



Incident Reporting in Medicines Information Scheme (IRMIS)

Q3: July to September 2023

Reports		
Total number enquiry incidents since	Total number publications incidents since April	
January 2005: 1046 (rolling total for 2023: 41)	2013: 16	
Enquiries	Publications/Pro-active work	
Number for this period: 19	Number for this period: 0	
Number of errors: 15	Number of errors: 0	
Number of near misses: 4	Number of near misses: 0	
Number related to data: 3	Number related to data: 0	
Number related to advice: 12	Number related to advice: 0	
Number where description 'not known': 4	Number where description 'not known': 0	

Report Summary

Top 3 recommendations from QRMG for this quarter:

- Take care when noting medicine names. Consider using tall man lettering for similar sounding/looking medicine names.
- When using past enquiries, check when the information was noted and revisit the resource as necessary.
- Contact specialist services for complicated questions or those requiring assistance, e.g. UKDILAS (UK Drugs in Lactation Advice Service).

IRMIS reports can be submitted via NHS networked devices at https://irmis.wales.nhs.uk/Login.aspx.

Most incidents reported this quarter were classified as error, i.e., the answer had been given out and the incident picked up later. The most common causes were documentation problems and inadequate research. The top enquiry type associated with choice of therapy/indications/contraindications, pharmaceutical, followed by breastfeeding.

One incident was considered to have a potentially catastrophic impact on patient care, and it related to medication excipient allergies for a patient undergoing surgery. Three incidents were rated to have a potentially moderate impact on patient outcome. One related to antibiotic allergies and choice of antibiotic, another related to cutting tablets to get half strength, and the last related to paternal exposure of medication. One incident was considered to have a potentially minor impact on patient outcome following a patient being supplied with an injection that should have been discarded post temperature excursion. All other incidents were deemed by reporters to have potentially negligible risks to patient care. Please refer to the IRMIS guidance notes at https://www.ukmi.nhs.uk/Resources?ContentID=8c0ef2f7-b950-43cb-8a25-6c1a158d3900 before completing an incident report. The guidance summarises potential risk to the patient as follows:

Potential Risk	Examples
Negligible	Minimal injury requiring no/minimal intervention or treatment, or informal
	complaint/inquiry, or potential for public concern.
Minor	Minor injury or illness requiring minor intervention, or formal complaint, or local
	media coverage - short-term reduction in public confidence.
Moderate	Moderate injury requiring professional intervention, or formal complaint, or
	local media coverage – long-term reduction in public confidence.

Major	Major injury leading to a long-term incapacity/disability, or mismanagement of patient care with long-term effects, or multiple complaints/independent review, or national media coverage with < 3 days service well below reasonable public expectation.
Catastrophic	Incident leading to death, or inquest/ombudsman inquiry, or national media coverage with > 3 days service well below reasonable public expectation, or total loss of public confidence.

Several incidents related to specialist topics such as breast feeding.

The incidents have highlighted the main causative area to be research and include lack of contacting specialist services for advice, missing resources from UKMi enquiry answering guidelines (EAG) that could impact the answer, and lack of familiarity with the content of resources.

- Chart 1 shows a guarterly 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.

No publication incidents were reported this quarter.

Help us improve

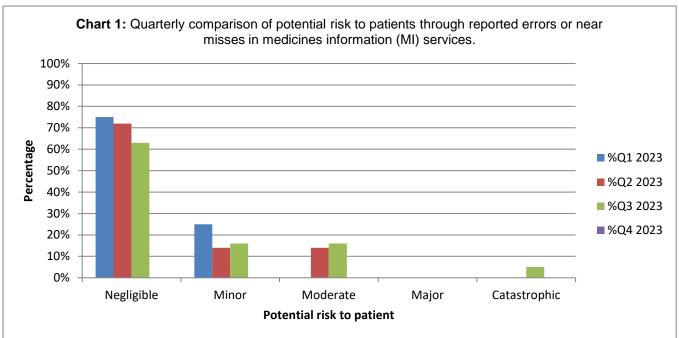
The QRMG are keen to get your views on the IRMIS report. Please email us at QRMG.ukmi@nhs.net.

