

**M O D E L
STANDARDS
FOR SELF AUDIT
IN COMMUNITY
PHARMACY
IN ENGLAND**

1

The Dispensing Process

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INTRODUCTION TO AUDIT STANDARDS

The purpose of this document is to:-

- define the main aspects of professional pharmacy practice
- propose criteria for good service in each aspect
- list standards of practice which contribute to successful accomplishment of each criterion.

What is contained in the manuals?

You will find criteria which reflect good pharmaceutical care. Proposed standards are given and it is these which can be amended to reflect your particular practice. Should a standard be mandatory, this is brought to your attention in the text.

Delete any standard which is not applicable to your situation. If you find that you undertake activities not covered by these booklets, add standards to cover them.

Most of the standards given are for self-audit of activities which take place on pharmacy premises. These activities are generally considered to be the core business of community pharmacy. You will be able to carry out audits which measure current “ability” against such standards and, thus, enable you to improve your practice should it be necessary.

The appendices contain written systems of work. Such protocols are becoming increasingly necessary to demonstrate adherence to good standards of practice. They are model documents to be amended as necessary for an individual pharmacy.

How were the standards determined and for what purpose?

Professional audit is a process which can help an individual or group to achieve and maintain standards of practice within their everyday working environment. The standards to be achieved are chosen by the people involved and are usually based on professional or business requirements.

These manuals have been produced, with the help of a grant from the Department of Health, by a research team at Keele University. They contain suggested criteria which can be used as written or amended to suit your situation.

The research team developed an initial list of criteria and possible standards. After discussion with a steering group of practising community pharmacists, a second draft set of standards was produced. The initial standards were amended and widened to include further aspects of practice.

A pharmacist researcher visited all participating pharmacies to measure the relevance of the proposed standards to pharmacy practice. Following this observational analysis, results from this study were anonymised and fed back to the participating pharmacists for further comment and discussion. It became clear that:

- **Some of the proposed standards were only necessary in some, not all, pharmacies**
- **Other standards were not currently achieved but could easily become so if pharmacists were given model written systems for adaptation**

For every aspect of standard setting the team sought to identify suitable outcome measurements. Pharmacists could then use them, within an audit cycle, to show the benefits of standard setting within their practice.

The refined standards were sent to 100 community pharmacists in a number of locations to seek their views. All comments received were considered by the research team and the standards modified when appropriate.

How to use the manual

1. Choose an aspect of practice that you wish to audit. Discuss areas of concern with your staff. This will highlight particular problems which worry everyone. Narrow them down to one question which everyone feels needs to be answered.
2. Explain the purpose of the audit you are undertaking to everyone concerned. Emphasise that audit is to improve work flow, give better patient care, identify gaps in advice giving, not to find fault. If the exact purpose of the study is explained to all those involved in it, everyone should benefit.
3. Look through the criteria to find which set of standards applies to the question chosen for the audit. Decide which are relevant and delete any which do not apply. There may be other standards which relate to your situation. Add them if necessary.
4. Think about the period of time or the number of prescriptions which will be studied during the audit. Do not attempt too much. An audit gives a “snapshot in time” result and is not meant to be continuous process. The same “picture” can be taken at a point in the future to see how things have changed.
5. Decide who will collect the data and when and how they will do it. Consider the most appropriate time for data collection. It will not help you to only look at the process during a “quiet time”. Counselling may be easy when there are few prescriptions but more difficult when dispensing is in full swing!
6. Collect the data.
7. Look at the results and compare them with the standards which seemed to be appropriate to your audit question. If all standards have been met you may decide to set more challenging targets when you repeat the audit. If you were unhappy with the results, look at ways you could improve the situation. These may involve changes in procedure, staff training or developing written material for staff or patients.
8. Implement any changes which will improve your services to patients.
9. Re-audit, after a suitable period of time, to monitor the effectiveness of any changes.
10. Advertise your achievements! The staff involved should already know how the study turned out but the people you service and your purchasers, such as the Health Authority, local surgeries or Social Services, may also find the results interesting.

