Complexity and Vulnerability of Compliance Pack Preparation

A MULTI-INCIDENT ANALYSIS BY ISMP CANADA

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INTRODUCTION

The patient arrived at the pharmacy at 4:30 P.M. and the pharmacy was scheduled to close at 5 P.M. The patient was discharged from a hospital with numerous changes to his blister pack. Several errors were made. (These errors were not discovered until the pharmacist was trying to fax the patient's family doctor for subsequent refills at a later time).

- *Two prescriptions from the hospital discharge order were put under the patient's family doctor's name and not the hospital discharge doctor's.*
- *The SIG on allopurinol was read "TO the once daily."*
- *Clopidogrel was supposed to be continued for 39 days after discharge as per the hospital discharge order, but it was only filled for 28 days without putting the refill for the remaining 11 days. (Note: 28-day supply was typical for blister packs for a four-week supply).*
- *The pharmacist was rushing to get new orders from the patient's family doctor and calling the hospital to clarify for warfarin since it was not on the hospital discharge order, and it was supposed to be restarted after clopidogrel was finished.*

The above scenario illustrates the complexity and vulnerability of compliance packs due to numerous changes and insufficient time in prescription preparation and dispensing. This may potentially lead to a greater risk of medication errors as compared to individual prescription filling. It is important to be aware of the differences and additional accountabilities associated with dispensing in compliance packs versus traditional prescriptions.[1]

Compliance packaging helps to enhance a patient's adherence to their medication schedule, particularly for those who are older, have cognitive impairment, and/or on a large number of medications, and ultimately optimizes the effectiveness of medication therapy.[1, 2] Approximately 70% of Canadian community pharmacists feel that the use of special packaging is one of the important factors to improve medication adherence.[3] Therefore, compliance packaging is becoming more common for medication management in community pharmacy practice.

Processing and dispensing traditional prescriptions in vials already involves high-level procedures. Owing to its multi-compartment design, compliance packaging introduces further complexity and vulnerability in the pharmacy workflow, which increases the unpredictability and variations of the medication-use system.[4] Therefore, the objective of this multi-incident analysis is to gain a better understanding of the potential contributing factors resulting from compliance pack-related incidents.

The Community Pharmacy Incident Reporting (CPhIR) Program (available at http://www.cphir.ca) is designed for community pharmacies to report near misses or medication incidents anonymously to ISMP Canada for further analysis and dissemination of shared learning from incidents. CPhIR has allowed the collection of invaluable information to help identify system-based vulnerable areas in community pharmacy practice in order to prevent medication incidents.[5] This article provides an overview of a multi-incident analysis of compliance pack-related incidents reported to the CPhIR program.

MULTI-INCIDENT ANALYSIS OF MEDICATION INCIDENTS RELATED TO COMPLIANCE PACK PREPARATION IN COMMUNITY PHARMACY PRACTICE

Reports of medication incidents involving "blister pack", "compliance pack", "pill pack" and/or "bubble" were extracted from the CPhIR Program from June 2012 to May 2013. In total, 170 incidents met inclusion criteria and were included in this qualitative, multi-incident analysis. The incidents were analyzed and categorized into two major themes: (1) order entry and (2) packaging process. The two major themes were further divided into subthemes, as shown in Table 1 and Table 2, respectively. (Note: The "Incident Examples" provided in Tables 1 and 2 were limited by what was inputted by pharmacy practitioners to the "Incident Description" field of the CPhIR program).

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TABLE 1. THEME 1 – ORDER ENTRY

Order entry is the stage where pharmacy staff enters new prescriptions or makes changes to existing prescriptions on the computer system.

SUBTHEME	INCIDENT EXAMPLE	POTENTIAL CONTRIBUTING FACTORS
Hospital Discharge Order	*Patient was released from the hospital and normally gets blister packs. Pharmacy technician filled the antibiotic and logged all the other medications from the discharge prescription. Two changes needed to be made. In previous prescriptions, patient had been taking 2 tablets of metformin BID and 1 tablet of lansoprazole BID, but with the recent hospital discharge prescription, it indicated 1 tablet of metformin BID and 1 tablet of lansoprazole once daily. Pharmacy technician copied from old prescriptions and left the SIGs as before. Pharmacist noted the errors, fixed the directions of use and quantities on the computer, and counseled the patient of the adjusted doses at home.*	• Numerous modifications on the patient's medication profile at one time • Copying from previous prescriptions • Lack of verification with the most up-to-date prescription(s) with the medications in the compliance pack
	Patient was prescribed a new medication, amlodipine, upon hospital discharge. Patient normally gets blister packs but was given this new medication in a vial to catch up to the blisters. However, whoever entered the medications onto the computer system did not flag it as batch or put it in the panel for next fill. So when the pharmacy filled the next batch of blister packs (i.e. 2 weeks in advance before the patient needs them), it was not prompted to ask the family doctor for refilling the amlodipine. Patient's son called the pharmacy as patient has run out of amlodipine in the vial and realized that the new blister packs did not contain amlodipine in them. Pharmacist also realized that they did the wrong quantity of catch-up dose since patient still has 1 week left of the old packs.	• New medication(s) being added in the middle of a compliance pack cycle
Discontinuation of Medication from New Order	*When pharmacist checked the compliance packs, 15 mg oxazepam had not been discontinued. Both oxazepam 15 mg and 30 mg showed up on the prescription labels. Pharmacist cancelled the 15 mg.*	• Lack of automatic alert on the computer system for potential duplication of therapy
New Prescription Update	*Doctor changed the strength of losartan/hydrochlorothiazide. The new strength was put in the blister pack but the old*	• Lack of automatic alert on the computer system

