# Policy and Research Methodology For Traditional Medicine

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# AYUSH Policy and Vision 20130

## Aligned to United Nations SDGs

- **Good Health and Wellbeing is the third Sustainable Development Goals (SDG 3) identified by UNDP.**
- SDG 3 aspires to ensure health and well-being for all, including a bold commitment to end the epidemics of AIDS, tuberculosis, malaria and other communicable diseases by 2030.
- It also aims to achieve universal health coverage, and provide access to safe and effective medicines and vaccines for all. Supporting research and development for vaccines is an essential part of this process as well as expanding access to affordable medicines.
-

# AYUSH Relevance

- Ayurveda and AYUSH systems have given top priority to ‘Health’
- It is evident that just the Medicine or drugs would not be sufficient to make the nation Healthy.
- Every system of medicine has certain strength areas, which could be utilized to bridge the gaps in the health care needs.
- It requires building upon the rich cultural heritage, in which are embedded the scientific principles for promotion of health and simple applications to take care of minor ailments at the primary level. India has adopted pluralistic system of medicine.
- Many disease conditions having no solution in modern medicine can be managed with AYUSH systems. AYUSH systems are affordable, acceptable to the community and are largely safe.

# AYUSH vision

- We vision to achieve, AYUSH as the status of first choice for prevention of diseases and for first line of treatment for commonly occurring diseases. The Ministry aspires to widen the AYUSH health care infrastructure to every village by 2030 to ensure **Easy accessibility** to the cost effective, safe and well accepted AYUSH health care delivery.
- India has large infrastructure of AYUSH consisting **7,87,564 registered AYUSH practitioners**, **24,289 dispensaries, and 3277 hospitals with 62,649 bed capacity**.
- Use of IT and Tele-communication should also be introduced to increase the AYUSH outreach to far-flung remote areas, for documentation, analysis and research.

# Policy highlights

- **Special drive for promotion and easy accessibility of Ayurveda services countrywide-**
  - Creating Ayurveda Public Health care infrastructure at every level i.e. at panchayat/village level, PHC etc.as well as District Hospital,
  - To develop tertiary care facilities by opening Ayurvedic Specialty treatment Centers at premier hospitals like AIIMS, PGI Chandigarh etc. as well as standalone Ayurvedic Hospitals
  - Improving supply chain of Ayurvedic drugs for easy availability of Ayurvedic medicines. Free distribution of Ayurvedic medicines at all public health services may be ensured.
  - Ayurvedic drug stores may be opened near all public health care centers on PPP basis. Classical Ayurvedic drugs may be made available @ 50% rate of MRP.

# Act amendments

- **Amendment in various Acts / development of New Acts to have common legal provision for all recognized medical systems.**
  - A common Act for 'Licensed Medical Practitioners', which would define and regulate practitioners of Allopathy as well as Ayurveda (ISM&H) under one category. This new Act proposed here, would put all medical professionals on same ground providing them equal opportunity, status and dignity.
  - A common D&C Act for Allopathy and Ayurveda defining the drugs of both systems under one definition. At present although both the systems are ruled under common D&C Act, even then there are different chapters for different system drugs defining the drugs separately.

# Integration and Mainstreaming

- **Integration of Ayurveda in all National Health programs-** In the 11th plan attempts have been made for physical integration of Ayurveda in NRHM (Deployment of Ayurveda graduates at PHC). However, not a single Ayurveda drug is being administered under any of the NHPs. The true integration could be achieved only after functional and philosophical integration of Ayurveda in various National Health Programs.
- **Special Ayurveda specific Health programs with adequate budgetary provision.-** Ayurveda has special strength in Mother and child care (MCH), prevention and control of Non Communicable diseases, Geriatric Health care. Special Ayurvedic National Health Programs should be developed to strengthen health care infrastructure.

# AYUSH in Public Health

- **Creation of Ayurveda specific Health care infrastructure in public sector on lines of DH, CHC, PHC**
- **Creation of Ayurveda Directorate and Directorate General of Ayurveda at Center.** There should be Directorate General of Ayurveda headed by Director General of Ayurveda- a Secretary level officer at the Central level supported by other ranks. Similar structure should be created at State level.
- **Special tax benefits to investors for investment in Ayurveda Hospital/ industry sector.-** Such provisions may attract venture capitalist in Ayurveda sector for investment in development of Hospitals etc.

# Industry and International

- **SEZ kind of special provisions for Ayurveda industry that includes Pharma sector as well as Hospitals.**
- **Close association with UN agencies-** Presently there is no close working linkage between Dept. of AYUSH and UN agencies like UNICEF, WHO, UNDP etc. Close working relationship should be established between UN agencies and Dept. of AYUSH.
- **WHO should have Ayurveda representative at Geneva HQ, WHO SEARO as well as WHO Country office.**

# Ayurveda Education

- Dept. of Ayurveda should be opened in all conventional Universities under UGC. This initiative would widen Ayurveda knowledge and interaction with other science streams. Thus research in Ayurveda could be promoted.
- Basic Ayurveda education could be made available to MBBS/MD students as Credit course / elective.
- Ayurveda and Yoga should introduced as part of training to IAS/IFS.

# Research Methodology and Evidence based Ayurveda

# What is the Right Evidence?

- Scientific evidence relies more on observations and well controlled, reproducible experimental results to support, refute, or modify any hypothesis or theory
- Evidence by definition is ‘the available body of facts or information indicating whether a belief or proposition is valid’
- Evidence is important for medicine to ensure safe, effective therapy
- Scientific Evidence is a rigorous process applicable to any system.
- It relies on cause – effect relationship

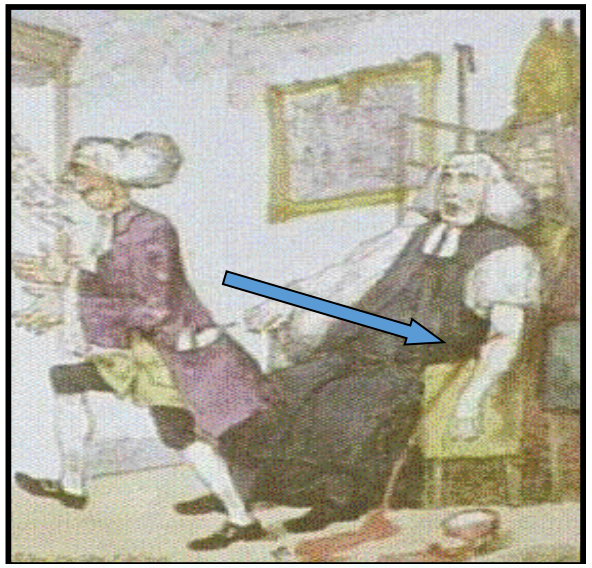
# Sir Bradford Hill Nine criteria for Causation

- **Strength of the association.** How large is the effect?
- **The consistency of the association.** Has the same association been observed by others, in different populations, using a different method?
- **Specificity.** Does altering only the cause alter the effect?
- **Temporal relationship.** Does the cause precede the effect?
- **Biological gradient.** Is there a dose response?
- **Biological plausibility.** Does it make sense?
- **Coherence.** Does the evidence fit with what is known regarding the natural history and biology of the outcome?
- **Experimental evidence.** Are there any clinical studies supporting the association?
- **Reasoning by analogy.** Is the observed association supported by similar associations?

# Smoking and lung cancer: Classic case

1. **Strength of Association.** *"The lung cancer rate for smokers was quite higher than for non-smokers*
2. **Temporality.** *Smoking in the vast majority of cases preceded the onset of lung cancer*
3. **Consistency.** *Different methods (e.g., prospective and retrospective studies) produced the same result.*
4. **Theoretical Plausibility.** *Biological theory of smoking causing tissue damage which over time results in cancer in the cells was a highly plausible explanation*
5. **Coherence.** *The conclusion (that smoking causes lung cancer) "made sense" given the current knowledge about the biology and history of the disease*
6. **Specificity in the causes.** *Lung cancer is best predicted from the incidence of smoking*
7. **Dose Response Relationship.** *Data showed a positive, linear relationship*
8. **Experimental Evidence.** *Tar painted on laboratory rabbits' ears was shown to produce cancer in the ear tissue over time. Hence, it was clear that carcinogens were present in tobacco tar.*
9. **Analogy.** *Induced smoking with laboratory rats showed a causal relationship. It, therefore, was not a great jump for scientists to apply this to humans*

# Bloodletting



n letting blood from a woman's arm as a physician looks on. Old painting by a
Flemish painter, 18th (?) century. Courtesy, Wellcome Library, London.

3000years ago

Egyptians, Greeks then Romans, Arabs and so on.

The cure for (hot, moist diseases) several medical conditions.

Galen was able to propagate his ideas through the force of personality and the power of the pen

# Pierre Louis (1787-1872)

Inventor of the “numeric method” and the “method of observation”

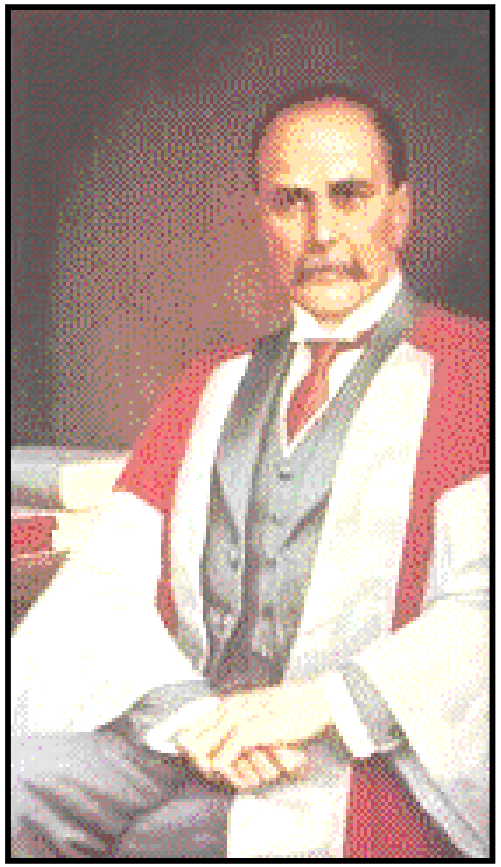
French physician who wanted to analyze the efficacy of bloodletting in the treatment of acute pneumonia