Introduction to The Dispensing Process Standards

The following criteria and standards ensure safe systems of work throughout the dispensing process.

Throughout this document where the standards proposed are close in wording or intent to those referred to in the Royal Pharmaceutical Society documents this has been indicated. They are annotated as legal (L), ethical (E) and standards of professional practice (S).

Criteria

- 1.1 *Safe systems of work exist for the dispensing process.*
- 1.2 *A formal dispensing procedure exists so that patients receive the correct medicine, correctly labelled.*
- 1.3 *A system exists to alert the pharmacist to clinically significant drug interactions, drug-patient interactions and inappropriate dosage regimes.*
- 1.4 *Suitable containers are used.*
- 1.5 *Special care is taken when medicines are supplied in unusual circumstances.*
- 1.6 *A protocol exists to record information when a GP has been contacted to query/clarify a prescription.*
- 1.7 *Arrangements exist for the safe supply of emergency medical products.*

A Patient at risk

It's a busy morning and your dispenser is counting tablets in the electronic tablet counter, but she is called to the telephone and leaves some tablets in the counter. You use the counter to count some more white uncoated tablets and you find that your tablets are mixed with those left in the counter by your dispenser.

The error did not leave the pharmacy but it makes you want to review your system.

A Patient Protected

Mrs James doesn't come into your pharmacy regularly, but you do have her patient medication records. Her prescription today is for Timoptol eye drops 0.5%. From your PMR system you can see that she suffers from asthma.

You ring your local prescriber who is very thankful for your call and together you agree to change the prescription to Pilocarpine eye drops. Another satisfied customer - she tells you that all of her prescriptions will come your way from now on.

A Patient Informed

Your regular locum compliments you on your staff organisation. You have also noticed that since you introduced your policy to formally train all staff and reorganise your system of work that you are no longer pre-occupied with the dispensing process and have more time to talk to patients.

In fact your customers now often tell you that they come to your pharmacy because you personally hand out the prescriptions and have time to give them advice.

1.1 Criterion

Safe systems of work exist for the dispensing process.

Standards

1. Dispensing staff are either formally trained or undertaking formal training.*
2. For each pharmacist and trained dispenser, no more than 30 items are dispensed in any one hour period per day.
3. The number of pharmacists reflects the number of prescriptions dispensed.
4. All dispensing staff certificates are displayed.**
5. All dispensing staff wear an identity badge.

Scoring	Score
Yes=2 No=0	
Yes=2 No=0	
Yes=2 No=0	
Yes=2 No=0	
####	

Total Score

RPSGB References

* S 7.1. competency

** L For pharmacists

Scoring hints for standard one

All dispensing staff are either formally trained or undertaking formal training. Score 2

Dispensing is undertaken by untrained staff.

Score 0

Measurement Option

- Certificates obtained.

Outcomes for the Pharmacist	Outcomes for the Patient, General Practitioner and/or FHSA
Reduced work stress.	Increased patient safety
Optimum use of pharmacist's time.	Patient has greater accessibility to the pharmacist's expertise.
Optimum use of dispenser time.	Patients are informed of staff qualifications.

1.2 Criterion

A formal dispensing procedure exists so that patients receive the correct medicine, correctly labelled.

Standards

1. A written dispensing procedure exists.
(see appendix one, Dispensing Process)
2. Upon receipt of the prescription:
 - a. Unless the person is known to the staff the patient's name and address is checked upon receipt of the prescription.*
 - b. Patients are informed of any waiting times of more than 10 minutes**
 - c. With the patient's agreement a patient medication record is created or amended.***
3. All prescriptions are checked by a pharmacist.****
4. The label is initialled for accountability.
5. All prescriptions are given out by a pharmacist or a qualified dispenser.*****
6. Patient identification is checked on supply of prescription.*****
7. Where numbers dictate a docket system is in place to ensure positive identification of patients receiving medicines.
8. A system exists for identifying patients on medicines new to them.
9. A written record is kept of all changes made to prescriptions.

