



Legal and Ethical Advisory Service Fact Sheet: Eight

Dealing with Dispensing Errors

This Fact Sheet has been prepared after consultation with the Society's Professional Standards Inspectors, the National Pharmacy Association and the Superintendent Pharmacists of the larger multiples whose experience of complaints gives an insight into the common causes and how the likelihood of errors can be minimised.

Its contents have not been issued as Council policy, but is intended as a resource which pharmacists may use to review their practices and policies. It is not intended to interpret the law, the Code of Ethics or Council policies, but offers common sense guidance on issues of topical interest.

If any questions arise, please do not hesitate to contact the Legal and Ethical Advisory Service on 020 7572 2308. Email queries may be sent to leadvice@rpsgb.org

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Introduction

Principle 1 of the Code of Ethics for Pharmacists and Pharmacy Technicians is to “make the care of patients your first concern” and to “undertake regular reviews, audits and risk assessments to improve the quality of services and minimize the risks to patients and public safety”.

In the unfortunate event of a dispensing error a pharmacist should remember that their first concern should be for the well being of the patient. The Fact Sheet will act as a guide on how to minimise the risk of a dispensing error occurring, what to do in the event of a dispensing error to try and minimise the potential harm to any patient and how to resolve the situation in the most amicable way possible. The Fact Sheet will also explain how the Society now handles complaints about one-off single dispensing errors.

How to minimise the risk of a dispensing error

Since 1st January 2005, the Royal Pharmaceutical Society introduced a requirement for pharmacists to put in place and operate written Standard Operating Procedures (SOPs) within individual pharmacies covering the dispensing process, including the transfer of prescribed items to patients. The requirement applies to both the hospital and community sectors and covers all of the activities which occur from the time that prescriptions are received in the pharmacy or by a pharmacist until medicines or other prescribed items have been collected or transferred to the patient.

SOPs help guarantee that the same high quality of service is offered in a consistent manner at all times. It also ensures that every member of the team understands their role and what is expected of them. This enables the pharmacist to delegate tasks to appropriately trained members of staff to fully utilise members of the pharmacy team in a safe and effective way.

The National Patient Safety Agency (NPSA) has published various documents (www.npsa.nhs.uk). One is entitled “A guide to the design of dispensed medicines”, which looks at the key aspects of labelling and presentation of a dispensed medicine.

Another publication, entitled “A guide to the design of dispensing environments”, provides guidance on how the design of a dispensary can improve patient safety. Whilst the physical design of the dispensary can inevitably improve the working environment and therefore patient safety other things should also be considered. For example, the workflow and how the dispensary area is utilised can improve the efficiency and improve safety.

Why complaints arise

There are three primary reasons why complaints are made to the Royal Pharmaceutical Society of Great Britain, (the Society), in the unfortunate event of a dispensing error.

- The fact that an error has been made at a pharmacy, which many members of the public believe should work to 100% accuracy;
- The patient has been harmed by the error, (and may be contemplating a claim for compensation);

- The patient or relative is dissatisfied with the way that the complaint was dealt with at the pharmacy.

It is a mandatory professional requirement under the Professional Standards for Pharmacist and Pharmacy Technicians in Positions of Authority (www.rpsqb.org/pdfs/coepsposauth.pdf), which supports the Code of Ethics, that an effective complaints handling procedure exists to deal with all complaints promptly, constructively and honestly. It is also necessary that all staff working in the pharmacy are familiar with the complaints procedure.

The way in which the complaint is handled in the pharmacy can determine how many complaints are referred to independent bodies such as the Society or the Primary Care Organisation. Where the patient has been harmed it is quite common for patients or their relatives to complain. Where no harm has been caused to the patient, it is our experience that complaints are made to an independent body only where the complainant is not satisfied with the response in the pharmacy.

What to do in the event of a complaint

In the event of a patient safety incident, pharmacists are encouraged to carry out a root cause analysis. This is a retrospective technique for looking for the underlying causes of a patient safety incident, behind the immediate and obvious cause. For example, one individual's human error might be the immediate cause, but several factors could have contributed to the error such as fatigue, an inadequate checking system or poor standard operating procedures.

