

Medicine and Society

Ethical and legal issues in cross-system practice in India: Past, present and future

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ABSTRACT

Recent changes in policies allowing practitioners of Ayurveda, Yoga, Naturopathy, Unani, Siddha and Homoeopathy (AYUSH) to integrate into the mainstream of healthcare and also allowing practitioners of Ayurveda and Homoeopathy to perform medical termination of pregnancy (MTP) under the proposed amendment to the MTP bill have brought cross-system practice into the limelight. We evaluate cross-system practice from its legal and ethical perspectives. Across judgments, the judiciary has held that cross-system practice is a form of medical negligence; however, it is permitted only in those states where the concerned governments have authorized it by a general or special order. Further, though a state government may authorize an alternative medicine doctor to prescribe allopathic medicines (or vice versa), it does not condone the prescription of wrong medicines or wrong diagnosis. Courts have also stated that prescribing allopathic medicines and misrepresenting these as traditional medicines is an unfair trade practice and not explaining the side-effects of a prescribed allopathic medicine amounts to medical negligence. Finally, the Supreme Court has cautioned that employing traditional medical practitioners who do not possess the required skill and competence to give allopathic treatment in hospitals and to let an emergency patient be treated by them is gross negligence. In the event of an unwanted outcome, the responsibility is completely on the hospital authorities. Therefore, there is an urgent need to abolish cross-system practice, invest in healthcare, and bring radical changes in health legislations to make right to healthcare a reality.

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INTRODUCTION

About 70% of the Indian population lives in rural areas and has access to only basic healthcare facilities. There is a scarcity of doctors in these areas as they are not willing to work in locations where the infrastructure is poor, and medicines and healthcare equipment are not available. This unmet need has caught the attention of politicians and policy-makers.¹ The government has responded to this issue by amending laws, implementing new

policies and initiating new medical courses. This response has raised some concerns.

The recent policy changes and discussions on the role of practitioners of alternative medicine in mainstream medical practice are in the following areas: (i) The new Medical Termination of Pregnancy (Amendment) Draft bill; which says that 'medical termination of pregnancy can be performed by Ayurveda and Homoeopathy practitioners';² (ii) The National Rural Health Mission (integrating practitioners of AYUSH [Ayurveda, Yoga, Naturopathy, Unani, Siddha and Homoeopathy] into the mainstream);^{3,4} (iii) some states allowing practitioners of AYUSH to prescribe allopathic medicines;⁵ (iv) employing AYUSH doctors in allopathic nursing homes/hospitals;⁶ (v) initiation of new medical courses such as the 3-year rural medical assistants programme to address the shortage of medical practitioners in rural areas;^{4,7,8} and (vi) increased litigations involving cross-system practice all over India.

'Cross-system prescription' is defined as a doctor of one system of medical practice prescribing medicines of another system, in which she/he has not been formally trained or studied.^{6,9} For example, allopathic doctors prescribing ayurvedic medicines or vice versa. Similarly, 'cross-system practice' means when a doctor of one system of medicine practices in another medical system, in which she/he has not been formally trained or studied.^{6,9} We evaluated cross-system practice from its ethical and legal perspectives.

METHODS

We did an electronic search of articles published in PubMed unrestricted for date. Terms such as cross-system practice, complementary alternative medicine, traditional medicine, and medical negligence were combined using the Boolean operator (AND). Cross-references of major articles and reviews, where relevant, were further reviewed.

To carry out searches related to legal issues, we used a combination of primary and secondary data. Online searches using various medical and law databases such as PubMed, EBSCO host, Science Direct, Proquest, Manupatra, Hein Online, Lexis Nexis, Jstor, Springer Link, Westlaw India and International, AIR (All India Reporter) online and SCC (Supreme Court cases) online were helpful. Besides these law reports, annual reports of the Ministry of Health and Family Welfare, press releases and other relevant news items were also considered. We found a wide range of published articles and case laws. We selected articles that we felt were relevant to a meaningful discussion for the review.