Examined the clinical course and outcomes of 77 patients

Concluded that effect of bloodletting procedure was actually much less helpful than has been commonly believed

# William Osler (1849 -1919)

First “attending physician” at Johns Hopkins



Author of hugely influential textbook, 'The Principles and Practice of Medicine' ***still advocated blood-letting*** in some cases

# From Acumen to Evidence

- Abraham Flexner's landmark report in the year 1910 revolutionized medical education in the US and propelled significant growth in biomedical research and development
- Medicine became too specialized and the sight of the whole picture became bleak.
- It strengthened scientific research and clinical practice confluence by creating physician scientists as against just medical practitioners
- This resulted in many scientific collaborations, projects and discoveries resulting in a huge increase in scientific literature in the field of medicine.
- During 2000 to 2013 just in 13 years almost 10 times more citations can be found than all put together in last 100 years.
- Due to increased impetus on science and technology related research there is significantly high quantity of quality scientific literature.
- Critical analysis of scientific information as evidence and decision support for medicine

# Search of Evidence

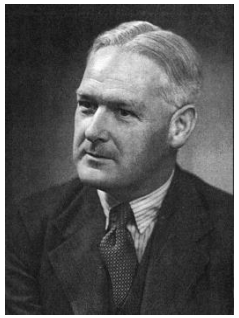
- Medical practice - observations from clinical experience, diagnostic tests, efficacy of treatment.
- Study of basic pathophysiologic principles as a guide for clinical practice
- Rigorous medical training and experiential clinical acumen was sufficient
- Decision making - experience, expertise, opinions and clinical acumen.
- Scientists raised the bar of evidence base with state-of-the-art in prognosis, diagnosis, prevention and treatment for better medicine.
- Work of famous scientist Archie Cochrane, systematic review, meta-analysis revolutionized RCTs interpretation
- Empowered clinicians and researchers decision making

|| विना तर्केण या सिद्धिः यदृच्छा सिद्धिरेव सा ||
चरकसंहिता

Outcome without logic or evidence is just a coincidence

# Some milestones in the history of EBM

**James Lind**
publishes review & clinical trial in *Treatise on Scurvy*



**Bradford-Hill**
publishes *Principles of Medical Statistics* &
MRC trial of streptomycin

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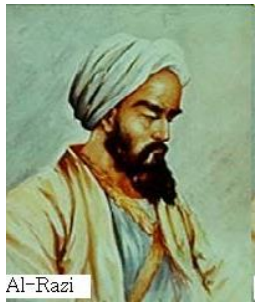
900 AD | 1780 | 1840 | 1937/48 | 1967 | 1970's

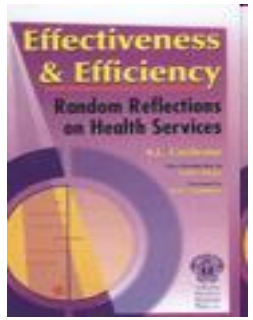



Al-Rhazi

For I once saved one group by it, while I intentionally neglected another group. By doing that, I wished to reach a conclusion .


Pierre Louis
Develops his "numerical method" and changes blood letting practice in France

**Alvan Feinstein**
publishes his book *Clinical Judgement*

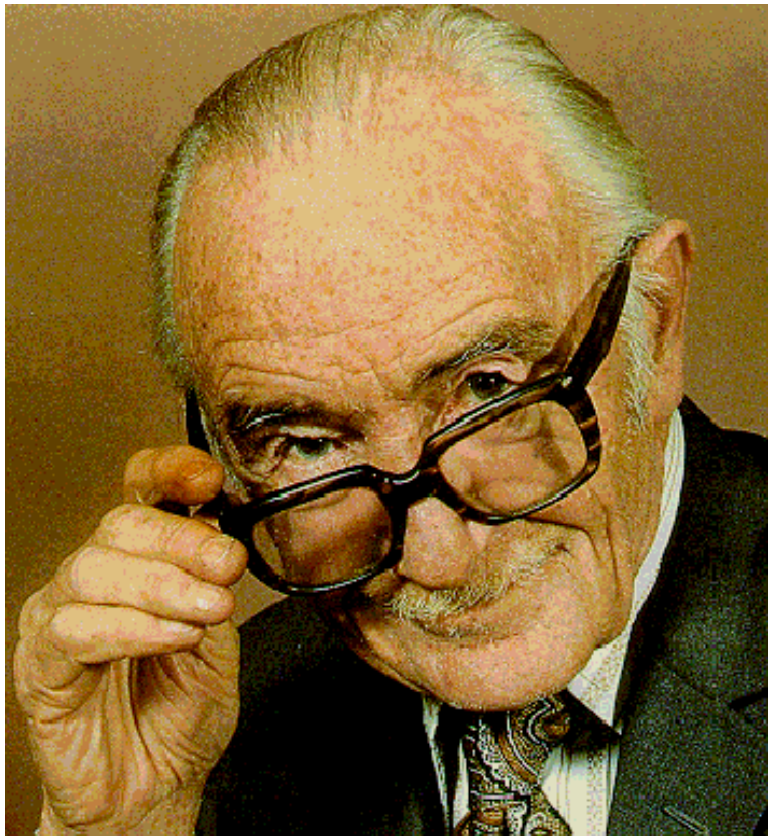


# Evolution of Evidence-Based Medicine

- McMaster University proposed a new approach, mechanism and process to bring more rational and analytical evidence for research based and research backed practice of medicine.
- Systematic reviews of medical literature, meta-analysis, risk-benefit analysis, and randomized controlled trials as evidence in everyday practice.
- Cochrane collaboration useful guidelines like CONSORT to improve clinical research
- The Grading of Recommendations Assessment, Development and Evaluation (GRADE) Working Group classify evidence in High, Moderate, Low and Very low quality.
- The strongest evidence for therapeutic interventions is provided by systematic review of randomized, triple-blind, placebo-controlled trials.
- Patient testimonials, case reports and expert opinions are not considered as strong evidence because of the incidences of natural remissions, placebo effect and the biases

# Prof Archibald Cochrane, CBE (1909 - 1988)

- The Cochrane Collaboration is named in honor of Archie Cochrane, a British researcher.
- In 1979 he wrote, **"It is surely a great criticism of our profession that we have not organized a critical summary, by specialty or subspecialty, adapted periodically, of all relevant randomized controlled trials"**



# Basic Principles of Evidence Based Medicine

1. **Conscientious** – being careful, and thorough, in what you do
2. **Explicit** – being “up-front”, open, clear and transparent
3. **Judicious** – using good judgement and common sense

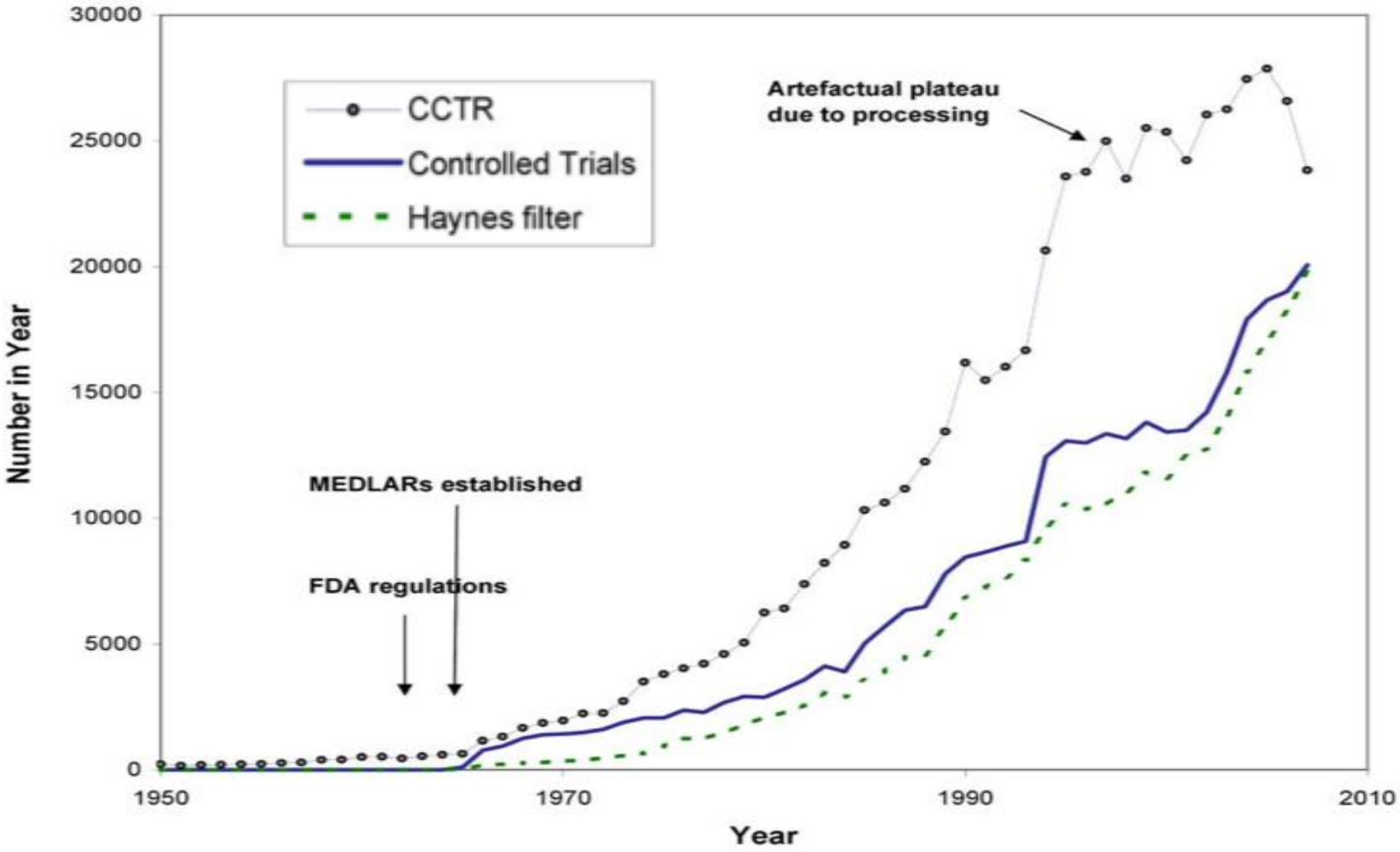
# EBM

- Sackett, et al. defined Evidence-Based Medicine (EBM) as ***"the integration of best research evidence with clinical expertise and patient values."***
  -- Sackett DL, Straus SE, Richardson WS, Rosenberg W Haynes RB. "Evidence-based Medicine: How to Practice and Teach EBM". Edinburgh: Churchill Livingstone.
- "EBM is nothing more than ***a process of life-long, self-directed learning in which caring for patients creates the need for clinically important information about diagnosis, prognosis, therapy, and other clinical and health care issues.***"
  -- The EBM Working Group

