**Title:** Observational analysis of ayurvedic principles, ayurvedic hospital data, and patient outcomes

By Vinay Mahajan, Girish Tillu, Ashwini Mathur, Darshan Shankar

**Short background:** Ayurveda has been practiced over many centuries in India. It will be safe to assume that the conceptual developments in ayurvedic knowledge base have taken place through every day observations and basic laws of nature. These fundamentals have been adjusted to the relevant times as per the passage of time, which is quite evident from vast literary history of Ayurveda which covers subjects like pharmacology, principle of diagnosis and treatment for all branches of medicine and surgery, philosophical framework and logic, pharmacy and numerous pharmacopeias. Traditional texts enumerate more than described for each disease condition (1).

Generating credible evidence for such a large pool only through modern experimental means such as trials is very challenging. Current hierarchical evidence model is being challenged by methodologists and the circular model comprising observational research methods are proposed for CAM research (2). Ayurveda like any other system of medicine, is practiced more in clinics than in clinical research setting, where there are no artificial restrictions on usage of medicines, duration of treatment or type of patients to treat, which is next to impossible in a protocol driven clinical trial setting. To plug the gap of missing empirical evidence, systematic analysis of observational clinical data is required. (3, 4) This project is focused on I-AIM clinical data for study of efficacy and safety trends. In our study of modern regulatory framework, we recognized similarity between concepts written by Charaka and ICH guidelines. This will form the philosophical basis for the research question.

**Problem:** To develop a replicable clinical documentation and HMIS system in I-AIM hospital setting, that can generate reliable data on disease classification, treatment protocols and outcomes. To test this system for assessing clinical and patient reported outcomes in musculoskeletal and metabolic diseases at I-AIM hospital.

**What is the present status in understanding the problem?** The problem of observational data analysis is split into 4 parts and is presented below. Each of the problem area is explained, the specific actions and possible outcomes are outlined.

1. **Literature review: Philosophical commonalities between the ICH and ayurvedic system:** *Charaka Samhita* will be studied and interpreted on broad parameters used by ICH framework quality, efficacy and safety. This will provide philosophical connections between two systems and will create evidence base for the subsequent research work. This work is an effort to bridge the gap between ayurvedic and bio medicinal researchers. Furthermore, *Charaka Samhita* will be studied to understand diagnosis and treatment paradigm and outcome measures. To keep the work within practical limits we will focus on musculoskeletal and metabolic diseases. In depth study of various possible variations of the disease, treatment options, diagnostic and prognostic parameters will be carried out.

**Specific actions:**

1. Study ICH guidelines (quality, efficacy, safety) and *Charaka Samhita* (e.g. Vimana sthana) – see Appendix table 1 below
2. Diagnosis approaches (e.g. *Dashavidhapariksha*)
3. Treatment options (See Appendix figure 1)
4. Outcome measures (Ayurvedic as well as bio medicinal endpoints)
5. **Hospital data analysis methods:**

Over the years, digitization of the hospital data has helped analytic discoveries, rather than only the straight facts. The day to day hospital settings generate a multifold data than clinical trials. This revolution has not been used by the ayurvedic medical industry. These advances should be used to improve patient wellness, better clinical decisions, better care coordination, cut down treatment abuse, and even to cut down costs.

**Specific actions:**

1. Review of the literature to understand the current methods employed across world
2. Check for potential solutions to be implemented at hospital (e.g. patient data dash boards)
3. Provide suggestions for improvements in day to day functioning at hospital

**(3) Data analysis of Treatment SOPs and implementation:**

The I-AIM hospital has generated 91,000 patient visits data over the years and perhaps the largest electronically available ayurvedic treatment database. What insights would come out of such a large database? A study will be carried out on patients in 2 disease areas musculoskeletal diseases, and metabolic diseases. This would provide us guidance for the future empirical research and analysis. The concepts explained in the ancient texts have not been proven empirically but have never been disproved either. The analysis of this database would present us with empirical insights never seen before.

**Inspection of the current database:**

1. I-AIM hospital database **INSTA** will be studied for
   1. What kind of data is collected?
   2. What are the issues with the current data
   3. Potential fixes for the future
2. Queries will be posted to the IT team
3. Specific reports or lists will be requested if considered necessary e.g. treatment data is not reported by INSTA reports fully.

