UKMi
UK Medicines Information

CONFIDENTIAL

The Incident Reporting in Medicines Information Scheme Database Report: Q1 2019 (January – March 2019)

Reports	
Total number enquiry incidents since January 2005: 876	**Total number publications incidents since April 2013: 10**
Enquiries	**Publications/Pro-active work**
Number for this period: 19	Number for this period: 0
Number of errors: 12	Number of errors: 0
Number of near misses: 7	Number of near misses: 0
Number related to data: 5	Number related to data: 0
Number related to advice: 14	Number related to advice: 0
Number not known : 0	Number not known : 0

Most common causes	Incident numbers	Proportion (%)*
Inadequate search	1079 1084 1087 1088 1093 1094 1096 1097	42
Inadequate analysis	1079 1082 1086 1087 1094 1095 1097	37
Urgent deadlines	1087 1089 1090 1095 1097	26
Inexperienced staff	1087 1088 1091 1094	21
Communication problem	1080 1083 1092	16
Documentation problem	1082 1083 1085	16
Inadequate background	1081	16

Enquiry categories	Incident numbers	Proportion (%)*
Administration/dosage	1079 1082 1084 1086 1090 1092 1095	37
Choice of therapy/indications/contra-indications	1081 1083 1088 1093 1096	26
Interactions	1079 1094 1097	16
Pharmaceutical	1084 1091	11
Breastfeeding, medicines in	1087	5
Complementary medicine	1089	5
Non-clinical	1085	5

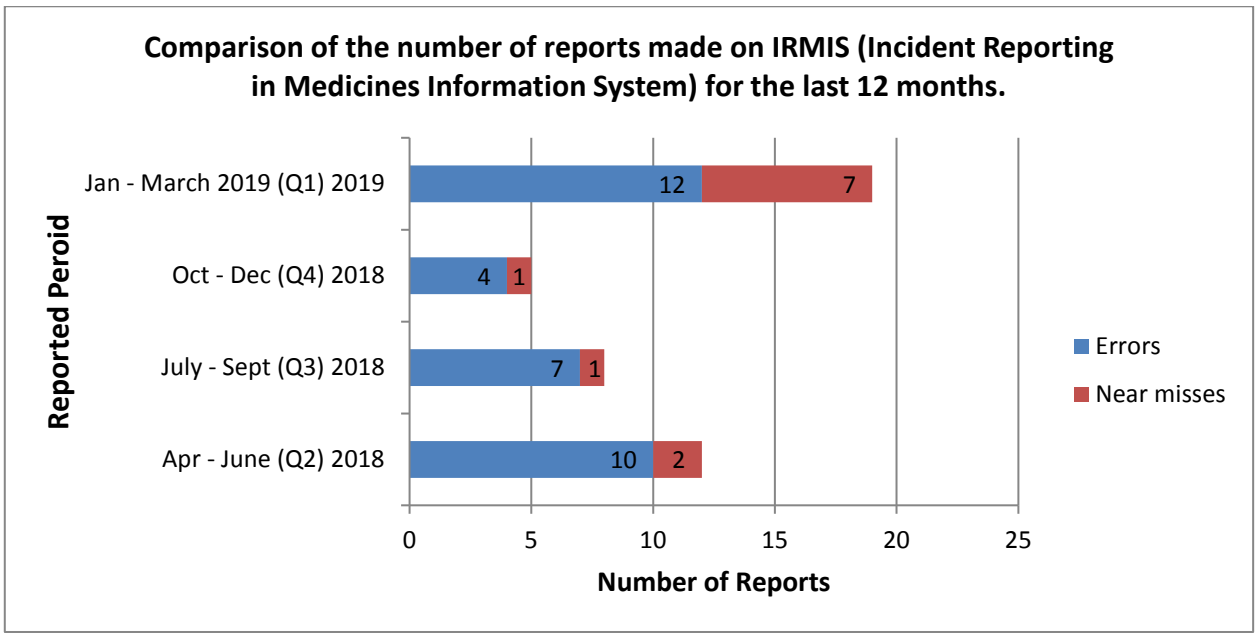
	1082 1083	
Other (Please specify)	1081 1090 1095	16
High workload	1086 1089	11
Incorrect information in resource	1080 1091	11
Low staffing levels	1086 1087	11
Complex enquiry (level 3)	1083	5
Inadequate training	1087	5
Interruptions	1086	5
Poor working environment	1087	5
Procedure not followed	1079	5

Renal disease, medicines in	1080	5

*Reflects multiple causes/enquiry categories per incident

Please note that very small amounts of text are in italics - as previously agreed, this is text amended by the IRMIS monitors so as to minimise the likelihood of identifying the reporting centre and individual patients.

