Medication Incidents Involving Metformin: A Multi-Incident Analysis

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Objectives

- Type 2 diabetes mellitus, a highly prevalent chronic disease, has been imposing a profound impact, ranging from individual patients to their families; and from communities to the health care system.
- As the first line pharmacological therapy for type 2 diabetes,[1] metformin plays a crucial role in disease management, and is among the top 10 prescription medications in 2015;[2] furthermore, listed by the Institute for Safe Medication Practices as a high-alert medication, metformin can pose significant threats to patient safety, if used incorrectly.[3]
- Newer classes of diabetes medications and combination products containing metformin have been developed, and they are common therapeutic options for patients as well.
- The objective of this multi-incident analysis was to gain an understanding of the potential contributing factors to incidents involving metformin and combination products containing metformin, and to provide recommendations to prevent error recurrences and enhance medication safety.

Methodology

- A total of 403 medication incidents involving metformin-related products were extracted from the Institute for Safe Medication Practices Canada (ISMP Canada) Community Pharmacy Incident Reporting (CPhIR) Program from January to December 2015. With subsequent incident screening based on exclusion criteria, we conducted a qualitative, thematic analysis on 312 incidents, which were then categorized into main themes and subthemes (Table 1).
- CPhIR provides users with a secure online interface to document medication incidents, export data for analysis, and view comparisons of individual pharmacy and aggregate data.[4]
- Limitations: As CPhIR is a voluntary reporting program, not all incidents involving metformin-related medications were captured; our interpretation of the incidents also depended on the descriptions provided by the reporters.

Results

- Three main themes were identified, with subthemes further derived from each main theme (Table 1).
- Based on the main themes and subthemes, potential contributing factors were determined and corresponding recommendations were developed (Tables 2, 3, and 4).

Table 1:

THEMES	SUBTHEMES
Therapeutic role in diabetes management	• Dosing regimen adjustment and maintenance • Tablet splitting
Choice of agent	• Drug selection • Formulation selection • Strength selection
Prescription preparation	• Data entry of prescription and patient care information • Blister pack preparation

Table 2:

Theme 1 – Therapeutic role in diabetes management

SUBTHEME – Dosing regimen adjustment and maintenance

INCIDENT EXAMPLE 1 (dosing regimen adjustment):
Dose of metformin was decreased to 1 tablet BID but the medication was filled based on the old dose of 2 tablets BID.

INCIDENT EXAMPLE 2 (dosing regimen maintenance):
The instruction on the prescription should have been "twice daily" for metformin, but the doctor put "once daily". The change was not intentional.

POTENTIAL CONTRIBUTING FACTORS:
- Therapeutic management itself is associated with a fair amount of dosing adjustments, based on patients' response/tolerance to the medication or the control/progression of the medical condition.
- Copying of previous prescriptions on patient profile.
- Mixing up of the old and new dosing regimens at the prescribing stage.

RECOMMENDATIONS:
- Actively engage patients in their health/disease management; remind and train staff to check with patients for further information when they present to the pharmacy with prescriptions of possible dosing adjustments.[5]
- Emphasize to staff and remind them of the importance of timely and effective communication with prescribers when encountering concerns related to dosing regimens.
- The "copy" functionality is available in most pharmacy software systems to improve workflow. Policies may be considered within the pharmacy to limit the use of the "copying" function from previous prescriptions (where applicable).

SUBTHEME – Tablet-splitting

INCIDENT EXAMPLE:
Patient brought metformin tablets back to be split as the dose was half a tablet and the tablets were normally split. There were notes for tablet-splitting on the prescription and in the patient comments which were missed.

POTENTIAL CONTRIBUTING FACTOR:
- The necessity for tablet splitting – tablet-splitting might be required when patients undergo dosing regimen adjustments or have difficulties swallowing tablets.

RECOMMENDATION:
- Perform independent double checks when possible, especially for medications with special requests such as tablet-splitting.[6]

Table 3: Theme 2 – Choice of agent

SUBTHEME – Drug selection

INCIDENT EXAMPLE:
New prescription entered as Janumet® when written as Januvia®. The error was caught by the pharmacist on first fill.

