EDITORIAL

Standard operating procedures for clinical practice

T. S. Sathyanarayana Rao, Rajiv Radhakrishnan[1], Chittaranjan Andrade[2]
Department of Psychiatry, JSS Medical College, Mysore, India, [1]Yale School of Medicine, New Haven, Connecticut, USA, [2]Department of Psychopharmacology, National Institute of Mental Health and Neurosciences, Bangalore, India

What are standard operating procedures (SOPs)? These are a specific set of practices that are required to be initiated and followed when specific circumstances arise. For example, emergency room physicians have SOPs for patients who are brought in an unconscious state; nurses in an operating theater have SOPs for the forceps and swabs that they hand over to the operating surgeons; and laboratory technicians have SOPs for handling, testing, and subsequently discarding body fluids obtained from patients.

The origins of the term SOP are obscure. The Encyclopedia Britannica indicates that the abbreviation came into use around the mid-1900s[1] and was already in use during World War II. Today, SOPs exist in contexts ranging from military operations to business routines, and from manufacturing processes to medical activities.

In military circles, the term *standard operating procedure* or *standing operating procedure* is used to describe a procedure or set of procedures for the performance of a given action or for a reaction to a given event. There is a popular misconception that SOPs are standardized across the universe of practice. However, the very nature of an SOP is that it is not universally applied, such as across a large military element (e.g. a corps or division), but rather describes the unique operating procedure of a smaller unit (e.g. a battalion or company) within that larger element. That the operating procedure in question is said to be *standing* indicates that it is in effect until further notice, and that it may later be amended or dissolved.

In the context of clinical trials, the International Conference on Harmonisation (ICH), born in 1990 out of an effort to harmonize regulatory requirements for medicinal products, defines SOPs as detailed, written instructions to achieve uniformity of the performance of a specific function. This is also in keeping with the goal of Good Clinical Practice.[2]

In present day medicine, clinicians are familiar with SOPs in restricted contexts, such as those described at the beginning of this article. Clinicians are also aware of the use of SOPs in the context of clinical trials, either with regard to the functioning of ethics committees or with regard to screening, consenting, assessing, and treating patients across the course of the clinical trial. An idea whose time has now come is the introduction of SOPs into routine clinical practice; that is, not for special patients (e.g. those who are unconscious) or for special circumstances (e.g. clinical trials), but for every patient in everyday clinical care.

To understand why such SOPs are necessary, let us first pose a question to the reader: How often in routine practice do we ask female patients of reproductive age about the date of their last menstrual period, or about contraceptive precautions that they may have adopted? Do we record these details? Chances are that such information is not regularly obtained; yet, it should be obvious that this information should be sought and recorded at every consultation (whether initial or follow-up) with every female patient in whom pregnancy is even a remote possibility. If SOPs are set in place, it is unlikely that such information would be neglected.

Digressing briefly, how are SOPs different from practice guidelines? The terms SOPs, guidelines and pathways are defined by different medical bodies.[3-8] Furthermore, whereas clinical practice guidelines are systematically developed statements that assist decisions about appropriate health care for specific circumstances,[9,10] SOPs are more specific than guidelines and are defined in

Address for correspondence: Dr. T. S. Sathyanarayana Rao, Department of Psychiatry, JSS University, JSS Medical College Hospital, M.G. Road, Mysore, India.-570004
Email: tssrao19@yahoo.com

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greater detail. They provide a comprehensive set of rigid criteria outlining the management steps for a single clinical condition or aspects of organization.[11]

Guidelines are rigorously developed using evidence-based medicine criteria and consist of two distinct components: the evidence summary and the detailed instructions for the application of that evidence to patient care.[8] For the common health care provider, guidelines require local adaptation to suit local circumstances and to achieve a feeling of ownership, both of which are important factors in guideline uptake and use.[12] SOPs, therefore, help bridge the gap between evidence-based medicine, clinical practice guidelines, and the local realities at the point-of-care.

It is fairly obvious that SOPs ensure a higher standard of medical attention in serious situations, examples of which include lithium toxicity and the neuroleptic malignant syndrome. In a study of the treatment of sepsis, Kortgen *et al*. (2006) found that the use of SOPs facilitated the implementation of new therapeutic strategies, particularly as bundles or packages, thereby improving the standard of care. SOPs also reduce the time lag between the publication of randomized controlled trials and the incorporation of the findings of these trials into clinical practice. Also, irrespective of their content, SOPs hasten the initiation of therapy for individual patients by increasing the awareness of the need to vigorously and rapidly treat such patients.[13]

