From: nss iric <nss.iric@nhs.scot>
Sent: 11 March 2021 19:53
Subject: Information Message IM/2021/001 - Supply disruption of sterile infusion sets and connectors manufactured by Becton Dickinson (BD)

IRIC **Incident Reporting & Investigation Centre**

Circulation
NHS Equipment Co-ordinators

Copied to
Local authority equipment co-ordinators
General distribution list

Reference: IM/2021/001
Subject: Supply disruption of sterile infusion sets and connectors manufactured by Becton Dickinson (BD)

This information message is sent to draw the attention of Equipment Co-ordinators to information which may be relevant to the safety of equipment and facilities in local authorities and health boards. Please find the information below:

National Patient Safety Alert NatPSA/2021/001/MHRA, *Supply disruption of sterile infusion sets and connectors manufactured by Becton Dickinson (BD)*, was issued in Scotland today. The covering message indicated that guidance was expected to be issued in the form of a CMO/CNO letter. The letter has now been issued and a copy is attached for Equipment Co-ordinators.

As the Equipment Co-ordinator for your organisation, we recommend that you assess whether or not to forward this information to managers and staff within your area of responsibility who might benefit from being aware of it.

For enquiries, if you received this message directly from IRIC, email us direct at nss.iric@nhs.scot or phone 0131 275 7575. Alternatively, if you have received this message from someone in your own organisation, please contact them in the first instance so they can collate enquiries and liaise with IRIC as required.

Incident Reporting & Investigation Centre (IRIC)
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The Scottish Government
Riaghaltas na h-Alba

From Chief Medical Officer : Chief Nursing Officer : Interim Chief Pharmaceutical Officer

To:
Board Nurse and Medical Directors
Board Medical Physics Leads
NHS Procurement Management SMT Leads

Copied to:
Directors of Pharmacy
Board Resilience Leads
Incident Reporting and Investigation Centre, Health Facilities Scotland
Chief Executive National Services Scotland
Chief Executive Healthcare Improvement Scotland
Scottish Independent Hospitals Association lead
Directors of Public Health

11 March 2021

URGENT AND IMPORTANT – RECALL OF BD INFUSION PRODUCTS

As you will be aware Becton Dickinson (BD) has issued a Field Safety Notice today accompanied by a Patient Safety Alert from the Medicines and Healthcare products Regulatory Agency (MHRA) National Patient Safety Alert: Supply disruption of sterile infusion sets and connectors manufactured by Becton Dickinson (BD) (NatPSA/2021/001/MHRA) - GOV.UK (www.gov.uk)

We are aware of the immediate acute pressures that this places on NHS Boards as a result. Together with a freeze on supply of certain BD sterile infusion sets and connectors, this has created both an immediate supply issue and ongoing clinical care requirements.

To respond to this, Scottish Government clinical leads and National Services Scotland have been working rapidly to put in place measures to alleviate the disruption that this will cause. This letter provides:

- Information and support on mitigating actions and clinical risk assessments. The initial clinical risk assessment outlined in the Annex will be reviewed with specialists and is for products where the clinical risk of an immediate withdrawal of products that are specialised is greater than the risk of continuing with their use

- Requests Board nominations of a clinical or nursing lead and Medical Physics lead to join the Incident Management Team in National Procurement. Nominations should be sent to sghru@gov.scot who will coordinate the list for National Procurement. Please could replies be sent by Monday 15th March 2021.

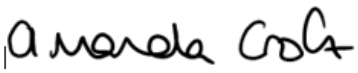
- A four country supply review is underway for the immediate pressures on specific items with mutual aid arrangements being put in place.

- A national overview of BD Infusion products use across NHS Boards has been compiled to inform a targeted approach to inform pressure points and areas of relative headroom.

National Procurement have established a Service Now portal for all Board queries https://nhsnss.service-now.com/covid_19_supplies Health boards should follow their local processes before sending in the supplies request.