POTENTIAL CONTRIBUTING FACTORS:
- Sound-alike medications
- Mixing up of metformin, metformin-containing combination products and other classes of oral diabetes medications

SUBTHEME – Formulation selection

INCIDENT EXAMPLE:
The patient was first prescribed Janumet® 50/1000. It was later changed to Janumet® XR 50/1000. This prescription was mistakenly entered as regular-release Janumet® 50/1000. The patient took this for 2 months before the error was caught; it was then changed to the correct formulation.

POTENTIAL CONTRIBUTING FACTORS:
- Environmental factors such as distractions from staff/patients, heavy workload and staff shortage, potentially leading to reduced cognitive alertness to such details
- Confirmation bias
- Lack of knowledge or awareness of pharmacy staff on the availability of various formulations and strengths of a medication.

SUBTHEME – Strength selection

INCIDENT EXAMPLE:
The patient had a new prescription for metformin 500 mg. Metformin 850 mg was dispensed. The patient caught this error before taking the medication and brought the prescription back to the pharmacy to be corrected.

POTENTIAL CONTRIBUTING FACTORS:
- Environmental factors such as distractions from staff/patients, heavy workload and staff shortage, potentially leading to reduced cognitive alertness to such details
- Confirmation bias
- Lack of knowledge or awareness of pharmacy staff on the availability of various formulations and strengths of a medication.

RECOMMENDATIONS:
- Create a section on the shelf where the most commonly dispensed metformin related products, formulations and strengths are organized and away from the products dispensed less frequently (creation/organization will be based on each pharmacy's individual product demand) – in an effort to minimize the chance of accidentally selecting the wrong one out of a pool of look-alike/sound-alike products, when all are kept in close proximity.
- Provide regular educational updates and training to pharmacy staff regarding new drug information (including new formulations and strengths of existing medications).
- Practice and offer patient counselling for both new and refill prescriptions to serve as the final check for production selection and therapeutic appropriateness before the medications are handed over to patients.[7]
- Consider patient education as an extra layer of independent double check for medication incidents in addition to the prescription-checking efforts of pharmacy staff.

Table 4: Theme 3 – Prescription preparation

SUBTHEME – Data entry of prescription and patient care information

INCIDENT EXAMPLE:
The prescription was written for 2 tabs BID, however, it was entered, logged and checked as 1 tab BID. Subsequent refill was filled as 1 tab BID. This error was found on pharmacist's check.

POTENTIAL CONTRIBUTING FACTORS:
- Confirmation bias
- External influences such as distractions and heavy workload, potentially leading to an increased chance of technical errors involved in prescription preparations

RECOMMENDATION:
- Incorporate independent double checks into workflow whenever possible, for example, by having the second pharmacy staff member conduct checking without any advance knowledge of expectation.[6]

SUBTHEME – Blister pack preparation

INCIDENT EXAMPLE 1:
Metformin was omitted from patient's blister packs. Patient went away on vacation at which point patient's daughter noticed metformin was not in her packs. Fortunately, the patient had a vial of extra metformin, which she was able to use while away until the situation could be reconciled when she arrived home.

INCIDENT EXAMPLE 2:
There was a packaging error involving extra metformin in the blister pack bubbles.

POTENTIAL CONTRIBUTING FACTOR:
- Complexities and vulnerabilities associated specifically with blister pack preparations[8]

RECOMMENDATIONS:
- Encourage pharmacy to create a list of high-alert medications that are also frequently prepared in blister packs based on the pharmacy's individual dispensing trends. The list can be displayed in the dispensary area as a reminder for the staff members (consult the List of High-Alert Medications in Community/Ambulatory Healthcare[3] if further information is needed). (Note: ISMP High-Alert Medications are available at http://www.ismp.org/Tools/highAlertMedicationLists.asp)
- Create a checklist that outlines the procedural steps of blister pack preparations, with an extra section of warning points/tips specifically for high-alert medications such as metformin.
- Consider redesigning work environment so that there is a specific work station for blister pack preparation, in an effort to minimize distractions and mixing-up with other prescription preparation procedures.

Conclusion

Metformin is used and dispensed highly frequently in pharmacy practice. Combination products containing metformin have also been utilized by patients. When used incorrectly, metformin can be associated with the potential to cause significant patient harm.

We hope our findings from this multi-incident analysis can provide a platform for reflection and shared learning. We provide potential recommendations here with an attempt to aid with the adoption of system-based error reduction strategies, which would then contribute to safe medication practices and a culture of patient safety.

References

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ISMP Canada
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www.ismp-canada.org

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CPhIR
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www.cphir.ca

Disclosures
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