IMPLICATIONS OF THE EUROPEAN COUNCIL DIRECTIVE 2010/32/EU ON PHARMACY ASEPTIC PRACTICES IN THE UK

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Background to the Directive

Main findings of the Newcastle work to influence drafting of UK legislation

Implications for pharmacy aseptic units

Update on situation in NE aseptic units

Risk assessment workshop
Needle-stick injuries account for 17% of all injuries incurred by NHS employees.

Since the late 1990s at least 17 healthcare workers have contracted hepatitis C and there have been five documented cases of HIV from sharps injuries.

Prevention of exposure is a priority of the directive.

The Directive stipulates that:

Where the results of a risk assessment reveal a risk of injuries with a sharp and/or infection, workers’ exposure must be eliminated by taking the following measures without prejudice to their order;

- The practice of recapping shall be banned with immediate effect.
BACKGROUND

- According to data from the Health Protection Agency and the Centres for Disease Control and Prevention in the USA re-sheathing causes sharps injuries
- Re-sheathing is common practice in pharmacy aseptic units in the North East
- Re-sheathing already prohibited in clinical areas
- Risks from re-sheathing not the same for pharmacy aseptic areas
- The Directive makes no exceptions
NEWCASTLE WORK

- **Primary aim:**

  *To conduct a risk assessment concerning needle re-sheathing for pharmacy aseptic units in the North East.*

- **Secondary aims:**

  *Present the results of the risk assessment to the Health and Safety Executive to influence wording of UK legislation*

  *Assess whether a re-sheathing device would be a practical method of mitigating against needle-stick injuries during the re-sheathing process*
METHOD

Identify problems

- Questionnaire to all validated pharmacy operators in the North East
- Asked the following:
  1. How often they re-sheath
  2. In what circumstances they re-sheath
  3. What number of operators have received a needle-stick injury and if any were due to re-sheathing
  4. In what circumstances these injuries occur
  5. What was the severity/outcome of such injuries
87% of pharmacy operators in the North East who completed the questionnaire re-sheath.
RESULTS

82% of these operators re-sheath more than 50 times each day.

The most common methods of re-sheathing were horizontal re-sheathing and gravity re-sheathing.
39% of the operators who completed the questionnaire had incurred a needle-stick injury in the past 3 years.
Preventative Action: Re-sheathing Devices

- Two different re-sheathing devices obtained
  - Safe-T-Cap and Needle-Safe II
- Trial in the Northern Centre for Cancer Care Pharmacy Aseptic Unit for 1 week
- Assess devices using a questionnaire and QC testing of initial bioburden at Stockton QC Laboratory
- Questionnaire used to assess impact of devices on operator technique and incidence of injuries
The questionnaire asked the following:

1. Did the operators incur any injuries while using the devices?

2. Were the devices easy to use and clean?

3. How did the devices impact on their current technique?

4. Did they need to resort to double-handed re-sheathing?

5. Did they believe the devices increased the risk of contamination within the unit?
# COMPARISON OF RE-SHEATHING DEVICES

<table>
<thead>
<tr>
<th>Properties</th>
<th>Needle-Safe II Re-Sheathing Device</th>
<th>Safe-T-Cap (now Britec) Re-Sheathing Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ease of cleaning</td>
<td>Poor</td>
<td>Good</td>
</tr>
<tr>
<td>Ease of use</td>
<td>Poor</td>
<td>Good</td>
</tr>
<tr>
<td>Ability to de-sheath</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Initial bioburden</td>
<td>None detected</td>
<td>None detected</td>
</tr>
<tr>
<td>Cost</td>
<td>£16+VAT</td>
<td>£50+VAT</td>
</tr>
</tbody>
</table>
Categorise problems

- Impact on operators
- Impact on product
- Impact on patients

Analysis of problems

- National Patient Safety Agency Risk Matrix for Risk Managers
Radioactive contamination of surfaces and equipment

Radiation dose to operators, particularly to fingers

Need to re-sheath to allow contents of syringes to be measured in a radionuclide calibrator

Used syringes must be removed from syringe shields prior to disposal
55 responses (33%) from aseptics or radiopharmacy