The National Patient Safety Agency (NPSA) is promoting root cause analysis and is encouraging organisations to identify the circumstances in which it should be used. This should take into account the severity of the incident and the scope for learning from it. Further information on root cause analysis can be found on the NPSA website at www.npsa.nhs.uk.

There are various ways of dealing with errors and you may wish to consider all the points itemised below when confronted with a complaint. Pharmacists engaged as locums, in addition to following the pharmacy procedures, may also wish to keep their own records in case they are contacted later.

- Establish if the patient has taken any medicine, and if so whether the patient has been harmed. If so, provide the complainant and the patient's GP with the advice they need immediately. It is essential that this takes priority over all other prescriptions waiting to be dispensed in the pharmacy when you receive the complaint. If appropriate contact the local drug information centre for advice on the possible effects if taken by the patient (giving details of concurrent medication). Even where no harm appears to have been caused, the GP should be informed if the patient has taken any of the incorrect medication. As soon as an error is suspected, there should be a system of recording details both to assist with the handling of the particular error, and as part of a later review of errors.
- Ask to inspect the incorrect medicine making it clear that you do not wish to retain it, and that inspecting the medicine can give valuable clues about what went wrong. If the patient does not want to hand the medicine over to you, suggest that the Royal Pharmaceutical Society or the Primary Care Organisation are independent bodies, who could hold the medicine safely. Never dispose of any medicine unless the patient has given consent, and even then, it should be retained carefully, for a reasonable period, in case of further developments.

- Do not be afraid of making an apology if you are in the wrong. Sometimes, when an error has occurred, the natural inclination is to say as little as possible for fear of incriminating yourself. However, if you are in the wrong, a complainant is far more likely to accept your explanation if this is accompanied by an apology. In the case of a dispensing error, an apology should not be confused with an admission of liability. The apology should always be made by a pharmacist. The pharmacist present at the time the error is reported should be prepared to apologise on behalf of the owner of the business and the pharmacist who made the error, rather than adopt an approach suggesting that because s/he did not make the error, s/he need not apologise.
- It is inadvisable to try to minimise the seriousness of an error. Such reactions are often perceived by the complainant as indifference. A balance must be struck that reassures the patient, if no harm is likely, but without suggesting that the error is inconsequential.
- Offhand remarks like *“Sorry about that”, “These things happen”, “We’re only human”, “I was working on my own”, “We were short staffed”, “Worse things happen at sea”* will often inflame the situation. Comments like: *“I was not on duty that day”, or “This isn’t the only mistake the pharmacist made that day”* are likely to lead to the complainant taking the complaint further for independent review, and undermines confidence.
- In all cases of dispensing errors, the over-riding responsibility is for the health and well-being of the patient. Whilst keeping this in mind, your professional indemnity insurers should be informed as soon as possible, in case a claim is later made against you. Where you are an employee pharmacist, you should follow the procedures laid down by your employer/Superintendent for notifying dispensing errors.
- If the patient has not been harmed and/or has not taken any of the medicine then the next thing to establish is what the complainant expects you to do about the error. It is difficult to know how to satisfy the complainant if you don’t know what they expect. It is important, however, that if compensation is requested, that you give no expectations that payment will be made. You should, in those circumstances, say that you will inform your insurers and they will be in contact. The owner/Superintendent pharmacist of the business should also be informed.
- Take the initiative by telling the complainant that you may need to make your own inquiries into any possible causes of the alleged error for preventative purposes unless it is clear from the facts known to you, how the error is likely to have occurred. You may need to speak to the person who presented or collected the prescription about the prevailing conditions in the pharmacy. Emphasise that this can be done later if the complainant is more concerned about the consequences of the error, but get a contact telephone number if necessary to retrieve this information. Make contact as soon as it is convenient as recollections fade or can become distorted.
- Explain that you are looking to the complainant to help you establish information that you may not recall yourself, such as, how busy was the pharmacy at the time, or was there any distraction at the time. The complainant hopefully will realise that you care what happens at the pharmacy and will make sufficient inquiry to determine what went wrong, so that systems can be reviewed if necessary. If it is practicable, consider making an offer to the complainant that a third party could be asked to assist in the investigation. In pharmacies owned by a multiple, this could be a pharmacist in another pharmacy in the company, and where the pharmacy is independently owned, could be

a pharmacist from another pharmacy with whom you have a good working relationship. Most complainants just want the pharmacy to be safe for themselves and others to use.