Prevalence of cross-practice

A cross-sectional study of prescriptions from patients attending

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clinics of AYUSH practitioners over a period of 5 weeks¹⁰ revealed that 97.7% of 401 prescriptions contained allopathic drugs. The study concluded that AYUSH practitioners prescribed allopathic drugs frequently and irrationally. The maximum irrational prescriptions were of fixed-drug combinations.¹⁰ In another comparative study, prescriptions of allopathic practitioners had 12% ayurvedic drugs and prescriptions of ayurvedic practitioners had 48% allopathic drugs.¹¹ Yet another study found that allopathic doctors (81%) had no knowledge about ayurveda and ayurvedic medicines which they were prescribing.¹² A study done in Maharashtra on the patterns of prescriptions of both allopathic and ayurvedic doctors revealed that the percentage of allopathic prescriptions with antibiotics (82%) and with injections (56%) was significantly more among ayurvedic doctors.¹³ The study concluded that if the government wants to continue with the practice of allowing ayurvedic doctors to prescribe modern medicine, pharmacology should become a mandatory part of their curriculum.¹³ This cross-system practice resulting in irrational prescription^{12,13} can be dangerous to patients and society.

REGULATORY LEGISLATIONS

Allopathy is regulated by the Indian Medical Council Act, 1956;¹⁴ AYUSH by the Indian Medicine Central Council Act, 1970;¹⁵ and Homoeopathy by the Homoeopathic Central Council Act, 1973.¹⁶ Under the Indian Medicine Central Council Act, 1970,¹⁵ there is the 'Central Register of Indian Medicine' and 'State Register of Indian medicine', which regulate the registration of practitioners of Indian medicine. Similarly, under the Indian Medical Council Act, 1956,¹⁴ there is the, 'Indian Medical Register' and 'State Medical Register', which regulate the registration of practitioners of medicine. These separate legislations and separate registers with different names (i.e. Register of Indian Medicine versus Indian Medical Register) indicate that the law-makers wanted the systems to be independent of each other. Another contentious issue relates to referring 'vaid' and 'hakim' as 'doctors' even though the Indian Medicine Central Council Act, 1970, does not contain the word 'doctor' at all and refers to such practitioners only as vaid and hakim.¹⁵

Specific to the AYUSH legislation in the Indian Medicine Central Council Act, 1970,¹⁵ Chapter-1, 2(e), 'Indian Medicine' means the system of Indian medicine commonly known as Ashtang Ayurveda, Siddha or Unani Tibb whether supplemented or not by such modern advances as the Central Council may declare by notification from time to time. This term 'modern advance' has been used to their advantage and many AYUSH practitioners want that they be allowed to practice allopathic medicine. However, the Supreme Court in its landmark decision of *Dr Mukhtiar Chand & Ors. v. State of Punjab*,¹⁷ observed, 'the definition of "Indian medicine" and "modern advance" have been clarified. The practitioners can make use of the modern advances in various sciences such as a radiology report, (X-ray), complete blood picture, lipids report, ECG, etc., for purpose of practice in their own system of medicine'.¹⁷ Further the Court held that 'a harmonious reading of Section 15 of the Indian Medical Council Act, 1956 and Section 17 of Indian Medicine Central Council Act, 1970 leads to the conclusion that there is no scope for a person enrolled on the State or Central Registers of Indian Medicine to practice modern scientific medicine in any of its branches unless that person is also enrolled on a State Medical Register within the meaning of the 1956 Act'.¹⁷

Further, the Supreme Court went on to state that the right to practise modern scientific medicine or Indian system of medicine

cannot be based on the provisions of the Drugs and Cosmetics Act, 1945 and declaration made thereunder by state governments.¹⁷ It also highlighted that the purpose of the Drugs and Cosmetics Act, 1945 is to control the research, manufacture, storage, sale, dispense and supply of drugs and not to control practice (prescription) of medicine.

State laws on health

In a broader sense, the right to prescribe drugs of a system of medicine would be synonymous with the right to practice that system of medicine. However, sub-section (2) in Section 15 of the 1956 Act¹⁴ occupied the field vide Central Act 24 of 1964, the benefit of the said rule would be available only in those states where the privilege of such rights to practice any system of medicine is conferred by the state law under which practitioners of Indian medicine are registered in the state, which is for the time being in force.¹⁷ In simple words, if any state Act recognized the qualification of an integrated course as sufficient qualification for registration in the State Medical Register of that state, the prohibition of Section 15(2)(b) will not be attracted. Hence, some state governments have authorized ayurvedic and homoeopathic doctors to prescribe allopathic drugs where there is a shortage of allopathic doctors.¹⁸ The Government of Maharashtra had issued a gazette notification in 1992 allowing vaid to practise allopathy. However, a writ petition has been filed by the Indian Medical Association, Pune in Bombay High Court against this in 2014 (WP 7846/2014 and 7847/2014).