We are continuing to monitor the supply issues closely and will update further in due course. In the meantime, should you have any queries, please contact sghru@gov.scot

Yours sincerely



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Annex

1. Clinical Engagement Group

2. BD infusion set limitation of stock and usage.

Purpose

This paper provides an initial risk assessment and risk mitigation around the use of BD infusion sets following the manufacturer field safety notice MDS-21-4072 issued on 11-3-2021 to remove current stock of:

- Infusion Sets for AlarisTM Pumps (GP, VP, CC, GW/GW800 and SE, IVAC 590 series) and
- Gravity Infusion sets and connectors.

It is based on the NHS National Services Scotland Incident Management Team and specific mitigations from the field safety notice released by BD: MDS-21-4072. It will be reviewed regularly and updated as required.

Background

BD has identified a problem with a 3rd party sterilisation services provider that following investigation means that BD is unable to guarantee the sterility of the products including infusion sets and connectors. BD have advised that the issue regarding the 3rd party sterilisation service may have been happening over many years however there was no data to indicate this had had any adverse impact, with no contamination isolated on from testing affected products. New certified sterile supplies of the listed BD infusion sets are anticipated to be available at the end of March 2021.

Across the UK BD provides approximately 60% of iv infusion equipment and consumables in NHS and other healthcare settings. The volumetric pumps and compatible infusion sets are unique to each manufacturer and there is no cross-manufacturer compatibility for the sets. Modification of other manufacturer's infusion sets to be compatible with BD pumps is not possible safely.

The products impacted are :

- Gravity infusion sets : These are generic and alternative products are available without change of clinical process

- Syringe Driver sets : These can use generic syringes and alternatives products are available without change of clinical process

- Volumetric infusion pump sets (These are pump specific and alternative manufacturers sets cannot be used)

- Specialist infusion pump Oncology Sets (These are pump specific and alternative manufacturers sets cannot be used)

Approach taken

An incident management team including critical care clinician input, product technology specialists, infection control and NSS National Procurement have been working to rapidly review the current position in relation to supplies in NHS Scotland Boards and the National Distribution Centre (NDC), and to recommend a range of local and national actions to address the current issues.

As an urgent priority, a Clinical Engagement SLWG including clinical input from each board and medical physics are to be brought together to review the current risks and relating to the immediate stock shortages of BD product, the continued use of BD product and the use of alternative manufacturer. The group will explore the care settings and clinical processes using the affected BD products and consider all options for ensuring the safe continued provision of care.

Outline of current risks for Clinical Engagement review

3. Risk

Immediate, prior to alternative manufacturer of pump provision, stock pressure on BD items which are anticipated to be depleted before new certified supplies can be provided. Certified supply of product from BD is expected to resume at the end of March 2021.

3.1 Impact

Administration sets cannot be provided for fluid and drug administration in care settings.
Care is delayed or cannot be provided for patients using these administration sets.

3.2 Mitigation

- For generic gravity infusion sets and syringe pump sets, identify alternative manufacture sets.
- Identify alternative BD products that can provide equivalent fluid or drug administration in specified care settings.
- Identify alternative process for fluid and drug administration in specified care settings.
    - Consider use of syringe pumps for high-alert medications that require continuous infusions (including weighed-based drugs) or gravity alternatives if clinically acceptable.
    - Consider use of gravity infusions for large volume infusates that do not require high-accuracy or weighed-based infusion.
    - Consider alternative arrangements for infusion therapy including conversion to oral therapy and the use of alternative types of infusion devices.
- Share national stock where use of BD product is immediate and uniquely necessary and no alternative can be identified.
- Elective care that requires unique equipment is considered for delay

4. Risk

Change of process for drug and fluid administration following the use of alternative product or alternative method of administration due to shortage or avoidance of BD product.

4.1 Impact

Adverse events related to drug administration or dosage may lead to serious harm or life-threatening conditions.

4.2 Mitigation

- Risk assessment in local care setting of change of process/product to minimise risk of harm.

- Training and sign off on change of process/product for each care setting.
- Audit on safe and compliant use of process/product for each care setting.
- Care with dose sensitive fluid/medication is delayed where possible

March 2021