- The patient will need a supply of the medicine that has been ordered on the prescription. It is not unlawful to make a supply of the correct medicine as this was authorised on the original prescription. As the pharmacist you also need to make a professional judgment about what needs to be done, e.g. does the patient's GP need to be informed.
- Pharmacists working within companies, may have a line manager and/or a Superintendent pharmacist's office to whom errors should be reported. Company procedures for such reporting must always be followed. Superintendent pharmacists and other line managers should also be consulted for advice.
- If the patient feels that the only way forward is to complain to an 'official body' then supply the complainant with the name and address of the Fitness to Practise Department of the Society. Explain that a Professional Standards Inspector from the Society may visit the pharmacy to undertake a review. The Primary Care Organisation details could also be given, so that the matter can be dealt with under the NHS complaints procedure.

When you carry out your own review to establish what went wrong make a written record of your finding using the mnemonic "CHAPS" to cover the various areas of the supply. "CHAPS" covers the following points.

C **Conditions in the pharmacy at the time.**

Some of this can be established from the complainant, some will be available from the records and computer. For example:- the identity of the pharmacist on duty, the number of prescriptions dispensed that day, the number of staff on duty. Had the pharmacist at the time of dispensing, been working without a break for a long period of time? The computer may show the exact time that the prescription was dispensed and give a breakdown of the frequency of prescriptions presented for dispensing around the time of the error. Interestingly most errors do not occur during busy periods of dispensing.

The layout of the dispensary and the availability of bench space should be reviewed. Some pharmacies use baskets or similar to hold dispensed items before checking and handing to the patient with counseling. The pharmacists who use this type of system report that it can help to prevent medicines being crossed from one patient to another, and also to keep the bench space tidy.

H **Health of the pharmacist and other members of the team.**

Was the pharmacist or other person involved in the dispensing process ill at the time? Were any of the staff on any medication which might have affected judgement or concentration? How good is their eyesight? Have they had an eye test recently or regularly?

A **Assistance.**

Was the pharmacist working alone or was he assisted? Identify the person who assisted. Make a judgement about the qualifications and competence of the assistant.

P Prescription should be recovered from the file or get a copy of it from the relevant Prescription Pricing Authority.

This may give clues about the error from the legibility of the prescription, whether hand written or computer printed, to possible associations between items, quantities or strengths that may have been read incorrectly, and endorsements are invaluable in determining what went wrong.

S Systems used for dispensing and checking must be reviewed.

Depending upon whether the pharmacist was working alone or with someone assisting, this covers every part of the dispensing process. The type of error may direct your attention to one area of dispensing practice. Usually the errors that pharmacists are responsible for fall into categories:-

- Misreading the prescription.
- Incorrect picking of the medicines.
- Transposing the label or labelling the medicine wrongly.
- Giving the wrong prescription to the wrong patient (for example, where the error involves placing the medicine in the wrong bag or where the patient's address is not checked properly when handing out the dispensed medicine).
- Selection of the wrong strength (or wrong preparation) from the PMRs when using the Repeats facility, then checking the stock against the label, not the original prescription.
- Incorrect compounding.
- Supplying contaminated or out-of-date stock.
- Dispensing against an incorrectly written owing slip, rather than the prescription.

If the complaint was about foreign bodies in the medicine then the hygiene of bottles may be a factor. It may be necessary to identify and quarantine the batch of the product if the medicine was contaminated.

