Medicines Safety Matters

Health and Social Care Board

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Sharing Learning Across Community Pharmacy In Northern Ireland

Incidents involving Monitored Dosage Systems (MDS)

Many patients have their medicines dispensed into monitored dosage systems (MDS) - also known as multi-compartment compliance aids (MCA). A Royal Pharmaceutical Society report[1] considered a range of issues about the use of MDS and noted that in general, there is insufficient evidence to support the benefits of MDS in improving medicines adherence in patients, or in improving patient outcomes. It is also recognised that removing medications from their original packaging and inserting them into an MDS is not without risk[1,2,4]

At least 30% of pharmacy incidents reported to the HSCB involve MDS. Using a selection of reported incidents, this bulletin examines some of the issues and the learning shared by the pharmacists involved.

MDS may be of value for those patients who have been *assessed* as having practical problems in managing their medicines. Each patient's needs must be assessed on an individual basis and any intervention must be tailored to the patient's specific requirements[1]

What are the risks[1]?

- Difficulty in identifying each tablet or capsule. This can cause problems for both patients and those involved in the dispensing process
- Introduces an extra step into the dispensing process where an error can occur
- The use of MDS can lead to reduced patient empowerment, and loss of skills and knowledge for carers and patients
- Carers and patients may have to use several different medicines administration systems e.g. original packs and MDS, which may increase the risk of the patient not taking their medicines as intended
- Medicines may not be stable when removed from their packaging and therefore potentially less effective - there is a lack of data on the efficiency of a sealed MDS in providing protection from moisture and air
- Where multiple medicines are repackaged within a single compartment, medicines can interact
- Inability to accommodate specific times for administration e.g. before/with/after meals, PRNs and doses which vary according to response
- Disadvantages in the supply of relevant necessary information e.g. patient information leaflets.

What can we do to reduce the risks?

The Pharmaceutical Society of Northern Ireland recently issued a regulatory statement[3] reminding pharmacists of their legislative obligations regarding the supply of medicine in an MDS. It advises that "…all pharmacists put in place adequate and appropriate risk management and governance arrangement to ensure the safe and effective supply of medicines by MCA [MDS] to patients"

- Pharmacies must have a written SOP for supplying medicines in an MDS
- Review your SOP using the learning and information resources included in this newsletter
- Have a plan for follow-up and regular review of patients
- Ensure you maintain up-to-date records of medication including medication changes
- Ensure you communicate directly with the prescriber regarding medication queries
- Notify the GP practice when patients are commenced on an MDS so that a record can be made on their clinical system
- Carry out a regular audit to ensure the established process for assembling, dispensing and supply of medication in an MDS is as robust and safe as possible
- Ensure that you have checked the stability of medicines dispensed in an MDS.

Patient received the wrong MDS

What happened?

A patient was given the wrong MDS. It contained the oral hypoglycaemics metformin, sitagliptin and gliclazide. The patient did not notice that the MDS had another patient's name on it and took the incorrect medication for one day.

Outcome

The patient collapsed and required admission to hospital for 8 days for treatment of hypoglycaemia, seizure and rhabdomyolysis.

Contributory factors

- The patients had similar names
- All the MDS used in the pharmacy were identical in appearance.

Learning

The pharmacy SOP had previously required a cross check of the first name and surname of the patient when handing out medication.
Now pharmacy staff **ask the patient to state their address** before handing over the medication.

Similar Incidents

A number of similar incidents have occurred where patients received the wrong MDS and required admission to hospital. In one case, where a patient was receiving 4 weekly supplies at once, they were given 3 weeks of their correct medication and 1 week of someone else's medicines.

Additional learning point

- Where more than one MDS is being supplied for a patient, check the name and address on **EACH** MDS prior to bagging and handing out.

- **How do you check patient identity before handing out an MDS?**
- **What about MDS delivered to a patient's home?**

Dose duplication

What happened?

A GP decreased a patient's Priadel® dose from 400mg to 200mg. At this time the patient was in a nursing home for respite and one month of Priadel® 200mg was prescribed. The GP advised the nursing home and family about the dose reduction.
After the patient returned home, all of their medicines were taken to the pharmacy by a relative to be re-dispensed into an MDS. The medicines included Priadel® 200mg and the discontinued 400mg which were both put into the MDS. The patient took a dose of 600mg for approximately one month.

Outcome

The patient was admitted to hospital with symptoms of lithium toxicity i.e. nausea, drowsiness and bradycardia.
The serum-lithium level was 2.6mmol/litre. Levels over 1.5mmol/litre may be fatal and require urgent treatment.

Contributory factors

- The pharmacist was a locum and the pharmacy was busy at the time
- There was no prescription to dispense against
- The relative was pressurising the pharmacist to act quickly
- The pharmacist was unable to get confirmation of the dose from the GP practice at that time and contacted the nursing home to confirm the dose. The incorrect dose was confirmed.

Learning

- Medications that have previously been dispensed to a patient should not be re-dispensed into an MDS
- Dose queries should be discussed directly with the prescriber
- Always dispense from a current prescription.

