

## Evidence-Based, Ethics-Driven Medicine

### Why in News?

The recent push to integrate ‘AYUSH’ medicinal systems into mainstream health care to achieve **universal health coverage** and ‘**decolonise medicine**’ is a pluralistic approach that would require every participating system to meet basic safety and efficacy standards.

- Homoeopathy does not meet these standards. But its supporters have argued in The Lancet Regional Health – Southeast Asia recently for expanding its use by citing demand and decolonisation, disregarding its flaws.

### India needs evidence-based, ethics-driven medicine

The recent push to integrate ‘AYUSH’ medicinal systems into mainstream health care to achieve universal health coverage and ‘decolonise medicine’ is a pluralistic approach that would require every participating system to meet basic safety and efficacy standards. Homoeopathy does not meet these standards. But its supporters have argued in *The Lancet Regional Health – Southeast Asia* recently for expanding its use by citing demand and decolonisation, disregarding its flaws.

#### Efficacy and safety of homoeopathy

Evidence on homoeopathy’s efficacy is weak. The first carefully conducted and well-reported double-blind randomised controlled trial (RCT), the Nuremberg Salt Test (1835), noted that “the symptoms or changes which the homoeopaths claimed to observe as an effect of their medicines were the fruit of imagination, self-deception and preconceived opinion – if not fraud.”

In the evidence-based medicine ladder, the topmost rung is systematic reviews and meta-analyses that exhaustively pool and critically appraise evidence from existing studies. Multiple systematic reviews and meta-analyses have found that, across ailments, population groups (adults versus children), study types (placebo-controlled versus other trial types), and treatment regimes (individualised versus non-individualised), homoeopathic treatments lack clinically significant effects. Reviews that somewhat support homoeopathy’s efficacy also caution over the low evidence quality and raise concerns about its clinical use.

Recently, researchers demonstrated that more than half of the 193 homoeopathic trials in the last two decades were not registered. Unregistered trials showed some evidence of efficacy but registered trials did not. There was reporting bias and other problematic practices, throwing the validity and reliability of evidence thus generated into doubt.

Further, the World Health Organization (WHO) has warned against homoeopathic treatments for HIV, tuberculosis, and malaria, as well as flu and



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diarrhoea in infants, saying it has “no place” in their treatment. Evidence is accumulating that homoeopathy does not work for cancers and may not help to reduce the adverse effects of cancer treatments, contrary to lay belief. Instead, treatments have been linked to both non-fatal and fatal adverse events as well as their aggravation. Seeking homoeopathic care also delays the application of evidence-based clinical care. In several cases, it has caused injuries and sometimes death.

#### On standards

Homoeopathy’s supporters argue that the standards commonly used in evidence-based medicine are not suitable for judging the “holistic effects” of homoeopathy. This claim can be debunked.

First, the standards are not conveniently chosen by practitioners of allopathic medicine for themselves. RCTs and other methods for collecting and assessing evidence are collaboratively set and updated by a global community pushing for evidence-based medicine that includes epidemiologists, biostatisticians, quality improvement researchers, implementation managers, and several others, beyond clinicians. These methods have weeded out practices in allopathic medicine that failed to meet the evidence criteria. Further, multiple disciplines such as psychology, economics, community health, implementation science, and public policy, beyond medicine have successfully adapted evidence synthesis methods to establish their claims.

Second, what are the methods that will work? Homoeopathy advocates have failed to invent valid alternative evidence synthesis frameworks suited for testing its efficacy and safety, which are also acceptable to the critics.

Third, the claim about homoeopathy being holistic is typically paired with evidence-based medicine being “reductionist”. In 2023, most exponents of evidence-based medicine are aware and accepting of biopsychosocial approaches toward health endorsed by WHO –

predominantly composed of evidence-based medicine practitioners and supporters.

Fourth, evidence-based medicine does not and should not stop at establishing empirical evidence. The quest is also to discover and explain the mechanisms underlying the evidence. In the last century, there has been no concrete evidence for proposed mechanisms of action for homoeopathy. No mechanistic (molecular, physiological, biochemical, or otherwise) evidence to explain how concepts such as “like cures like”, “extreme dilution”, and “dematerialised spiritual force” result in better health. In the same period, several allopathic/modern medicine practices have updated themselves based on growing scientific evidence.