Scoring	Score
Yes=1 No=0	

Yes=2 No=0	
Yes=0.5 No=0	
Yes=1 No=0	
Yes=1 No=0	
Yes=0.5 No=0	
Yes=0.5 No=0	
Yes=0.5 No=0	
####	

Total Score

RPSGB References

- * S 5.4 forged prescriptions
- ** The Patients Charter for NHS pharmaceutical care
- *** L Data Protection Act
- **** L and S 5.2 Supervision of Dispensing and Sales (a & d)
- ***** S 5.2 Supervision of Dispensing and Sales (f)
- ***** S 5.2 Supervision of Dispensing and Sales (g)

Scoring hints for standard two

Where standards are covered all of the time	Score 1
Where standards are covered 90% of the time	Score 0.5
Where standards are covered 80% of the time or less	Score 0

Measurement Options

For safe systems of work:

- Maintenance of an incident book listing mistakes (those which did not reach the patient and those which did) and the steps taken to correct the process. An example of a suggested page layout can be found in appendix two.
- Record of the occasions where the pharmacist intervened to prevent a medication error as a result of errors on the part of the GP and staff.

An example of an intervention report form can be found in Appendix three.

A research project pack is available from the Pharmacy Practice Research Resource Centre entitled 'A Method for recording and analysing pharmacist prescription interventions'.

Outcomes for the Pharmacist	Outcomes for the Patient, General Practitioner and/or FHSA
Reduction in errors.	Increased patient safety.
A quality assurance system is in operation.	A record is available for later queries.
Reduction in litigation.	
A record is available for later queries.	

1.3 Criterion

A system exists to alert the pharmacist to clinically significant drug interactions, drug/patient interactions and inappropriate dosage regimes.

Standards	Scoring	Score
1. A computerised PMR system is used.	Yes=2 No=0	
2. The computerised system is used to obtain information including:*		
a. Patient identification details, including age.	Yes=0.5 No=0	
b. A record of chronic disease.	Yes=0.5 No=0	
c. Drug sensitivities and allergies.	Yes=0.5 No=0	
d. A drug interaction programme.	Yes=0.5 No=0	
e. Excessive quantities.	Yes=0.5 No=0	
f. Excessive prescription frequency.	Yes=0.5 No=0	
3. The pharmacist has completed an approved training course on PMRs.	Yes=1 No=0	
4. No patient medication records are kept, without the patients' consent.**	Yes=2 No=0	
5. The PMR system is registered under the Data Protection Act.***	Yes=2 No=0	
Total Score	####	

RPSGB References

- * Guidelines on pharmacy computer systems
- ** Data Protection Act 1984
- *** L Data Protection Act 1984
S 5 Standard for Dispensing Procedures, Guidance 4(a)

Measurement Options

- Measure the number of drug/drug interactions with an assessment of their severity, ie minor or major.
- Measure the number of drug/patient interactions with an assessment of their severity, ie minor or major.
- Record number of prescriptions with excessive quantity or frequency for discussion with prescribers / FHSA professional advisers.

Outcomes for the Pharmacist	Outcomes for the Patient, General Practitioner and/or FHSA
Effective advice on the use of medicines.	Reduction in drug interactions that may have a detrimental effect on patient care.
Informed communication between pharmacists and GPs.	Fail safe mechanism for both the patient and GP.
PMR allowance obtained.	Informed communication between pharmacists and GPs.
	Identification of problems with repeat prescribing.

1.4 Criterion

Suitable containers are used.

