Patient safety quarterly report (England): Quarter 2 (April - June) 2018

Dear Superintendent,

This is the NPA Medication Safety Officer's (MSO) patient safety report for Quarter 2 of 2018 which includes a summary of the most common dispensing errors reported to the NPA during the quarter along with top tips for minimising patient safety incidents.

Introduction

An increase of 64% in patient safety incidents were reported in Quarter 2 compared to Quarter 1, and the submission of reports almost doubled in the month of June compared to the months of April and May.

IMPORTANT

- Please ensure that ALL reports submitted are complete reports
- Avoid selecting '*other*' when answering questions
- Please read our guidance for completing the Patient Safety Incident Report Form if there is any uncertainty on how to complete the form

NOTICEBOARD

Valproate: Pregnancy Prevention Programme

In April 2018, the MHRA issued regulatory changes that meant that valproate medicines (Epilim®, Depakote® and other generic brands) must not be prescribed to women or girls of childbearing potential unless they are on the Pregnancy Prevention Programme (PPP). MHRA has now published resource materials online to support the new valproate PPP.

The NPA has developed a suite of Medicines in pregnancy and patient safety resources, including a poster to highlight to patients the importance of speaking to the pharmacy team before taking any medicines in pregnancy or when trying to conceive.

MHRA Class 1 recall: Valsartan

The Medicines & Healthcare Products Regulatory Agency (MHRA) Defective Medicines Report Centre (DMRC) recently issued a Class 1 recall for all affected batches of valsartan containing medicines manufactured by Actavis (now Accord), and Dexcel Pharma. It is regarding concerns of possible contamination with, N-nitrosodimethylamine (NDMA). The impurity NDMA is considered to be genotoxic and has carcinogenic potential. Further information, including details of affected batches, can be found on the MHRA website.

MHRA alert: pressurised metered dose inhalers (pMDI) – risk of airway obstruction/choking

The MHRA has recently issued a reminder to healthcare professionals of the potential risks of airway obstruction from aspiration and choking of loose/foreign objects when inhaling pMDI. Reports have suggested that loose objects can become trapped within the mouthpiece. The MHRA has issued the following advice to healthcare professionals, including pharmacists, to minimise these events from occurring:

- Ensure patients are trained to correctly use their inhaler – refer to patient information leaflet for further instructions
- Before inhaling, advise patients to remove the mouthpiece cover, shake the inhaler to remove loose/foreign objects that may be present and check the mouthpiece is clear
- Remind patients to replace the mouthpiece immediately after use to prevent loose/foreign objects (for example, tissues, stickers, coins, plastic items) entering the mouthpiece during storage
- Pharmacists should emphasise patients to check their pMDI for any signs of damage and to also clean their device regularly (as per manufacturer's instructions)

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- To report any adverse incidents as well as suspected adverse reactions during the use of inhalers via Yellow Card Scheme

The NPA has produced an *"Inhaler identification checker"* resource to support pharmacy teams distinguish between brand/generic inhalers and reduce dispensing incidents associated with generic inhaler prescriptions.

Frequent errors – common themes

Errors involving delivery drivers

Although dispensing errors involving delivery drivers constituted up to 2% of incidents reported during Quarter 2 of 2018, this is a decrease compared to Quarter 1 of 2018 (4%). Most of the common errors involved medication being delivered to the incorrect address due to the prescription being labelled under a different but similar sounding name.

Errors involving breach of confidentiality

Dispensing errors involving breach of patient confidentiality made up 8% of incidents under the '*other*' category reported during Quarter 2 of 2018. The most common errors included:

- Handing out medication to the wrong patient due to similar looking/sounding names (LASA)
- Bagging up medication and attaching the repeat prescription slip in another bag for a different patient
- Incorrect patient name on the label due to different name selected on patient medication record, resulting in an incorrect address label being produced
- Delivering medication to the incorrect recipient

These examples are all types of personal **data breaches**. Pharmacy contractors are required to have robust procedures in place for investigating and reporting data breaches. Under GDPR, some data breaches require pharmacy contractors to notify the Information Commissioner's Office (ICO). Further information about data breaches can be found in our suite of GDPR resources from the NPA website.