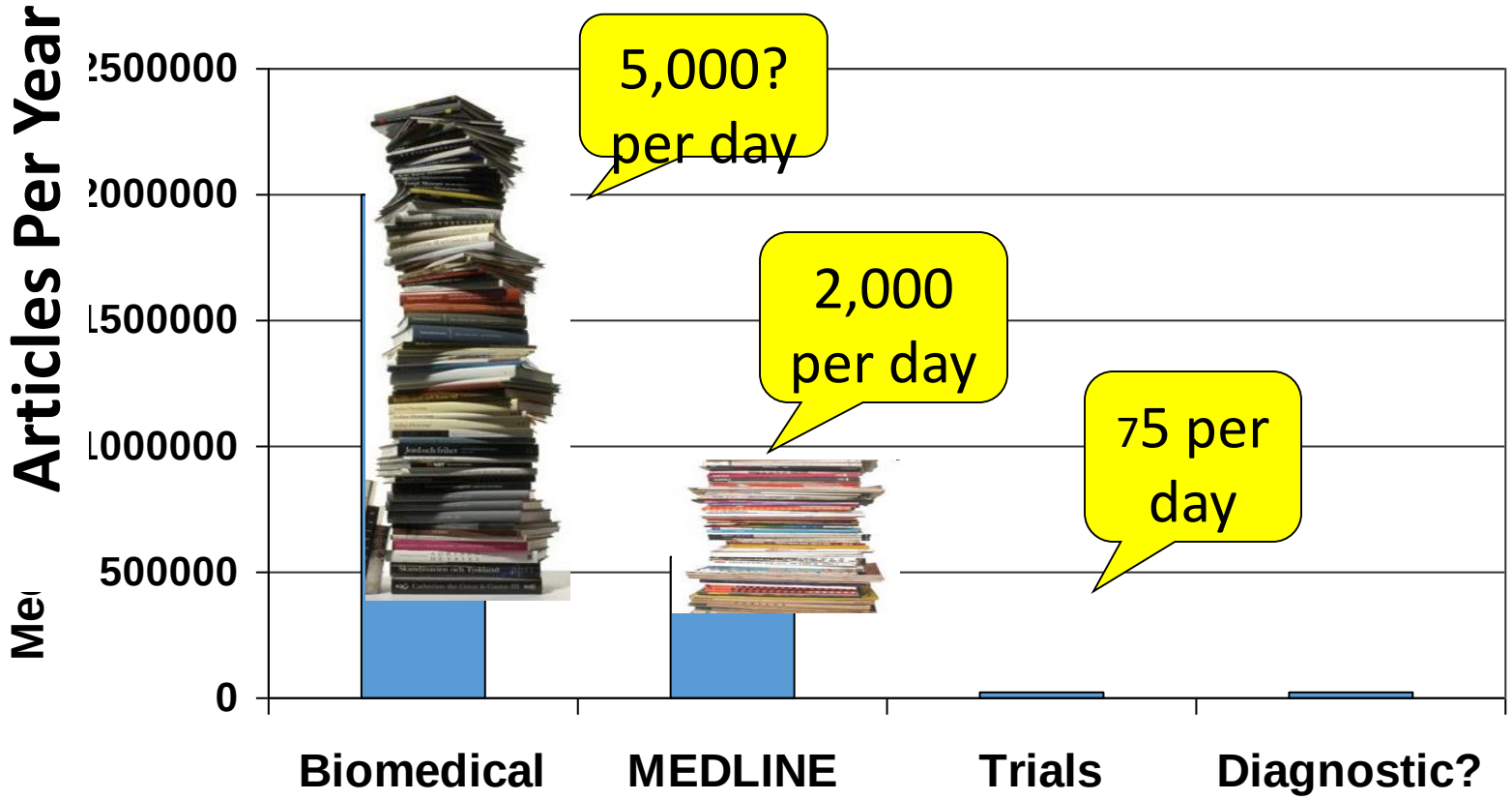
# Why the sudden interest in EBM?

- Increasing realization among clinicians that years of experience unaccompanied by updating of knowledge can result in decline of clinical performance
- The need for valid information about diagnosis, therapy, prognosis, and prevention in this era of consumer activism
- Explosion of knowledge and experimental data

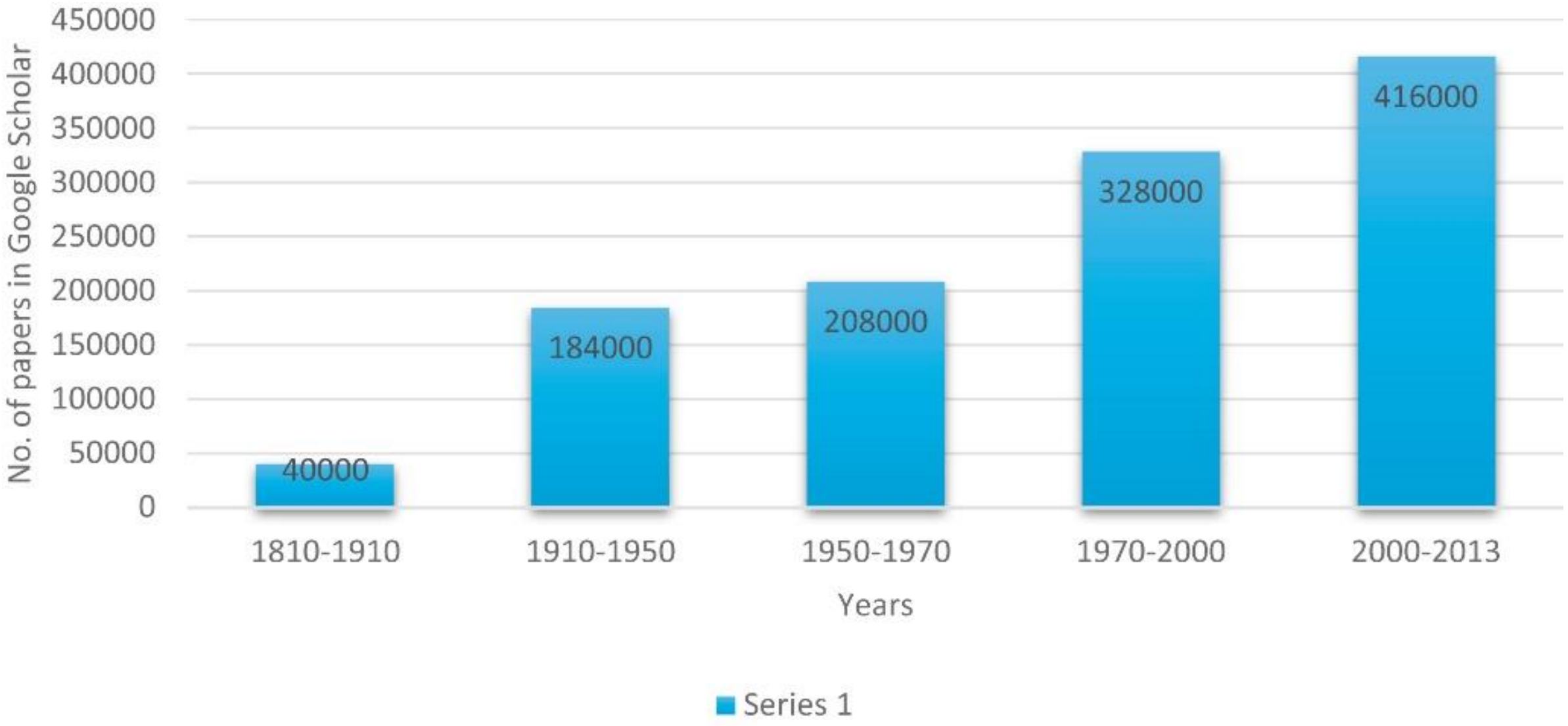
# Knowledge is increasing rapidly, we need better skills to keep up-to-date more efficiently than before



# Why do we need to use evidence efficiently? Knowledge is increasing rapidly, we need better skills to keep up-to-date more efficiently than before



