Incident Reporting in Medicines Information Scheme (IRMIS)

Q1: January to March 2024

Reports	
Total number of enquiry incidents since January 2005: 1070 (rolling total for 2024: **13**)	**Total number of publication incidents since April 2013: 20** (rolling total for 2024: **3**)
Enquiries	**Publications/Pro-active work**
Number for this period: 13	Number for this period: 3
Number of errors: 9	Number of errors: 3
Number of near misses: 4	Number of near misses: 0
Number related to data: 2	Number related to data: 3
Number related to advice: 9	Number related to advice: 0
Number where description 'not known':2	Number where description 'not known': 0

Report Summary

Top 3 recommendations from QRMG for this quarter:

- Have a plan in place for staff to follow when unplanned leave affects the enquiry answering service, e.g. check what enquiries they are working on and review enquiry deadlines. Consider having a business continuity plan.
- All staff should know how to use resources for medicines questions and understand the resource limitations.
- Format written responses in a way that makes them easy to read. Address the questions asked and highlight any additional considerations and actions.

Most incidents reported this quarter were errors, i.e., the answer had been given out, and the incident picked up later. The most common causes were documentation problems, urgent deadlines, and inadequate searches.

The enquiry types most frequently associated with incidents were administration/dosage, choice/indication/contraindication, pharmaceutical, and adverse effects.

Incident 1322 had a potentially major risk to the patient since the answer suggested a subtherapeutic conversion when switching from carbamazepine modified-release to immediate-release.

Incident 1325 highlighted an error in setting up a user account in MiDatabank which allowed a Trainee Pharmacist (TP) to authorise their own enquiries. When setting up new users in MiDatabank, be careful when selecting the user permissions.

Incident 1329 was entered in error, and 1333 was a duplicate entry, so both were removed from the 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-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.

Three publication errors were reported this quarter. One involved an incorrect hyperlink, another involved the transfer of an incorrect drug name from a template document, and the third stated a misoprostol dose of 600mg instead of 600 micrograms.

Contact

Author: Iram Husain, QRMG.ukmi@nhs.net.
IRMIS database technical queries: pharmacy.support@wales.nhs.uk
You can submit IRMIS reports via NHS networked devices at https://irmis.wales.nhs.uk/Login.aspx.

*Reflects multiple causes/enquiry categories per incident

Chart 1: Quarterly comparison of potential risk to patients through reported enquiry errors or near misses in medicines information (MI) services.

