



UKMi Active Learning from Events and Risk Tracking (ALERT) report

Executive summary

Q1: January to March 2025

Reports			
Total number of enquiry incidents since	Total number of publication incidents since April		
Enquiries	Publications/Pro-active work		
Number for this period: 6	Number for this period: 1		
Number of errors: 4	Number of errors: 1		
Number of near misses: 2	Number of near misses: 0		

Top 3 recommendations from QRMG for this quarter

- Where possible, have a second person independently verify your calculations.
- Always write down your calculations in a step-by-step manner to identify any errors and to help understand any reasonings when checking.
- Check excipient lists in the SmPC and PIL before contacting the manufacturers for clarity. Do not assume if it is not listed or mentioned then it isn't a problem.

Most incidents reported this quarter were errors, i.e., the incorrect answer had been given out and the incident picked up later. The potential impact on patient safety assigned by reporters was mainly negligible with one minor. The most common cause for incidents was high workload. This was followed by low staffing and interruptions. The enquiry types most frequently associated with incidents were pharmaceutical, followed by administration or dosage enquiries. Most of the errors were detected by the processor (after the answer had been given) or by the enquirer.

There was one publication error in a resource used by an MI service.

Data Integration

As part of the transition to the new national incident reporting process via Microsoft (MS) Forms, the Q1 2025 report incorporates data from two separate systems: the legacy reporting platform and the new MS Formsbased system. This dual-source approach was necessary to ensure continuity of reporting during the transition period.

However, due to differences in data structure, terminology, and reporting formats between the two systems, there may be some inconsistencies and limitations in the combined dataset. We have taken steps to align and reconcile the data as much as possible, but users should be aware that some trends or totals may not be directly comparable with previous quarters.

This report should be viewed as a transitional snapshot, and we expect future reports to benefit from improved consistency and data quality as the new system becomes fully embedded.

We appreciate your understanding and welcome any feedback to help refine the new reporting process.

UKMi Quality and Risk Management Group UKMi Active Learning from Events and Risk Tracking (ALERT) report

- Chart 1 shows a quarterly comparison of potential risks to the patient due to errors or near misses.
- Data relating to identified causes and enquiry types for incidents is in charts 2 and 3.
- Table 1 (a-d) summarises the incidents reported and provides suggested actions and/or reminders from the QRMG to aid mitigation of risks at each stage of the enquiry answering process and for publications.



UKMi Quality and Risk Management Group Incident Reporting in Medicines Information Scheme (IRMIS)

Table 1: QRMG Recommendations

(a) Enquiry answering process – receiving the enquiry

Incident summary	QRMG recommendations
None	

(b) Enquiry answering process – researching the enquiry

Incident summary	QRMG recommendations
Incident 1368 related to excipients in HRT products for a patient with soya intolerance. An advanced search on the eMC provided 3 products which did not list the specified excipients and were recommended. The patient later identified the Estradot patches contain soya and should be avoided in patients with allergies. The manufacturer stated that Estradot products were derived from soya but transfer into the end-product was unlikely. The patient did not start the product.	 The European Medicines Agency (EMA) <u>guidance on labelling of excipients lists</u> excipients with known action or effect and provides information on safe limits. These excipients must feature in the product information for the medicine. This includes the Summary of Product Characteristics (SmPC) and the Patient Information Leaflet (PIL). The EMA state 'soya oil' needs to be stated if present in any formulation. Manufacturers are not required to state whether an ingredient is derived from animals, plants, or synthetic processes unless it has implications for safety or efficacy. Always check the SmPC and PIL and then contact the manufacturers to confirm excipients and/or derivatives if not clear from the SmPC or PIL. The <u>UKMi Enquiry Answering Guidelines</u> have a section for excipients under the Pharmaceutical section. SPS provides guidance on how to run an advanced eMC search.