# Sharp rise in medical literature

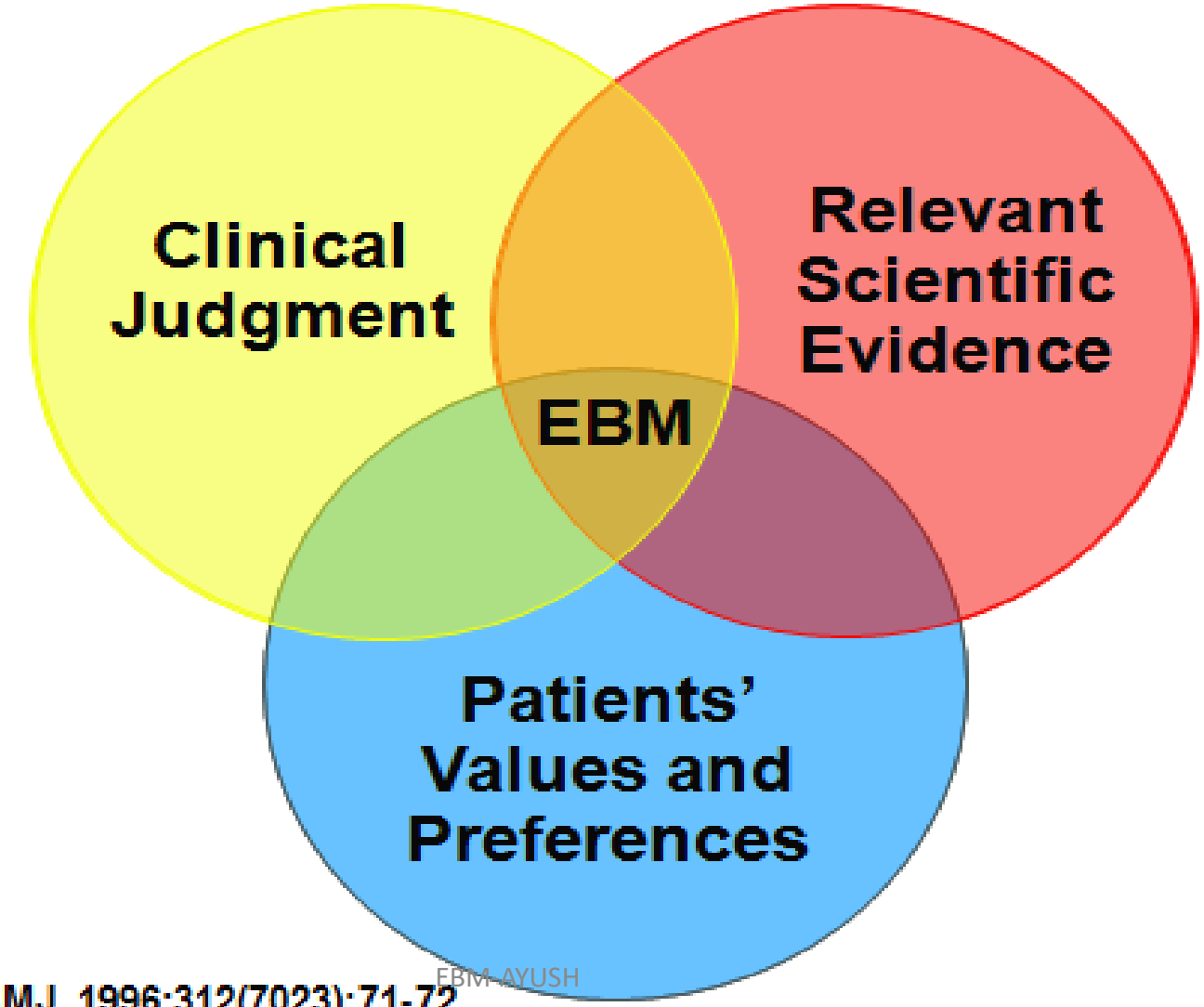



Integrative Approaches for Health: Biomedical Research, Ayurveda and Yoga, Chapter 4-1

# What are the benefits of adopting EBM?

- Get most updated reliable scientific information
- Minimize the errors in patient care
- Reduces the cost of treatment to the patient
- Optimizes the quality of patient care

# What Is Evidence-Based Medicine?

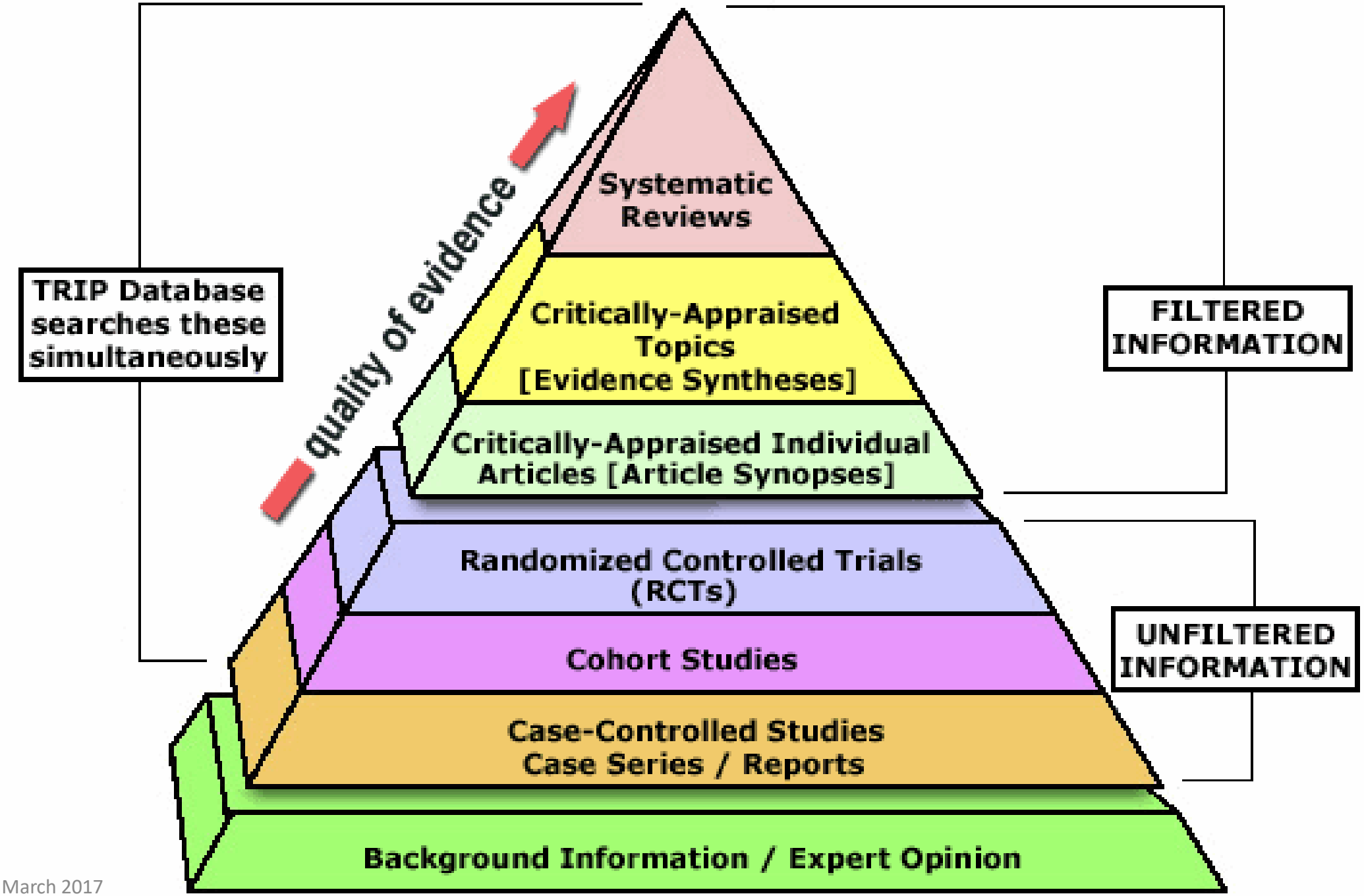


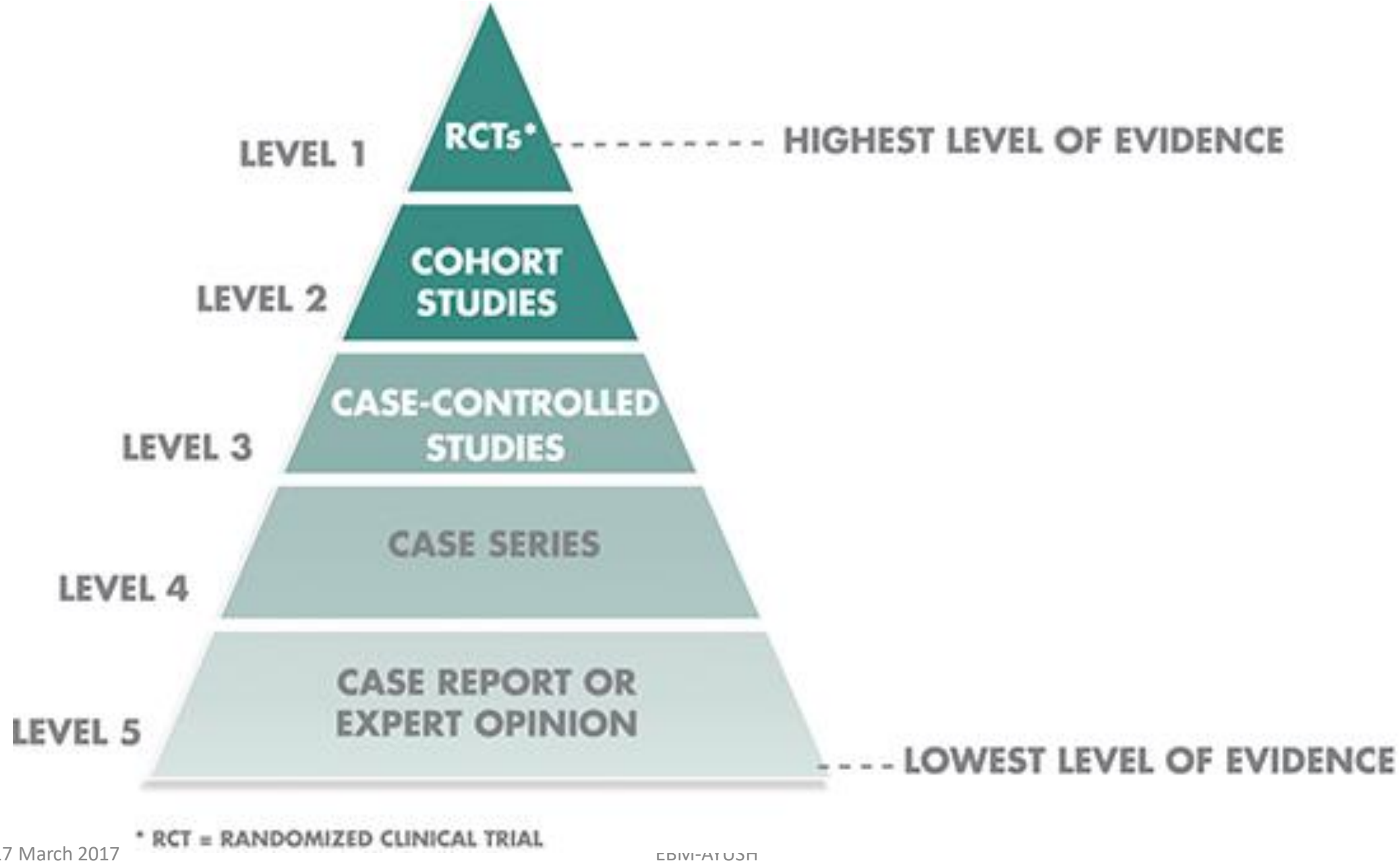

Sackett DL, et al. BMJ. 1996;312(7023):71-72.