- **How do you check clinical queries with the prescriber?**
- **How do you manage requests to re-dispense into a MDS?**

Discontinued medicines dispensed

What happened?

A pharmacy dispensed two medicines which had been discontinued into an MDS. The pharmacy process for dispensing into MDS was complicated involving use of charts listing the prescribed medicines and a photocopy of the prescription (the original script having been sent to BSO). An old chart and photocopy of a prescription with an unclear date were selected in error. Nitrazepam and mirtazapine had been discontinued but were included in the list and on the photocopy and were dispensed in error.

Outcome

The patient was admitted to hospital following a fall and the error was subsequently detected.

Contributory factors

- The MDS was not prepared using the current prescription

Learning

- Dispensing into an MDS should be undertaken using the current prescription and cross checked with the patient's PMR
- All pharmacies must have written procedures for managing medication changes for patients receiving MDS.

- **Are you dispensing into MDS using the current prescription?**
- **What are your procedures for managing changes to medication?**

Duplication of Medication

What happened?

The patient was prescribed an Ebixa® (memantine) titration pack which was dispensed in its original pack and separate from their other medicines which were dispensed in an MDS. The patient did not start the Ebixa® as intended and the titration pack was found 4 weeks later by a family member. When the pharmacist was notified of this, a note was made for action the next day.
However, the patient's MDS for the next week had already been delivered and included the Ebixa® **maintenance** dose (20mg). The pharmacist spoke with patient's son who removed the 20mg dose from the MDS and started the titration dose as advised. Another MDS delivered by the pharmacy the following week still contained the 20mg tablet. As a result the patient took 10mg from titration pack and 20mg from the MDS for 5 days.

Outcome

The patient was admitted to hospital with drowsiness and confusion.

Contributory Factors

- Different medication administration systems were used leading to confusion for the patient
- Advice on new medication was not understood by the patient/carer
- Problems with communication of medication changes within the pharmacy

Learning

- Discuss changes in medicines ensuring the patient/carer is aware of:
    - New medicines and the dosage regimen
    - Medicines that have not been included in an MDS e.g. not suitable for inclusion or which have been supplied from the hospital
- Review of procedure to action mid-cycle medication changes.

- **How are mid-cycle dose changes managed within your pharmacy?**
- **What records of medication changes do you keep?**

Stability of medicines in an MDS

The removal of a medicine from the manufacturer's original packaging and its repackaging into an MDS will often be an unlicensed use of the product. This may impact upon the stability of the medicine. Removal of medication from its original packaging therefore, transfers responsibility from the manufacturer, to the prescriber and pharmacist.[1,4]

UKMI has developed an MDS database which makes recommendations on the suitability of medicines for transfer from the manufacturer's original packaging into an MDS.

Advice is based on a traffic light system (see examples) based on:

- Drug stability and characteristics
- Manufacturers advice, if available
- Data on storage in an MDS, if available

(Remember the guide offers general advice and your own professional judgement is still required).

RED unsuitable	Nifedipine	Protect from light
RED unsuitable	Dabigatran	Very sensitive to moisture. Must be left in individual foil wrapping
AMBER risks	Omeprazole	Protect from moisture & light Max 2 weeks in an MDS
AMBER risks	Aspirin	Drug hydrolyses in moist air Max 8 days in an MDS

Have you used the MDS database?

Are the medicines that you supply in an MDS stable for the period between dispensing and administration?

http://www.ukmi.nhs.uk/applications/MDS/

Incorrect or missing labels

Legislation requires a label to be prepared for each item that is dispensed into an MDS and be attached directly to the packaging each time the medicine is dispensed.

Pharmacists should aim to use a device which can be fully labelled. With some MDS, there is insufficient space to accommodate all the labels and as a pragmatic solution the labels are attached to a separate accompanying card.

Incidents have occurred where labels have been missing or the wrong card has been taken into hospital by the patient and the wrong medicines prescribed.
In this case, systems should be in place to ensure that:

- The labels attached to the card are up to date
- There is no risk of separation of labels from the medication
- Patients understand the importance of referring to the most recent dispensing labels.

Do you provide a label every time a medicine is dispensed in an MDS?

[1]Improving Patient Outcomes – the better use of multi-compartment compliance aids. 2013
http://www.rpharms.com/unsecure-support-resources/improving-patient-outcomes-through-the-better-use-of-MDSs.asp
[2]HSC Pharmacy Safety Alert – Risks when dispensing medicines into monitored dosage systems. 2010
http://www.medicinesgovernance.hscni.net/primary-care/medicines-safety-advice-letters/
[3]PSNI Regulatory Statement on MDS. 2015
http://www.psni.org.uk/news/recent-publications/
[4]Multi-compartment compliance aids: do you need to review what you do? Wang Pharm J Vol 291, p120
http://www.pharmaceutical-journal.com/learning/learning-article/multi-compartment-compliance-aids-do-you-need-to-review-what-you-do/11123667.article

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