STANDARDS ARE THE INSTRUMENTS WE USE TO MANAGE RISK AND IMPROVE QUALITY IN OUR DECONTAMINATION UNITS.
About us
Statistics

SURGICAL SPECIALTIES

- ENT: 23%
- Neurosurgery: 29%
- Ophthalmology: 8%
- Orthopaedics: 13%
- Plastic Surgery: 6%
- Surgery: 21%

Children's University Hospital
Temple Street, Dublin

Achieved 6 Times
ABOUT US

Decontamination Unit became the first ISO 13485 and MDD registered hospital in the Republic of Ireland (October 2009).
Presentation Content

► What national changes?
► Researching the efficacy of implementation.
► Using standards to manage risk in the CDU.
► What are the benefits?
► Practical examples
► Conclusion
PART 3: RECOMMENDED PRACTICES FOR
CENTRAL DECONTAMINATION UNITS

Health Service Executive
Code of Practice for
Decontamination of
Reusable Invasive Medical Devices

PART 4: RECOMMENDED PRACTICES
FOR ENDOSCOPY UNITS

Health Service Executive
Code of Practice for
Decontamination of
Reusable Invasive Medical Devices
National Decontamination Audit

- Audit HSE, part of their national strategy for decontamination services 2007.
- The audit findings:
- ISO standards and best practice guidance, specific to decontamination equipment and facilities.
CUH Outcome

Statement & Conformances
Observations
Low Risk
Medium Risk
High Risk

82.68
13.5
2.05
1.27
0.5
Researching Literature / Why Implement?

“One guarantee that we cannot give patients is that they will not be harmed by the system meant to look after them (2002).”

Implement systems to:
► Identify and control decontamination risks
► Prevent / minimise the potential for the occurrence of an Adverse Event / harm to a patient.

ADVERSE EVENTS

► “Unintended injuries or complications resulting in death, disability or prolonged hospital stay that arise from health care management”.

2.9%-16% 1 or more AE
10% EU Average
37%-51% Preventable.

• Most common AE
• Healthcare-associated infections (HAIs)
• 1.4 million people affected world wide / any given time.

• **A HAI prevalence survey UK and Ireland (2006). NICE at least 5% develop SSI**
• **2007 NHS SCOTLAND NATIONAL HAI PREVALENCE SURVEY).**

<table>
<thead>
<tr>
<th>HAI Type Infections</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bone and Joint Infection</td>
<td>6</td>
<td>0.5</td>
</tr>
<tr>
<td>Blood Stream Infection</td>
<td>55</td>
<td>4.4</td>
</tr>
<tr>
<td>Central Nervous System Infection</td>
<td>2</td>
<td>0.2</td>
</tr>
<tr>
<td>Cardiovascular System Infection</td>
<td>11</td>
<td>0.9</td>
</tr>
<tr>
<td>Eye, Ear, Nose, Throat or Mouth Infection</td>
<td>155</td>
<td>12.5</td>
</tr>
<tr>
<td>Gastrointestinal Infection</td>
<td>191</td>
<td>15.4</td>
</tr>
<tr>
<td>Lower Respiratory Tract Infection other than Pneumonia</td>
<td>139</td>
<td>11.2</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>109</td>
<td>8.8</td>
</tr>
<tr>
<td>Reproductive System Infection</td>
<td>17</td>
<td>1.4</td>
</tr>
<tr>
<td>Systemic Infection</td>
<td>2</td>
<td>0.2</td>
</tr>
<tr>
<td>Surgical Site Infection</td>
<td>197</td>
<td>15.9</td>
</tr>
<tr>
<td>Skin and Soft Tissue Infection</td>
<td>137</td>
<td>11.0</td>
</tr>
<tr>
<td>Urinary Tract Infection</td>
<td>222</td>
<td>17.9</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>1243</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Risk factors for Surgical Site Infection (SSI)

**Exogenous**
- Environment
- Medical Devices
- Duration of operation

**Endogenous**
- Patients own Flora
- Blood transfusion

**Patient Factors** co-morbidities, concomitant infection at other sites, increased age, presence of foreign bodies, immune status etc.

However mortality rates attributed to unsterilized medical devices remains unknown!!
Impact of SSI

- Average increase in the length of stay for patients with SSI = 8.2 days
- 3 days for gynaecology patients.
- 9.9 days for general surgery patients.
- 19.8 days for orthopaedic surgery patients.

Study by Coella R et al (2001)
Second GPSC
Safe Surgery Saves Lives.

1 of 4 criteria

Clean Surgery

Background Paper (2006)

► Control of contamination at all levels of patient care is essential.

► Careful quality control practices.

Risk of transmission of (CJD) via surgical procedures

- Well documented risks.
- Underpinned the development of standards for decontamination practices internationally.
- Traceability of instruments.
- UK NICE recommendations for a separate pool of neurosurgical instruments for all children born post 1997.
- Use of single use accessories for neurosurgical procedures etc.
- Risks still present /extremely rare.
Our Journey to ISO and MDD Certification

Essential requirements of the MDD:
► “should be regarded as the minimum acceptable Standard whether or not the decontamination unit qualifies as a ‘manufacturer’ within the terms of the Directive”.

What have been the benefits of implementing ISO:13485 and MDD?

- Meet the needs and expectations of service users.
- Management engagement is a requirement.
- Achieve, maintain and improve our performance.

![Graph showing CDU Complaints Comparison 2010-2011]

**Activity** ↑ 16 % on 2010.

**Overall complaints** ↓ 50%
Benefits contd

- Effective planning, operation and control of the Decontamination process.
- Develop a risk management plan in support of meeting “Essential requirements” of the MDD 93/42 EEC.
- Section 7 (ISO 13485) Production realisation, clause 7.1 planning of product realization requires risk management throughout product realisation.
- Third party audit of our system for continued compliance
What Standards did we use for the risk management process?

- EN ISO 14971-2009 “Application of Risk Management to Medical Devices.”
- **Why:** “Compliance with all the requirement clauses in this standard will ensure that general aspects of medical devices related to patient risk and safety have been addressed” .(ISO 14971:2009).
If you are not aware of the hazard........
Risk Management in Healthcare

• Joint Commission defines risk management in healthcare:
  “clinical and administrative activities undertaken to identify, evaluate and reduce the risk of injury or harm to patients, staff and visitors and the risk of loss to the organisation itself”.

Carroll, R. 2009
Risk Management Process
ISO 14971

Risk analysis
- Intended use and identification of characteristics related to the safety of the medical device
- Identification of hazards
- Estimation of the risk(s) for each hazardous situation

Risk evaluation

Risk control
- Risk control option analysis
- Implementation of risk control measure(s)
- Residual risk evaluation
- Risk/benefit analysis
- Risks arising from risk control measures
- Completeness of risk control

Evaluation of overall residual risk acceptability

Risk management report

Production and post-production Information
What is Risk?

- **Combination**
  - *a)* the probability of occurrence of harm.
  - *b)* and the consequences / severity of that harm.
### Categories of Risk Index
Qualitative/Quantitative Analysis

#### Severity

| Low | Medium | High |
|----------------------------------|
| Improbable | Rare | Probable |

#### Likelihood

<p>| Low | Med Risk | High Risk |
|----------------------------------|
| Improbable | Frequent |  |</p>
<table>
<thead>
<tr>
<th>Occurrence</th>
<th>Severity</th>
<th>Effect</th>
<th>Quantity / Year</th>
<th>Outcome</th>
<th>Quantity / Year</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>Occasional</td>
<td>Moderate</td>
<td>Device Does not Work</td>
<td>10,000</td>
<td>25 devices fail/ year</td>
<td>500,000</td>
<td>1,250/ fail/ year</td>
</tr>
<tr>
<td>Rare</td>
<td>Catastrophic</td>
<td>Death or Serious Injury</td>
<td>10,000</td>
<td>One possible death every 2 years</td>
<td>500,000</td>
<td>25 deaths/ year.</td>
</tr>
</tbody>
</table>
## Risk Estimation Post Controls

= Critical x Improbable = Low

<table>
<thead>
<tr>
<th>POTENTIAL HAZARD</th>
<th>SEVERITY</th>
<th>OCCURRENCE</th>
<th>Risk Reduction/ Controls</th>
<th>Risk Estimation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device design does not allow for adequate decontamination</td>
<td><strong>Critical</strong>&lt;br&gt; If the device design is in conflict with the methods for decontamination and the CDU cannot guarantee a sterile product. <em>Infection Risk to Patient.</em></td>
<td><strong>Probable</strong></td>
<td>• Investigate any product which presents a decontamination challenge.  &lt;br&gt;• A risk assessment of risks relating to the decontamination of that product.  &lt;br&gt;• Presented to stakeholders &amp; IMB.  &lt;br&gt;• Risk Benefit Analysis.  &lt;br&gt;• Residual risks assessed.  &lt;br&gt;• Medical Device Equipment Management Committee.</td>
<td><strong>High</strong></td>
</tr>
</tbody>
</table>
Example
Functionality

- Metal pins are used to apply skeletal traction or in the management of orthopaedic fractures.
- These pins protrude through the skin and are attached to the external fixator by **rod to pin** clamps.
- Research shows pin tract infection (PTI) is a major complication of external fixation rates 0.5-30%
- Most common etiology *Staphylococcus aureus* and *Staphylococcus epidermidis*

After manual, ultrasonic and washer x 2
Could not be cleaned.
MEDICAL DEVICE RISK

Residual risks must be:
- Acceptable
- Reasonable
- Justifiable.
Risk Assessment

- **Device**: *Rod to pin clamp*
- **Intended Use**: *External Fixator*
- Identify known or foreseeable hazard: *Unable to Decontaminate*
- Is a risk reduction necessary?: *Yes*
- If so can the risk be reducible?: *Yes*
- Detail action required: *Recommend single use only.*
- Are other hazards generated if the risk is reduced? *Cost*
- Do medical benefits outweigh the residual risk?: *Yes*
- Details of actions taken? Informed *IMB, Theatre, Microbiologist, Manufacturer.*
- Follow up assessment necessary?: *Yes*
- Details: *Review costing for bulk order/ single use product design by manufacturer*
- Signed and dated.
<table>
<thead>
<tr>
<th>HAZARDS</th>
<th>TYPE RELATED TO THE DECONTAMINATION OF DEVICE</th>
<th>A/NA</th>
<th>Associated Risk</th>
<th>Total Risk after Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.Biological</td>
<td>Contamination /Cross Infection</td>
<td>A</td>
<td>Infection Risk to Patient</td>
<td>Low</td>
</tr>
<tr>
<td>2.Environmental</td>
<td>Adventitious Contamination of Product</td>
<td>A</td>
<td>Infection Risk to Patient</td>
<td>Low</td>
</tr>
<tr>
<td>3.Hazards relating to device decontamination</td>
<td>Instruction/ Training/ Device Design</td>
<td>A</td>
<td>Infection Risk to Patient</td>
<td>Low</td>
</tr>
<tr>
<td>4.Hazards Arising from Functional Failure, Ageing</td>
<td>Decontamination Equipment Power or service supply failure/ Instrumentation maintenance.</td>
<td>A</td>
<td>Infection Risk to Patient/ Equipment not available.</td>
<td>Low</td>
</tr>
<tr>
<td>5.Occupational Hazards</td>
<td>MH / OBE/ CHEM/ EQUIP/ Service Planning !</td>
<td>A</td>
<td>Risk to Staff</td>
<td>Low/ Medium</td>
</tr>
<tr>
<td>6.Communication</td>
<td>Ineffective Communication</td>
<td>A</td>
<td>Risk to Patients and staff</td>
<td>Low</td>
</tr>
<tr>
<td>7. Loan Equipment</td>
<td>Inappropriate Management Process</td>
<td>A</td>
<td>Risk to Patients</td>
<td>Low</td>
</tr>
</tbody>
</table>
Conclusion

“The most important knowledge in the field of “Patient Safety” is how to prevent harm to patients during treatment or care”. (WHO).

Daunting Task!

Certification to ISO 13485 and MDD provides external validation of your risk management framework for decontamination services. Quality Assurance!
Managing Risk

A pessimist sees the difficulty in every opportunity;
an optimist sees the opportunity in every difficulty -

Winston Churchill
THANK YOU FOR LISTENING!

GO RAIBH MAITH AGAIBH!

OBRIGADO ESCUTANDO!