tullamore very positive feedback was received. The Irish Medicines Board has also expressed an interest in reviewing its potential for wider use.

Contact for further details
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Michael Gantly, Regional Materials Management – michael.gantly@nehb.ie

Hazard Notification Flow Chart
In 1998, Greenpeace and Health Care Without Harm brought media attention to concerns around the presence of DEHP in PVC.

PVC is a plastic polymer used in a wide range of medical devices. Without the addition of a plasticiser, PVC is hard and brittle but with the addition of DEHP, which is a plasticiser, the PVC is rendered more flexible.

Devices which include DEHP plasticised PVC include for example intravenous bags and tubing, blood bags and tubing, enteral feeding bags, nasogastric tubes, peritoneal dialysis bags, haemodialysis tubing, etc.

The amount of DEHP which can leach out of the PVC into the fluid in contact with the device is influenced by temperature, duration of contact with the device and the lipid content of the fluid.

The concerns about the use of DEHP centre around its possible effects on human reproduction. Animal studies have shown that rats exposed to high oral doses of DEHP have suffered adverse effects on male reproductive system development and the production of normal sperm.

Examples of highest risk procedures for exposure to phthalates would include procedures where the patient is young for example:
- Male foetus or neonate, at developmental stage
- Peri-pubertal male, is exposed to DEHP cumulatively
- Multiple procedures, enteral exposure
- Enteral feeding with lipids etc.

Several countries have reviewed the scientific data to date and have issued guidelines on how to minimise the possible risk to humans but recommendations vary from country to country.

The FDA in its Public Health Notification of July 12th 2002 notes that no adverse events have been recorded to date in humans linked to the use of DEHP in PVC. However it points out that no studies in humans have been done to rule it out.

In the report from Health Canada of January 11th 2002 it is noted that there is no data to confirm the toxicity of DEHP in humans. On the basis of the animal studies to date 12 recommendations to minimise the possible risks are outlined.

In December 2002 the Medical Devices Expert Group of the European Commission reviewed the September 2002 Opinion of the Scientific Committee on Medicinal Products and Medical Devices. The group agreed that there was a need:
1. To encourage further research on DEHP
2. To monitor closely any new scientific evidence on the subject and re-analyse it as appropriate
3. To establish a task force to deal with the issue

This decision was adopted by the European Commission in April 2003.


In-house Medical Devices & the Need for Clinical Investigations

- A medical device manufactured in-house within a hospital (the legal entity) and for use on patients within the same legal entity is not subject to the provisions of the Medical Devices legislation and the Irish Medicines Board (IMB) as Competent Authority does not require notification of the investigation. Ethics Committee approval may be necessary for in-house studies but it may differ from hospital to hospital. Please note that the device in this instance is not being “made available” or being “placed on the market” in the context of the Directive.
- If a device is undergoing a clinical investigation for the purpose of eventual commercial use then it is subject to the provisions of the Medical Devices legislation and therefore notification to the IMB for approval to commence the clinical investigation must be made.
- If a device manufactured in-house is being used outside the legal entity e.g. in another hospital then it is subject to the provisions of the Medical Devices legislation as the device is seen to be “placed on the market”.
- If during testing for proof of concept a manufacturer including an in-house manufacturer sees and intends a medical application in the results generated from the testing of a product then that product is no longer a research tool but falls within the definition of a medical device.
- If a clinical investigation is being performed using a device, which is CE marked and provided that the use of the device remains within the conditions of the CE marking the IMB does not require notification of the clinical investigation.
- When a submission is made to the IMB for clinical investigation approval, Ethics Committee opinion must accompany the submission i.e. Ethics Committee opinion forms part of the application. See Annex VIII of 93/42/EEC and related S.I. No. 252 of 1994.
- Guidelines issued by the hospital Ethics Committee would indicate whose responsibility it is to obtain Ethics Committee approval. For a normal clinical investigation, which is being notified to the IMB, the manufacturer applies for approval for a clinical investigation to the Ethics Committee. The sponsor who is normally a senior hospital doctor normally informs the Ethics Committee.
Regulatory Update

The Commission Communication on the functioning of the Medical Devices Directives was adopted on 02 July 2003. The Communication recommends making better use of available measures, including the redaction of devices, use of the precautionary principle and safeguard clause, developing guidance documents on implementation and regulatory clarification. The Communication also announced that a study is to be carried out in cooperation with national authorities and industry in relation to the impact of medical devices on public health spending and ways to improve the conditions for increasing competitiveness. More detail can be found on the European Commission website.