# 5 A's of Evidence Based Practice Process


- Ask
- Acquire
- Appraise
- Apply
- Analyze

1. Converting information needs into focused questions.
2. Efficiently tracking down the best evidence with which to answer the question.
3. Critically appraising the evidence for validity and clinical usefulness.
4. Applying the results in clinical practice.
5. Evaluating the performance of the evidence in clinical application.


TRIP Database searches these simultaneously
quality of evidence
Systematic Reviews
Critically-Appraised Topics [Evidence Syntheses]
Critically-Appraised Individual Articles [Article Synopses]
Randomized Controlled Trials (RCTs)
Cohort Studies
Case-Controlled Studies Case Series / Reports
Background Information / Expert Opinion
FILTERED INFORMATION
UNFILTERED INFORMATION


LEVEL 1
RCTs*
HIGHEST LEVEL OF EVIDENCE
LEVEL 2
COHORT STUDIES
LEVEL 3
CASE-CONTROLLED STUDIES
LEVEL 4
CASE SERIES
LEVEL 5
CASE REPORT OR EXPERT OPINION
LOWEST LEVEL OF EVIDENCE
* RCT = RANDOMIZED CLINICAL TRIAL

## High Evidence Low Ethics

Commercialization

- Increased R & D costs
- Industry funded research
- Scientific frauds
- Desperation for profits
- Compromized ethics
- Corporate crimes
- Nexus with regulators and doctors

- Expensive medical education
- Fee-for-service culture
- Referral commission, Cut practice
- High costs of diagnostics equipments
- Desperate pharmaceutical industry

Value Systems

Integrative Approaches for Health: Biomedical Reesearch, Ayurveda and Yoga. Chapter 4-4

# High in Evidence Low in Ethics

- Scientists are working more for industry than for people
  - A systematic review - industry sponsored drug and device studies are often favorable to the sponsor's products
- Desperate Pharmaceutical Industry yielding to Unethical Practices
  - According to Public Citizen Report the drug industry had paid nearly $20 billion penalties during 20 years for violations of the False Claim Act
  - GlaxoSmithKline, Pfizer, Eli Lilly and Schering-Plough accounted for half of this
- Low Medical Ethics in Clinical Practice
  - Fee-for-service culture, referral commission, cut practice, prescription abuse
  - Increased commercialization of medical profession
  - Expensive medical education - pressure for early recovery
  - Investment intensive Diagnostics & Surgery making breakeven difficult

# Deteriorating Medical Ethics

in.reuters.com/article/2013/05/13/ranbaxy-settlement-felony-usa-idINDEE94C0DA20

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Tue May 14, 2013 3:42am IST

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## Police Say Sexual Favors Spur $1.5 Billion Glaxo China Sales

By Bloomberg News | Jul 16, 2013 4:27 PM GMT+0530 | 31 Comments Email Print

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**GlaxoSmithKline Plc's (GSK)** sales in China jumped 20 percent to about 1 billion pounds ($1.5 billion) last year, almost quadruple the pace of growth across its **emerging markets**. Police say bribes and sexual favors spurred the gain.

The drugmaker now faces allegations of economic crimes involving 3 billion **yuan** ($489 million) of spurious travel and meeting expenses, and trade in sexual favors, the Public Security Ministry said yesterday. The allegations are "shameful"


July 16 (Bloomberg) -- China is investigating at least four multinational drugmakers as it widens its probe of GlaxoSmithKline Plc, according to a lawyer in Hong Kong whose firm advises companies on cross-border anti-corruption. Olivia Sterns reports on

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*Health Care for Women International*, 34:513–521, 2013

ISSN: 0739-9332 print / 1096-4665 online
DOI: 10.1080/07399332.2012.721416

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## The Boom in Unnecessary Caesarean Surgeries Is Jeopardizing Women's Health

SAOJI AJEET and KASTURWAR NANDKISHORE
*Department of Community Medicine, NKP Salve Institute of Medical Sciences and Research Center, Nagpur, India*

*High caesarean birth rates present an issue of international public health concern. We explore the prevalence and sociodemographic and medical factors associated with cesarean-section births among*

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CBS Philly

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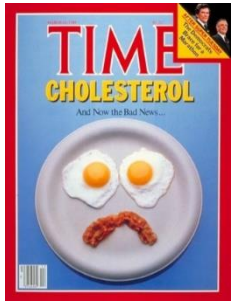


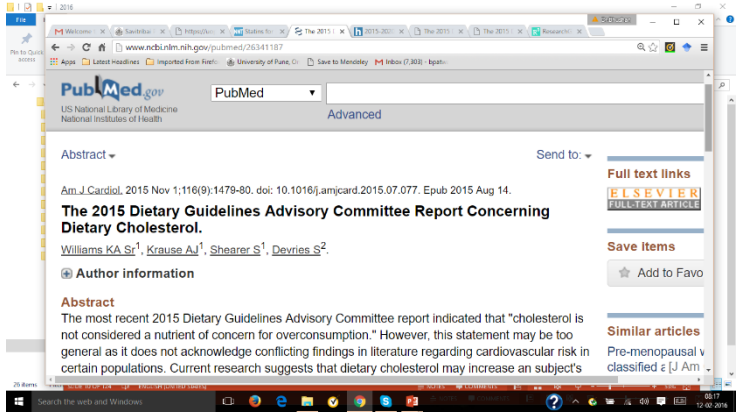

# Statin Story Evidence is Relative & Dynamic

## 30 Years of Time

- Lovastatin (1987)
- Pravastatin (1991)
- Atorvastatin (1997)
- Cerivastatin Withdrawals due to risk of rhabdomyolysis. (2001)
- Incidences of diabetes (2008-2009)
- First meta-analysis demonstrates statin-induced diabetes (2010)

- Simvastatin (1988)
- Fluvastatin (1994)
- cerivastatin (1998)
- Rosurvastatin (2003)
- Pitavastatin (2009)
- USFDA & EU added warning about diabetes risk to labels (2012)

Patent Expired





2014

# Absence of Evidence is NOT evidence of Absence

- Osteopathy, Acupuncture, Traditional Chinese Medicine and Homeopathy underwent huge turmoil while attempting scientific evidence
- Shang et al in their landmark study concluded that clinical effects of Homoeopathy are placebo effects.
- Inability to measure using scientific methods is not a proof of nonexistence
- TCM created large body of scientific evidence to support safety, pharmacology and clinical efficacy.
- Ayurvedic medicine also needs build scientific evidence with certain level of objectivity and consistency in clinical decision making

# THE CASE OF HOMEOPATHY

- Proponents indicate epistemological relationship to evidence ignored when studying complex interventions.
- Point out that clinically beneficial, phenomena can occur during homeopathic treatment.
- Homeopathic outcome measures different from conventional medicine.
- Comparative studies involving homeopathy and modern medicine need to be designed.
- Dr David Shaw (Institute of Biomedical Ethics, University of Basel, Switzerland): “It should by now be very clear that homeopathy is a form of faith healing”.

# PLACEBO AND NOCEBO EFFECTS

- Homeopathy: ineffective in animals, cell systems; favors its placebo effect.
- Maryland study: highly diluted homeopathic remedies for cancer show no measurable effects on cell growth, or gene expression, *in vitro*.
- Veterinary Clinical Research Database in Homeopathy (April 2012 ): 302 data records did not show homeopathic intervention better than placebo.
- Strengthens view that homeopathy is actually a treatment based on placebos.
- Dr Edzard Ernst (2010, Cochrane database): most reliable evidence fails to demonstrate that homeopathic medicines have effects beyond that of a placebo.

# PLACEBO AND NOCEBO EFFECTS

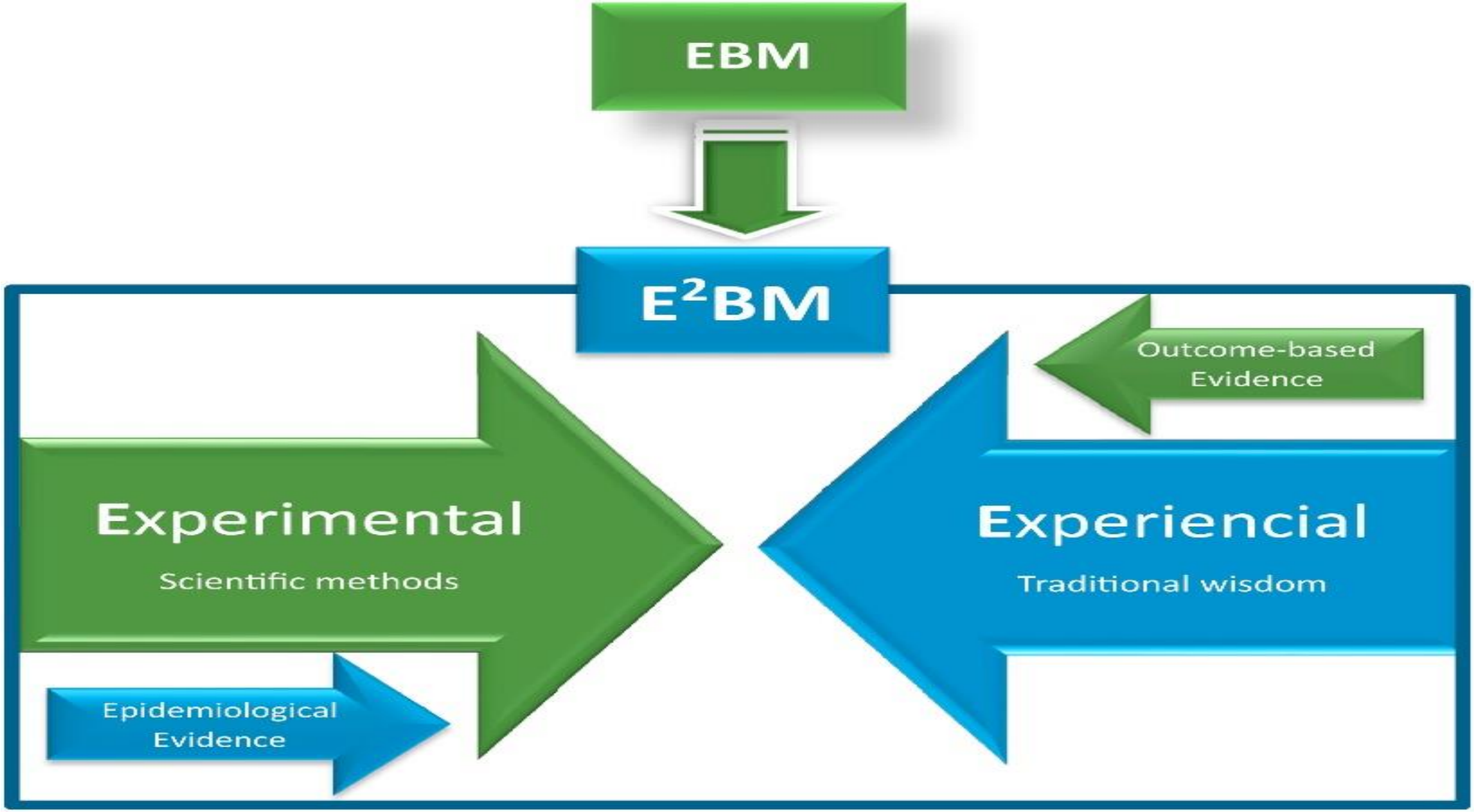
- Bias, variability, and confounders: challenges in clinical research
- Use of placebo one of the approaches to minimize investigators' and patients' biases.
- Placebo: inactive substance or preparation used as a control to determine effectiveness of a pharmaceutical preparation.
- Henry Beecher (1955): recognized the clinical importance of placebo effect.
- Placebo effect usually lasts only short time.
- Untoward effects of placebo: nocebo effect.