Quarterly comparison of IRMIS statistics over the last 12 months:



Main points to consider/highlight:

- Avoid answering enquiries immediately without time to reflect on the clinical situation or circumstances, and consideration for any associated issues. Clinically assess all enquiries received and do not take at face value.
- Use at least two resources when researching and formulating the answer to avoid incorrect information/advice being given.
- Take time to re-check written responses or ask a colleague to read. Ensure the response answers the question asked and the issues raised.
- Consider having an inhouse process or policy for dealing with high risk drugs requiring complicated or unusual dosing calculations.
- When completing an IRMIS entry, provide details of the scenario and incident sufficient for third party analysis.

Enquiry answering process – receiving the question

Incident 1079 resulted when trying to respond to an enquiry over the phone immediately and then following up the enquiry later in the day due to a lack of depth with the question asked. The risk was increased by a lack of communication with colleagues and the staff handling the enquiry being unavailable. This risk was also seen in incident 1081 where advice was given to a patient based on the details provided by the patient (caller) however reviewing the clinical notes at a later stage suggested a different outcome.

Incident 1082 highlighted the need to repeat the question and pertinent details to the caller before ending the initial call to ensure correct details were noted by MI staff. In this incident, the dosing of theophylline was incorrect resulting in an incorrect dose conversion for a patient with swallow difficulties.

Incident 1084 resulted from a lack of understanding of what seemed to be a simple question. The caller wanted to know if a solid dosage formulation could be halved to administer a smaller dose. The answer suggested crushing and dispersing the drug in water and then removing the quantity required. This practice assumed the drug to have a uniform distribution in solution and highlighted a lack of understanding around dosage formulation.

Incident 1088 also resulted from a lack of understanding of a simple question. The request was for a lactose free product and the advice was to switch to a liquid formulation when a lactose-free solid dosage form was available. The Specialist Pharmacy Services hosts numerous medicines Q&As including one on factors to consider when prescribing for lactose intolerant adults. Furthermore, when suggesting an off-license liquid formulation, consider the source of the drug – is a lactose-containing form of the drug being used to formulate a more palatable formulation?

Incident 1095 involved a drug calculation which was double checked but answered under pressure. The result was that the dose advised was greater than the maximum licensed dose. It is not clear if the incident reporters had access to the Injectable Medicines Guide (or similar) where example calculations are often available for drugs such as intravenous iron.

Incident 1096 highlighted the need to avoid using hyperlinks to web-based documents from previous enquiries – no matter how recent – but to actually locate the most recent version of the document found previously. The incident refers to the latest influenza update from Public Health England. Updates to national documents are included in daily news feeds such as the NICE Medicines Awareness Service (MAS).

Quality and Risk Management Group Recommendations:

- Avoid answering enquiries immediately whilst the enquirer is on hold since this adds unnecessary pressure to the situation.
- Document all medicines related questions, no matter how simple.
- Handle enquiries as per the UKMi Enquiry Answering Guidelines.
- Where MiDatabank (or similar) is available, use features such as the comments box, notes field or control M to document the enquiry status, e.g. awaiting caller to contact MI with further information – see question field, email draft written – requires check.
- Repeat the question to the caller before hanging up to ensure the correct question has been documented.
- Have a clear understanding of the question and consider the impact of the answer developed.
- Encourage pharmacy staff to sign up to news feeds such as NICE MAS.

