





Incident Reporting in Medicines Information Scheme (IRMIS)

Q1: January to March 2022

Reports		
Total number enquiry incidents since	Total number publications incidents since April	
January 2005: 1008 (rolling total for 2022: 13) Enguiries	2013: 15 Publications/Pro-active work	
Number for this period: 13	Number for this period: 0	
Number of errors: 10	Number of errors: 0	
Number of near misses: 3	Number of near misses: 0	
Number related to data: 3	Number related to data: 0	
Number related to advice: 10	Number related to advice: 0	
Number where description 'not known': 0	Number where description 'not known': 0	

Report Summary

Top 3 recommendations from QRMG for this quarter:

- For telephone enquiries, repeat the question before ending the call.
- Obtain manufacturer responses in writing and do not rely on verbal responses alone.
- Cross check the answer prepared against the question asked before relaying to the enquirer.

The most common incidents this quarter were due to inadequate analysis and background, as well as communication problems. The main enquiry categories resulting in reports this quarter were around administration and dosage, and pharmaceutical issues. No incident resulted in patient harm. Mishearing the question, researching whilst the caller was on hold and not re-reading written responses were

Mishearing the question, researching whilst the caller was on hold and not re-reading written responses were the main contributory factors to errors.

One incident provided little information regarding the error. Reporters are reminded to ensure sufficient information is provided regarding the incident to allow third party review.

Chart 1 shows a quarterly comparison of potential risk to the patient due to error or near misses.

Data relating to identified causes and enquiry types for incidents is presented in chart 2 and 3.

Table 1 (a-c) 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.

Help us improve

The QRMG are keen to get your views on the IRMIS report. Please email us at <u>QRMG.ukmi@nhs.net</u>.

Contact

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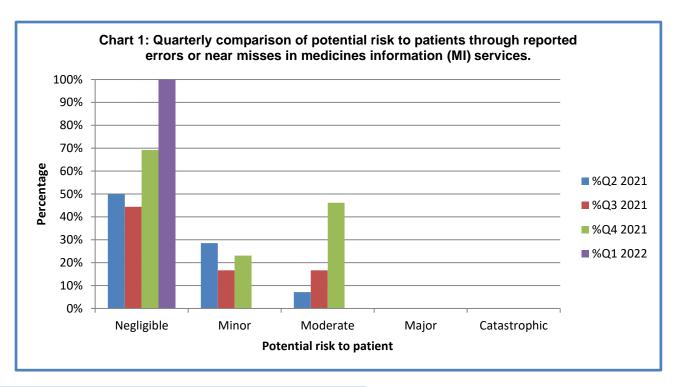
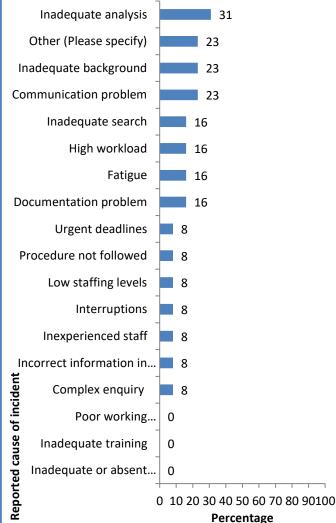
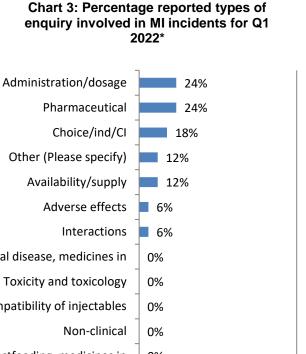
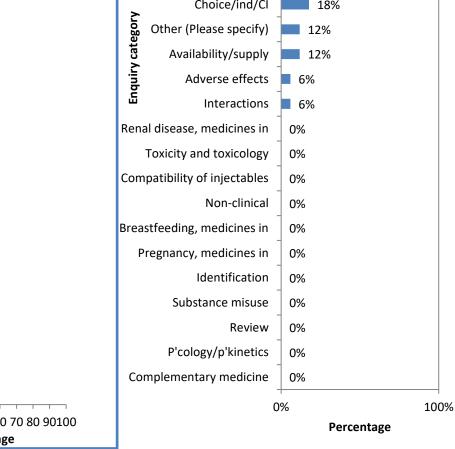