According to the Supreme Court judgment, Ayurveda, Siddha, Unani and Homoeopathy practitioners can prescribe allopathic medicines only in those states where they are authorized to do so by a general or special order made by the concerned state government in that regard.¹⁷⁻¹⁹ To enable this the Ministry of Health and Family Welfare, Government of India issued a notification (vide Letter no D.O. No. V.11025/65/2012-MEP.I dated 19.05.2013) requesting all state medical councils to establish a separate register for vaid, hakim, etc. which would enable them to practise allopathy.

In an interesting case,²⁰ an Ayurvedic doctor could not diagnose Stevens-Johnson syndrome, the life-threatening side-effect of an allopathic medicine, which he himself had prescribed. Unfortunately, he continued to treat the child for measles. The consumer forum took note of the inadequate knowledge and lack of skills of the ayurvedic doctor. In this landmark case, the forum said that the state government may authorize an AYUSH doctor to prescribe medicines for allopathy, but that does not authorize the doctor to prescribe wrong medicines and to diagnose the disease wrongly. Hence, the doctor was found negligent and was asked to pay compensation.²⁰

The above incident indicates that courts have acknowledged that state rules or orders for cross-system practice are valid. However, the outcome in this instance did not benefit the patient, for the benefit of whom these rules/orders have been made. The forum also said that in the event of medical negligence due to cross-system practice, the onus of responsibility is on the practitioner.

DECISIONS OF THE SUPREME COURT

The apex court in another landmark decision of *Dr Laxman Balakrishna Joshi v. Dr Trimbak Babu Godbole*²¹ had laid down that, when a patient consults a doctor, the doctor has certain duties, namely (i) duty of care in deciding whether to undertake the case; (ii) duty of care in deciding what treatment to give; and

(iii) duty of care in the administration of that treatment. A breach of any of these duties gives a cause of action for negligence.²¹ A person who does not have knowledge of a particular system of medicine but practises in that system is a 'quack' and a pretender to medical knowledge or skill, or a charlatan.²² There is no restriction to practise the medicine for which a person is qualified and registered under the law to do so. The problem would arise only when they attempt to cross-practise without proper degree, training and registration in the respective system of medicine.²² The Supreme Court clearly stated that a professional may be held liable for negligence on one of the two findings: either of not possessing the requisite skill or that he did not exercise, with reasonable competence in a given case, the skill which he did possess.^{23,24} It is a well-settled law that, if a person claims that he has a particular competence, the onus is on the practitioner to demonstrate that he has the requisite knowledge and skill to prescribe that medicine and to treat the patient in a particular system.²⁴

A registered homoeopathic medical practitioner under the Madhya Pradesh Homoeopathic and Bio-chemic Practitioners Act, 1951, issued a pamphlet advertising that he was capable of treating guinea worm infestation. A 20-year-old patient visited the homoeopathic medical practitioner for treatment and was administered 24 drops of mother tincture stramonium and a leaf of datura. Soon after taking the medicine, the patient died. The Supreme Court held that it was a rash and negligent act to prescribe poisonous medicines without studying their probable effects.²⁵

In another instance, a homoeopathic doctor administered allopathic drugs to a patient who was subsequently shifted to a nursing home where he died. In this case, the Supreme Court reviewed the provisions of the Bombay Homoeopathic Practitioners' Act 1959, which defined 'Homoeopathy' as a system of medicine and that a practitioner registered under that Act shall practise homoeopathy only, i.e. such a practitioner was entitled to treat patients only according to the homoeopathic system of medicine. Further, the allopathic system of medicine was regulated under the Indian Medical Council Act, 1956, which made practising allopathic system of medicine without the requisite qualification punishable.²² The Supreme Court held 'that a person who does not have knowledge of a particular system of medicine but practices in that system is a quack. Where a person is guilty of negligence per se, no further proof is needed'.^{22,23} However, in rare instances, where the state government had authorized cross-system practice after required training, the person has to prove that she/he possesses requisite knowledge and skill to prescribe that medicine according to that system of medicine, not in the system she/he possesses a registration. She/he may have to undergo continuous medical education in that system of medicine and also in the system that she/he possesses registration keeping public safety in mind.