If the product had to be made from ingredients then the competence of technical staff and the quality of accuracy checks during preparation may suggest a cause. Before any extemporaneous dispensing is carried out, the pharmacist must assure himself of the quality and accuracy of any equipment used as well as the ensuring the premises are themselves suitable for extemporaneous preparation.

If the error occurred at the time the prescription was read then it may depend upon the sight of the reader, the legibility of the prescription, the care with which the prescription was read, or whether two people were reading the prescription differently. Misreading is a common reason for errors, and the final accuracy check (preferably carried out by a second person) must be made by reading the prescription first before examining the stock and dispensed item.

If the error was a mistake in picking the stock then the location of stock on the shelf could be a cause. The error may have originated at the wholesaler, when the medicine was selected for supply to the pharmacy. Alternatively, the medicine may have been placed on the dispensary shelf incorrectly when the order was being put away. This problem is more likely where medicines are packaged in containers of a similar colour, shape or design. Many

manufacturers have corporate colour schemes, and therefore it is essential that the label is read properly, rather than relying upon appearance of the carton. The person putting stock away onto the dispensing shelves should take care, since items placed in the wrong location could be mispicked because of appearance and location. Regular cleaning schedules should also be used as an opportunity for identifying errors in putting away stock with associated expiry date checking. Repeats of stock placement errors should be investigated fully, and weaknesses addressed.

If the error involved mislabelling the medicine, the order of the work on the dispensing bench, or the number of people involved in the process may have contributed to the error. There should never be unlabelled containers on the dispensing bench. Each container should be labelled as it is prepared, before moving onto the next container.

If the error was from the owing slip, then it may be that the wrong code was entered into the computer when printing off the owing slip, resulting in an incorrectly written owing slip or the writing on the slip may be illegible. Pharmacists should double-check the owing slip against the original prescription, so as to prevent any error by subsequent pharmacists or locums, before handing it to the patient. Where owings are dispensed and the pharmacist does not have the original prescription, there should be suitable procedures in place to verify what was ordered. This may include a need for a photocopy of the prescription to be produced against which the balance can then be checked.

Whatever weaknesses there are in the system, the final accuracy checks must overcome them. It is most important to review these critically. It is suggested that the following principles are used.

- Create a mental break between dispensing and checking so that any preconceived ideas about the prescription are forgotten.
- It is essential that all accuracy checks are made against the original prescription re-reading the prescription first.
- Use the mnemonic “HELP” when making the final check on the dispensed medicine, to ensure that all the necessary checks have been made. “Help” stands for the following:-
 - H** “How much” has been dispensed. (Open all unsealed blister cartons to check the contents are of the correct product at the correct strength) and check that the correct leaflet is present.
 - E** “Expiry date” check.
 - L** “Label” checks for the correct patient’s name, the correct product name, the correct dose and the correct warning(s).
 - P** “Product” check ie. check that the correct medication and strength has been supplied.

Trained staff must carry out handing out of dispensed medicines. To avoid handing medicines to the wrong person, prescription receipts may provide useful safeguards, although even these are not foolproof. The person collecting the dispensed medicine should be asked for the address of the patient, which should be checked against the prescription.

When reviewing dispensing errors which have resulted in a serious patient safety incident, the NPSA incident decision tree helps to identify why individuals acted in a certain way, and this

may be a very useful tool for pharmacists, managers and organisations to consider using. Information on the incident decision tree can be found at www.npsa.nhs.uk.

How the Society handles complaints about dispensing errors

The Society's Council has agreed that subject to certain criteria (see Appendix 1) single dispensing errors which are not likely to amount to professional misconduct should not be referred to the Society's Investigating Committee.

Currently, allegations of dispensing errors that are reported to the Society are logged and investigated by the Inspectorate.

Investigation includes:

- the collection of sufficient evidence to confirm the fact of the alleged error;
- a visit to the pharmacy to monitor and inspect premises, procedures and personnel;
- identification of the supervising pharmacist at the relevant time;
- discussion with the complainant and the relevant pharmacist involved and possibly the owner and/or superintendent pharmacist about the facts and circumstances surrounding the alleged error.