Errors involving owings

Some of the errors involving owings include:

- Reading from the label when the remainder supply needs to be given to the patient, as opposed to reading what the prescription states
- Owing slips not handed to patients
- Misplaced 'owing' prescriptions – not segregated separately from other prescriptions

Other interesting errors – examples

Needle stick injury

During Quarter 2 of 2018, one patient safety incident reported involved a needle stick injury whilst administering the flu vaccination service to a patient. The needle penetrated the skin whilst the pharmacist was unsheathing the needle, leading to panic and visiting the Accident & Emergency (A&E) department of the hospital to ensure the pharmacist was not harmed any further.

As the flu vaccination season will be starting in the coming months, pharmacists are advised to prepare and familiarise themselves with the vaccination Standard Operating Procedures (SOPs) to ensure they are fully competent when administering vaccines. **The NPA has produced an SOP on needle stick injury and biohazard spillages as well as a range of resources to support pharmacy teams delivering flu vaccinations services (currently being updated for the 2018/19 season).**

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Errors leading to patient hospitalisation

A number of cases reported in Quarter 2 of 2018 highlighted errors leading to the patient being hospitalised. The errors ranged from minor to serious incidents. Examples of these errors are as follows.

1. A patient self-administered Humalog® Kwikpen® insulin instead of Humulin® I Kwikpen® due to the pharmacy giving out the wrong insulin, which resulted in the patient suffering from a hypoglycaemic episode during the night. Fortunately, the patient's partner recognised hypoglycaemic symptoms and administered glucose. NHS 111 was informed and an ambulance was sent to the patients' home for a full medical assessment to be performed.

2. A patient received the incorrect strength of Asacol® tablets. Instead of 800mg tablets, a lower strength of 400mg was dispensed to the patient. The patient took the incorrect tablets for three weeks and suffered an acute attack of ulcerative colitis, resulting in the patient being hospitalised for a few days.

3. A patient received a double dose of sodium valproate modified release tablets instead of ranolazine hydrochloride modified release tablets in their monthly blister packs. The error was first highlighted when the wrong formulation of sodium valproate was placed into the blister pack initially. Having tried to rectify the mistake by swapping the correct sodium valprorate formulation, the ranolazine had been taken out of the blister pack instead. This resulted in the patient not having any ranolazine but instead a double dose of sodium valproate. Two weeks later the patient was administered to hospital diagnosed with Ventricular Tachycardia (VT) storm. A few weeks later the patient representative came into the pharmacy to inform that the patient was now being treated under palliative care.

Controlled Drug (CD) key taken home

Under the Misuse of Drugs (Safe Custody) Regulations 1973 (and amendments), CD cabinet keys should be kept by a pharmacist to prevent unauthorised access to such drugs. In one incident, the Responsible Pharmacist on duty in the morning took the CD keys home. This resulted in extreme chaos at the pharmacy because the second pharmacist of the day could not find the keys and needed to access the CD cupboard in order to fulfil prescriptions. Having found a spare set it came to the realisation that internal processes and SOPs were not followed.

Please see below for top tips regarding storage of CD keys.

Key statistics and frequently appearing drugs

Medication error categories

Figure 1 illustrates the main medication error categories and incidence reported during Quarter 2.