Unfair trade practice

In the Bhanwar Kanwar v. Gupta case,²⁶ an ayurvedic doctor had advertised in a newspaper, offering patients with seizures treatment with ayurvedic medicines and also claimed total cure. A family sought ayurvedic treatment of their 4-year-old child. In spite of giving the prescribed medicine, the child continued to have seizures and his condition started to worsen. The family consulted the practitioner many times over the next 3 years but the seizures did not stop. Later the family came to know that the ayurvedic doctor was prescribing allopathic medications in the

name of ayurvedic ones. In a landmark judgment, the Supreme Court upheld that the ayurvedic doctor was entitled to practise allopathy in the state of Uttar Pradesh (UP), as per letter No.726/712200315 dated 24th February, 2003 of the Secretary, Medical Education Department, Government of UP. However, to curb a false representation and to restore faith of the people in the ayurvedic system, the Court opined that the ayurvedic doctor was guilty of unfair trade practice and adopted unfair methods and deceptive practice by making false statements orally as well as in writing that he was prescribing only ayurvedic medicines. Thus, the victim was entitled for compensation for the injury suffered.²⁶ Hence, now cross-system practitioners need to declare and also inform patients that they have prescribed a medicine from another system of medicine than the system in which they are registered. Ultimately, it is the patient's choice, safety and informed consent that play a major role.²⁴

ETHICAL GUIDELINES

The Medical Council of India (Professional Conduct, Etiquette and Ethics) Regulations, 2002, Clause 1.1.3(27) clearly says that no person other than a doctor with a qualification recognized by the Medical Council of India (MCI) and registered with the MCI/State Medical Council(s) is allowed to practise the modern system of medicine or surgery. A person obtaining qualification in any other system of medicine is not allowed to practise modern system of medicine in any form.²⁷ MCI, Clause 6.5., states that prescribing or dispensing by a physician, secret remedial agents of which he does not know the composition, or the manufacturer, or promotion of their use is unethical and as such prohibited.²⁷ By inserting this clause, MCI prohibits allopathic practitioners to prescribe complementary alternative medicines. If qualified practitioners of modern medicine have been barred from using complementary and alternative medicines, the same ruling should apply to doctors of all other systems of medicine, i.e. avoid cross-prescribing and respect each other's profession. Unfortunately, such clauses do not exist in the Practitioners of Indian Medicine Standards of Professional Conduct, Etiquette and Code of Ethics 1982.²⁸ It would be prudent to add similar clauses in the Practitioners of Indian Medicine Code of Ethics, to preserve the rich tradition and heritage of the Indian system of medicine.

Medical (allopathic) graduates from the erstwhile USSR, China and Nepal appealed for consideration of grant of recognition and registration under the MCI.^{29,30} In this case, the Supreme Court observed that the 2001 amendment to the Indian Medical Council Act prohibits registration of MBBS degree holders from other countries in India without undergoing a screening test. A person who is not duly qualified as prescribed by MCI cannot be permitted to involve himself in public healthcare and play with the lives of human beings.^{29,30} The Supreme Court said that when the Medical Council Act prohibits registration of MBBS (Allopathic) degree holders from other countries in India without undergoing a screening test, it is not open to medical practitioners of other systems of medicine to claim their right to practise in modern medicine without qualification in the said system.³¹

EMPLOYING PRACTITIONERS OF INDIAN MEDICINE IN ALLOPATHIC HOSPITALS

There are many private and corporate allopathic hospitals that employ AYUSH medical officers for purely commercial reasons. These doctors administer allopathic medicines under the supervision of an allopathic consultant. In the event of a misadventure, the allopathic consultant or the hospital is held

responsible.⁶ In one such situation, the National Consumer Commission has said that 'it is high time that hospital authorities realize that the practice of employing non-medical practitioners such as doctors specialized in the Unani system or other system of Indian medicine and who do not possess the required skill and competence to give allopathic treatment and to let an emergency patient be treated in their hands is gross negligence and the responsibility is on the hospital authorities'. Accordingly, the hospital was directed to pay a compensation.³² More importantly, the Commission has made it clear that the very act of employing an unqualified person opens up the hospital to the charge of gross negligence. In another case, the Supreme Court found that there was clear dereliction of duty on the part of the nurse and that the hospital was negligent in having employed an unqualified person as a nurse and entrusting the child to her care.³³ In a similar case, the Court has noted that merely because the petitioner possesses a degree in pharmacy (modern medicine) and is stated to be running a medical shop, he is not entitled to dispense drugs without a prescription and also he should not on any account prescribe medicines for a patient on his own.³⁴