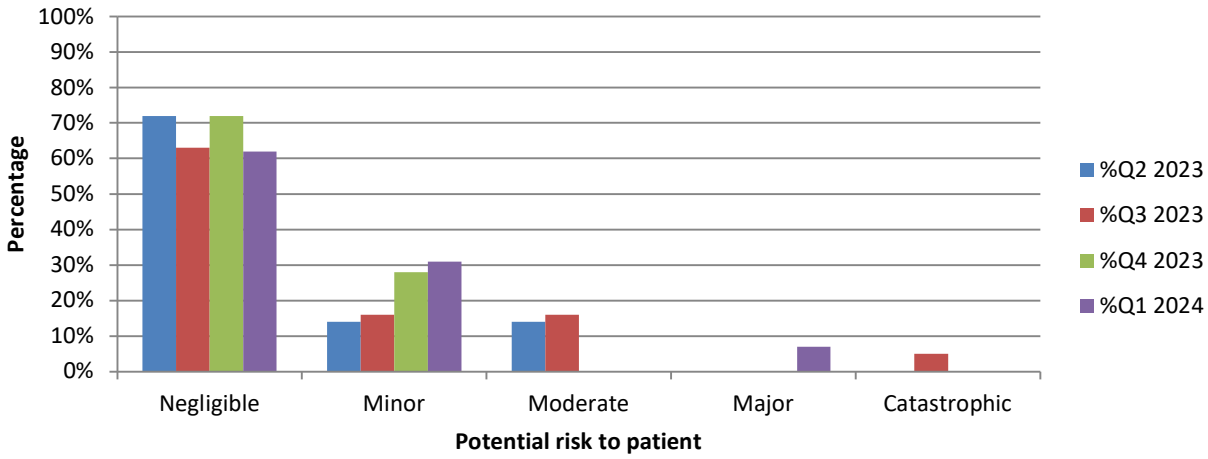

Chart 2: Percentage reported common causes of MI enquiry incidents for Q1 2024*

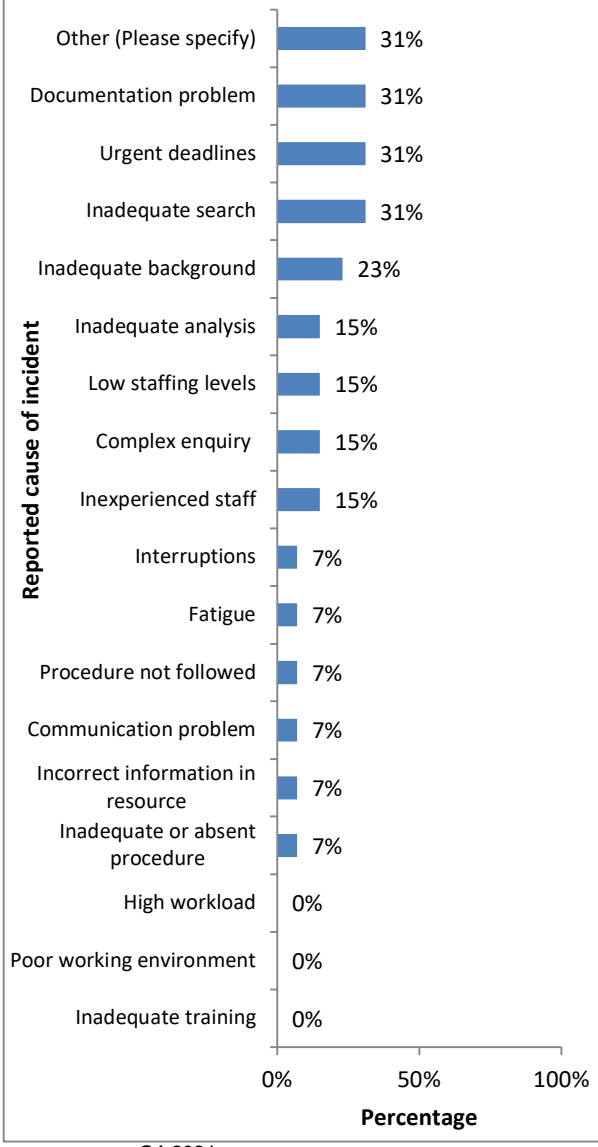

Chart 3: Percentage reported types of enquiry involved in MI incidents for Q1 2024*