The text of the draft Commission Directive on the reclassification of total joint replacements was presented at the recent meeting of Medical Devices Experts Group (MDEG) in Brussels. Comments have been requested from interested parties. It is proposed that total hip, knee and shoulder replacements are to be reclassified from class IIb to class III category (high risk) due to the particular complexity of the joint function to be restored and the consequent increased risk of failure due to the device itself. In particular, it was felt that hip and knee replacements are weight bearing and extremely sophisticated implants for which risk for revision surgery is significantly greater than for other joints and that shoulders are subject to similar to acting dynamic forces. The fact that replacement surgery is also taking place in younger patients was also a consideration.

As software plays an increasingly important role in the quality and performance of medical devices e.g. imaging, life saving implantable medical devices, it was agreed at the Medical Devices Expert Group (MDEG) that a new Working Group on medical device software would be formed. It will look at issues such as software design, quality assurance throughout the software life cycle, including updates, risk management guidance for medical software, design validation within conformity assessment procedures for devices, validation of commercial off the shelf (COTS) software for medical appliances, guidance for Notified Bodies involved in software assessment, quality of European medical software standards.

The Eudamed database remains on target to be up and running by January 2004. A pilot study is underway in the Member States to upload registration records and mock Competent Authority reports from national systems to the Eudamed. This pilot is to be completed in early October and the outcome will be reviewed at the next Eudamed Working Group in the autumn.

The Vigilance Working Group at a recent meeting decided to update the Med.Dev 2.12-1 rev 4 on “Guidelines on a Medical Device Vigilance System” to reference the Global Harmonisation Task Force vigilance documents. There will be no specific update for in-vitro diagnostic medical devices (IVD’s) with the exception of a tick box for IVD’s to be incorporated. It was also agreed that post market surveillance and vigilance workshop would be held for Accession countries at the end of the year. Ireland as part of the Troika will be expected to assist with the development of such a workshop.

The use of electronic instructions for use (IFU’s) was raised by Eucomed and Ireland at the MDEG in July. In principle use of electronic IFU’s could be considered but the legal basis for it needs to be reviewed. The trade associations for consideration at MDEG will develop more detailed papers.

The issue of “research use only products” in relation to IVD’s was discussed at the July meeting of MDEG. Following discussions Ireland, Portugal and EDMA agreed to prepare a discussion paper.

Upcoming Events

IMB / IMDA IVD Information Day

The Medical Devices Department of the IMB will be holding an In-vitro Diagnostic (IVD) Information Day in association with the Irish Medical Device Association (IMDA) on Monday 08 September 2003. This IVD Information Day will be held in the IBEC Offices, 84 - 86 Lower Baggot Street, Dublin 2. A fee of €100 + VAT per head will apply to help cover costs for the day. Companies are permitted to register a maximum of two persons per company. A copy of the agenda for this event, can be downloaded from the IMB Medical Devices website www.imb.ie or from the IMDA website www.ibec.ie/imda. Agenda items include:

- Introduction to In-vitro Diagnostic Medical Devices Legislation
- Registration of all IVDs and Key Issues to Date
- Outcome of IVD Visits and Key Issues Arising
- The National Vigilance System for IVDs
- Following the presentations, two workshops will take place:
  - Case Studies on Vigilance Issues
  - How to Handle Recalls – Case Study
- There will also be time for discussion and a demonstration of the on-line registration system and the on-line vigilance reporting system will also take place.
- To register for this event, please go to www.ibec.ie/imda and click on events and then on the button for the workshop. If you have any queries regarding this event, please contact sharon.higgins@ibec.ie.