

# Writing Standard Operating Procedures (SOPs)

SOPs are living documents that detail written instructions describing specific steps to follow in all activities under defined conditions. SOPs are necessary to ensure the continuity of processes to achieve quality performance and quality products/preparations. They form part of clinical governance and show that pharmacists are putting in place strategies for risk management and harm minimisation.

There are different ways and formats of writing SOPs but the main aim is to get pharmacy staff to write down what they do and, at the same time, to have an opportunity to review what they are doing. The main benefits of SOPs are seen as ensuring that good practice is always achieved, clarifying who does what and giving guidance for locums, part time staff and new employees.

SOPs should allow for the continual improvement of standards of service and provide evidence of commitment towards protecting patients. Additional benefits are:

- Help to assure quality and consistency of service;
- Help to ensure that good practice is achieved at all times;
- Provide an opportunity to fully utilise the expertise of all team members;
- Enable pharmacists to delegate;
- Help to avoid confusion over who does what (role clarification);
- Provide advice and guidance to locums and part-time staff;
- They are useful tools for training new members of staff;
- Provide a contribution to the audit process.

All pharmacies operate differently, and SOPs need to reflect this. However, there are some general principles that will apply. SOPs should:

- be pharmacy specific;
- be dependent on the competence of the staff working in that pharmacy;
- under normal circumstances, be applicable at all times i.e., not dependent on the presence of the pharmacist under whose authority the procedure was prepared.

SOPs should help to ensure that, other than in exceptional circumstances, recommended procedures are followed at all times. Their introduction provides an opportunity for pharmacists to define and assess their own practice, to communicate this to staff and help to improve teamwork within the pharmacy.

## Who should write SOPs?

Ideally, SOPs should be written by “teams” as it is a good idea to involve staff in developing, reading and commenting on SOPs so they are happy to use them. Getting staff who are involved in specialist tasks to do the first draft of procedures can help, especially if the Charge Pharmacist has less experience in that area. Team writing accomplishes several goals besides just producing an SOP:

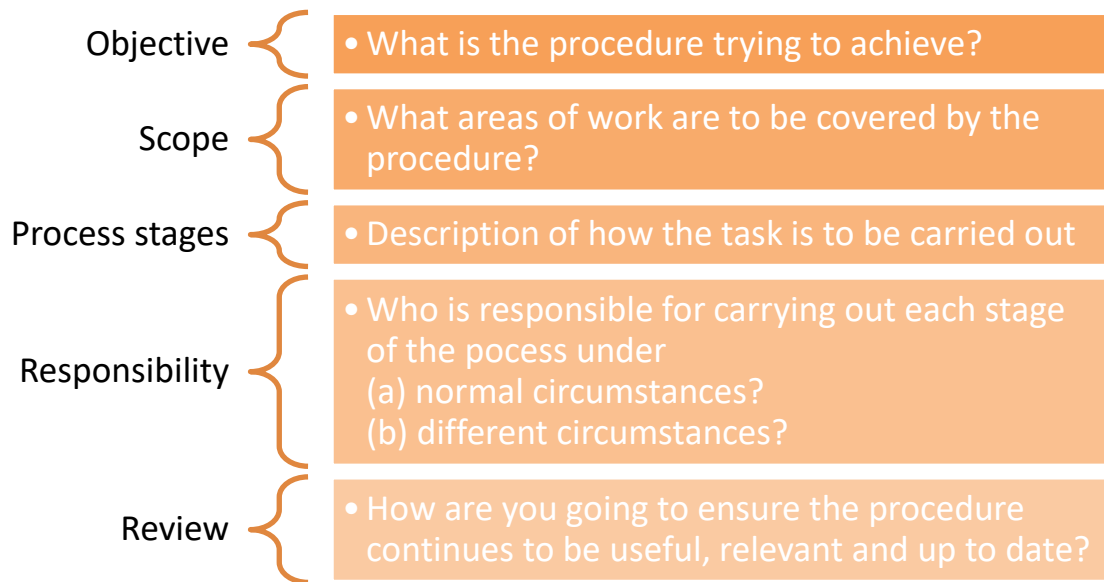
- it ensures that comprehensive knowledge acquired from different perspectives is applied to the SOP
- it creates "buy-in," which increases the likelihood that the SOPs will be implemented under the guidance of the writers
- having participated in in-depth decision making about the SOP, writers know it intimately and are more likely to be effective trainers (coaches)

- it involves people with differing roles, which helps ensure that when new and modified processes are implemented, someone goes back and updates the SOP

SOPs should not be wordy and complicated; if short sentences or bullet points will do the trick, use them. The step-by-step parts of an SOP can be described as a numbered list or by using flow charts.

