UKMi
UK Medicines Information

CONFIDENTIAL

Quality and Risk Management Working Group (QRMG) Incident Reporting in Medicines Information Scheme (IRMIS) Report

Q1: January – March 2020

Reports	
Total number enquiry incidents since January 2005: 911	**Total number publications incidents since April 2013: 12**
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
Number related to data: 1	Number related to data: 1
Number related to advice: 5	Number related to advice: 0
Number not known: 0	Number not known : 0

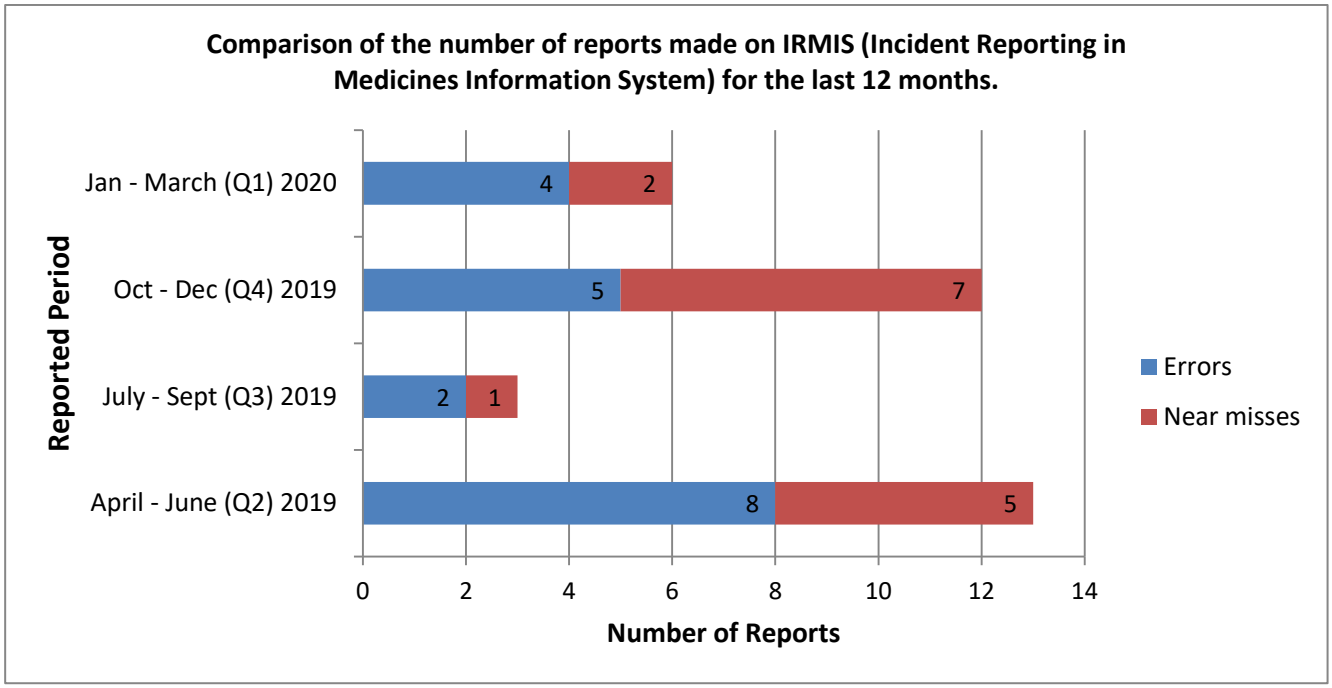
Most common causes	Incident numbers	Proportion (%)**
Documentation problem	1131 1132	33
Inadequate analysis	1130 1134	33
Inadequate or absent procedure	1131 1134	33
Inadequate search	1130 1133	33
Interruptions	1131 1132	33
High workload	1129	16
Incorrect information in resource	1130	16
Inexperienced staff	1134	16
Low staffing levels	1129	16
Poor working environment	1132	16
Urgent deadlines	1131	16

Enquiry categories	Incident numbers	Proportion (%)**
Pharmaceutical	1130 1131 1134	50
Administration and dosage	1129 1133	33
Adverse effects	1132	16
Choice of therapy / indications / contraindications	1131	16
Pregnancy, medicines in	1133	16

**Reflects multiple causes/enquiry categories per incident

Quarterly comparison of IRMIS statistics over the last 12 months:

In March 2020, a pandemic was declared across the country resulting in lockdown from the 23rd March 2020. Staff providing a local MI service may have been deployed to other areas of their Trust during March to support the NHS response to the pandemic. As a result, it is likely that the MI services had a reduced capacity to handle enquiries or produce publications. This may be reflected in the low Q1 incidents reported and is likely to continue impacting on reports for the foreseeable future.



Main points to consider/highlight:
This quarters incidents reflect issues with resources, answering enquiries on the spot, getting the drug name wrong and dealing with fridge enquiries where the drug shouldn't be returned to the fridge after a temperature excursion.

Enquiry answering process – receiving the question
Incident 1131 related to an error when answering an enquiry at the point of contact. The enquiry was straight forward (a lactose free formulation of zopiclone) but required some investigation using the eMC. The eMC was searched and SPCs consulted whilst the enquirer held the line in a busy MI environment, with distractions. The result was an error in searching the eMC and in reading the SPC, leading to a product being recommended that was later found to contain lactose. The patient did not receive the product due to the vigilance of the enquirer.
Incident 1129 involved an error when inputting the wrong drug name into the title of an enquiry that was emailed to the centre. This resulted in the wrong drug being researched: melatonin instead of memantine. These are similar sounding drugs and it may have been helpful to note the indication and dosing to assist in drug clarity.
Incident 1132 also involved similar sounding drugs when a near miss occurred due to the drug being researched changing from baricitinib to tofacitinib. This incident highlights the importance of having written responses re-checked before sending. The incident occurred due to loss of MiDatabank during a working day.