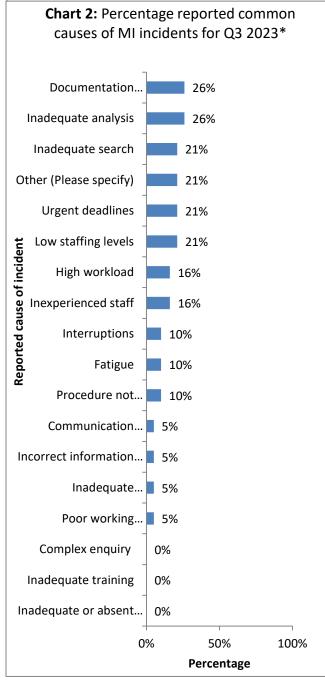
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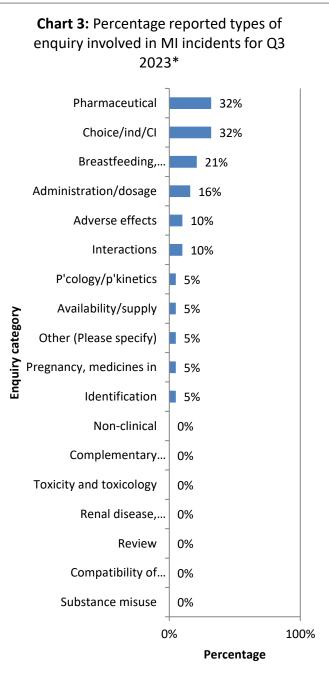
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Table 1: QRMG Recommendations

(a) Enquiry answering process – receiving the enquiry

Incident summary	QRMG recommendations
ucident 1295 occurred when the wrong patient hospital umber was recorded. The answer provided was generalised this case and did not result in an error.	 Consider recording both patient hospital number and name where needed to process the enquiry. Do not record person identifiable data when it is not necessary.
Incident 1300 did result in an error when the incorrect spelling for the user's name and email address was noted. The answer was sent to the wrong person who had a similar sounding name. No person identifiable data was sent but the enquiry answer for the suitability of COVID and flu vaccines in a person with excipient allergies was delayed.	 Repeat the user's contact details before ending a call. Consider using a phonetic alphabet to assist.
Incident 1302 involved information on zonisamide being sent to the wrong user due to a similar situation.	

(b) Enquiry answering process - researching

Incident summary	QRMG recommendations
Incident 1291 related to a patient with extensive excipient allergies requiring surgery. Several medicines required review of excipients to identify suitability for the patient. During research, the information for ephedrine and epinephrine were confused resulting in the user receiving the wrong information during an interim verbal update (unchecked). The reporter considered the potential risk to the patient to be catastrophic since epinephrine contained one of the contraindicated excipients and could potentially have been used during the surgery.	 Answers containing long lists of medications should be checked before being given out. This should include a cross check between the medicines in question and discussed in the answer, as well as reviewing the information gathered. Do not feel pressurised into giving an answer without a check, where needed. Take extra care with similar sounding names to recheck the right one is being researched and the correct information is being documented. Consider tall man lettering, e.g., EPINEPHrine and ePHEDrine Identify the clinical priority for the answer rather than the user's priority, and then prioritise workload to reduce unnecessary pressures.

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Incident 1297 lacks detail but appears to be similar in relating to antibiotic choice in a patient with multiple antibiotic allergies. The initial answer was given verbally and under time pressure, resulting in the incorrect advice being given and retracted within an hour.	• WI	
Incident 1294 used a past enquiry from 2018 to provide an answer to the CD status of phenobarbitone. The MEP used at the time of the original enquiry had not been interpreted correctly. A similar incident (1296) occurred when outdated perioperative guidelines were used to advise on mepolizumab.	WI ma pa Cc	
Incident 1298 referred to fridge stability data for Daktacort	ed	

Incident 1298 referred to fridge stability data for Daktacort cream based on a past enquiry from January 2022. The manufacturers were also contacted and later responded that data from the past enquiry was no longer supported.

Incident 1301 also used past enquiries to respond to whether a particular brand of cefalexin tablets could be cut to give half a dose. The past enquiry suggested it could be however the SmPC stated the score line was for ease of administration and did not give equal doses. The SmPC had been checked but only the past enquiry advice was included in the answer (following a double check).

Incident 1299 resulted when specialist resources were not consulted for a breast milk storage enquiry and rushing to answer an enquiry. The enquiry related to fexofenadine in breast milk being stored by a milk bank.

Incident 1303 was similar where identification of 4 medicines from South Africa (SA) were required by a user. Only 2 medicines were identified using the usual resources. When researching, staff did not check the SA regulatory sites which did list the 2 additional medicines.

Incident 1304 resulted when the wrong SmPC was consulted for a temperature excursion enquiry. An SmPC for

 Where an urgent question requires uninterrupted attention, consider using voicemail or requesting colleague assistance to take messages.