# We Need A Balance Between the Scientific Evidence and Traditional Experience

Evidence Based Medicine

AND

Experience Based Medicine


EBM
E²BM
Outcome-based Evidence
Experimental
Scientific methods
Experiencial
Traditional wisdom
Epidemiological Evidence

# Indian Way to Health & Wellness

- Renewed interest in complementary, alternative and traditional medicine
- Indian systems of medicine (AYUSH) can play a major role
- Holistic and integrative health approaches are gaining importance
- Non-pharmacology approaches such as lifestyle modifications, dietary adjustments, breathing exercises, meditation, Yoga and such affordable solutions can also be offered
- Ayurveda with advancements in science and technology can play a significant role to resolve present crises in healthcare.
- Ayurveda may offer a new route to healthy life style, treatment of syndromes as also to the discovery, development and delivery of new natural products with enhanced performance, better safety and efficacy at a significantly reduced price

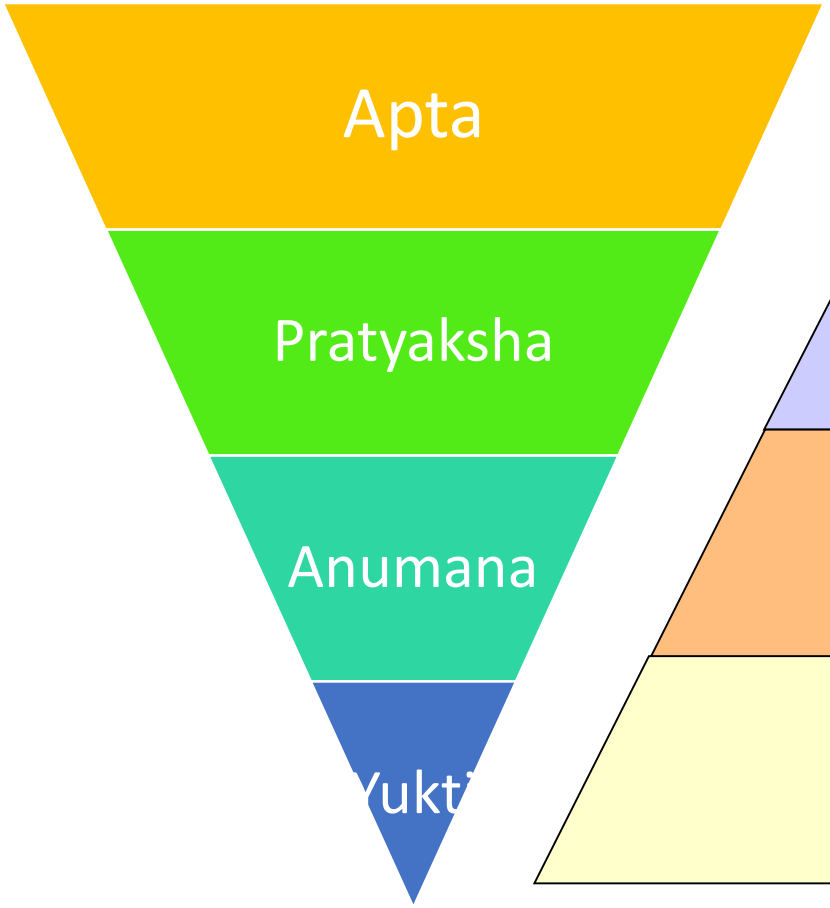
# Need for Scientific Research and Evidence

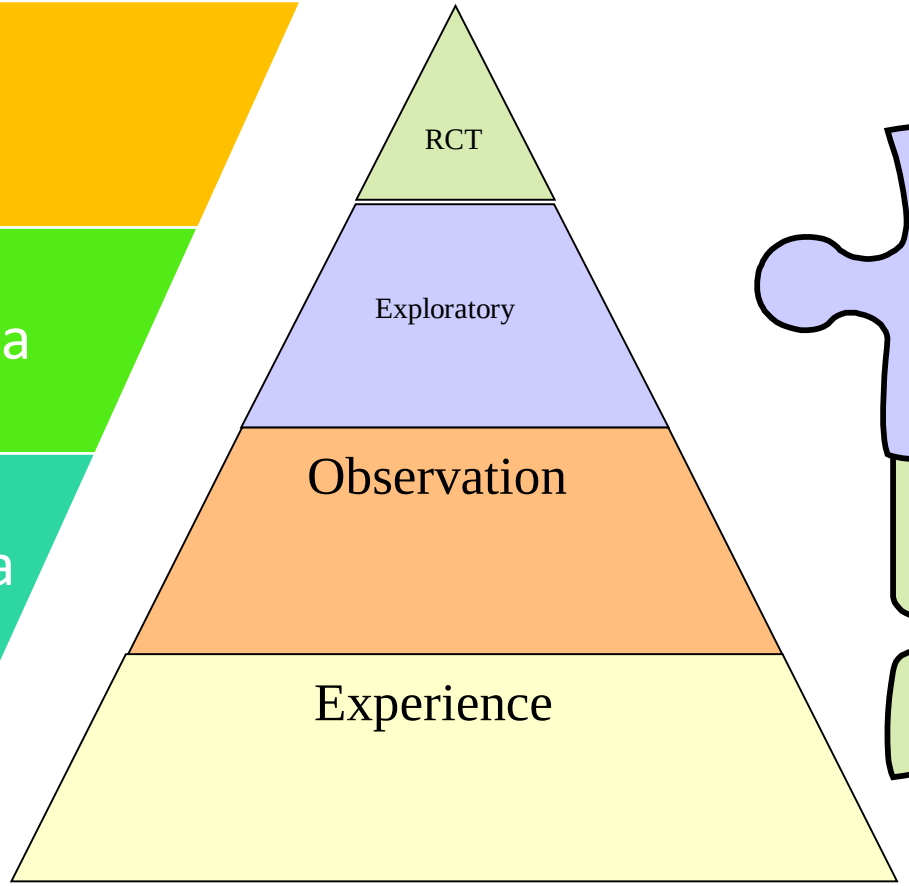
## Science is dynamic and so Ayurveda should be

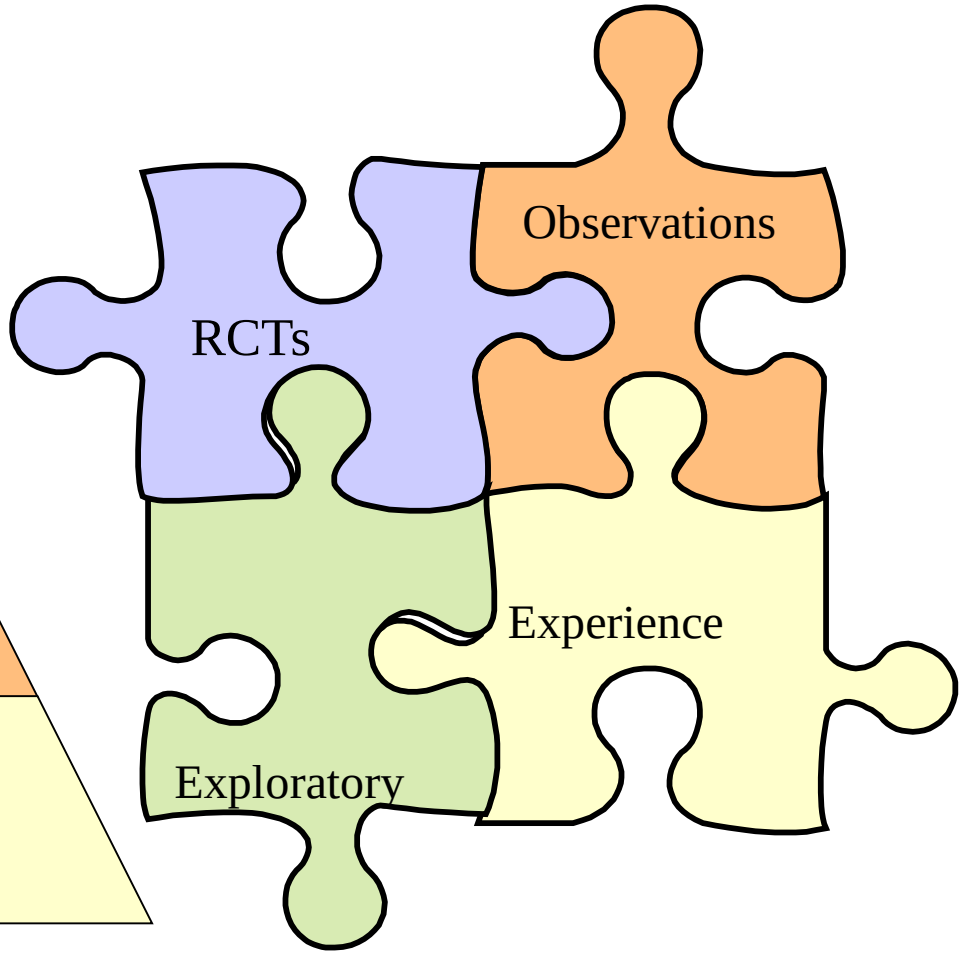
- The objective of any medical research should be to assess health effects, minimize bias, chance effects and confounders.
- Ayurveda needs contemporary scientific evidence
- The nature of evidence for Ayurveda may be different than that of western biomedicine.
- Need for appropriate models to demonstrate scientific evidence.
- Blend of modern science, rigorous trial methods and observational studies.