SUBTHEME	INCIDENT EXAMPLE	POTENTIAL CONTRIBUTING FACTORS
	strength was not removed. Patient ingested one dose and brought back the packs the next day. The pharmacist corrected the error. Patient did not suffer any long-term effects but felt a bit dizzy that night.	for potential duplication of therapy • Lack of systematic process for independent double checks • Lack of verification with the most up-to-date prescription(s) and the medications in the compliance pack
	Pharmacist noticed that there were 7 capsules short for gabapentin after filling the rest of the pill packs. It was then realized that the medication was put in both the morning and bedtime slot as was in the prior pill pack. When the latest prescription was entered, the time of administration was not updated to reflect that gabapentin was now to be taken only once a day instead of twice a day.	
Prospective Update	*Tecta® was given BID in the compliance pack but the pharmacy billed for once daily dosing. From looking up at the original prescription, it was a hospital discharge order and written as BID for the first month and then continue with once daily dosing. Pharmacy forgot to inactivate the BID prescription after the first month and showed up in the 2nd month blister pack and forgot to activate the once daily dosing. When pharmacist checked the hardcopies/billings, it only indicated for 28 tablets. The compliance pack was fixed by relabeling and inactivated BID order and put through the once daily order. Pharmacist also physically removed the bedtime doses, so only the morning doses were in the compliance card.*	• Lack of notifications on the computer system for prospective changes from the prescription • Lack of verification with the original prescription(s) and the medications in the compliance pack • Inappropriate storage of miscellaneous medications for future use
	A prescription was put through the computer system and filled the blister packs on November 23 for Kadian® 50 mg po BID. When the pharmacist was checking the prescription, she noted that the prescription was post-dated for November 26. The pharmacist cancelled the prescription but the capsules were left in the blister packs and put aside to be re-entered on November 26 as opposed to punching the medications out of the cards and putting them back into the stock bottles. On November 26, the prescription was filled again except it was put through as Kadian® 100 mg po BID instead of 50 mg po BID on the prescription. The compliance cards were labeled as 100 mg capsules even though the correct dose (i.e. 50 mg) was in the cards.	
Miscalculation	*The direction of use for olanzapine indicated 1 tablet in the morning and 2 tablets at bedtime. Prescription had been logged as 84 tablets but the "next quantity" was put through as 28 tablets. When the prescription was filled, it only billed for 28 tablets, which should have been 84 tablets.*	• Lack of awareness of the differences in entering compliance pack versus individual prescription order
	Physician had allowed 3 months with 3 repeats for captopril. Pharmacy had to switch to 1 month with appropriate refills for blister packs and had a confirmation with the doctor. It was mistakenly put in as 5 repeats when it should have been 11 repeats.	

TABLE 2. THEME 2 – PACKAGING PROCESS

Packaging process is the stage that involves the preparation of blister packs for each individual patient.

SUBTHEME	INCIDENT EXAMPLE	POTENTIAL CONTRIBUTING FACTORS
Labeling	*When preparing for the blister packs, the right drug (risperidone) was in the packs but the rabeprazole EC label was on it by accident.*	• Look-alike sound-alike (LASA) drugs • Lack of systematic process for independent double checks in workflow
Incorrect Time of Administration	*A new compliance-pack patient from nursing home was given instructions to take Toloxin® 4 times weekly. The patient had been taking it on Monday, Tuesday, Wednesday, and Thursday. It got packaged as Monday, Wednesday, Friday, and Sunday. The nurse noticed the discrepancy before it was given to the patient.* *A patient on blister pack who gets methotrexate weekly at bedtime. Blisters were done incorrectly with methotrexate by putting in the morning slot instead of the bedtime slot. Pharmacist missed when checking and patient discovered the error.*	• No specific day or time has been specified on the prescription label • Lack of systematic process for independent double checks in workflow
	The doses for atorvastatin and rabeprazole were double in the bedtime slot for Saturday and no dose for both of the medications for Sunday.	• Numerous bubbles/slots on the compliance card with no physical barrier between the bubbles corresponding to the appropriate day and time
	Prescription for methotrexate was supposed to be 3 tablets once weekly on Sunday. Pharmacy technician put 1 tablet in the Monday, Wednesday, and Friday's suppertime slot. Note: for Novasen and vitamin B12, 1 tablet each at supper time slot on Monday, Wednesday, and Friday. Pharmacist noticed when checking and bubbles were fixed.	• Filling multiple medications in multiple bubbles/slots simultaneously • Confirmation bias
Half-tablet Medications	*Patient is on Synthroid® 25 mcg (1.5 tablets) in the morning plus trazodone 50 mg (1.5 tablets) at bedtime. When checking the blister packs, the pharmacist noticed that $\frac{1}{2}$ tablet of trazodone was placed in the morning slot along with Synthroid® due to similar physical appearance.*	• Look-alike sound-alike (LASA) drugs • Lack of systematic process for independent double checks in workflow
Improper Return-to-stock Procedure	*Blister packs were never picked up and needed to be restocked. When restocking some of the irbesartan 75 mg tablets, they got in with the gliclazide MR 30 mg bottles. It was noticed when checking some pill packs.*	• Look-alike sound-alike (LASA) drugs • Lack of systematic process for independent double checks in workflow