- When using past enquiries, check the date for all resources since information may have changed. This will reduce the risk of using outdated information from past enquiries.
- Consider rechecking the information in the resources used, especially if new editions have been published since the previous research.
- When using online guidelines, check that they are the most recent by searching the homepage rather than using links or attachments on past enquiries.
- The <u>SPS Fridge Tool</u> provides manufacturer supplied data for stability and actions when storage conditions deviate from 2-8 degrees Celsius.
- For temperature excursions not covered by the tool, contact the manufacturer and await a response before responding to the user.
- Take a short break away from enquiries when checking back to back to ensure answers are reviewed accurately, including the research information.
- Junior staff covering MI services in the absence of senior staff should have clear guidance on points of referral when unsure.
- All MI services should have an SOP or guidance for responsibilities in the MI manager's absence.
- High risk questions should not be rushed, and a second check obtain before responding.
- Use the standard search patterns provided in the <u>UKMi Enquiry Answering</u>
 <u>Guidelines</u> (EAG).

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Pegfilgrastim was used though the specific brand was not clear. An SmPC from another manufacturer was used and advice given to dispense the product. Later advice from the correct manufacturer resulted in advice to discard. The patient had received the product but not administered it resulting in a resupply.

Incident 1305 involved the impact of leflunomide paternal exposure. BUMPs contained information on this topic but the UKTIS HCP document did not. UKTIS were contacted and agreed that there was a mismatch in the information in the two resources.

Incident 1308 related to a breastfeeding question. The research was completed and reviewed on separate days. This highlighted that the incorrect medicine had been researched in the resources: trazodone rather than tramadol.

Incident 1309 occurred when a complex breastfeeding enquiry was researched without input from specialists such as UKDILAS. The enquiry had been researched by a trainee pharmacist and checked. UKDILAS were able to provide clarification on the half life to use when calculating the time required for dihydrocodeine to be cleared from breast milk.

Incident 1307 was a near miss when staff were in the process of planning their research and realised they were thinking about COVID vaccines rather than flu vaccines which was the user's question. The topic related to fridge stability.

- Always identify the product in question, e.g. Brand name, manufacturer, medicine name, strength, formulation, etc.
- The eMC is not comprehensive for all UK licensed products. Consider using the
 manufacturers website to locate the SmPC. The MHRA site contains all UK
 products but is difficult to filter for product information. Also see tips, hints, and
 limitations for use of common medicines information resources at
 https://www.ukmi.nhs.uk/fileDownloader.aspx?ID=44.
- The SPS Fridge Tool does not contain all fridge items only those where manufacturers information is available. Manufacturers should be contacted directly for any fridge products not listed in the tool.
- Be familiar with how to navigate and the content of resources used. Take time to get familiar with a new, recently updated, or rarely used resource.
- Consider using BUMPs alongside the UKTIS HCP information in case of mismatch. Also advisable for other publishers who have a patient facing and HCP facing portal.
- Inform the publishers directly when errors in content are identified.
- Risk of errors when researching medicines can be reduced by taking a break from the enquiry and revisiting it later.
- Refer to the specialist advise centres for complex or enquiries requiring reassurance before responding to the user, e.g. breast feeding (UKDILAS), pregnancy (UKTIS), dental (North West MI).
- Have clear questions in the input field of MiDatabank.
- It is good practice to plan research with the user questions in mind.
- Reiterating the questions asked at the start of an answer will aid in reducing the risk of answering the wrong question or missing questions.
- Check the enquiry title reflects the question asked before archiving the enquiry.

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(c) Enquiry answering process – giving the answer

Incident summary	QRMG recommendations
Incident 1292 involved multiple drugs and breast feeding. The answer was required the same day. After giving the answer out it was noted that one requested medicine was missing from the answer.	 Cross check answers with the information in the question field before responding. High risk questions should be double checked before responding, either after taking a break or by another colleague. Providing an initial or interim answer should be subject to the usual checking before giving out.
Incident 1293 related to mistaking levofloxacin for linezolid in the answer and adding additional interaction information unrelated to the medicine in question, levofloxacin. The answer was given based on personal knowledge.	 Take extra care with similar sounding names. Consider tall man lettering – see https://www.ismp.org/recommendations/tall-man-letters-list. Cross check answers with the information in the question field before responding. High risk questions or topics with which there is poor familiarity should be double checked before responding, either after taking a break or by another colleague. When adding additional information to answers, consider checking in the appropriate resource, e.g. Stockley's for additional interaction information. When using personal knowledge alone, take a moment to revisit the question and consider the clinical scenario. When giving the answer, repeat the question back to the enquirer and restate the medicine names to add clarity.
Incident 1306 resulted when the answer to switching fluoxetine to duloxetine was given over the phone. Text was read out from Maudsley as requested by the user. The incorrect information was read out as staff did not realise at the time that duloxetine was an SNRI, and not an SSRI.	 Do not be pressured into giving an answer over the phone. Consider clinical urgency over enquirer urgency or impatience. Do not assume the user knows the most appropriate resources to looks in, understand the clinical scenario when taking questions in to assist in tailoring the answer.

Publication Incidents

Recommendations:

There were no publication errors reported this quarter.

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