Standards	Scoring	Score
1. Medicine containers are stored in a clean environment.	Yes=2 No=0	
2. Medicine containers to be stored suitably capped.	Yes=2 No=0	
3. No plastic medicine containers or caps are reused.*	Yes=2 No=0	
4. All medicines are supplied in child resistant containers, except in certain circumstances (see below).**	Yes=2 No=0	
5. Medicines are supplied without child resistant closures either:** a. On patient request or b. On patient's representative request.	Yes=1 No=0	
6. A record is kept of requests for medication to be dispensed without child resistant closures.	Yes=1 No=0	
Total Score	####	

RPSGB References

* S 5.6 Reuse of containers (a)

** S 5.5 Dispensing containers (c)

Measurement Option

- Maintenance of a record of the number of patient complaints about inappropriate containers.

Outcome for the Pharmacist	Outcomes for the Patient, General Practitioner and/or FHSA
Protection against litigation.	Improved compliance. Reduction in accidental poisoning of children.

1.5 Criterion

Special care is taken when medicines are supplied in unusual circumstances.

Standards

Scoring	Score
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1. When medicines are delivered to the patients home the following points are observed*:

a. The medicines are given directly to the patient.

Yes=0.5 No=0	
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b. The medicines are given to a known carer.

Yes=0.5 No=0	
-----------------	--

c. The medicines are left in an agreed place.

Yes=0.5 No=0	
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d. Further verbal information is given if required. (see appendix four, Delivery Policy).

Yes=0.5 No=0	
-----------------	--

2. Medicines are only sent by post if**:

a. The patient is unable to receive them by any other means.

Yes=1 No=0	
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b. Supplementary written information is sent with the medicine if required.**

Yes=1 No=0	
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c. All medicines are securely wrapped.**

Yes=1 No=0	
---------------	--

d. Recorded delivery is used.

Yes=1 No=0	
---------------	--

3. Medicines are not supplied to a child unless***:

a. The pharmacist is satisfied that the child will deliver it safely.

--	--

Yes=2 No=0	
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b. A record is kept of the transaction.

Yes=1 No=0	
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c. The reasons are recorded.

Yes=1 No=0	
---------------	--

Total Score

####	
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RPSGB References

- * E. Guidance on obligation 1.1 (collection and delivery)
- ** E. Obligation on 1.13
- *** Legal requirement Obligation on 1.15

Measurement Options

- Retention of recorded delivery slips.
- Keep a record of prescriptions issued to children.

Outcomes for the Pharmacist	Outcome for the Patient, General Practitioner, and/or FHSA
Ensures customer loyalty.	Increased safety.
Reduced likelihood of medicines going astray.	Continuity of supply.
Reduction in the possibility of litigation.	Increased child safety.

1.6 Criterion

A protocol exists to record information when a GP has been contacted to query / clarify a prescription.

Standards

1. When a doctor is contacted to clarify a prescription, a record of the outcome is made.*
2. This record should include:
 - a. Date
 - b. Patient name
 - c. Doctor name
 - d. Problem
 - e. Action taken
 - f. Pharmacist's name
3. The records are easily retrievable.
4. The patient is informed of the outcome of the discussion, if in the pharmacist's opinion this is appropriate.

Scoring	Score
Yes=2 No=0	

Yes=1 No=0	
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Yes=1 No=0	
---------------	--

Yes=1 No=0	
---------------	--

Yes=1 No=0	
---------------	--

Yes=1 No=0	
---------------	--

Yes=1 No=0	
---------------	--

Yes=1 No=0	
---------------	--

Yes=1 No=0	
---------------	--

Total Score

####	
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RPSGB References

- * E Guidance on Obligation 1.18
E 9.1

Measurement Option

- Examine written records.

An example of an intervention report form can be found in Appendix Four.

Outcomes for the Pharmacist	Outcomes for the Patient, General Practitioner and/or FHSA
Patient safety.	Patient safety.
A record is available for later queries.	A record is available for later queries.

1.7 Criterion

Arrangements exist for the safe supply of emergency medicinal products.