Currently, as of August 2016, at IAIM hospital, treatment SOPs are written for musculoskeletal diseases, and metabolic diseases. Several modifications for diagnosis, treatment and outcome measures have been suggested. These will be implemented in the hospital practice over the coming months. The collected data based on these revised SOPs will be analyzed to validate the findings.

**Specific actions:**

1. Statistical methods to be employed:
   1. Graphical methods to display a lot of data in a concise form, trellis graphics, heat maps, etc.
   2. Pattern or trend analysis: to understand the underlying clusters within the data
   3. Decision theory analysis: to understand how the treatment gets assigned and what calculations, algorithms go through a doctor’s mind
   4. Multi-variate analysis: to model the data and gain more insights
2. Innovative and emerging tools and techniques from Omics / bioinformatics etc.

**(4) Development of robust and replicable clinical documentation based on SOP:**

**Specific actions:**

1. Define factors for the completeness, robustness of SOPs
2. Create a detailed analysis plan for analyzing the implementation
3. Analyze the results for completeness, robustness and replicability of the SOPs,
4. If any shortcomings are observed then revisions to the SOPs will be suggested

**Expected outcomes:**

1. Philosophical linking between the ayurvedic scientific concepts and western medicinal concepts – building bridges between sciences
2. Baseline understanding of the data and descriptive analysis of the current facts of ayurvedic hospital data
3. Hospital data analysis methods development

**Reference:**

1. AyuSoft data
2. Circular instead of hierarchical: methodological principles for the evaluation of complex interventions <http://bmcmedresmethodol.biomedcentral.com/articles/10.1186/1471-2288-6-29>
3. Vaidya Rama, Observational therapeutics: Scope, challenges, and organization, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3255445/>
4. Healthcare outcomes assessed with observational study designs compared with those assessed in randomized trials. <http://onlinelibrary.wiley.com/doi/10.1002/14651858.MR000034.pub2/abstract;jsessionid=1951EC6CD7534A7205C1FFE7E6890FCF.f04t03>

**Appendix:**

Table 1: Cells highlighted in Green show similarities between ICH framework and *Charaka Samhita*.

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| --- | --- | --- | --- |
| Quality | Efficacy | | Safety |
| Q1A – Q1F Stability | E1 Clinical Safety for Drugs used in Long-Term Treatment | E14 Clinical Evaluation of QT | S1A - S1C Carcinogenicity Studies |
| Q2 Analytical Validation | E2A – E2F Pharmacovigilance | E15 Definitions in Pharmacogenetics / Pharmacogenomics | S2 Genotoxicity Studies |
| Q3A – Q3D Impurities | E3 Clinical Study Reports | E16 Qualification of Genomic Biomarkers | S3A - S3B Toxicokinetics and Pharmacokinetics |
| Q4 – Q4B Pharmacopeias | E4 Dose-Response Studies | E17 Multi-Regional Clinical Trials | S4 Toxicity Testing |
| Q5A – Q5E Quality of Biotechnological Products | E5 Ethnic Factors | E18 Genomic Sampling | S5 Reproductive Toxicology |
| Q6A – Q6B Specifications | E6 Good Clinical Practice |  | S6 Biotechnological Products |
| Q7 Good manufacturing practice | E7 Clinical Trials in Geriatrics Population |  | S7A - S7B Pharmacology Studies |
| Q8 Pharmaceutical Development | E8 General Considerations for Clinical Trials |  | S8 Immunotoxicology Studies |
| Q9 Quality Risk Management | E9 Statistical Principles |  | S9 Nonclinical Evaluation for Anticancer Pharmaceuticals |
| Q10 Pharmaceutical Quality system | E10 Choice of Control Group |  | S10 Photosafety Evaluation |
| Q11 Development and manufacturing of Drug Substance | E11 Clinical Trials in Pediatric Population |  | S11 Nonclinical Safety Testing |
| Q12 Lifecycle Management | E12 Clinical Evaluation by Therapeutic Category |  |  |

Figure 1:

