MISUSE OR MODIFICATION OF MEDICAL DEVICES / NON-MEDICAL PRODUCTS: SAFETY, SUITABILITY AND EFFECTIVENESS ISSUES

SUMMARY

The misuse or modification of medical devices, and the use of non-medical products for medical purposes, involves risks relating to safety, suitability and effectiveness. Guidance is provided.

BACKGROUND

1. The Medicines and Healthcare products Regulatory Agency (MHRA), the regulator for Medical Devices in the UK, has identified a trend for:
   a) off-label use of medical devices (where a device is used for a purpose other than that intended by the manufacturer),
   b) modification of medical devices by the user (excluding modifications sanctioned in the Instructions for Use),
   c) adaptation and use of non-medical products for clinical purposes.

2. The Medical Device Regulations stipulate that the manufacturer of a device is responsible for establishing that the device is safe and that it is suitable for its intended purpose. To establish this, manufacturers implement appropriate controls on the device design and manufacture, and evaluate the safety and performance of the device in its intended application. This involves an analysis of risks that could arise during use, an assessment of relevant pre-clinical and clinical data, the preparation of appropriate instructions for use and, if necessary, specific training schemes. From such activities, manufacturers are able to verify that risks have been eliminated or minimised and are judged acceptable when weighed against the anticipated benefits to patients.

3. Devices that are used off-label (e.g. urinary catheters for wound closure\(^1\)), modified by the user (e.g. finger pulse oximeter attached to ear with wooden clothes peg\(^2\)) or not intended for medical use (e.g. paper clips in wound closure\(^3\), synthetic acrylic nails as splints for nailbed lacerations\(^4\) or digital cameras and cellular phones used to send digital images of x-ray films to remote locations) will not have undergone this level of scrutiny. The consequent lack of verification of device performance means that it cannot be assured to be safe, suitable or effective. The use of a device in these circumstances exposes users and patients to unknown and therefore unacceptable risks and may have legal and ethical implications.

<table>
<thead>
<tr>
<th>Suggested Distribution</th>
<th>Accident &amp; Emergency</th>
<th>Ambulance Services</th>
<th>Anaesthetics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Care Home Services</td>
<td>Community Care</td>
<td>Dental Hospitals</td>
<td>Device Managers</td>
</tr>
<tr>
<td>District Nursing</td>
<td>Health &amp; Safety</td>
<td>Health Centres</td>
<td>Hospices</td>
</tr>
<tr>
<td>Infection Control Staff</td>
<td>Medical Physics</td>
<td>Operating Departments</td>
<td>Practice Nurses</td>
</tr>
<tr>
<td>Risk Management</td>
<td>Wards</td>
<td>All Nursing, Medical and Professions Allied to Medicine</td>
<td></td>
</tr>
</tbody>
</table>
4. Examples of potential dangers include:
   a) adverse reactions,
   b) inadequate sterilization,
   c) insufficient mechanical strength and/or structural integrity,
   d) insufficient durability,
   e) misuse due to lack of adequate training.

5. As well as the possible risks to the patient and user, there is a potential for litigation against the hospital or healthcare professional. Liability for off-label use rests with the user, not the manufacturer of the medical device or product in question. Healthcare professionals should also be aware that the modification of a medical device (other than those sanctioned by the Instructions for Use) may lead to the healthcare professional becoming the manufacturer of a new device and thus subject to the requirements of the Medical Device Regulations.

6. The consequences of using even simple medical devices outside their intended purpose can be serious. For example, use of tongue depressors (Class 1 medical devices) in a neonatal ITU as limb splints led to two deaths and one amputation because of fungal infection. Advice has also been issued on the risk of entrapment and asphyxiation of people in beds used with incompatible side rails.

7. Healthcare professionals should be aware that consequences of using off-label or modified devices may include:
   a) risk to patients,
   b) contravention to duty of care with regard to patient safety,
   c) legal implications (responsibility for safety and performance of the device may move from the manufacturer of the device to the healthcare professional).

ACTION

8. This notice should be brought to the attention of all appropriate managers and staff especially medical, nursing and professions allied to medicine.

9. Medical devices should only be used for their intended purpose in accordance with the manufacturer’s Instructions for Use.
10. Medical devices should not be modified, including alterations to their function or structure, unless specifically sanctioned in the Instructions for Use.

11. Modified medical devices and non-medical products should not be used for clinical purposes unless there is no suitable CE-marked alternative.

12. Where the healthcare organisation or healthcare professional judges that there is no alternative but to use a medical device off-label, or to modify an existing medical or non-medical device, a full risk assessment should be carried out and documented, with consideration given to ethical and legal implications.

13. Where a clinician judges there is no alternative to off-label device use, patients should be fully informed during the consent procedure and a note made in the patient’s records.

REFERENCES

6. HAZ(SC)96/07, Wooden tongue depressors used as limb splints: potentially fatal fungal infection in neonates, Scottish Healthcare Supplies, 1 May 1996.