### What to include

1. Write a title (with a descriptive verb) that defines the purpose of the SOP.
2. Use document reference numbers if necessary to link SOPs and add revision dates on the title or cover page and the first page of text.
3. Identify the specific points of activity for which the SOP has been written.
4. State the purpose of the SOP. Include information about process and regulatory standards. Some SOPs include both desirable and undesirable consequences.
5. Job descriptions e.g. technician, can be used to describe levels of responsibility if there is a high turnover of staff, or there are a number of part-time staff, so locums know who is responsible for what activities. Using names instead of descriptions may mean the SOP will need to be amended each time a member of staff leaves.
6. Write a "scope" statement that tells what related subjects the SOP will not cover if there is any chance someone will be confused and make a mistake. Scope statements are useful for two reasons: to focus your attention as a writer and to clarify things for a reader.
7. If any "tools" are required for following the SOP e.g. extemporaneous compounding, list these where they apply (possibly in a table).
8. Give an overview of the steps in the SOP that describes the process in terms of its major functions. Include anticipated safety, health, environmental and operational issues.
9. Define terms and concepts. If the SOP contains terms and concepts that readers may be unfamiliar with e.g. in aseptic dispensing, define these in their own paragraph so that readers know that there are unusual words or concepts, and can find them easily for use when needed.
10. A long list of terms may fit better in a glossary. If you decide that a simple list of terms and definitions is better, include the list within the write up, perhaps right before the list of steps to be performed.
11. Place safety warnings, cautions and notes prominently within the SOP before the actual step to be described. Never place safety items at the end of a step.
12. List and explain the process steps in sequential order in which a SOP user should perform the steps.
13. For each procedure, think about the following:



## Dispensing SOPs

Pharmacists are accountable for the dispensing process, but in developing and working to SOPs, should be able to benchmark current practice and ensure that systems of practice operating within their pharmacy is safe. SOPs should cover all aspects of the dispensing process, including the delivery of the medicine or product to the patient, and must comply with professional requirements applying to the dispensing process. The added value of the pharmaceutical service i.e. the pharmacist's professional input into the assessment of the safety and appropriateness of a prescription and, in the provision of information and counselling when completed prescriptions are transferred to patients, should be explicit.

The dispensing process should be clearly defined in the SOP and it should specify which activities must be carried out personally by a pharmacist (e.g. clinical check<sup>1</sup>), which activities can be delegated to identified competent support staff and how the checks for accuracy are to be carried out. It is good practice for SOPs to incorporate an audit trail so that the pharmacist can determine who is responsible for each aspect of the process i.e. for each item on the prescription, the dispenser, the pharmacy accuracy checking technicians (PACT<sup>2</sup>) and checking pharmacist should be clearly identified.

<sup>1</sup> Clinical check involves the identification of potential or actual pharmacotherapeutic problems through an analysis of all the information available. Such information may include patient characteristics (e.g. elderly, paediatric, pregnant, breastfeeding), disease states, medication history and dosing information. Additional information may be obtained from the patient or their representatives, the prescriber or other healthcare professionals involved in the patient's care.

<sup>2</sup> A certified PACT who can competently undertake the final accuracy check on a dispensed item that has been clinically approved by a registered practising pharmacist and in accordance with the pharmacy's Licence to Operate Pharmacy Condition.

## Keeping SOPs current

All SOPs should be numbered and should 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. Pharmacists should ensure that any changes to SOPs are brought to the attention of relevant staff. A responsible person<sup>3</sup> must ensure that the pharmacy has appropriate and up-to-date procedures and policies in place for the provision of pharmacy services, in accordance with the conditions of the Licence to Operate Pharmacy under the Medicines Act 1981.

## Conclusion

Writing detailed procedures and developing document management systems seem tedious and, for many, are not core competencies. However, procedures are the cornerstone of a strong quality system; they provide infrastructure; and allow for audit processes against procedures.

Creating appropriate procedures<sup>4</sup> eliminates the need for interpretation by employees and ensures that procedures are being followed as intended. If developed appropriately, well-written procedures demonstrate that a pharmacy is conducting business in a controlled quality system environment. It also supports meeting the overall goal of providing the public with safe and effective medical products, which, at the end of the day, is what all pharmacies strive to achieve.

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<sup>3</sup> Medsafe Responsible Persons (Pharmacy) Guidance document defines key responsibilities of a pharmacist proprietor and/ or the pharmacist(s) who are named as the responsible person on the Licence to Operate Pharmacy under the Medicines Act 1981 [Responsible Persons](#).

<sup>4</sup> The Pharmacy Council of New Zealand kindly acknowledges the permission granted by the Royal Pharmaceutical Society of Great Britain for allowing their guidance "Developing and implementing standard operating procedures for dispensing" to inform the first original version of this statement.