QRMG (Quality and Risk Management Group) Recommendations:

- Avoid answering MI enquiries on the spot which require searching through a resource. Some MI services acknowledge that there are times when answering at the point of contact are appropriate. Make sure all MI staff are aware of which enquiries they can consider answering immediately. Ideally, all enquiries should be taken in and the enquirer contacted with the answer to avoid simple mistakes being made due to workload pressures.

- Take care with similar sounding drug names. Obtaining the drug and indication can assist in clarity of the drug in question. The Institute for Safe Medication Practices and the MHRA have provided some advice and lists for HCPs.
- Copy the full email (as received) into MiDatabank and then summarise the pertinent points in the question field to ensure no error occurs in transcription. Remove patient identifiable data from both eth question and answer fields.
- It is good practice to check all answers against the question(s) asked before responding and sense check the enquiry before archiving.
- MI services are reminded that they should have a contingency plan in place in the event of the loss of critical equipment and that their Risk Management Policy should be reviewed annually. It may also be useful to locally assess the full MI service against the UKMi Audit standards on a regular basis, e.g. every few years.

Enquiry answering process – researching

Incident 1131 highlighted the limitations in some commonly used resources. The advanced search function of the eMC is not a comprehensive search since the term being searched must fall under a specific section of an SPC and, in the main, only SPCs from manufacturers who are ABPI members are provided. If the wrong section is selected then a potentially useful SPC could be omitted from the search results. SPCs can also be searched 'by word or phrase', which searches for the words across the whole SPC, without needing to specify a section. This is likely to generate a lot of results so users should filter the results by active ingredient.
Incident 1130 and 1134 related to errors involving temperature excursion enquiries whereby the MI services advised that the items in question be marked, returned to a working fridge and noted as quarantined until they responded with the actions to take. Following manufacturer's advice, some items (octreotide and glucagon) had to be discarded but could have been retained had not been returned to the fridge initially. The Fridge Database is one resource which indicates if a fridge item should not be returned to the fridge following a temperature excursion. More recently, the Specialist Pharmacy Services (SPS) have a produced a document (Refrigerated and ambient stability during COVID-19 for ITU injectable medicines) in response to the pressures during the current pandemic. Incident 1134 used one resource (SPC) and had a delayed response from the manufacturers (weeks).
Incident 1133 was an error due to a lower USA-based dose being stated in a written response rather than the higher UK dose. Higher doses could have been used in the patient for tuberculosis treatment.

QRMG Recommendations:

- Always consult the full SPC when using the advanced search feature and ensure sufficient time is given to reading the SPC (take care when scanning through an SPC or using 'control F' since the terms may not match the text, e.g. pig and porcine are used interchangeably.
- Make sure pharmacy staff are aware of the advanced search feature on the eMC, how to use it and its limitations.
- It is good practice not to rely on one resource when answering an enquiry.
- All resources have limitations and pharmacy staff using common resources should be made aware of these. The UKMi Limitations of Common Information Sources highlights some.
- Professional judgement should be used and documented when deciding if such items should be discarded; taking into account the data actually available from the manufacturers, e.g. is it a lack of data or actual instability data. The QRMG notes that some device mechanisms could be affected by returning to the fridge.

Enquiry answering process – giving the answer

Incident 1131 noted that the fact that the enquiry was written up on the next working day contributed to the error since had the enquiry been entered and processed in MiDatabank, the lactose error may have been identified before responding.

QRMG Recommendations:

- Input, research and complete enquiries directly in the enquiry answering database to maintain an audit trail and allow time to review the research before giving an answer.
- Enquiries should be archived the next working day, or as soon as reasonably possible, to reduce the volume of answered enquiries appearing in the 'in-progress' field of MiDatabank.
- The database used for enquiry recording should provide an ability to date stamp when the answer was given, e.g. control M in MiDatabank.

Publication Incident

One reported publication error (incident 153) relating to wrong data being presented.

The publication update was issued nationally on the SPS website and sent via a targeted distribution list (audience>500) in October 2019. A reader contacted the reporter a month later to highlight an error in definitions used for blood pressure and an error in the treatment step choices.
The blood pressure statement read 150/99 (149/94) but should have stated 159/99 (145/94). The treatment choice steps read 'A and C' but should have stated 'if on A, add C or D; If on C, add A or D'.

Due to staff shortages, the draft publication was part-checked by a relatively inexperienced non-pharmacist and part-checked by the author. The author had copied a table from an authoritative source without realising the advice was not the same as given in the drafted text.
An apology was sent to the reader, an amended document was republished on SPS, and the email distribution list informed.
The author acknowledges that the correct procedure for checking national publications was not followed and advises that authors should not be tempted to final check their own publications (even in part). A new local QA checking form was generated as a result of this incident which had more specific steps for accountability.

QRMG Recommendations:

- A publication procedure and checklist should be in place to ensure appropriate QA checks are completed before further distribution. The details of the procedure and checklist will vary depending on the type of publication. E.g. most regional MI services will have a Medicines Q&A procedure and checklist.

If you require further information regarding IRMIS or the reports, please contact QRMG.ukmi@nhs.net.

Summary of reported incident data

Table 1 and 2 below provide data taken from individual reports of specific incidents and so may reflect local situations. Please note that where text is presented in *italics*, this text has been amended by the IRMIS monitor so as to minimise the likelihood of identifying the reporting centre and individual patients. The information in this report is intended solely for the purposes of raising awareness and training and must never be used as a source of information or advice for specific enquiries.