

REVIEW

REVIEWING THE VALUES OF A STANDARD OPERATING PROCEDURE

Gidey Amare

ABSTRACT

This article addresses the values of a standard operating procedure based on review of articles. It describes the application and importance of a standard operating procedure from different perspectives while emphasizing its critical relevance to medical practice and pharmaceutical service. The review further discusses shortcomings related to nonexistence of standard operating procedure including inconsistent quality of service; performance variation; procedural mix-ups; and misinterpretation or miscommunication of information. In conclusion, standard operating procedure, if realized and materialized as a component of an effective management system, helps cultivate transparent functions; implement error prevention measures and facilitate corrective actions and transfer knowledge and skill.

Keywords: Information, performance variation, quality of service, standard operating procedure values.

INTRODUCTION

This article describes the importance of SOP based on a review of articles that focused on discussing and promoting the values. It presents the application of SOP from different perspectives while emphasizing its critical relevance to medical practice and pharmaceutical service.

The review begins by providing the definition of SOP and then moves on to describing its roles in producing consistent quality, addressing safety concerns, and minimizing chances for miscommunication. Following this, the article presents the process of developing SOP and answers the question, "who should write an SOP?" In the end, the article discusses some pitfalls related to nonexistence of a standard operating procedure including inconsistent quality of service; performance variation; and misinterpretation of information. Finally, makes a conclusion that standard operating procedure, if realized and materialized as a component of an effective management system, helps cultivate transparent functions; implement error prevention measures and facilitate corrective actions and transfer knowledge and skill.

METHODS

This article employs a narrative review to describe the values of a standard operating procedure. In order to review and discuss the matter, by retrieving relevant sources of information, a search for articles were made through a Google search engine using heading terms including standard operating procedure, standard operating procedures, SOP, SOPs, and process of developing SOP. Accordingly, numerous search results were obtained but only the articles included in the reference list sufficiently fulfill the objective of the review.

REVIEWING SOP

Definition, Application, and Values: What is Standard Operating Procedure (SOP) in the first place? Different writers defined SOP with slight variations. For example, the U.S Environmental Protection Agency (1) and European Medicines Agency (2) defined it as, "a set of written and detailed instructions that document a routine or repetitive activity followed by an organization to achieve uniformity of the performance of a specific function". SOP describes a set of steps

that a person or group of people must perform to complete a job by removing variation (3). It is a process document that details the way an operator should perform a given function (4). In short, SOP is a document that clearly defines who does what, where, how and why.

Some of us might have the assumption that the application of SOP is only relevant to complex businesses and organizations. However, it extends to cover even the most minor aspects of work (5). Sometimes one might not recognize that they follow certain steps in their routine functions. For example, think of what one does before and after dining. They seem nonexistent but there are certain steps that we all intuitively follow when dining and yet, if one disregards such steps, it will not be hard to imagine the consequences-an unhygienic and a messy situation.

The application of SOP is even more important and relevant to some areas of practice. For example, medical and pharmacy practices are among those where the application requires an earnest attention because the responsibility deals with procedures and medications that conspicuously has adverse effects and is, therefore, critical to meet certain standard of practices.

In some business or service environs, the values of SOP are highly acknowledged, while in many others the case may be different. In those where its values are appreciated, SOP is claimed to have the role of minimizing errors that may occur due to misinterpretation or miscommunication of information; circumventing procedural mix-ups; evading uncertainties and confusions; and serving as a vital tool to transfer knowledge and skill.

According to the U.S Environmental Protection Agency (EPA, p. 1), SOP avoids variations regardless of the operator and time of operation; provides individuals with the information to perform a job properly; facilitates consistency in quality of an end-result; addresses safety concerns; and minimizes chances for miscommunication, even if there are temporary or permanent personnel changes.

de Treville et al. (p.232) also described that SOP ensures that all workers are performing tasks in the same way, which is a necessary condition to obtain consistent output; and asserted that if a workforce cannot operate the parlor consistently,

then the whole operation will fail. A modern-day SOP enables organizations to ensure uniformity and consistency in the process, across departments that affect their products and services (6). Edelson & Bennett (as cited in de Treville et al, 2005) described SOP as a component of a total quality management that plays an integral role in improving the output of a given process consistently and efficiently. SOP ensures compliance, accountability, and efficiency among clinical investigators (7).

According to **Biologic Technological Applications** (EBTE) Consultants, SOP standardizes activities of a specific procedure; speeds up the integration of an individual into the organization during an initial phase of an employment; improves transparency within the organization; serves as a valuable structure for internal communication; shares best practices within the organization; and provides valuable background information for management policy development and change.

SOP also helps facilitate the transfer of knowledge and skill. Over a course of time, there is one inevitable challenge that employers face i.e. talented and experienced individuals may either temporarily be out of work or permanently change their work place or may retire for good for that matter. In such cases, the organization definitely loses its accumulated knowledge and skill and as a result, the organization may suffer from the symptoms of service hiccups. Levinthal & March (as cited in de Treville et al, p.231) asserted that SOP has the ability to facilitate the transfer of knowledge that leads to variability reduction and organizational effectiveness.

The Process of Developing SOP: Apparently, SOP is not one-size-fits-all. Specific SOP should exist for every single task that addresses some essential elements. According to Edelson & Bennett (as cited in Treville et al, p.232), the domains of a typical SOP include purpose of operation, equipment and materials required, and the operations required for the process.

