

Developing a Cross-Site Standard Operating Procedure (SOP) System

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Introduction

SOPs are detailed written documents formally approved by the Accountable Pharmacists for units operating under the Section 10 exemption of the Medicines Act 1968 (1). They describe the operations to be carried out, the precautions to be taken and the measures to be applied that are directly or indirectly related to the preparation and supply of the product (1). They give directions for performing operations to ensure that they are performed to a consistent standard. This forms part of quality assurance, by ensuring the products prepared are of the appropriate quality to ensure patient safety (1).

Aim

To develop a cross-site SOP system for two aseptic units within the Trust.

Method

A project team was created, which included the Accountable Pharmacists, QA Management team and Production Management team. A project plan was developed, which was documented in the change control system:

1. Develop a new SOP numbering system.
2. Develop a new SOP template.
3. Review all SOPs to determine the new numbers and titles, as well as whether they are cross-site or site specific.
4. Design a spreadsheet for the new SOP system.
5. Design the review and approval process for the SOPs.
6. Update all current SOPs and write new SOPs where required.
7. Review, approve and release the new/updated SOPs.
8. All staff in both units to read new/updated SOPs and be trained against them.

Results

Number of SOPs BEFORE Implementation of Cross-Site SOP System				Number of SOPs AFTER Implementation of Cross-Site SOP System			
Cross-site	Site 1 Specific	Site 2 Specific	Total	Cross-site	Site 1 Specific	Site 2 Specific	Total
0	81	99	180	93	15	25	133

The total number of SOPs in the QMS was reduced from 180 to 133. Of the 133 SOPs, 70% are cross-site.

Conclusions

Developing the cross-site SOP system required extra staff input and time. The process for writing, reviewing and approving each SOP was lengthened, due to the required updates and extra approvers for cross-site SOPs. A time saving is expected however now that the total number of SOPs has reduced by 47. This could predict a 26% reduction in workload associated with the SOP review process.

Since the cross-site SOP system was implemented, it has facilitated cross-site working, with all staff working at Site 2 regularly on weekends. It also assisted in ensuring the service was maintained during a contingency implementation process when Site 1 closed due to unsafe capacity and staffing levels. This has shown an improvement in the Trusts business continuity plans for aseptic services.