Adopting a pluralistic approach in medicine can decolonise medicine. In India, homoeopathy is at odds with this. Homoeopathy was introduced in 1839 in India by Austrian physician J.M. Honigberger. While defining traditional medicine can be subjective, homoeopathy was introduced quite recently in India’s history during the colonial period for colonial benefit. Hence, its traditional tag is untenable. Of course, not all colonial-era practices need to be surrendered. Those with health and developmental benefits such as evidence-based elements of allopathic medicine and gender role and caste reforms should be retained.

The argument to reject homoeopathy is not just based on its coloniality, but chiefly on the lack of evidence for efficacy, some evidence for lack of safety, no substantive progress on mechanisms of action in the last century, and homoeopathic practitioners’ escapist arguments.

Homoeopathy’s supporters offer testimonials from luminaries such as Gandhi and Tagore. But Gandhi’s writings have scant mentions. We could not find any archival evidence of favourable comments by Tagore. Hence, decolonisation cannot be a reason to support homoeopathy.

India’s path to universal health care must be grounded in evidence-based and ethics-driven medicine.

### AYUSH

**AYUSH** stands for the medical systems practiced in India, which include **Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homeopathy**.

These systems are founded on well-defined medical philosophies, emphasizing a healthy lifestyle with proven concepts for disease prevention and health promotion. All of these systems adopt a holistic approach to health, disease, and treatment.

### Integrated System Of Medicine

An integrated healthcare system involves the fusion of diverse medical approaches, including conventional medicine, traditional practices, complementary therapies, or alternative medicine. The primary objective is to deliver all-encompassing and patient-centric care.

### Universal Health Coverage

The United Nations defines UHC as “everyone, everywhere should have access to the health services they need without risk of financial hardship.”

- Sustainable Development Goals target 3.8 (“Achieve universal health coverage, including financial risk protection, access to quality essential healthcare services and access to safe, effective, quality and affordable essential medicines and vaccines for all”) also focuses on achieving universal health coverage.

## Efficacy and Safety of Homoeopathy

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- In the evidence-based medicine ladder, the topmost rung is **systematic reviews** and **meta-analyses** that **exhaustively pool and critically appraise evidence** from existing studies.
  - Multiple systematic reviews and meta-analyses have found that, across ailments, population groups (adults versus children), study types (placebo-controlled versus other trial types), and treatment regimes (individualised versus non-individualised), homoeopathic treatments lack clinically significant effects.
  - Reviews that somewhat support homoeopathy's efficacy also caution over the low evidence quality and raise concerns about its clinical use.
- Recently, researchers demonstrated that more than half of the **193 homoeopathic trials** in the last two decades were **not registered**.
  - Unregistered trials showed some evidence of efficacy but registered trials did not.
  - There was reporting **bias** and other **problematic practices**, throwing the validity and reliability of evidence thus generated into doubt.
- Further, the World Health Organization (WHO) has warned against homoeopathic treatments for HIV, tuberculosis, and malaria, as well as flu and diarrhoea in infants, saying it has “no place” in their treatment.
- Evidence is accumulating that homoeopathy does not work for cancers and may not help to reduce the adverse effects of cancer treatments, contrary to lay belief.
- Instead, treatments have been linked to both non-fatal and fatal adverse events as well as their aggravation.
- Seeking homoeopathic care also delays the application of evidence-based clinical care. In several cases, it has caused injuries and sometimes death.

Homoeopathic treatments lack clinically significant effects

Many homoeopathic trials not registered

Bias and problematic practices

WHO says homoeopathic treatments has “no place” in their treatment.

Delays the application of evidence-based clinical care.

## Homoeopathy

- Homoeopathy was introduced in 1839 in India by Austrian physician J.M. Honigberger.
- Homeopathy is a medical system based on the belief that the body can cure itself. Those who practice it use natural substances like plants and minerals to treat the disease. They believe these stimulate the healing process.
- This is based on the idea that a substance that causes symptoms in a healthy individual can stimulate the body's natural healing response to overcome similar symptoms in an ill person.

While defining traditional medicine can be subjective, homoeopathy was introduced quite recently in India's history during the colonial period for colonial benefit. Hence, its traditional tag is untenable. Of course, not all colonial-era practices need to be surrendered.

- Those with health and developmental benefits such as evidence-based elements of allopathic medicine and gender role and caste reforms should be retained.
- The argument to reject homoeopathy is not just based on its coloniality, but chiefly on the lack of evidence for efficacy, some evidence for lack of safety, no substantive progress on mechanisms of action in the last century, and homoeopathic practitioners' escapist arguments.

### Principles of Homeopathy

#### The Law of Similar

- Homeopathy follows the principle that a substance that produces symptoms in a healthy person can be used to treat similar symptoms in a sick person.

