


Adverse events reporting at naturopathy clinical settings: importance of accreditation systems in improving quality of care and patient safety

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INTRODUCTION

The popularity of complementary and alternative medicine (CAM) is growing across the globe, with a growing number of patients using these services as adjuvant care for their ailments. Unlike conventional medicine, reports on adverse events during or after CAM interventions are scarce. This may be due to limited awareness or under-reporting of adverse events by CAM practitioners and/or patients.¹ Yoga and naturopathy is one among the CAM systems which use non-invasive techniques (except acupuncture and enema) such as hydrotherapy, fasting, sun exposure, mud therapy, etc to manage various diseases.²

Yoga and naturopathy physicians promote this system of medicine as a system without any potential side effects. At the same time, due to the nature of therapies used in naturopathy settings such as heat therapies, acupuncture, water therapies (packs and baths), sun exposure etc, there is always a likelihood of developing potential adverse events like burns, infections, needle stick injuries, etc. Reporting these events can help in improving quality and ensuring patient safety while implementing CAM protocols. However, there were no exclusive safety/quality systems developed in India until 2009 for yoga and naturopathy, after which the National Accreditation Board for Hospitals & Healthcare Providers (NABH) started accrediting yoga and naturopathy hospitals after evaluating their quality and patient safety measure standards.³

METHODS

In April 2020, Sant Hirdaram Yoga and Nature Cure Hospital (Madhya Pradesh, India) became the first yoga and naturopathy medical college and teaching hospital to be accredited

by NABH in India. We implemented an incidence monitoring mechanism as a part of our quality improvement protocol as per the standards of NABH accreditation.³ All the medical and non-medical staff involved in patient care were instructed to report all the events under the categories adverse events, treatment errors, near-miss events and sentinel events. The quality control committee examined the reported events, and appropriate quality improvement steps were introduced after analysing the root cause. The present report summarises the adverse events, treatment errors, and near-miss events identified and the quality improvement achieved as a result of adherence to NABH protocols. **Figure 1** depicts the flow of events in incidence reporting and the quality improvement process.

RESULTS

There were a total of 22 adverse events, 5 treatment errors and 5 near-miss events identified from April 2020 through August 2022 from a total population of 27237 patients who underwent yoga and naturopathy therapies. Burn injuries were the most frequently reported adverse event, followed by allergic reactions to massage therapy oils, syncope, giddiness and vomiting. Online supplemental table 1 outlines the detailed adverse events, treatment errors and near-miss events reported during the year, April 2020 to August 2022. On investigation, problem areas like lack of adherence—to treatment protocols, Standard Operating procedures, lack of patient education about protocols, etc—were identified as the root cause (online supplemental table 1).

DISCUSSION

This is the first-ever report on adverse events and prospective quality improvement

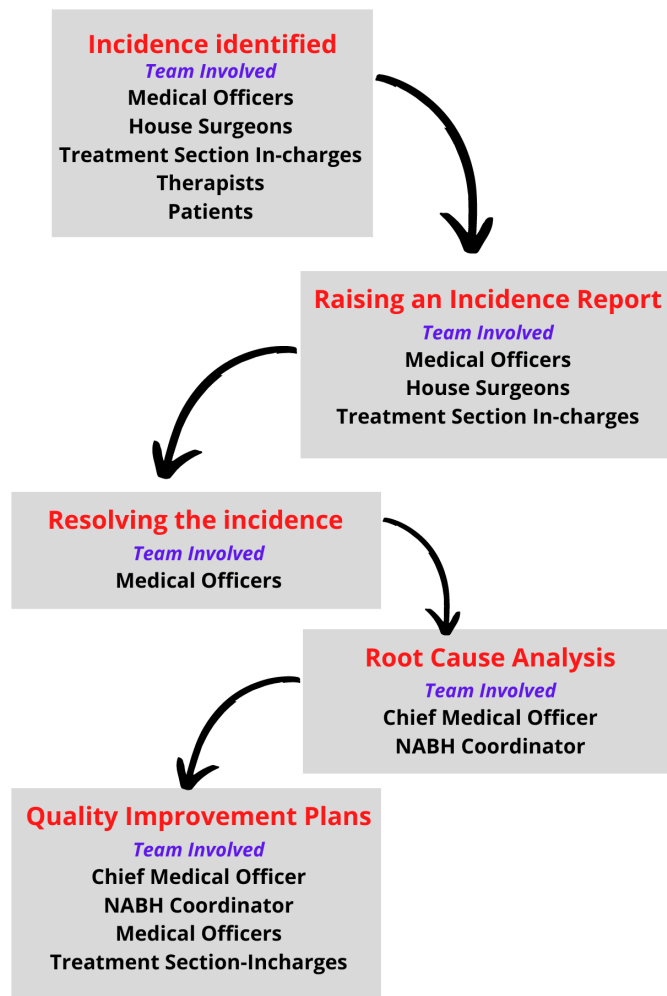


Figure 1 Flow of events in incidence reporting and quality improvement process. National Accreditation Board for Hospitals & Healthcare Providers (NABH).

