Decontamination of Reusable Medical Devices: A Risk Management Perspective.

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Contents:

- > Why we should manage risks and relevant definitions.
- Framework documentation.
- Perception to healthcare related risks.
- Reusable device design requirements.
- Device design deficiencies related to reusability.

Why Manage Risks?

Legal Argument:

- Criminal Prosecution
- Civil Claim for Personal Injury
- Personal Accountability

Moral Argument:

- Employee Welfare
- Reduce Pain & Suffering

Organizational Argument:

- Integral Part of Business Management
- Protect Reputation
- Cost Effective

Principles of Biomedical Ethics:

Beneficence:

- Patients should benefit from treatment.

Non-maleficence:

- Universal obligation to avoid harming others.

Justice:

- Equitable distribution of resources to maximise benefit and minimise harm to patients.

> Autonomy:

- Respect the right of others to make their own decisions. *(Relates to informed consent).*

Source: Beauchamp T.L, Childress J.F. 1983 Principles of Biomedical Ethics (2nd Edition). New York/Oxford: Oxford University Press.

Balance of Benefits Against Risks:

- Government takes the macro approach and evaluates benefits/risks for the population.
- Healthcare provider takes the organizational approach and evaluates benefits/risks for the patient whilst also taking into consideration organisational needs and objectives (including financial constraints).
- Patient evaluates benefit/risks on the basis of personal beliefs and aspirations.

Framework Documentation for Reusable Devices:

- National and international legal requirements with which manufacturers' must comply.
- Guidance documentation published by government agencies on recommended best practice for safely decontaminating used equipment.

Device Directives:

Medical Devices Directive 93/42/EEC (MDD).

Directive on Active Implantable Medical Devices 90/385/EEC (AIMDD).

In Vitro Diagnostic Medical Devices 98/79/EC (IVDMDD).

CE Marking:

> 93/42/EEC is meant to ensure EU wide free movement of products which carry the CE marking.

It does not mean goods are quality products, but that "the product conforms to the <u>minimum legal requirements.</u>" (Ortiz, K. 1999)

Device Categorisation:

Single-use Devices:

 Designated to be used once only then discarded.
(In UK - MHRA Device Bulletin MDA DB 2000(04) – Single-use Medical Devices: Implications and Consequences of Reuse).

Reusable Devices:

- Designed for multiple use. To be designated reusable a device must be capable of being safely and repeatedly reprocessed i.e. decontaminated. *(certain products may have a limited number of recommended uses e.g. Laryngeal Mask Airways [LMA's])*

Why Single-use Devices Should Not Be Re-used:

- Validated by manufacturer for one use only.
- Products are not designed with decontamination in mind.
- Materials and adhesives may break-down during decontamination processes and or reuse.
- Dyes used in materials may become unstable and leech from product to patient during use.
- > In the UK, it is against government guidelines.

Reusable Device Characteristics:

- Must comply with MDD and be CE marked.
- Where necessary, devices must disassemble to facilitate decontamination.
- Critical surface exposure to processes.
- Materials must be cleanable, preferably by an automated process as opposed to manual.
- Materials must be capable of withstanding process dynamics e.g:
 - mechanical
 - thermal
 - chemical.

Pre-purchase Questionnaires (PPQ):

Advisable in order to determine if the product will meet national guidelines and organisational needs.

Necessary to determine if the device can be decontaminated utilising existing in-house means. Or highlight the need to purchase additional decontamination equipment.

Contamination:

Defined as:

- "soiling or pollution of inanimate objects or living material with, harmful, potentially infectious or other unwanted material. In the clinical situation, this is most likely to be organic matter and microorganisms but may also include other undesirable inorganic substances such as dust, chemical residues, degradation products etc.
- However, the degree of risk to the host will depend on many factors, including the nature of the investigation or procedure, the susceptibility of the host and the nature and extent of the contamination. The nature and extent of microbial contamination is referred to as the BIOBURDEN.

Decontamination:

Defined as:

* "the combination of processes (including cleaning, disinfection and sterilization) used to make a reusable item safe for further use on patients and handling by staff."

Source: Health Service Circular HSC 2000/032 (Decontamination of Medical Devices). NHS Executive, London. UK.

Reusable Medical Device Life Cycle: (Source: NHS Estates)



Public Perception:

> Historical view - medical matters inherently safe.

Opinion reshaped through:

- Improved standards of education and media coverage of adverse medical events.
- Greater willingness to question.
- Wish to know risks and expected results.
- Rising intolerance to sub-optimal outcomes.

Professional Concerns (Decontamination):

- Device design.
- Design verification.
- Design validation.
- Decontamination instructions.
- Staff training.
- ≻ Time.

Design Requirements:

Manufacturers must apply the following principles:

- Eliminate or reduce risks as far as possible (inherently safe design and construction).
- Where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated.

Inform users of the residual risks due to any shortcomings of the protection measures adopted. (Source: MDD, Essential Requirement 2)

Design Verification:

Defined as:

"the method used to determine that the device meets or exceeds the manufacturers' predetermined specifications."

Source: ISO 17664: Sterilization of medical devices – Information to be provided by the manufacturer for the reprocessing of resterilizable medical devices.

Design Validation:

Defined as:

"the method used to determine that the device meets the users' need."

Source: ISO 17664: Sterilization of medical devices – Information to be provided by the manufacturer for the reprocessing of resterilizable medical devices.

Device Risk Assessment:

- ENISO 14971:2001 Medical devices Application of risk management to medical devices.
- Compatibility with processes.
- Compatibility with other products during decontamination process.
- Public Perception.

Need For Device Tracking & Traceability:

- Sets of instruments as well as instruments within Sets.
- Product Recall.
- Patient Safety.
- Risk Containment.

Evaluating Risk:

Evaluation should include a review of existing controls and any relevant accident or incident data.

The "acceptability" or "tolerability" of risk relates to internal and external standards; and to perception of the general public.

Medical Devices Vigilance System:

European Commission Guidelines.

- MDD & AIMDD include requirements for device manufacturers to report certain types of incidents to Competent Authorities. (MHRA in the UK).
- The Vigilance System is the name given to the process of notification and evaluation of these adverse events.
- System was set up under medical devices Directives to minimise risks to the health & safety of patients, users and others by reducing the likelihood of a serious incident involving a medical device being repeated in different places within the EU.

Conclusion:

Devices are required to be safe. Whilst safe does not necessarily mean risk free, residual risks must be:

- > Acceptable
- > Reasonable
- Justifiable.

Thank you for listening.