Concern that ban on re-sheathing would have serious consequences for patient safety

“...HSE will consider if Regulation 4(1)(c) can be redrafted to clarify that recapping is only to be used where it is necessary to control a risk (which will include risk to patient safety); in addition to retaining the requirement in the draft for the risk to employees to be controlled by a suitable appliance, tool or equipment. This will allow pharmacists etc to carry out the necessary procedures to prepare medicines. However, they will need to review how they currently recap needles and ensure that suitable risk control measures are in place.”
Avoid the use of sharps where possible

- Review the devices currently in use
- Can non-sharp devices be used in their place? (These devices may be more expensive than existing ones though.)
Use safer sharps

- Where use of sharps cannot be avoided, aseptic units must then look at how ‘safer sharps’ can be substituted, where reasonably practicable.

- These are devices where the needle is protected from causing injury, eg. shielded or automatically contained.
Use of existing sharps and re-sheathing needles

- Only if non-sharp or safer-sharp devices are not reasonably practical can existing exposed sharps be used. The HSE recognises this and has specifically allowed for re-sheathing in the UK legislation provided that:

  - Re-capping is only undertaken if the process requires it,
  - A risk assessment for the process is undertaken,
  - The risk of injury to employees is effectively controlled by the use of a suitable appliance, tool or other equipment – i.e. a re-sheathing device.
THE LATEST SITUATION IN NORTH EAST

- Have you implemented the Regulations?
  - In full 10%/ partially 60%/ not at all 30%
- If only partially or not at all, have you added this to your risk register
  - Yes 20%  No/Not sure 80%
- Have you moved over totally or partially to needle-free devices?
  - No 60%
THE LATEST SITUATION IN NORTH EAST

- Which devices have you introduced?
  - Blunt needles (25%), Vented vial spikes (55%),
  - Bags with needle-free access (11%)

- Do you have a residual need to re-sheath sharps?
  - Yes 80%  No 20%

- Has your Trust implementation group been to assess pharmacy or are you involved in implementation at a Trust level?
  - No 90%
Use of existing sharps and re-sheathing needles

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  - Re-capping is only undertaken if the process requires it,
  - A risk assessment for the process is undertaken,
  - The risk of injury to employees is effectively controlled by the use of a suitable appliance, tool or other equipment – i.e. a re-sheathing device.
### Risk Assessment Methodology

**Likelihood**

\[
\text{Risk score} = \text{Likelihood} \times \text{Consequence}
\]

<table>
<thead>
<tr>
<th>Likelihood score</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Descriptor</strong></td>
<td>Rare</td>
<td>Unlikely</td>
<td>Possible</td>
<td>Likely</td>
<td>Almost certain</td>
</tr>
<tr>
<td><strong>Frequency</strong></td>
<td>This will probably never happen/ recur</td>
<td>Do not expect it to happen/ recur but it is possible it may do so</td>
<td>Might happen or recur occasionally</td>
<td>Will probably happen/ recur but it is not a persisting issue</td>
<td>Will undoubtedly happen/ recur, possibly frequently</td>
</tr>
<tr>
<td>Domains</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>--------------------------------</td>
<td>---------------------------</td>
<td>--------------------------------</td>
<td>--------------------------------</td>
<td>----------------------------------------</td>
</tr>
<tr>
<td></td>
<td>Negligible</td>
<td>Minor</td>
<td>Moderate</td>
<td>Major</td>
<td>Catastrophic</td>
</tr>
<tr>
<td>Minimal injury requiring no/minimal intervention or treatment</td>
<td>Minimal injury requiring minor intervention</td>
<td>Minor injury or illness, requiring minor intervention</td>
<td>Moderate injury requiring professional intervention</td>
<td>Major injury leading to long-term incapacity/disability</td>
<td>Incident leading to death</td>
</tr>
<tr>
<td>No time off work</td>
<td>Requiring time off work for &lt; 3 days</td>
<td>Requiring time off work for &gt; 3 days</td>
<td>Requiring time off work for &gt; 14 days</td>
<td>Mismanagement of patient care with long term effects</td>
<td>Multiple permanent injuries or irreversible health effects</td>
</tr>
<tr>
<td></td>
<td>Increase in length of hospital stay by 1-3 days</td>
<td>Increase in length of hospital stay by 1-3 days</td>
<td>Increase in length of hospital stay by 1-3 days</td>
<td>Mismanagement of patient care with long term effects</td>
<td>An event which impacts on a large number of patients</td>
</tr>
</tbody>
</table>
### Risk Assessment for use of un-sheathed needles in Pharmacy Aseptic Units.