The process of developing an effective SOP is critical to its successful implementation and the process should be inclusive which considers the input of everyone (8). The best practice to develop SOP calls for active involvement of workers. Highly successful managers actively engage their

teams and it is human nature that people support what they help create and managers who write SOP without input from workers run the risk of upsetting them while those who enlist the talents of their workers increase buy-in (Stup R., p. 6).

Adler, Imai, MacDuffie and Monden, (as cited in Treville et al, p.234), claimed that companies that test, refine, and implement workers' creative suggestions are likely to end up with higher quality SOP; they have the advantage to foster teamwork; and the motivational implications of SOP use are moderated by workers' ability to participate in the process. For continuous organizational improvement, established procedures need a continuous enhancement; and thus, requiring creative and novel ideas appropriate to the task from those individuals using those procedures (Treville et al, p. 233).

Apparently, the convincing reason to involve workforce is that individuals who participate in the process are positive to generate ideas, accept

the SOP, and feel a sense of ownership in it, which is not the case when workers feel that management is imposing an SOP without regard to their input. One of the earliest known models for managing SOP development is Plan-Do-Check-Act cycle i.e. first, you plan; next do what you planned; then check what and how you did and how things went; and finally, act on what you learned (9). The chart below summarizes the steps believed to generate an effective SOP, which are extracted from Stup R. (pp. 6-7, 2001) and summarized and presented in a flow chart.

Once SOP is developed, the next critical stage is adherence to it. The expectation is that everyone should adhere to the established SOP. However, according to Imai, Edelson & Bennett (as cited in Treville et al, P.236), adhering to SOP does not happen automatically and ensuring workers adherence to SOP is one of the primary jobs of management and requires discipline and management intervention.

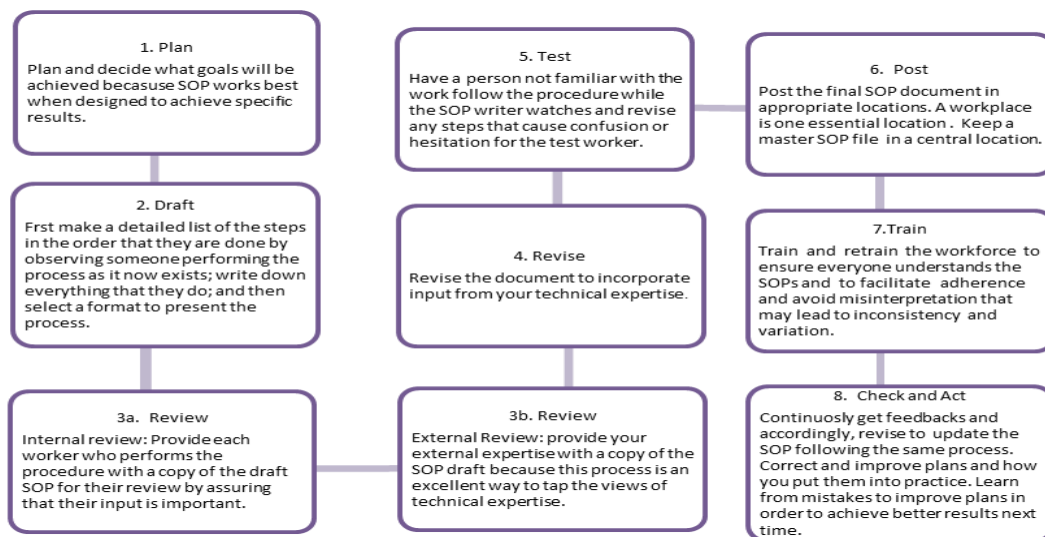


Chart: the steps and processes of developing effective SOP

The other relevant question is, “who should write SOP?” EBTE Consultants pointed out that the logical step is to let the user write a draft of the SOP. EPA also reported that individuals who are well informed about the activity and the organization's internal structure should write SOP because they are essentially subject-matter experts who actually perform the work or use the process. EBTE Consultants noted that the user-author practice prevents the working procedure appearing

to the reader unfamiliar or awkward and it is much likely that this practice will result in an improved sense of responsibility for the obligation to use and comply with the SOP and if not, it is likely that the user would resist using it. According to EPA, a team approach is another option and is particularly relevant to write SOP for multi tasked processes where the experiences of a number of individuals are critical. Whoever writes the SOP, the most important thing is it should convey a

clear instruction in a manner that is easier to understand by everyone

Pitfalls of SOP: It would be reasonable and relevant to briefly describe some disadvantages of SOP to help compare with the advantages. Some of the pitfalls mainly emanate from the fear that SOP limits creativity, restricts shortcuts, weakens competition, and denies flexibility. According to EBTE Consultants, the potential disadvantages include that the use of SOP can become more and more restrictive; reduce individual liberty and approach to work; and can become very time consuming; and create a complete controlled environment – ideal for bureaucratic management style.

Some individuals see SOP as a threat that diminishes their importance at work and so are unwilling to share their knowledge and skills. Job security is another factor. Some workers feel insecure in their position if everybody knows their skills and knowledge.

In conclusion, SOP is applicable to any entity and it should be an essential domain of an effective management system to help cultivate transparent systems, implement error preventive measures, and facilitate corrective actions. When it comes to the practice of medicine and pharmaceutical care, its relevance and importance becomes critical to ensure safety. SOP helps provide an efficient and quality service and having an efficient SOP in place minimizes errors, clears the way forward by avoiding uncertainties, and serves as a vital tool to transfer knowledge and skill.

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