# Levels of Evidence & Clinical Judgment

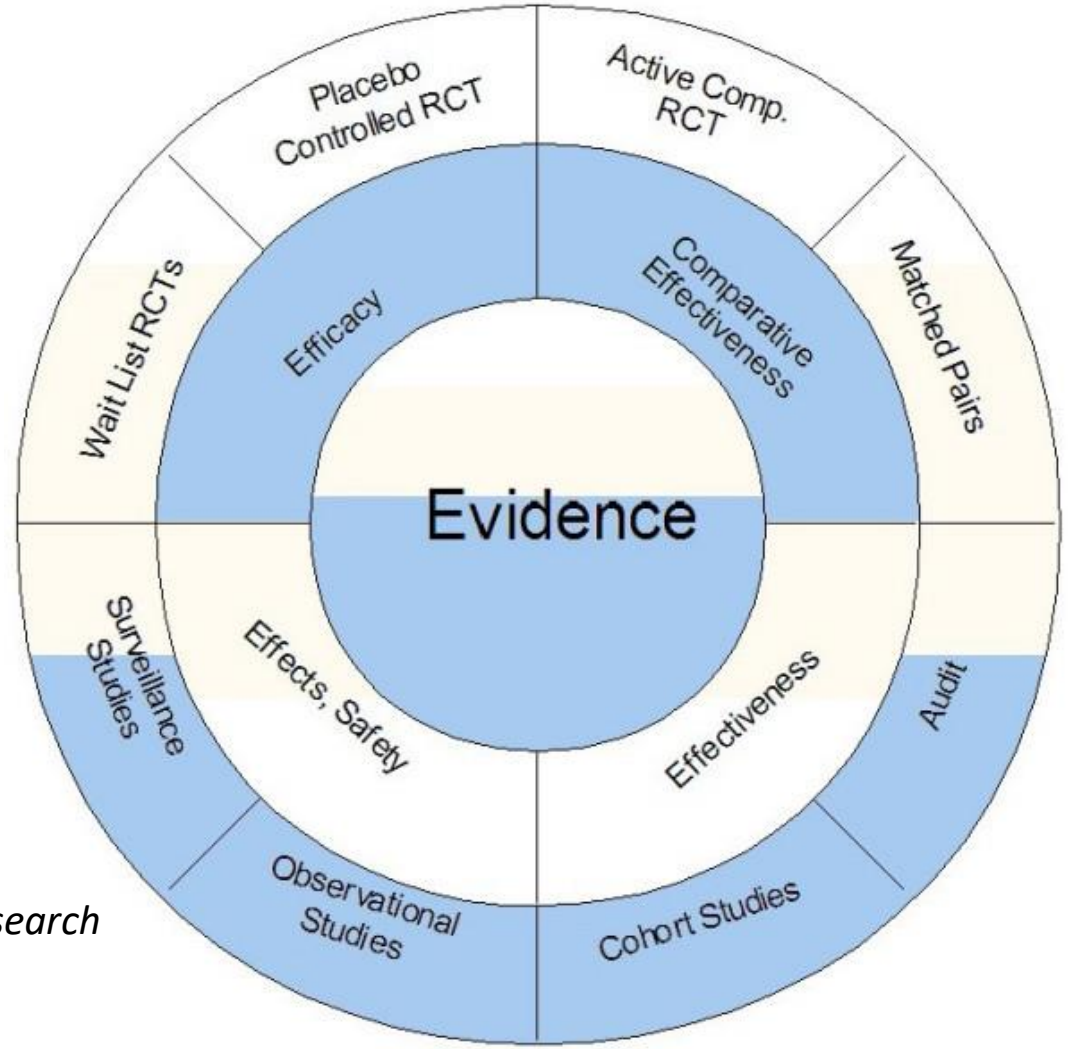
Observation ➔ Application of logic ➔ Consideration of multiple factors ➔ Conclusion



# Not Hierarchical Levels but Circular Evidence




*Walach et al BMC Medical Research Methodology* 2006, **6**:29

# Status of Ayurvedic Medicine

## Evidence and Experience

- Clinical Practice
- Scientific Evidence
- Patient Perception

# Ayurvedic Clinical Practice

- The clinical practice of classical Ayurveda is rare.
- Ayurvedic practitioners are reported to adopt allopathic practices for better acceptance in urban settings.
- Practice of Ayurveda draws significantly from the three classic Samhitas including Charak, Sushrut and Vagbhat, significant variations in clinical practice exist in different parts of India.
- Systematic data on actual use and evidence of reproducible outcomes is not available in public domain.
- Standard treatment protocols for practitioners are not available.

# Evidence for Clinical Practice

- 495 UG and 106 PG Colleges 3,277 Hospitals, 62,649 Beds, 8,644 Manufacturing units and 7,85,185 registered Practitioners and over Rs 1000 crores yearly budget,
- Hardly any systematic clinical data or analysis are available. Systematic documentation and reliable data on pharmacoepidemiology and pharmacovigilence for clinical practice, safety and adverse drug reactions is not available
- The status of professional, continuing education and attitudes of practitioners towards safety are worrying.
- No scientific or clinical data is required for manufacture and sale of classical Ayurvedic medicines
- Technically sound Pharmacopoeia, Good Manufacturing Practices, quality control and pharmaceutical technologies for Ayurvedic medicine are still evolving
- Appropriate research methodologies, treatment protocols have not been evolved
- Needs better coordination between stakeholders, dialogue with scientific community, curriculum and pedagogy overhaul and cross talks between different streams
- Evidence base to support good clinical practice, guidelines and documentation in Ayurvedic medicine remain scant and grossly inadequate

# Scientific Evidence

- Ayurveda lags far behind in scientific evidence in quantity and quality of randomized controlled clinical trials and systematic reviews
- For instance, out of 7864 systematic reviews in Cochrane Library, Ayurveda has just one, while Homoeopathy and TCM have 5 and 14 respectively
- Despite significant investments by reputed laboratories hardly any noteworthy outcomes in terms of products or protocols have emerged
- Ayurvedic medicine continues to remain subcritical in research publications as an important indicator of external evidence.

Scitometric search for specific terms using Google Scholar including papers, patents and citations

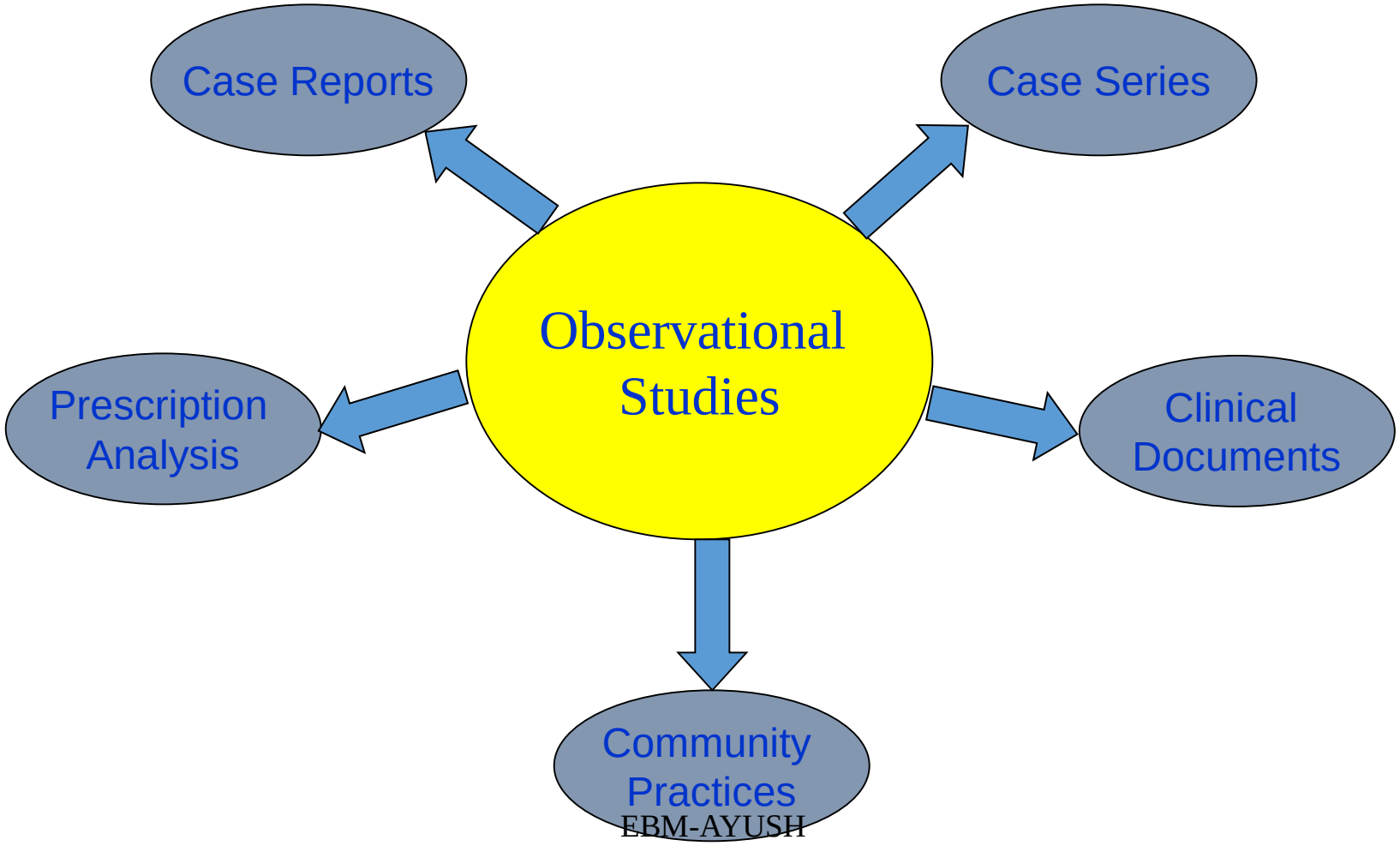
# Ayurvedic Medicine Need

- Needs serious discourse, fierce debate, studied evaluation, cautious claims and prudent implementation
- Need to go beyond mere scholarly recitals, reviews and defensive interpretations, which are abundant in current literature
- Needs to be studied, experimented with help of new models based on modern science and biology
- Need to develop epistemologically and culturally sensitive scientific research methodology for evaluating safety, quality and efficacy
- Needs government patronage, peer respect, scientific empowerment, professional confidence and capacity building, educational reforms, and above all unbiased and free exchange of innovative ideas leading to experimentation.