Standards

1. If the patient is not known to the pharmacist his identity is established*.
2. If it is suspected that the substance is liable for misuse the prescriber is contacted**.
3. Other medicinal products being taken by the patient are noted.
4. The frequency of use of the requested medicine is established.
5. A record is kept of the emergency supply***.

Scoring	Score
Yes=2 No=0	
Yes=2 No=0	
Yes=2 No=0	
Yes=2 No=0	
Yes=2 No=0	
####	

Total Score

RPSGB References

- * E Guidance on Obligation 1.16 number 2
- ** E Guidance on Obligation 1.16 number 3
- *** L, E Guidance on Obligation 1.16 number 7

Measurement Option

- Maintenance of a written record of all emergency supplies.

Outcome for the Pharmacist	Outcome for the Patient, General Practitioner, and/or FHSA
Protection against litigation.	Continuity of treatment.

Appendix 1 – The Dispensing Process

Introduction

The dispensing of all prescriptions must be carried out either by a pharmacist or under the supervision of a pharmacist. (Supervision means that the pharmacist personally oversees the work, so that he/she is aware of what is going on and can intervene, if necessary, to ensure that the task is completed in the correct manner).

The actual task of dispensing can be carried out by a pharmacist, a pre-registration pharmacist, pharmacy dispenser or other dispensary staff as designated by the pharmacist.

Dispensing Process

Receipt of prescriptions

1. Upon receipt of a prescription, the name and address of the patient is checked, the patient name is clearly printed on the prescription if necessary.
2. Where a docket system is used, the patient is given a numbered docket and advised of the waiting time for the prescription and the availability of the items prescribed. The corresponding pharmacy numbered docket is attached to the prescription, this receipt is annotated to inform dispensary staff if the patient is waiting or calling back for the prescription and of prescription charges paid.

Dispensing Procedure

1. For all prescriptions the following process is followed and checks made:
 - a. The patient's name.
 - b. The age, if a child.
 - c. Legal requirements are satisfied.
 - d. Name of medication, strength and quantity.
 - e. Dose and dosage.
 - f. Incompatibilities, either pharmaceutical or therapeutic.
 - g. Previous medication.
 - h. The possibility of prescription forgery is considered.
2. If any of the above points need clarification contact the prescriber if appropriate and record changes made.
3. Prepare the label in accordance with your labelling policy,
4. Assemble the product. Observing RPSGB standards for dispensing procedures,
5. Check complete item against prescription.
6. The prescription should be checked in accordance with the checking policy.

7. Prepare a bag for the items, which should bear the patient's name, address and docket if used.
8. Record owings and ensure patients are given owings slips if appropriate.
9. Endorse the prescription with the date of dispensing and any changes made to the prescription.
10. Keep a separate record of all changes made to prescriptions.
11. Give the medication to the patient. To ensure patient safety this should be done by the Pharmacist wherever possible (see handing out policy).
12. Give additional verbal advice to at risk patient groups.
13. Give additional verbal advice with identified medicines.

Checking Policy

All dispensing of medicines should be carried out by or under the supervision of a qualified pharmacist.

1. All dispensing should be checked by a second person wherever possible.
2. A pharmacist checks all prescriptions.
3. A qualified dispenser or member of the dispensary staff as identified by the pharmacist, may check a pharmacist.

Handing Out Policy

1. No prescriptions can be handed out unless the pharmacist is present.
2. The pharmacist should hand out all prescriptions when possible.
3. If the pharmacist does not hand out the prescription any additional advice needed is attached to the bag.
4. When the prescription is not handed out by the pharmacist any verbal requests for additional information are referred back to the pharmacist or trained dispenser.

Carole Blackshaw
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Appendix 2 - INCIDENT REPORT

Name of person filling this form
Date form completed

Location of incident: Dispensary / Back shop area / Front shop area
Date and time of incident
Members of staff involved
Other staff on duty at time

Name and address of customer (if available)
.....
.....
.....
.....