achieved by a yoga and naturopathy medical college and its teaching hospital accredited with NABH. These incidence reports collected over a period of time helped us in developing newer insights on quality improvement, identifying the vulnerable areas and improving clinical governance, which was never the case before NABH accreditation. Additionally, due to the improvement in quality metrics, our hospital was also empanelled to treat central government employees under central government health schemes as of September 2020. This indicates that adhering to quality can improve the acceptability of its service among various stakeholders. Moreover, quality improvement and patient safety should be the primary goals of any hospital, as millions of patients succumb to disabilities, life-threatening events or death every year due to unwarranted medical practice.⁴

There are approximately 5000 yoga and naturopathy hospitals/medical colleges/clinics in India, however, as

per the NABH database as of August 2022, only 9 yoga and naturopathy hospitals are accredited by NABH.⁵ This indicates a large scope for improvement in the quality and patient safety goals among yoga and naturopathy hospitals. Further, the observations from this report are very encouraging to incorporate NABH accreditation as a quality improvement goal for all yoga and naturopathy settings, as NABH accreditation is a public endorsement of quality healthcare service in India.⁶ Nevertheless, this may also help in identifying new avenues of quality improvement in less explored CAM systems like yoga and naturopathy.

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Table 1: Summary of adverse events and its impact on policy related to the quality of care

Incidences	Number of clinical incidences	Treatment types	Patient Diagnosis	Category of events	Root cause identified	Policy changes introduced to improve quality of care
Burn injury	9	Gastro-Hepatic Pack Wax application Oil compress Local steam Moxibustion Hot fomentation	Osteoarthritis Obesity Hypertension Low backache Rheumatoid arthritis	Adverse event	Lack of patient education on treatment effects Skin sensitivity tests have not been done	Introduced Patient induction sessions before initiating the treatments. Introduced checklist for temperature sensitivity monitoring.
Giddiness	2	Acupuncture	Hypothyroidism Oligomenorrhoea Cervical Spondylosis Vertigo	Adverse event	Non-adherence to Standard Operating Procedure (SOP) regarding meal timings and treatment	Patient education on SOPs regarding acupuncture was introduced during consultation. Introduced probable adverse events to be expected during acupuncture sessions in informed consent forms.
Syncope	2	Warm immersion bath Acupuncture	Hypotension Migraine	Adverse event	Non-adherence to Standard Operating Procedure (SOP) of treatments.	Implemented a new protocol to check the vitals before and after the intervention to avoid any adverse events.

Uneasiness, headache, chills	1	Mud pack to eyes	Migraine	Adverse event	Patient temperature sensitivity or trigger factor was not identified before intervention.	Introduced double layered supervision at the treatment sections. A colour flagging system was introduced to identify if there are any special needs for the patient/caution that needs to be exercised before treatments.
Bleeding	1	Scalp Acupuncture	Cerebral ataxia	Adverse event	Poor quality in locating acupuncture points	Training on point selection was introduced once a month for the house-surgeons by the Head of the Acupuncture department.
Ulceration in anal mucosa	1	Enema	Obesity	Adverse event	Improper insertion/expulsion of the catheter Non-adherence to preoperative examination procedures	Two layered supervision including the treatment section in-charges and house surgeons were introduced before invasive procedures.

Infection	1	Enema	Fatty Liver	Adverse event	Improper selection of medium for enema. Non-adherence to preoperative examination procedures	Two layered supervision including the treatment section in-charges and house surgeons were formed before to monitor the adherence to hand-hygiene protocol and use of disposable gloves to ensure a sterile environment before performing invasive procedures.
Allergic reactions	2	Full body massage- Allergic to mustard oil	Obesity	Adverse event	Patients' skin patch test not performed.	Introduced skin patch tests for all patients before the massage.
Pain	1	Full body massage	Positive Health Promotion	Adverse event	Feedback on the pressure threshold was not taken. Inadequate patient education on the treatment experience	Periodic training for massage therapists was introduced to ensure the quality. Patient education on treatment procedures and experiences was introduced during the induction session.

Vomiting	2	Mud bath Colon Hydrotherapy	Constipation Acid Peptic Disease	Adverse event	Non-adherence to SOP regarding meal timings and treatment	Introduced Patient induction sessions before initiating the treatments and to remain empty stomach during these treatments.
Treatment errors	5	Hip bath prescribed during menstruation. A hot foot bath was given instead of a hip bath. Hot packs were given instead of cold. Oil compress was given on calf instead of back.	Not applicable	Treatment errors	Non-compliance on adherence to patient safety goals. Lack of patient education. Non-adherence to SOPs	Introduced Patient induction sessions before initiating the treatments. Two-layered supervision was introduced before the treatment delivery to avoid any possible treatment errors.

Fall incidences	5	Mud bath Cold Shower Massage	Not applicable	Near miss	Non-adherence to SOPs for post-operative procedures. Absence of anti-skid mats in the respective areas. Mopping time is not appropriate. Wet treatment areas	Patient education for using anti-skid footwear. Anti-skid mats have been set up on the identified floor areas. Mopping with caution boards has been introduced.
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