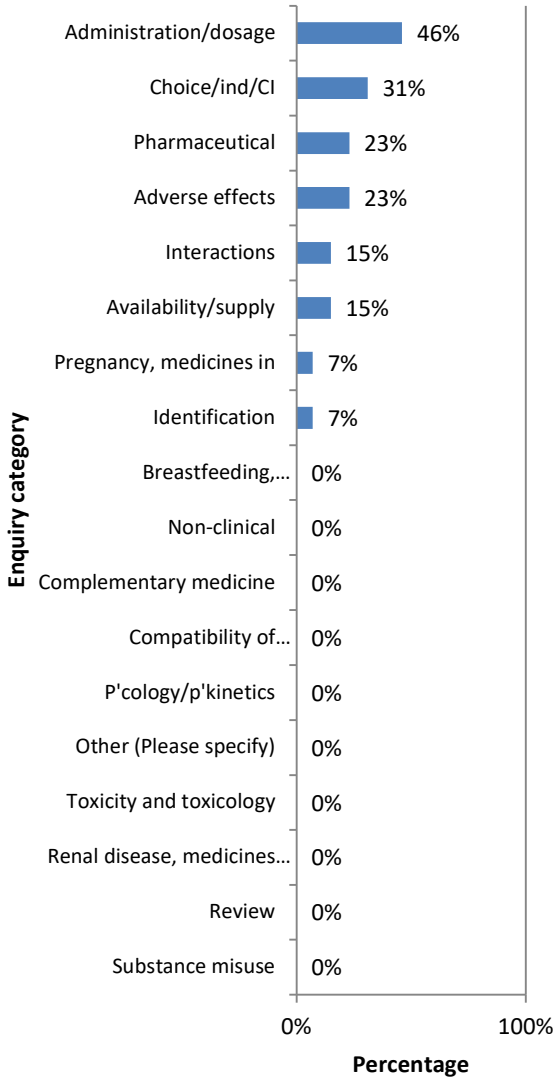

Table 1: QRMG Recommendations

(a) Enquiry answering process – receiving the enquiry

Incident summary	QRMG recommendations
Incident 1323 related to using COVID vaccines past their expiry date. The initial information lacked detail, resulting in multiple contacts with the enquirer and manufacturer to clarify. Advice was sought for post-expiry use from the manufacturers. The information requested was for the initial enquiry put in (6 days post expiry) and not the actual scenario which was 4 days post expiry. The latter was incorrectly relayed to the enquirer. This enquiry resulted in further time being required to gather information on the actual scenario.	• When planning the day's workload, review all enquiries, including those in progress, in case work needs to be reallocated to meet deadlines. • If a staff member is absent unexpectedly, or for longer than expected, review their in-progress enquiries and other tasks/work to see if anything needs attention/reassignment. • Use a generic/departmental email address to receive emailed enquiries. Ensure all the email account folders (including spam) are checked at least daily. • Consider the clinical urgency of enquiries and the current workload when negotiating deadlines with the enquirer. • Consider what training staff need to take in enquiries. The UKMi Enquiry Answering Guidelines have tips on background information for different types of enquiry. • For potentially complex or lengthy enquiries, include a note in the comments field of MiDatabank (where used) to 'start early' and amend the due date to reflect this (with the actual due date in the question or "comments" field). • See the UKMi IRMIS alert on instant answers increase the risk of error. answers. • When completing a "multi-part" answer, such as one regarding multiple products, consider listing all the products at the beginning of the answer and check that all information has been included. You may find it helpful to use highlighting/colour changes to track progress.
Incident 1324 highlighted a processing issue. A travel vaccination enquiry had been started by staff who were now on sick leave. The enquiry was due that day, but when reviewing enquiries due that day, the in-progress enquiries were not included. Consequently, this enquiry was not identified as due until later in the day, adding a time pressure to a lengthy enquiry. The research and answer were documented after the answer had been given out, during which it was identified that one vaccine (polio) had been missed from the answer. Similarly, incident 1331 highlighted a processing issue where an nhs.net email enquiry was received into the spam folder and missed for several days.	

(b) Enquiry answering process - researching

Incident summary	QRMG recommendations
Incident 1321 related to a cefiderocol injection left out of the fridge. Written information from the manufacturer was misread. The company advised that the product could be used in this case, with a standard statement implying that use outside the product license was not advised. The latter was incorrectly taken as the answer and relayed to the enquirer.	• Take time to read through the information in resources and note the pertinent points. Do not skim-read. • When using past enquiries, check that the information is complete, current and of good quality. • For fast-moving or topical issues, consider checking for current resources which may highlight any national alerts or provide practical advice. • Medicines are listed alphabetically by the name of the active ingredient and not by brand name in iDAPs. • iDAPs advise that the active ingredient as mentioned in the SmPC or PIL should be used when searching. However, sometimes the name under which a drug is listed in iDAPs is unexpected. In the case of Berinert, the active ingredient is listed as "complement C1 esterase inhibitor." See "Tips, hints and limitations for use of common Medicines Information Resources" for further information. • Raise concerns regarding the content of resources directly with the publisher. • Consider whether you need to ask another team/specialist for advice. For instance, it may be useful to discuss supply shortages with local procurement teams who may already be aware of the issue. • Individual supply issues can be emailed directly to the DHSC via DHSCmedicinesupplyteam@dhsc.gov.uk. • eMIMs (https://www.mims.co.uk/, subscription required) provide a live tracker for drug shortages which can complement the DHSC information at
Incident 1326 involved an enquiry processed by multiple staff relating to the safety of fluoxetine in pregnancy. The answer was largely influenced by a poorly-presented past enquiry. The answer was amended for the current enquiry, but mistakenly omitted the risk of postpartum haemorrhage with SSRIs or the MHRA Drug Safety alert (which were mentioned in the original enquiry answer).	
In incident 1328, information from a past enquiry was used without checking its currency. The answer advised that an oral testosterone product could be imported. It later transpired that the product was no longer available.	
Incident 1330 resulted when using the MHRA iDAPs. Neither the brand name nor C1 esterase inhibitor were listed in the iDAPs. When the enquiry was reviewed, the iDAP was located under 'complement C1 esterase inhibitor'.	
Incident 1334 concerned a supply shortage of tobramycin nebules. The national tool provided no data, so a local database was used. The in-house database was out of date and provided incorrect information on the choice of product.	