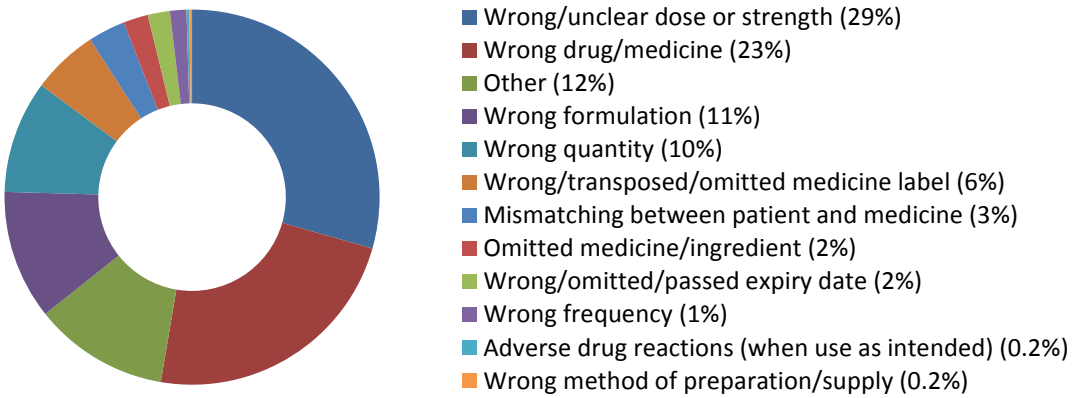

Figure 1. Medication errors reported during Quarter 1 by category

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Key findings

- The two most common error categories reported continued to be dispensing a **wrong/unclear dose or strength** (29%) and dispensing the **wrong drug/medicine** (23%)
    - These percentages are very similar to Quarter 1 2018 figures with differences of 2% for each category.
- The top look-alike and sound-alike (LASA) medicines reported in the **'wrong drug/medicine'** category are listed in the table below.

Commonly mistaken medicines	
Amitriptyline	Atenolol / Amlodipine
Bisoprolol	Bendroflumethiazide
Gabapentin	Pregabalin
Novomix	Novorapid
Pantoprazole	Pravastatin

- A rare but serious incident occurred whereby a patient was given prochlorperazine tablets 5mg instead of prednisolone tablets 5mg, resulting in the patient taking eight tablets as a single dose; the patient was hospitalised for a few days due to serious side effects and accidental overdose
- Other trends which were found in the wrong drug/medicine category are as below.

Type of medication	Commonly mistaken medicines/devices	
Eye drops	Bimatoprost	Bimatoprost/timolol
		Brinzolamide
	Brinzolamide	Brinzolamide/timolol
	Carbomer	Chloramphenicol
	Latanoprost	Latanoprost/timolol
	Travoprost	Travoprost/timolol
Creams/ointments	Aqueous	Aquamax®
	Balneum bath oil	Balneum Plus bath oil
	Canesten® external/internal	Canesten® HC
	Daktacort®	Daktarin®
Chemical reagents	Contour	Contour Next
	FastClix	Freestyle
	Finetest Lite	Freestyle Lite
	GlucoRx	GlucoRx Safety
	TrueResult®	TrueYou®

- The most common **"wrong formulation"** errors included:
    - Paracetamol capsules/ tablets/ soluble tablets
    - Ramipril capsules/ tablets
    - Salbutamol inhaler/ breath actuated inhaler
    - Symbicort pressurised inhaler/ turbohaler
    - Tegretol tablets/ modified release tablets

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Contributing factors

Figure 2 illustrates the most commonly reported contributing factors to patient safety incidents during Quarter 2.