# Study Models and Protocols

- Basic concepts of Ayurveda should not be distorted to suit convenience or availability of biomedical research models.
- Prevailing pre-clinical methods and clinical models like RCTs may not be suitable to validate Ayurveda.
- The onus of developing suitable models to build evidence is on Ayurveda community.
- Some efforts in the direction to conduct the whole system clinical trials are already in progress.

# Observational Studies



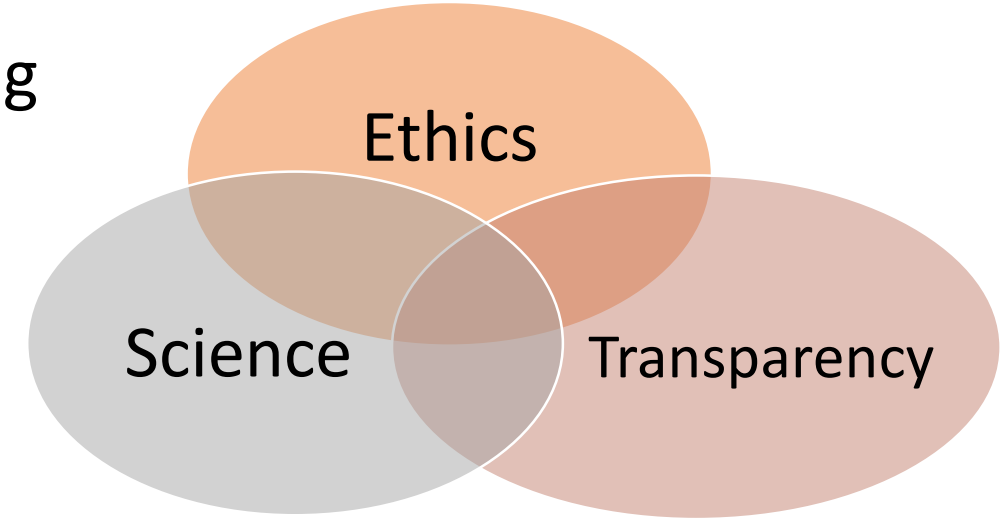
# Pharmacoepidemiology

- Many a times traditional practitioners and more so the healers, do not maintain clinical records. What weight one should give to traditional or observational experiences and how to bring in consistency and objectivity in clinical studies on TM still remains to be attended satisfactorily. The pharmacoepidemiological studies become important in such situations.

Vaidya R. et al. Ayurvedic Pharmacoepidemiology, J. Asso. Physicians India 2003.

# Development of Reporting Standards for Clinical Research in Ayurveda

- Take cognizance of important initiatives like STandards for Reporting Observational Epidemiology (STROBE) and CONsolidated Standards On Reporting Trial (CONSORT)
- Clinical trial reporting should be based on ethically conducted studies
- Honest and accurate reporting
- Minimize bias



# Where is Evidence based AYUSH? Should mere RCTs or statistics decide ???

- Rationale
- Experience
- Observation
- Documentation

- Safety
- Acceptability
- Availability
- Affordability

# Statistics is Not Simple


- A frequentist or classical statistician views probability as a long-run frequency when a tossed coin will land heads half the time.
- A Bayesian argues based on the symmetry of the coin where there is no reason to think that one side is more likely to come up than the other side.
- This is usually termed subjective probability and is used to describe uncertainty of a statement about an unknown parameter in terms of probability, which a frequentist cannot do.
- The US FDA has given detailed guidelines on use of Bayesian statistics for clinical research.
- Bayesian methods seem to be better suited for complex biological processes; population based studies and so may be better suited for Ayurveda.

bmj.com

# Parachute use to prevent death and major trauma related to gravitational challenge: systematic review of randomised controlled trials

Gordon C S Smith and Jill P Pell

*BMJ* 2003;327;1459-1461
doi:10.1136/bmj.327.7429.1459

**Conclusions** As with many interventions intended to prevent ill health, the effectiveness of parachutes has not been subjected to rigorous evaluation by using randomised controlled trials. Advocates of evidence based medicine have criticised the adoption of interventions evaluated by using only observational data. We think that everyone might benefit if the most radical protagonists of evidence based medicine organised and participated in a double blind, randomised, placebo controlled, crossover trial of the parachute.

**Any volunteers for this RCT?**

HULTON/GETTY

Parachutes reduce the risk of injury after gravitational challenge, but their effectiveness has not been proved with randomised controlled trials

# Key Factors for Evidence-Based Ayurveda

## Good Agricultural Practices for Natural Materials

**Ethical Bioprospecting** | **Traditional Knowledge Practices** | **Correct Identification**

Pharmacopoeia Monographs for Drugs and Formulations

Standardization and Quality Control

## Good Manufacturing Practices for Products

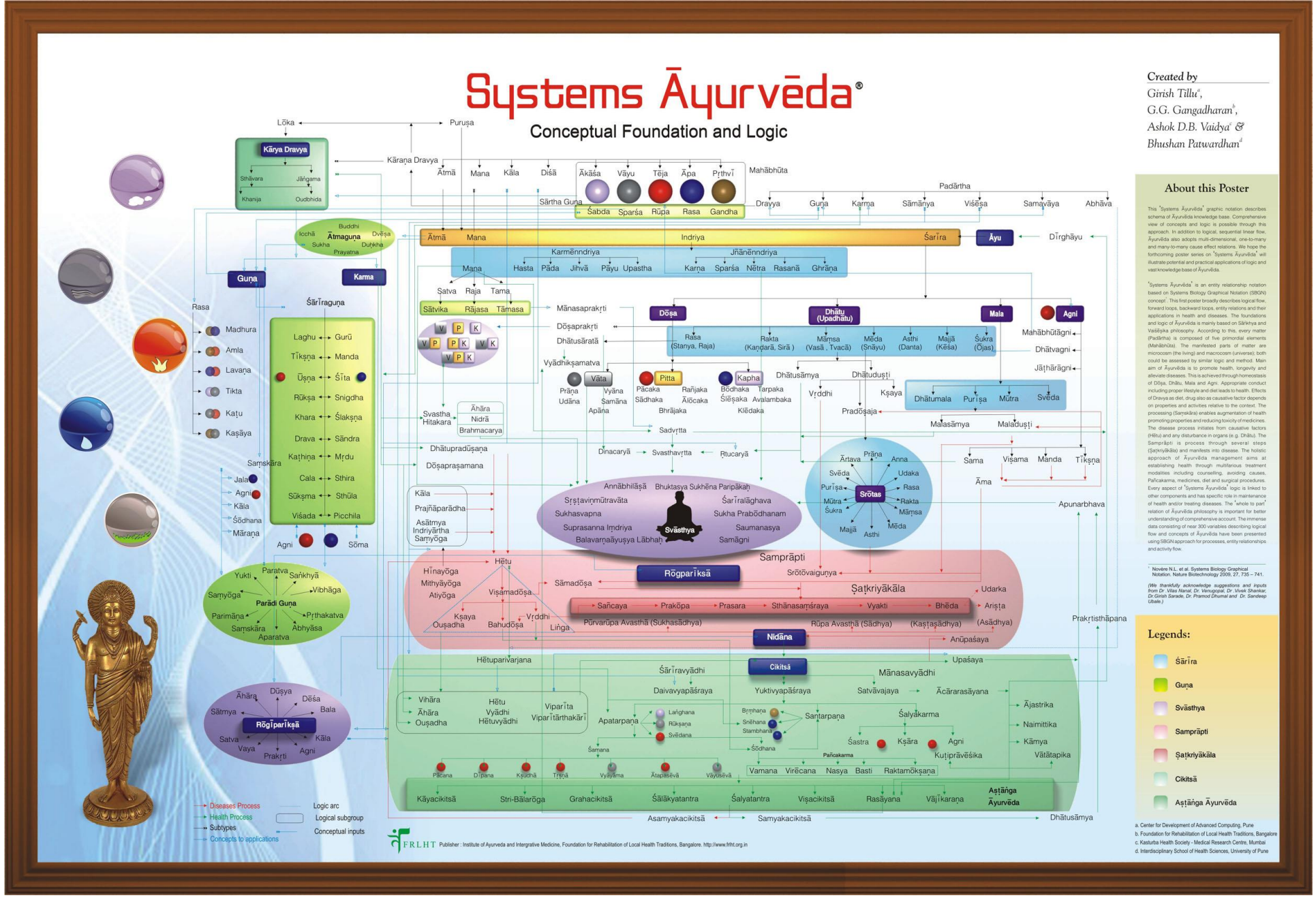
**Pharmacoepidemiology** | **Regulatory Compliance** | **Systematic Documentation**

Safety, Toxicity, Pharmacodynamic, Non Clinical

Documentation of Clinical Practice

## Good Laboratory & Clinical Practices for Research

Robust Protocols & Reporting Standards | Scientific Excellence | Collaborations | Systematic Reviews & Meta-Analysis | Controlled Clinical Studies


Systems Āyurvēda®
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Created by
Girish Tillu[a], G.G. Gangadharan[b], Ashok D.B. Vaidya[c] & Bhushan Patwardhan[d]
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Rōgaparīkṣā
Nidāna
Cikitsā
Kārya Dravya
Kāraṇa Dravya
Guṇa
Karma
Āyu
Dōṣa
Dhātu (Upadhātu)
Mala
Agni
Srōtas
Svāsthya
Pañcakarma
Aṣṭāṅga Āyurvēda
Publisher : Institute of Ayurveda and Intergrative Medicine, Foundation for Rehabilitation of Local Health Traditions, Bangalore. http://www.frlht.org.in