#### Minimum Dose

- Homeopathic remedies are prepared through a process of dilution and potentization, which involves repeatedly diluting the original substance and shaking it vigorously. The belief is that this process enhances the remedy's healing properties while minimizing any potential toxicity.

#### Individualization

- Homeopathy treats each person as a unique individual and tailors the treatment to address their specific symptoms and overall constitution.

#### Totality of Symptoms

- Rather than focusing solely on a specific disease or isolated symptoms, homeopathy takes into account the totality of a person's physical, mental, and emotional symptoms to find an appropriate remedy.

### Issues with standards and claims of Homeopathy

Homoeopathy's **supporters argue** that the standards commonly used in evidence-based medicine are not suitable for judging the "holistic effects" of homoeopathy. This claim can be debunked.

Homoeopathy has its long historical usage and widespread popularity. Around the world, more than 300 million people in at least 70 countries use homoeopathy either alone or in combination with other care to treat themselves.

Homoeopathy is popular in India and Africa and is getting popular in the UAE, Iran, Singapore, Japan and also in China.

Historical Usage

Individualization of Treatment

Minimal Side Effects

Holistic Approach

Anecdotal Testimonials

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epidemiologists, biostatisticians, quality improvement researchers, implementation managers, and several others, beyond clinicians.

- These methods have weeded out practices in allopathic medicine that failed to meet the evidence criteria.
- Further, multiple disciplines such as psychology, economics, community health, implementation science, and public policy, beyond medicine have successfully adapted evidence synthesis methods to establish their claims.
- **Second**, Homoeopathy advocates have failed to invent valid alternative evidence synthesis frameworks suited for testing its efficacy and safety, which are also acceptable to the critics.
- **Third**, the claim about homoeopathy being holistic is typically paired with evidence-based medicine being “reductionist”.
  - In 2023, most exponents of evidence-based medicine are aware and accepting of biopsychosocial approaches toward health endorsed by WHO — predominantly composed of evidence-based medicine practitioners and supporters.
- **Fourth**, evidence-based medicine does not and should not stop at establishing empirical evidence.
  - The quest is also to discover and explain the mechanisms underlying the evidence.
  - In the last century, there has been no concrete evidence for proposed mechanisms of action for homoeopathy.
  - No mechanistic (molecular, physiological, biochemical, or otherwise) evidence to explain how concepts such as “like cures like”, “extreme dilution”, and “dematerialised spiritual force” result in better health. In the same period, several allopathic/modern medicine practices have updated themselves based on growing scientific evidence.

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## Way Forward



- ✓ **Prioritizing of Safety & Efficacy:** The current drive to incorporate 'AYUSH' medicinal practices into mainstream healthcare, aiming for universal health coverage and promoting a more inclusive approach to medicine, necessitates that each participating system adheres to fundamental safety and efficacy standards.
- ✓ **Evidence with Ethics:** India's journey towards achieving universal healthcare must be founded on the principles of evidence-based and ethically-guided medicine.

- ✓ **Evidence-Based Medicine:** India should give utmost importance to evidence-based medicine within all healthcare systems, including homeopathy. Thorough research, clinical trials, and systematic reviews must be undertaken to assess the effectiveness and safety of homeopathic treatments.
- ✓ **Integration and Pluralism:** India ought to embrace a well-rounded healthcare approach that combines different medicinal systems, such as allopathy and AYUSH. This should be done with a focus on integrating evidence-based and efficient practices into the mainstream healthcare system.
- ✓ **Regulatory Oversight:** Enhance the capacity of regulatory authorities to supervise homeopathic practices, ensuring strict compliance with quality standards and ethical principles. By doing so, we can safeguard patient safety and cultivate confidence in the healthcare system.
- ✓ **Awareness & Education:** In order to foster informed decision-making and uphold the right to choose, it is essential to promote education and raise awareness on the subject. This approach will aid healthcare professionals and the general public in understanding the advantages and limitations of homeopathy.
- ✓ **An Ongoing Process & Continuous Improvement:** To become better is an ongoing process and for that proper research, evidence and clinical trials should be performed in an accountable and transparent manner.
  - The healthcare system will become more responsive and effective by consistently evaluating and revising the incorporation of homeopathy and other medical systems, considering emerging evidence and evolving healthcare demands. This ongoing process ensures an improved and adaptive healthcare approach.
- ✓ **Holistic Health Approach:** Promote a comprehensive healthcare approach that addresses not just physical symptoms, but also incorporates mental, emotional, and social well-being. This inclusive methodology must be seamlessly integrated across all medical systems, including homeopathy.