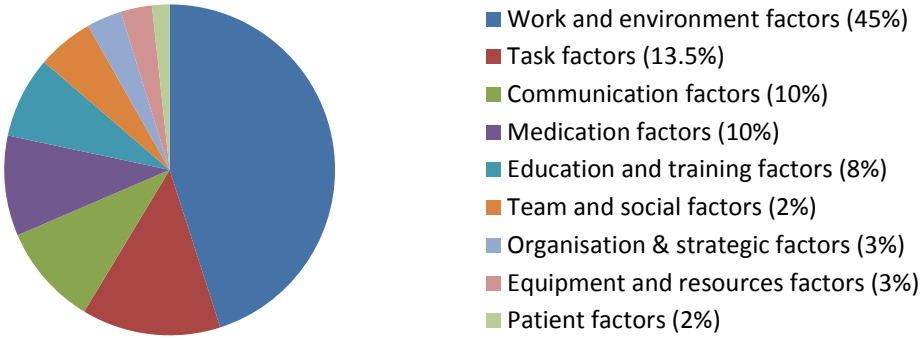


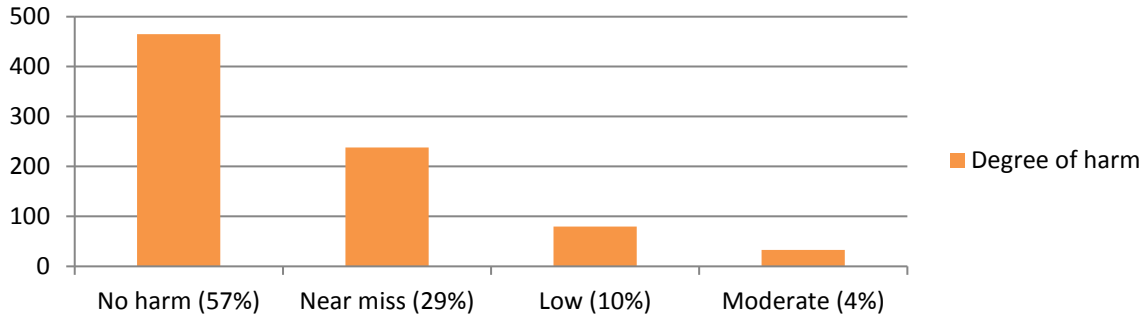
Figure 2. Contributing factors to errors reported in Quarter 2.

Key findings

- 'Work and environment factors' (45%) significantly increased compared to Quarter 1 2018 (4%), which contributed to work load and time pressures
- Task factors (13.5%) and communication factors (10%) continue to be some the main contributing factors

Degree of harm

Figure 3 illustrates the degree of harm caused to patients by incidents reported during Quarter 2.



Key findings

- Errors resulting in no harm to the patient continue to be reported and these make up the majority of submissions (57% of errors reported)
- These figures may have been contributed by the fact that 33% of the errors involved a pharmacist self-checking their own work; please see below for top tips when self-checking prescriptions

Top tips for minimising risk /general action points

Storage of CD keys overnight

Current CD legislation does not mention the storage CD keys in particular. There is information available in the Home Office (HO) document "*General security guidance for controlled drug suppliers*" which provides advice on keys and locking mechanisms. It is recommended to use a safe or cabinets fitted with a combination lock to store CDs in order to avoid the need to make arrangements for safe storage of keys.

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Where keys are used, the HO recommends the following:

- ✓ Record and audit access to individual keys
- ✓ Key signing in and out procedure to include a witness
- ✓ Keep spare keys in a separate safe with access available to only a few individuals (for example, senior managers)

! It is not considered good practice to lock a key in a desk drawer, whether or not the key is locked in an additional box.

Suggested procedure for CD keys:

- ✓ At the end of the working day, the CD key is placed in an envelope, signed by the authorised key holder, dated and sealed and handed to a relevant member of staff
- ✓ The key is then stored in a suitable place (as above)
- ✓ At the start of the next working day, before opening, the CD key holder should confirm that the envelop has not been tampered with

Self-checking prescriptions

'Self-checking' is defined as a pharmacist carrying out all steps in the dispensing process themselves, including the clinical check of the prescription and accuracy check of the assembled items. Guidance on self-checking is not currently available from the General Pharmaceutical Council (GPhC).

Where self-checking is unavoidable due to practical reasons, the NPA strongly recommends that:

- Robust procedures are put in place to ensure that patient safety is not compromised
  - Consider checklists/reminders to highlight medicines with similar looking/sounding names
  - Place these reminders near the dispensing workbench/terminal
- To avoid picking errors, ensure similar looking/sounding names, similar looking packaging is segregated
  - Check near miss logs and patient safety incident reports to find out common errors which are recurrently happening
- Ensure pharmacy shelves are clearly labelled to help reduce any picking errors
- Any new or changes to medicines/dosages are discussed with the patient and/or prescriber

If self-checking is required, additional steps should be undertaken, such as:

- ✓ Pick each item against the prescription - do **NOT** read from the label
- ✓ Read the prescription out loud (ensuring patient confidentiality) each time whilst picking the item, labelling and checking
- ✓ Ask another member of the pharmacy team to undertake at least one step of the dispensing process, such as picking items from the shelves
- ✓ Take a break between each step (picking the items, labelling the items and accuracy checking)

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For further information, advice and/or support on any patient safety or pharmacy topic/mater, please contact the NPA Pharmacy Services team on 01727 891800 or email at: pharmacyservices@npa.co.uk.

Kind regards,

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NPA