We now return to our contention that SOPs need to be introduced into the clinical routine and not be reserved for special patients or special circumstances. To start with the general consultation, SOPs regarding the structure of outpatient consultations are necessary for every patient to ensure that the patient and/or his family are aware of the nature of the diagnosis, the prognosis, the nature and duration of treatment, the time course of treatment response, possible adverse effects of treatment, and related issues; some of such education will need to be repeated at follow-up visits because no client will remember all that has been conveyed at the first meeting. Such SOPs can be constructed by structuring the duration and component parts of the consultation. Research shows that in longer consultations doctors prescribe less,[14,15] listen better to their patients, identify more problems, explore more psychosocial problems, and provide more health promotion.[16,17] If these measures are viewed as a proxy for quality, longer consultations appear better.[18,19] In longer consultations, the patient gives more information, especially about lifestyle and social behaviors.[20] The consultation can be structured as an SOP with component parts that include the duration of consultation, social behavior, agreement, rapport building, partnership building, giving directions, giving information, asking questions and counseling.[20]

SOPs for initial assessment and work-up are necessary to identify factors such as danger to life (e.g. high suicidal risk in a patient with mood disorder), risk of adverse effects with medication (e.g. a family history of diabetes mellitus in a patient advised olanzapine), comorbid medical disorders (e.g. acid-peptic disease in a patient advised fluoxetine), and drug interactions (e.g. thiazide diuretic use in a patient advised lithium). SOPs remind clinicians that there may be interactions between medical illnesses or the treatment thereof with psychiatric illnesses or the treatment thereof. The use of a treatment algorithm for patients at suicide risk, based on a failure modes and effects analysis (FMEA) model, can reduce in-patient suicide risk.[21] Similarly, application of SOPs can reduce treatment-related adverse event rates.[22]

SOPs are necessary to remind clinicians of the need for medical evaluations such as ultrasonography of the ovaries in young women advised valproate, physical and metabolic monitoring in patients advised olanzapine, and thyroid assessments in patients with mood disorders. Incorporating reminders in the form of SOPs can improve the rate of compliance with the relevant guidelines.[23]

SOPS are necessary to incorporate aspects of treatment which are not highlighted in guidelines[13] or which are parts of different guidelines. This will ensure that attention is paid to areas as diverse as problem-solving, communication, social support, family burden, and caregiver stress. SOPs are necessary to ensure that easily implemented strategies that benefit mental health are not neglected; examples of behavioral targets are diet, exercise, sleep, stress management, and the pursuit of leisure and pleasure activities. SOPs are necessary to monitor medication compliance, a variable that can make or break the success of a psychopharmacological treatment plan.

SOPs are necessary for special settings such as the electroconvulsive therapy (ECT) unit. Here, SOPs are required not only for routines related to consenting and investigating fitness for ECT but also for emergency situations that may arise, such as ECT-induced cardiac arrhythmias, prolonged seizures, or prolonged apnea.

All SOPs should be prominently available in the clinician's consulting chamber, in the outpatient department, in the hospital wards, in the ECT suite, and in any zone related to patient care.

Taking the subject to the final frontier, client-individualized SOPs can also be developed. Just as there could be specific SOPs for women, for elderly patients, for patients with a particular diagnosis, for patients advised a particular drug, for patients with a particular medical comorbidity, and for patients in different stages of therapy, there could be customized SOPs which would address combinations of such patient characteristics. Thus, for example, there could be a special SOP for elderly women with depression

and diabetes, who may be prescribed mirtazapine during maintenance therapy. Is this a ridiculous and impossible suggestion? Not at all. If SOPs are available in spreadsheet format for each subcategory of gender, age, diagnosis, comorbidity, drug, and so on, then a few mouse clicks can easily customize a pooled SOP for the combination of subcategories in a specific patient. Printouts of such tailor-made SOPs can be inserted into patient files.

We remind readers who consider our suggestions impractical that SOPs of a sort are already in place in everyday clinical practice; as an obvious example, undergraduate and postgraduate students have a clear framework for obtaining a clinical history and for conducting a general examination, systemic examination, and mental status examination. To a certain extent, SOPs also exist for aspects of record-keeping and hospital administration. An extension of such structure into routine clinical care is what we are now suggesting. The use of SOPs will have the added advantages of utilizing an optimized process for care, implementation of best evidence-based medicine, cost-effectiveness, improved continuing medical education, improved induction of new hospital staff, integrated quality control, transparency and enhanced protection from malpractice.[24] When all these SOPs are in place, the quality of patient care will substantially improve.

The Indian Psychiatric Society has constituted task forces for various activities and has issued treatment guidelines for different psychiatric disorders and contexts. The formulation of SOPs for routine clinical practice at all levels of care is a potential activity that the Society should address in the future. Such SOPs will of necessity be templates that can be customized to individual contexts, depending on what happens to be practical and expedient in the environment in which they are applied.

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