Telephone number:
Report of incident:
.....
.....
.....
.....
.....

(continue overleaf if necessary)
Action taken
.....
.....
.....
.....

Reaction from aggrieved party
.....
.....
.....
.....

Further action necessary? YES/NO
.....
.....
.....

Signature of pharmacist on duty
.....

A photocopy of till receipt, prescription etc should be attached
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Appendix 3

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Pharmacist Rx Intervention Report Form

1. Type of Intervention

(please tick one)

- 1 Problem with prescription form
2 Problem with item

2. Reason for Intervention

(tick as many as apply)

Rx Illegal:

- 01 No GP signature
02 No date
03 No patient address
04 No patient name
05 Doesn't conform with CD requirements
06 No age (under 12 only)

Queries about Rx:

- 07 about form
08 about strength
09 about dose
10 about timing for dose
11 about drug item/brand
12 about frequency
13 about quantity
14 about patient name
15 incorrect spelling
16 Rx ambiguous
17 Rx illegible/incoherent
18 possible interaction
19 possible ADR
20 supply/availability problem
21 Rx not in drug tariff
22 Other (please state on reverse of form)

3. Query initiated by:

(please tick one)

- 1 Pharmacist
2 Other pharmacy staff
3 Customer/patient/patient representative
4 Patient Medication Record (PMR)
5 Other (please state) _____

4. BNF Therapeutic Category

(please tick one)

- 01 1. Gastro-intestinal System
02 2. Cardiovascular System
03 3. Respiratory System
04 4. Central Nervous System
05 5. Infections
06 6. Endocrine System
07 7. Obstetrics, Gynaecology, Urinary Tract
08 8. Malignant Diseases
09 9. Nutrition and Blood
10 10. Musculoskeletal and Joint Disease
11 11. Eye
12 12. Ear, Nose and Oropharynx
13 13. Skin
14 14. Immunological Products and vaccines
15 15. Anaesthesia
16 ***Appliances***
17 Miscellaneous

5. Prescription Information

- 1 New prescription OR 2 Repeat prescription
1 Hand written OR 2 Computer generated

6. Age Group of Patient

(if known tick one)

- 1 < 12 yrs 2 12 - 19yrs
3 20 - 60/65 yrs 4 60/65 yrs +

7. Seriousness of problem

(please tick one)

- 1 Type A: Potentially serious
2 Type B: Major nuisance
3 Type C: Minor nuisance
4 Type D: Trivial

8. Query solved by/Action taken

(please tick all that apply)

- 1 GP contacted
2 Practice manager/receptionist contacted
3 Patient consulted (or patient's representative)
4 PMR checked
5 Took own action/decision - without GP contact
6 Consulted own reference sources (e.g. MIMS)
7 Consulted Drug Information Centre
8 Consulted other information sources
9 Other (please state) _____

9. Outcome

(please tick one)

- 1 Script confirmed as written
2 Script clarified
3 Script changed in accordance with pharmacist's advice
4 Script changed other than in accordance with pharmacist's advice
5 Script not dispensed - patient referred to GP
6 Patient took script away
7 Patient counselled

10. Time taken to resolve query

Approximate time taken (in minutes) ____
Number of local calls to resolve the matter ____
Number of long distance calls ____

(please tick as applicable)

- 1 Resolved by letter?
2 Resolved by personal visit?
3 Resolved urgently?

Intervention ID Number: _____ Date: _____

GP responsible for the script (code #) _____

Appendix 4 - Delivery Policy

1. All medicines are delivered to patients at an agreed time whenever possible.
2. When medicines are delivered by a person other than a pharmacist a note is attached inviting telephone enquiries should these be needed.
3. If the patient is not present when the delivery is made the medicines are left in a safe place which has been agreed by the patient and pharmacist.
4. In the absence of a safe place to leave the medicines they are taken back to the pharmacy.
5. All staff delivering medicines carry some form of identification.

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