UKMi Quality and Risk Management Group UKMi Active Learning from Events and Risk Tracking (ALERT) report

(c) Enquiry answering process – checking or giving the enquiry answer

Incident summary	QRMG recommendations
Incident 1369 related to checking a calculation for syringe driver compatibility. The concentration calculated for alfentanil was 12 times greater than it should have been. The calculation had been checked by a colleague, but the error had not been noticed. The error did not leave the department.	 Stick to a step-by-step approach when doing calculations and write down each step to reduce mental math errors. Think about the answer. Does it make sense? Is it within the licensed dosing range for the formulation? Is the volume appropriate for administration?
Incident 1370 also involved a calculation which was not second checked and resulted in a double dose being advised. The calculation required the conversion of oral tranexamic acid 1g three times a day to an IM injection due to the patient having swallowing difficulties. The error was detected after given the answer out. The patient did not receive the advised IM dose.	 Consider if you need to use the base of salt when converting between formulations, calculating equivalent doses, and switching between brands and generics for example. Check the BNF and SmPC to find out how the dose is expressed, as a base or as the salt, and use that for the equivalent dosing.
Incident 1371 involved the correct answer being given but staff then doubting their response due to a follow up question. The original enquiry to convert oral prednisolone to IM dexamethasone or IM hydrocortisone was correctly answered. The follow up question requested further information on prescribing dexamethasone and staff were confused as to whether dexamethasone base or salt should have been used in their original calculation.	 Minimise distractions when doing calculations and avoid multi-tasking. If you are a lone worker, take a break and recheck your calculation later. If you get a double check, make sure the checker performs the calculation independently and doesn't just verify your calculation. Have them calculate from scratch and then compare your answers. Compare your reasoning if answers do not match in case of misunderstandings in the calculation. Make sure all staff involved in the calculation sign it off before giving out the
Incident 1 involved a typo in the answer which suggested that zinc sulfate salt contained 23% of elemental iron. The text should have read zinc sulfate salt contained 23% of elemental zinc. The enquiry was completed by a Trainee Pharmacist and checked before being sent.	 answer. The <u>UKMi Guidance on Checking MI Enquiries</u> has a section on calculations. When replying to an emailed enquiry, reply to the email string rather than create a new email. This preserves the content of the original question and keeps all communications in one place. If the topic has changed, such as a
response by a Trainee Pharmacist stated the wrong enquiry. The answer given was correct but the cross-referenced enquiry title incorrect. This was checked before being sent. The enquiry had come in by phone and an email response was required.	follow up question unrelated to the original question, then consider starting a new email string (similar to starting a new entry in MiDatabank if the patient is the same but the question has changed significantly).

UKMi Quality and Risk Management Group UKMi Active Learning from Events and Risk Tracking (ALERT) report

(d) Learning from publication errors (new)

Resource	Description of error	QRMG recommendations
Specialist Pharmacy Services: <u>Refrigerated</u> medicine stability tool	Resource stated Dupixent can be returned to fridge after temperature excursion between 8 to 25 degrees. Manufacturers stated that it cannot be returned to fridge. Outcome: the product was discarded following 1 hour at room temperature on advice of manufacturers. Risk: Product with compromised stability could have been administered to patient.	The SPS tool provides general stability guidance based on available data, but it may not always align with specific manufacturer recommendations. The tool is a support aid. Consider the clinical context, patient-specific factors, and manufacturer advice before making decisions. The data in the tool is updated on a rolling basis. Report discrepancies or issues to SPS, which helps improve the tool over time. SPS require written manufacturers data and changes are not always immediate following feedback.

Useful information

Author: Iram Husain, <u>QRMG.ukmi@nhs.net</u>. Enquiry incident submission: <u>https://forms.office.com/e/wPNkxCc31Y</u>. Publication incident submission: <u>https://forms.office.com/e/G3TJGJjBn2</u> Incident reporting guidance, previous ALERTS and Incident Spotlights: <u>UKMI Resources</u>