<table>
<thead>
<tr>
<th>Risks</th>
<th>Likelihood</th>
<th>Consequence</th>
<th>RISK SCORE for un-sheathed needles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure to blood-borne viruses</td>
<td>N/A</td>
<td>5</td>
<td>N/A</td>
</tr>
<tr>
<td>Needle-stick injury due to un-sheathed needles on workbench during transfer or during volume checks</td>
<td>4</td>
<td>1</td>
<td>4</td>
</tr>
</tbody>
</table>

**Risk Assessment Workshop**

- **Risk Assessment**
  - **RISK SCORE** = Likelihood x Consequence

<table>
<thead>
<tr>
<th>Likelihood score</th>
<th>1</th>
<th>2</th>
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<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Descriptor</td>
<td>Rare</td>
<td>Unlikely</td>
<td>Possible</td>
<td>Likely</td>
<td>Almost certain</td>
</tr>
</tbody>
</table>

- **Likelihood**:
  - 1: Almost certain
  - 2: Likely
  - 3: Possible
  - 4: Unlikely
  - 5: Rare

- **Consequence**:
  - 1: Extreme risk
  - 2: High risk
  - 3: Moderate risk
  - 4: Low risk
  - 5: N/A

**1-3 RISK SCORE**
- Low risk

**4-6**
- Moderate risk

**8-12**
- High risk

**15-25**
- Extreme risk
Risk Assessment Workshop

| Consequence score (severity levels) and descriptors |
|------------------------|----------------|----------------|----------------|
|                        | 1              | 2              | 3              | 4              | 5              |
| Domains                | Negligible     | Minor          | Moderate       | Major          | Catastrophic   |

Risk Assessment for use of re-sheathed needles in Pharmacy Aseptic Units.

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Exposure to blood-borne viruses</td>
<td>N/A</td>
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<td>N/A</td>
</tr>
<tr>
<td>Needle-stick injury due to unsheathed needles on workbench during transfer or during volume checks</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
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1-3  Low risk
4-6  Moderate risk
8-12 High risk
15-25 Extreme risk
# Risk Assessment for Un-sheathed Needle-sticks in Pharmacy

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<td>N/A</td>
</tr>
<tr>
<td>Needle-stick injury due to un-sheathed needles on workbench during transfer or during volume checks</td>
<td>4</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Contamination of environment due to un-sheathed needles on workbench during transfer or during volume checks</td>
<td>5</td>
<td>3</td>
<td>15</td>
</tr>
<tr>
<td>Contamination of product due to un-sheathed needles on workbench between transfer or during volume checks</td>
<td>4</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>Needle-stick injury due to un-sheathed needles in sharps bin</td>
<td>5</td>
<td>1</td>
<td>5</td>
</tr>
</tbody>
</table>

| Risk score | Description     |
|------------|----------------|----------------|
| 1-3        | Risk score: Low risk |
| 4-6        | Risk score: Moderate risk |
| 8-12       | Risk score: High risk |
| 15-25      | Risk score: Extreme risk |
# Risk Assessment for Re-sheathed Needles in Pharmacy

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<td>3</td>
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<tr>
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<td>1</td>
<td>1</td>
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Directive 2010/32/EU has significant implications for pharmacy. Pharmacies should:

- Avoid the use of sharps where possible
- Use safer sharps
- Only continue to use existing sharps and to re-sheath needles if the above are not practical after performing a risk assessment to justify re-sheathing by mitigating risks by using a re-sheathing device.
QUESTIONS ???

Thank You for Listening