Enquiry answering process – researching

Incident 1080 involved the Renal Drug Database whereby the user was unaware of the available formulations of a drug. The database lists the administration routes considered and users should scroll to the bottom of the monograph to view this. The incident entry also suggests that providing the enquirer with the monograph may mitigate risks however resources with user licenses should not have their terms and conditions breached (since this could result in the withdrawal of the resource subscription by the provider). Where one resource is being accessed on behalf of the enquirer and no interpretation of the resource information is given but the stated information simply relayed, then it may be useful to record these occasions on a log sheet for monitoring purposes. Where usage is high or MI cannot be contacted for access, there may be a local case for purchasing a multi-user license.

Incident 1086 relied on current Trust guidance to inform the answer even though other resources suggested a different answer. On reviewing the Trust guidance, the resources used were outdated and the advice was no longer evidence based.

Incident 1087 highlighted once again the problems with using one resource and had the added risk of a high risk area (drugs in breastfeeding). The cause of the incident was related to a lack of training of pharmacy staff in dealing with medicines related questions. Incident 1094may have also benefitted from the use of the UKMi enquiry answering guidelines when checking drug interactions though MI staff made the incorrect assumption that carbamazepine and oxcarbazepine had the same interaction profile. The guidance may have also helped in reducing the risk with incident 1097.

Incident 1090 resulted when the wrong drug was researched (though the question clearly stated the correct drug). The drug names did not look-alike or sound-alike. It may be useful for staff new to MI to copy and paste the question at the top of each resource entry to ensure they focus their research and reduce the risk of noting information from the wrong drug. A similar situation occurred with incident 1092 where desmopressin and dexamethasone were confused. This risk could have been reduced by confirming the dosages (low micrograms dosing for desmopressin versus high microgram to milligram dosing for dexamethasone) and indication (enuresis versus palliative care, for example).

Incident 1091 highlights the risk of assuming that no data means the drug is fine to use. A Summary of Product Characteristics (SPC) for a drug did not suggest the excipients to contain bovine for porcine products. On contacting the manufacturers, it was confirmed that the raw materials were extracted from animal based gelatin thus changing the answer (had the SPC been used alone).

Quality and Risk Management Group Recommendations:

- Pharmacy staff using MI suggested resources (either purchased or freely available) should know how to use the resources and understand the limitations of common information sources as part of their training.
- MI managers should be aware of the terms of use for resources they have purchased.
- A log sheet may assist in monitoring the number of enquiries for accessing a resource such as the Renal Drug Database, NEWT guidelines, etc.
- When using local guidance, re-check the main resources used for currency to ensure out-dated evidence is not being used. Where errors are identified then take timely action to bring these to the attention of the author(s).
- Include the UKMi enquiry answering guidelines and limitations document in the training of all pharmacy staff handling questions about medicines.
- New MI staff may benefit from copying and pasting the question into each resource entry to maintain focus.
- If the SPC information is not conclusive regarding excipient information, contact the manufacturer for further data. Ensure staff know how to use the advance search in eMC to locate relevant SPCs, e.g. products containing or not containing latex.
- Consider highlighting a list of sound alike drugs – various lists are available online such as MHRA and ISMP, for example.
- Pharmacy staff should be encouraged to subscribe to current awareness news services such as the daily NICE Medicines Awareness Service (https://www.nice.org.uk/news/nice-newsletters-and-alerts).

Enquiry answering process – giving the answer

Incident 1083 forwarded the manufacturer's response as the answer to the enquirer's question, however, the manufacturer's answer referred to a different disease state and did not answer the caller's question.
Incident 1085 resulted when an amount was incorrectly copied into the written answer. Risks with written responses can be reduced by second checks or returning to the written response after a break and re-reading the answer with context. Incident 1089 also resulted due to an error in the written response.
Incident 1093 resulted when the question asked was answered but the issue of the recommended drug interacting with current medication had not been considered.

Quality and Risk Management Group Recommendations:

- Always re-read third party provided information to ensure that they have addressed your question.
- Restate the enquirer's question in written responses, e.g. subject heading.
- Written responses should always be re-read in context either by a second person (not involved in the enquiry) or by returning to the answer after a break (before sending).
- Whenever a new drug or change in dosing is advised, check for drug interactions with the patient's current drug therapy.

Publication Incident

There were no publication incidents reported this quarter.

*****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*****