SUBTHEME	INCIDENT EXAMPLE	POTENTIAL CONTRIBUTING FACTORS
Dose/Medication Omission	*Patient gets 10 medications blister packed and clopidogrel was omitted from morning slot (which contained 8 other pills). Pharmacist discovered the error when doing the final check.* *Patient has his medications blister packed 4 weeks at a time, including metoprolol 50 mg 3 tablets BID. Patient's family realized the morning dose for metoprolol was missing from 2 of the 4 blister packs, including the one patient had already started. This meant that the patient had missed 2 days of metoprolol in the morning. Patient was hospitalized for shortness of breath and was given an increased dose of diuretic.*	• Multiple medications in the same bubble/slot • Lack of systematic process for independent double checks in workflow • Lack of cross-reference check with other compliance packs of the same patient
Incorrect Medication	*Atorvastatin 10 mg was placed instead of rosuvastatin 10 mg in the blister pack. Error was found when checking the blister package.*	• Look-alike sound-alike (LASA) drugs • Lack of systematic process for independent double checks in workflow
Incorrect Strength	*Synthroid® 0.05 mg was placed in blister pack instead of 0.15 mg and patient took the wrong dose for 5 days before noticing the error. Patient reported feeling "more tired" than usual.*	• Multiple strengths of the medication are available from the same manufacturer • Lack of systematic process for independent double checks in workflow • Confirmation bias

HOW IS COMPLIANCE PACKAGING DIFFERENT FROM PREPARING TRADITIONAL PRESCRIPTIONS?

Comparing to traditional prescription preparation, compliance packaging often presents with unique features that are more prone to medication incidents. For example, during order entry (see Table 1) pharmacy staff typically enters the dispensing quantity, the number of refills, and the days supply as directed by the prescriber. However, since compliance packs are typically filled on a weekly, biweekly, or monthly basis, the number of refills and days supply may need to be modified during order entry in order to fit the compliance packaging schedule. This extra step will require additional cognitive processes performed by pharmacy staff during order entry, which may lead to an increased risk of error.

Moreover, for compliance packaging, the pharmacy staff would need to place individual medication into each bubble of the compliance pack, corresponding to the appropriate day of the week and administration time indicated on the prescription label. Since there are no permanent physical barriers between each bubble (as opposed to individual vial per medication in traditional dispensing), compliance packaging is more prone to a medication being misplaced in another bubble or slot during the sealing process.

WHAT ARE SOME IMPORTANT CONSIDERATIONS FOR SAFE MEDICATION PRACTICES WITH COMPLIANCE PACKAGING?

Based on the potential contributing factors that have been identified from this multi-incident analysis, consider the following when preparing compliance packs for individual patients:

- Verify the printed prescription labels with the most current prescription order(s), especially when there is a new update or change to the patient's profile, including hospital discharge order, new prescription, and/or discontinuation of medications, etc.;
- Incorporate reminders on the computer system that will automatically flag any prospective changes needed to be made during the next compliance pack cycle;[1]
- Conduct independent double checks whenever possible in the pharmacy workflow;[7]
- Implement barcode scanning (if possible) which serves as an automated independent double check to verify that the drug product and strength selected from the inventory matches with what has been entered into the patient's profile;[6]
- Encourage collaboration and dialogue with patients, caregivers, and other primary care practitioners to maintain good communication and ensure appropriate medication regimen is prepared in each compliance-pack cycle.[6]
- Consult the *Guideline on Multi-Medication Compliance Aids* (available from http://www.ocpinfo.com/regulations-standards/policies-guidelines/compliance-aids/), which was updated by the Ontario College of Pharmacists in 2013.

CONCLUSION

The incidents gathered from this multi-incident analysis have reinforced the complexity and vulnerability of compliance pack preparation. Although compliance packs heighten patient's adherence and treatment outcomes, the complexity of the design and procedures for preparation may potentially lead to negative health consequences.[8] As a result, this multi-incident analysis is intended to recognize the vulnerabilities with compliance pack preparation, which create opportunities for community pharmacy practitioners to implement additional safeguards to enhance medication safety.

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