Building healthier lives

University Hospitals Birmingham
NHS Foundation Trust

Developing a Pharmacovigilance Assessment Form for a Pharmacy Aseptic Unit

Jennifer Young, Specialist Pharmacist – Oncology Clinical Trials

Introduction

- It is a requirement to report all suspected adverse drug reactions (ADRs) for unlicensed products (such as those prepared under Section 10) to the Medicines and Healthcare products Regulatory Agency (MHRA), regardless of how severe or common the reaction is.
- Systemic anti-cancer therapy (SACT) products include a high proportion of black triangle drugs whereby it is a necessary to report all suspected ADRs.
- SACT products are associated with more serious side effects – any ADR classed as serious should always be reported to the MHRA.
- The information collected through the Yellow Card reporting scheme is an important tool in helping the MHRA and Commission on Human Medicines (CHM) monitor drug safety, evaluate and detect previously unidentified hazards/ADRs and may lead to guidance or regulatory changes to improve medicine safety.
- Alongside submitting a Yellow Card report, the aseptic unit needs to be informed of any suspected ADRs relating to a product they have supplied to evaluate whether the ADR could be due to the product manufacture, issues with raw materials, product supply or storage.

Aims

- To implement a robust process to assess suspected ADRs reported to Melchett Road Aseptic Production Unit (MRAPU), to ascertain whether the processing and/or handling of the product at MRAPU could have contributed to the reaction being reported.

Method

- An engagement exercise was conducted with a full range of stakeholders to identify the key considerations that need to be investigated as part of pharmacovigilance for aseptic products.
- A Pharmacovigilance Assessment Form was created to incorporate all the factors identified – see figure 1.
- The Deviations SOP was updated to include the Pharmacovigilance Assessment Form to ensure corrective and preventive actions (CAPA) and root cause analysis (RCA) is undertaken, if indicated by the assessment.
- An ADR Report Form was created for the clinical team to use to inform MRAPU of a suspected ADR. This ensures the correct information is collected to complete the Pharmacovigilance Assessment Form and Yellow Card report – see figure 2.
- A CPD Bulletin was created to communicate the new process with the clinical team and highlight the importance of completing a Yellow Card report and informing MRAPU of any suspected ADRs in a timely manner.

Figure 1. Pharmacovigilance: factors to consider

Product Storage	Was the product labelled with the correct storage conditions? Was the product stored correctly during transport and on the ward?
Product Administration	Was the product administered as per protocol?
Starting Materials	Were there any changes to the starting materials? New brands or manufacturers?
Production Processes	Any changes to the production processes or equipment used? Review worksheet for deviations/ errors.
Operator Training and Validation	Were the operator's training and validation up to date?
Shelf life	Was the product nearing its shelf life/stability? Was any extended stability data applied? If so, was it robust?
Review of SmPC	Is the suspected ADR listed in the SmPC? How common is the side effect?
Outsourced Products	Ensure suspected ADRs relating to outsourced products supplied are reported to the manufacturer.
Yellow Card Report	Has a yellow card report been completed?

Figure 2. Information required on ADR report form

Patient information – name, DOB, ward/clinic
Drug(s) and dose
Details of reaction
Contact details of person reporting ADR
Yellow card completed (Y/N)

Results

- The Pharmacovigilance Assessment Form is in use at MRAPU and is completed every time a pharmacovigilance event is reported.
- A review of the deviations relating to suspected ADRs found that prior to implementation of the Pharmacovigilance Assessment Form several factors were routinely omitted from consideration: -
  - Storage
  - Administration
  - Shelf life of product
  - Operator training and validation
- Since implementation 10 pharmacovigilance events have been reported to MRAPU and 100% were completed fully.
- It is noted that the number of suspected ADRs reported to MRAPU is low and has remained low since the implementation of the new process, despite the information given to the clinical team in the CPD Bulletin. This likely reflects the increasing workload within cancer services, lack of time to report, and attitude towards reporting suspected ADRs (i.e., not beneficial if reaction expected).
- The number of ADRs reported to MRAPU may not reflect how many Yellow Card reports are being submitted by the clinical team in the clinical areas.

Conclusions

- There is now an appropriate process in place for assessing suspected ADRs related to products supplied by MRAPU.
- This ensures that if a suspected ADR is reported to MRAPU it can be assessed using the form, which considers all the relevant factors, and appropriate actions can be taken to manage any risks identified and to prevent future occurrences.
- More education and training is needed to ensure suspected ADRs are reported to MRAPU alongside completing Yellow Card reports so that data can be collated, and trends assessed to help identify problems at the earliest opportunity.

References

1. **https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/**
2. **https://yellowcard.mhra.gov.uk/resources/**
3. **CPPE, Adverse drug reactions Part 1 - Adverse drug reactions and medicines safety - e-learning**
4. **CPPE, Adverse drug reactions Part 2 - Reporting adverse drug reactions - e-learning**

Contact Details

Jennifer.young@uhb.nhs.uk