Health legislation amendments: An urgent need

The Constitution of India defines the distribution of power between the federal government (the Centre) and the states. The legislative section is divided into three lists: Union list, states list and concurrent list.^{35,36} At present 'healthcare' is in the state list. Hence, the Central Government cannot play a major role in the states regarding issues of health.^{35,36} It is entirely up to the state governments to take the initiative, have the drive, long-term vision, enact laws, policies, invest in health, increase manpower and regulate the system. Unless state governments act, nothing will work.

Unfortunately, the right to healthcare is not a fundamental right under the Constitution of India. It falls under the obligation of the State, called, Directive Principles of State Policy. The Directive Principles of State Policy cannot be enforced by any court. Directive Principles prescribe the goal to be attained in securing welfare, social and economic freedom by appropriate State action.³⁶ However, in various judgments, the Supreme Court of India has brought the right to health under Article 21, right to life and liberty through various landmark judicial decisions.³⁷⁻⁴⁰

In the process of bringing healthcare access to the people and making health-for-all a reality, it is high time for law-makers to enact an enabling legislation. The following can bring in a revolutionary change in healthcare: (i) make right to healthcare as a fundamental right; (ii) bring healthcare into the Central list; and (iii) enact a right to healthcare legislation. These amendments will bring a new approach in taking healthcare to the people and also in ensuring equal distribution of health resources across India.

According to the WHO,⁴¹ the right to healthcare contains four elements:

1. **Availability:** A sufficient quantity of functioning public health and healthcare facilities, goods and services, as well as programmes.
2. **Accessibility:** Health facilities, goods and services accessible to everyone. Accessibility has four overlapping dimensions: non-discrimination, physical accessibility, economic accessibility (affordability) and information accessibility.
3. **Acceptability:** All health facilities, goods and services must be respectful of medical ethics and culturally appropriate as well as sensitive to gender and life-cycle requirements.

4. **Quality:** Health facilities, goods and services must be scientifically and medically appropriate and of good quality.

This means states have to respect and not interfere with the right to health. States also need to protect, promote and ensure that no one infringes upon the enjoyment of the right to health. Finally, the State should take positive steps to realize the right to health by adopting appropriate legislations, policies or budgetary measures.⁴¹ Amending laws and proclaiming the right to health of all citizens will ensure health for all and make the State accountable. The health of all Indian citizens has to be given the highest priority in public policy⁴² and mandated by appropriate legislation.

In conclusion, across judgments, courts have held that cross-system practice is medical negligence; however, it is permitted only in those states where such practitioners are authorized to do so by a general or special order of the concerned state government. Further, state governments may authorize an AYUSH doctor to prescribe medicines from allopathy, but that does not allow her/him to prescribe wrong medicines and to diagnose the disease incorrectly. The courts have also stated that prescribing allopathic medicines and misrepresenting these as traditional medicines is an unfair trade practice, and placing misleading advertisements that a person practises only traditional medicine and not explaining the side-effects of a prescribed allopathic medicine—all invite a case for medical negligence. However, in certain situations the courts have considered the grim public health scenario and permitted short-term courses such as BSc in Community Health to fill gaps in human resources. For example, the Delhi High Court granted a petitioner's request for a short-term medical course empowering graduates to practise allopathy to a fair extent.⁴³ The Supreme Court has also cautioned that the (i) practice of employing practitioners of Indian medicine in allopathic hospitals; (ii) those who do not possess the required skill and competence to give allopathic treatment; and (iii) to let an emergency patient be treated in their hands is gross negligence and the responsibility is on the hospital authorities. Thus, there is an urgent need to abolish cross-system practice, invest in health and bring radical and proactive change through appropriate amendments in existing laws to make right to healthcare a reality.

DECLARATION

An article on a related theme of cross-system practice has been previously published by the same authors. The bibliographic details are: Math SB, Sydney M, Kumar NC. Public health perspectives in cross system practice: Past, present and future. *Indian J Med Ethics* 2015;**12**:131-6.

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