If the investigation reveals that the facts and circumstances surrounding the alleged dispensing error fall below the threshold criteria agreed by Council, the inspector will recommend that the case is handled in accordance with the agreed Council procedure, where the individual admits the allegations made and accepts the advice provided.

In these circumstances a letter of advice is written by the Chief Inspector to the pharmacist involved. This letter is copied to the owner of the pharmacy or the superintendent pharmacist, as appropriate. There is no referral of the matter to a fitness to practise committee unless the registrant elects this course of action.

Records are currently maintained to show that the individual has admitted to the allegations made and accepted the advice provided. This record forms part of the fitness to practise history of the registrant and this information will be considered if a further allegation of a dispensing error is made against the registrant.

Information about how the Society handles a case of misconduct can be found on the website: www.rpsgb.org/protectingthepublic.

Summary

If you are unsure about your conclusions when you have reviewed an error, whether or not it has led to a complaint, or you wish to discuss the matter with someone, please contact your Superintendent pharmacist, pharmacist owner and/or local Professional Standards Inspector.

Like you our prime concern must be the welfare of the patients.

Appendix 1- Threshold criteria

Cases are **likely** to be referred to the Investigating Committee if one or more of the following statements are true;

- There is potential for, or evidence that moderate or severe harm or death was caused as a result of the incident (the definitions of these are from the NPSA definitions for grading patient safety incidents).
- There is evidence that there was a deliberate attempt to cause harm to patients or the public.
- There is evidence of ill health or substance abuse by the pharmacist.
- There is evidence that the individual departed from agreed safe protocols or standards operating procedures and in doing so took an unacceptable risk.
- There are no systems to record dispensing errors in the pharmacy (this should result in the Superintendent/Pharmacy owner being referred).
- There has been a failure to make a dispensing error log (if aware of the error).
- There are no systems to learn from incident in the pharmacy (this may result in the Superintendent/Pharmacy owner being referred).
- No attempt has been made to learn from the incident.
- The Society has previously given advice that would have prevented the incident if it had been implemented.
- There has been an attempt to cover up.
- There has been a failure to co-operate with an investigation carried out by the Society's Inspector or other investigatory body.
- There is evidence of other misconduct that would form the basis of a complaint.
- There is a failure to apologise/provide an explanation to the patient/representative (where appropriate).

Appendix 2: NPSA definitions for grading patient safety incidents

Grade of patient safety incident	Definition
No harm	<ul style="list-style-type: none"> • Incident prevented – any patient safety incident that had the potential to cause harm but was prevented, and no harm was caused to patients receiving NHS-funded care. • Incident not prevented – any patient safety incident that occurred but no harm was caused to patients receiving NHS-funded care.
Low harm	<p>Any patient safety incident that required extra observation or minor treatment* and caused minimal harm to one or more patients receiving NHS-funded care.</p> <p>*Minor treatment is defined as first aid, additional therapy, or additional medication. It does not include any extra stay in hospital or any extra time as an outpatient, or continued treatment over and above the treatment already planned; nor does it include a return to surgery or readmission.</p>
Moderate harm	<p>Any patient safety incident that resulted in a moderate increase in treatment* and that caused significant but not permanent harm to one or more patients receiving NHS-funded care.</p> <p>*Moderate increase in treatment is defined as a return to surgery, an unplanned readmission, a prolonged episode of care, extra time in hospital or as an outpatient, cancelling of treatment, or transfer to another area such as intensive care as a result of the incident.</p>
Severe harm	<p>Any patient safety incident that appears to have resulted in permanent harm* to one or more patients receiving NHS-funded care.</p> <p>*Permanent harm directly related to the incident and not related to the natural course of the patient's illness or underlying condition is defined as permanent lessening of bodily functions, sensory, motor, physiologic or intellectual, including removal of the wrong limb or organ or brain damage.</p>
Death	<p>Any patient safety incident that directly resulted in the death* of one or more patients receiving NHS-funded care.</p> <p>*The death must be related to the incident rather than to the natural course of the patient's illness or underlying condition.</p>