Incident 1335 related to converting from desvenlafaxine to venlafaxine. Confusion arose regarding how the desvenlafaxine succinate dose was expressed, resulting in a potentially subtherapeutic venlafaxine dose being recommended.	https://www.sps.nhs.uk/home/tools/medicines-supply-tool/. • Always get calculations double checked. • Understand the pharmacology and indications of the medicines before advising on switching, and ensure you understand how the doses of different formulations are expressed. • Be aware that differences in salt or formulation may make an enquiry more complex than it first appears.

(c) Enquiry answering process – giving the answer

Incident summary	QRMG recommendations
Incident 1322 related to carbamazepine formulation switching from modified-release to an immediate-release preparation (indication not stated). The answer gave two different dosing frequencies post-switch, resulting in ambiguity. The patient could have received subtherapeutic dosing of carbamazepine post-switch. The incident was considered to have a major potential risk to patient safety.	• Restate the question(s) being asked when giving the answer. Bullet points may be useful. • Cross-check the answer against the questions asked and concerns raised, and make sure all concerns have been addressed before giving the answer. Consider using subheadings for lengthy written responses. • See our IRMIS alert on reducing the risk of getting drug names wrong. • Sense check answers especially those involving high-risk medicines or situations. • Take a break before re-reading an answer and sending it. • Consider checking answers in MiDatabank and adding a control M stamp with a note to indicate the enquiry answer can be given. • Document enquiries (question, research and answer) in your enquiry management system as you go and avoid retrospective entries. • For complex enquiries or lengthy answers, request an accuracy check from another member of staff before giving the answer out.
Incident 1325 highlighted an error in setting up a user account in MiDatabank which allowed a TP to authorise their own enquiries. The TP replied to 6 enquiries before this was identified. All enquiries had been checked by senior staff, but this was not documented in MiDatabank.	
In incident 1327, the wrong drug name was used in the answer. The enquiry was about the suspending agent used for an amiodarone suspension. The answer initially stated amiodarone but later referred to amlodipine.	

Incidents 1324 and 1332 were similar: they both missed out a medicine from the answer. The first related to missing polio vaccine in the recommended travel vaccines for a patient. The second missed omeprazole which was part of the patient's current medication list. The enquirer later questioned this enquiry answer as it did not provide advice on actions to take based on the information provided.	• Consider the clinical scenario and how the information provided should be used. Remember to provide practical advice where possible to assist the enquirer in their decision-making process.

Publication incidents and recommendations

Number	Summary of incident	Suggested cause	Learning
161	Linked text was incorrect when reviewed against the link.	Possibly carried over from template, or introduced as author, checker and final checker had been involved in publication of similar pages	Highlights importance of checking links as a two-stage process. Ensure link reads correct and then check that it points to where it should. Always check all parts of a document.
162	When preparing a PIL, a similar drug PIL was used as a template. The old drug was incorrectly stated in the new PIL on one occasion.	Look alike drug names	Use blank templates rather than over writing a final document. Consider setting up Word templates as ".dotx" documents rather than the usual ".doc". Dotx files are Word templates which save document settings such as styles, page layouts, and more. For a better understanding of the different documents that Word can save, see Microsoft Support. Be careful with lookalike / sound alike drug names.
163	Misoprostol dosage was written as '600 mg', when it should have said '600 micrograms'.	Nil listed	Where a document has been through numerous versions, consider getting a final check from a third party who is removed from the project.