Chart 2: Percentage reported common causes of MI incidents for Q1 2022*







*Reflects multiple causes/enquiry categories per incident

Table 1: QRMG Recommendations

(a) Enquiry answering process – receiving the enquiry

Incident summary	QRMG recommendations
Incident 1238 resulted when assumptions were made about the formulation of cladribine in question. The enquirer was referring to the IV formulation whereas the MI staff researched the tablets. As a result, the answer included advice relating to the tablets rather than IV. A similar situation arose with incident 1246 where the drug name was misheard as valaciclovir rather than famciclovir. And again, with incident 1249 where a temperature excursion was noted as 20 hours rather than 1 day and 20 hours.	 For all enquiries obtain the full medication details including indication, dose, frequency, and formulation. Refer to the UKMi Enquiry Answering Guidelines. It is good practice to have enquirers <u>phonetically spell</u> <u>commonly confused drug names</u> or when MI staff are in doubt. Before ending the call, repeat the question back to the caller as confirmation. Avoid using terms that are commonly misheard such as 'hypo' and 'hyper'. For example, consider saying high blood pressure and low blood pressure.
Incident 1245 highlights a lack of understanding around excipients in a patient with a history of a serious allergy.	 The <u>UKMi Enquiry Answering Guidelines</u> has a useful section on dealing with excipient questions and allergies. If in doubt, contact the manufacturers for written confirmation. Some excipients can be listed under different names. SPS has a useful MQA on <u>handling questions about</u> <u>excipients</u>.

(b) Enquiry answering process - researching

Incident summary QRMG recommendations

Incident 1239 resulted when one in-house resource was relied upon for the answer and was subject to misinterpretation by both enquirer and MI staff. The resource was later prioritised for updating as a result.	Consider consulting the background references and/or involving the authors of in-house guidelines/protocols where content related questions arise.
Incident 1241 provided minimal information on the incident. It is assumed the incident resulted due to lack of awareness when using the website in question. As a result, important information was missed and impacted on the answer.	 MI staff should be familiar with how to use the recommended/held resources for enquiry answering. Refer to the <u>UKMi Tips, hints and limitations for use of common Mi resource</u>. Information may be included in different parts of the website, so ensure all areas of a website are checked
Incident 1248 highlighted the need to consult both tertiary resources and primary literature when searching for evidence for a drug in an unlicensed indication. A first line tertiary resource was used and did not locate any data that was later found in the primary literature.	 Questions relating to evidence for unlicensed indications will often require a review of the primary literature. Deadlines should be negotiated to account for this and research started early. Always verify information in more than one resource. This has many advantages, such as verifying information, resolving conflict, but may also prevent the need for a primary literature search in some cases.

(c) Enquiry answering process – giving the answer

Incident summary	QRMG recommendations
Incident 1240 resulted when information provided verbally by a manufacturer differed to that later sent in writing. The MI answer was given based on the verbal information and later corrected following the written communication.	 Obtain information from manufacturers in writing. This may delay the response. Inform the enquirer that a delay has occurred due to information awaited from manufacturers. UKMi provides a <u>How to Use Pharma MI</u> guide written jointly with <u>PIPA</u>.
Incident 1242 occurred when the answer referred to the incorrect drug. A similar situation resulted in incident 1243 when the incorrect formulation was discussed in the answer.	

Incident 1244 appears to have occurred when responding to a telephone enquiry immediately. The question related to a paediatric dose and required some calculations and conferring with colleagues. A similar situation occurred with incident 1247 where it was missed that the patient was elderly, and that a lower starting dose should have been advised. Incident 1250 highlighted missing valuable information in the answer relayed even though it was researched.	 Revisit the question asked when formulating the answer. Consider restating the question at the start of the answer. Obtain a <u>second check</u> on written responses were possible or take a break and revisit the answer afresh before relaying. Avoid researching MI enquiries whilst the caller is on hold since rushing is known to be a high-risk practice, especially for complicated or unusual questions. Get all calculations second-checked. Again, this should not be done while the enquirer is on hold. It is good practice to review current patient drug and medical histories, including relevant demographics, where available, prior to responding to patient specific questions. Knowing the patient's age for example is often key for dosing recommendations and also when filling in a yellow card report.
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Publication Incidents

QRMG Recommendations:

There were no publication errors reported this quarter.