NHS
Dorset
Clinical Commissioning Group

MEDICINES STANDARD D1:
DEVELOPMENT AND IMPLEMENTATION OF SOPS

The CCG will expect all providers of commissioned services to deliver safe medicines management, which includes use of standard operating procedures where legally required.

DEFINITION OF A STANDARD OPERATING PROCEDURE

An SOP is an unambiguous document, describing the responsibilities and the procedures, including audit, necessary to safely and accountably manage any set of processes. An SOP is a working document detailing the current agreed working practice that takes account of all the areas that are applicable to the management of medicines in an individual setting.

SOPs are needed to:

- Improve governance of medicines within the organisation
- Provide clarity and consistency for all staff handling medicines
- Define accountability and responsibilities and clarify where responsibility can be delegated
- Ensure practice is in line with the regulatory frameworks
- Serve as a training tool for new and existing staff

THE BENEFITS OF SOPS

SOPS have many benefits including:

- Helping to assure the quality and consistency of the service;
- Helping help to ensure that good practice is achieved at all times;
- Helping provide an opportunity to fully utilise expertise of all members of the team;
- Helping to avoid confusion over who does what (role clarification);
- Providing advice and guidance to locums and part-time staff;
- Helping with training new members of staff;
- Providing a contribution to the audit process.

AREAS TO BE INCLUDED IN THE SOP

SOPs are needed for every stage of the medicine journey from procurement (ordering, receipt, transport), to safe storage, supply, administration, destruction and guidance for dealing with a medicine related incident.

The practice will need to decide how much to include in a single SOP and may need specific SOPs for specific areas.

The following table is to assist in identifying the steps in handling medicines that need to be considered in the SOP and what is appropriate for each practice.

Equipment	Specify any equipment, facilities and data required, and where/who to obtain it from Specify any appropriate information or instructions required, and where/who to obtain it from
Responsibility and accountability	Who is responsible and/or accountable for which parts of the process? Can responsibility be delegated? If yes, when, and who to?
Record keeping	What records are kept of the process, including ordering and receipt? Who keeps these records? Where are the records stored? How are the records maintained (paper/electronic)?
Ordering	Named person(s) (consider deputy / locum) with Authority to order Organisational tendering processes – purchasing for safety
Transport	Who transports the medicines? (Particularly if not wholesaler / manufacturer) How is security maintained?
Receipt	Personnel authorised to receive the medicines into stock Record keeping of receipt Security of medicines receipt
Storage	Where are the medicines stored? Security and key/code security Personnel with access to medicines and/or CDs Appropriateness of storage location for product e.g. temperature Contingency plans for extended closure Register entry Arrangements for controlled stationery (prescriptions) Action to take if any discrepancies Regular (need to specify when) check / audit Process for reconciliation when necessary Describe how product integrity is maintained (eg storage at controlled temperatures)
Training and competencies	What training is required before carrying out the process? How often should this training be completed? What records are kept of training?
Risk assessment and safety	Are there any concerns about safety? (e.g. handling cytotoxic drugs). Are there any concerns with security? Does a risk assessment need to be carried out?

Other information	Are there any relevant links to legal/guidance documents to include? Which Dorset CCG Medicines Standard(s) does this SOP link to? What happens if the process described in the SOP isn't followed? (i.e. adverse incident reporting) What happens if there is a medicines related incident? (i.e. adverse incident reporting) What happens if there is a controlled drug related incident? (i.e. CD Accountable Officer reporting)

DESCRIBING THE PROCESS IN THE SOP

- Describe how to carry out each task in detail, so that the SOP is comprehensive and reproducible.
- Specify any equipment, facilities and data associated with the task described.
- Specify any records that must be kept, and where and how to make those records.
- Ensure that all activities described comply with legal regulations and local or relevant national policies.
- The SOP should identify those persons currently authorised and/or trained to undertake any particular activity. Where electronic systems are used or as part of the activity, a system of control should exist through which activities/menus are restricted to those authorised to use them.

WORKING WITH SOPS

It is important that SOPs are readily available to relevant staff at all times. This is particularly important in the case of locums or bank staff.

SOPs should specify an appropriate level of responsibility for each member of staff involved in the process. This should be based on an assessment of each person's competence and level of qualification. It is not appropriate to ask someone to carry out a task which they would not normally do or which they are not competent to complete.

SOPs should be clearly marked with the date of preparation and/or date of review/amendment. They should be kept up to date and relevant at all times and should be regularly reviewed to allow for changes in practice or circumstances, for example, legislative changes or changes of staff. In the absence of any obvious changes, reviews should be undertaken at least once every two years.

When SOPs are first drafted, or when new members of staff are appointed, it is good practice to ask staff to sign to say they have read and understood them. As well as clarifying staff roles, this can also offer an opportunity for staff training and development. Senior managers should ensure that any changes to SOPs are brought to the attention of relevant staff.

VALIDATION OF SOPS

SOPs may need to be reviewed and updated at any time prior to their review date, taking account of the following:

- following a critical incident, to include the learning from such incidents
- significant change in legislation or best practice
- where a specific named person is included in a SOP and personnel circumstances change

The changes to the SOP, and where appropriate the background to those changes (e.g. legislation change), should be adequately cascaded to all staff using the SOP.

DUTIES/RESPONSIBILITES AND ACCOUNTABILITY

All members of staff who have any involvement or responsibilities outlined in the SOP or have to have a knowledge of the procedure outlined must ensure they have read the SOP and are fully aware of their responsibilities and accountability in the procedure.

SOPs should allow for the continual improvement of standards of service and provide evidence of commitment to protecting patients.

REFERENCES

Medicines, Ethics and Practice: A guide for pharmacists and pharmacy technicians (member access only)

Dispensary Services Quality Scheme – Guidance (BMA)

APPENDIX 1 TEMPLATE STANDARD OPERATING PROCEDURE

Standard Operating Procedure for [insert subject]

Objectives

What is the aim of this SOP?

Scope

What activity/processes are covered by this SOP?
*What activity/processes are **not** covered by this SOP?*

The Stages of the process

Be specific!

- *Describe each different part of the activity/process, so the SOP is comprehensive and the results of the process are reproducible*
- *Specify any equipment, facilities and data required, and where/who to obtain it from*
- *Specify any appropriate information or instructions required, and where/who to obtain it from*
- *Describe the transportation and security of materials necessary for the activity/process*
- *Describe how product integrity is maintained (e.g. storage at controlled temperatures)*
- *Describe measures taken to increase safety (to protect staff and patients from adverse incidents).*
- *Include who is responsible/accountable for the activity/process.*

Responsibility and accountability

Who is responsible and/or accountable for which parts of the process?
Can responsibility be delegated?

Training and competencies

What training is required before carrying out the process?
How often should this training be completed?

Record keeping

What records are kept of the process?
Who keeps these records?
Where are the records stored?
How are the records maintained (paper/electronic)?

Other information

Are there any relevant links to legal/guidance documents to include?
Which CCG Medicines Standard(s) does this SOP link to?
What happens if the process described in the SOP isn't followed? (i.e. adverse incident reporting)

Review

This SOP will be subject to review on a yearly basis or sooner in the light of new local or national guidance.

Date of preparation	
Review date	

Author name	
Author signature	
Authorising manager Name (PRINT)	
Authorising manager signature	

I have read and understood the SOP for [insert subject]

Name (PRINT)	Sign	Date