

## Medical Herbalism Research, Shifting the Paradigm

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### Abstract

This paper seeks to establish a paradigm for Medical Herbalism research, harmonious with the manner in which Medical Herbalism is conducted. Researching herbal medicines in controlled experiments with un-standardised extracts to identify causal relationships is inherently difficult. The poly-phytochemical nature and complex interactions of medicinal herbs make definitively identifying active ingredients challenging. The effects and variability of the phytochemical makeup within plant material also complicate controlling for phytochemical consistency and observed effect. Utilising pharmaceutical research methods, where a single chemical can be isolated, standardised and its effect observed, is not possible for the conduct of herbal medicinal research. It requires a significant deviation from the natural variations in plants' poly- phytochemical profiles occurring within species, which is assumed implicitly in Medical Herbalism.

We propose a paradigm which shifts the observation from the phytochemicals to observable effects, by utilising continuous biomonitoring technology through using Wearable Health Technology. The purpose is to observe quantitative and qualitative patterns of change in actual people engaged in their everyday activities, which is then subjected to Machine Learning analysis of the gathered data to find patterns of physiological change and develop ontological databases of effects. We may overlay the quantitative research with qualitative data to understand the experience of people as a result of the changes. For this we need to explore and develop Medical Herbalism specific approaches.

The necessity of shifting the focus from the poly-phytochemical problem to quantitative changes in the experimental subject opens new horizons. It shifts the focus from causative to statistical correlative methods and provides a platform for more targeted phytochemical profile research, utilising Machine Learning methods such as Semantic Similarity to identify complex effects resulting from variations within the poly- phytochemical profiles of herbs. Such a framework would require ontological databases of effects linked to herbs, providing infrastructure for more targeted phytochemical research.

### Shifting the Paradigm

Here my working definition of Medical Herbalism is the application of Medicinal Traditions developed around the use of herbs and coherent well developed theories of aetiology and therapeutics. As a working definition, I am limiting Medical Herbalism to Ayurveda, Unani and Traditional Chinese Medicine (TCM) and Physiomedicalism (a more modern system).

### The Tradition is the Tradition

In the attempt to produce a modern scientific evidence base around these traditions, a fundamental epistemological problem is encountered. Biomedicine's reductionist and hegemonic approach (Fil, 2004) is epistemologically inconsistent with these Medical Herbalist traditions (Jiang, 2005; Benzie and Wachtel-Galor, 2011). Pathological processes and diagnostics are modelled differently, so that very different therapeutic strategies and approaches are employed (Jiang, 2005). Jiang's conclusions regarding TCM are as val-

id for the other systems of Medical Herbalism; patterns of pathology are diagnosed and therapeutic interventions address the patterns of disharmony in a manner which displaces and corrects the underlying imbalance, by restoring and supporting natural self regulation (Jiang, 2005). The approaches modulate interlinked multi-systemic and multi-organic layers to restore self-regulation, in the face of pathological disharmony (Jiang, 2005). These systems do not treat diseases as specific pathologies or merely address symptoms, but as underlying disharmonies which will display differently in different patients, and identical symptoms may mean very different things in different patients (Jiang, 2005). Hence, a medicinal formula contains a large number of herbs with hundreds of active ingredients in order to fulfil their multi-systemic, multi-organ and terrain altering, therapeutic strategies (Jiang, 2005). In order to conduct research utilising current Biomedical Models and strategies of research design we are forced to fundamentally alter the way that these Medicinal Traditions treat, and this produces an evidence base whilst destroying theoretical foundations of the tradition. At the end the evidence base no longer represents the methodological nature of these Medicinal Traditions' therapeutic intervention, in other words the tradition no longer remains the tradition if it shapes itself according to the evidential base produced by the scientific investigation.

### *Shifting the Paradigm*

Medical Herbalism research needs to be distinguished from the pharmaceutically driven search for phyto-chemicals with medical uses. Medical Herbalism research is conducted to understand the therapeutic interventions, which include herbal formulas, but to understand what the patterns of multi-systemic and multi-organic interventions target in modern physiology and to optimise and develop Medical Herbalism. Research which focuses upon this must remain consistent with the traditional therapeutic strategies. By focusing upon the physiological outcomes of the patient as a result of the intervention, we focus both upon the therapeutic intervention and its outcome. The therapeutic intervention is modelled as the intervention and the outcome variables record the result (as a matrix of values assigned to track the change). This is in harmony with the way that herbalists within these traditions actually work. We must ask the questions:

1. Did the intervention change the internal terrain of the patient in the direction we intended?
2. Did the formulas traditionally adjusted to modulate the change of the patient's internal terrain make the expected change?

The challenge is how do we do this whilst maintaining rigorous research standards?

### *Collecting the Data: The Opportunity of Wearable Health Technology*

Wearable health technology allows the remote monitoring of patients by caregivers, and is able to generate continuous automated streams of biodata, without the need of the intervention of the caregiver (Kulkarni and Sathe, 2014). In 2015 Apple released their ResearchKit framework as an open source software framework for medical research, which leverages the iPhone's capacity to collect data, track movement and take measurements. With the iPhone's capacity for interconnectivity it provides an extensible research framework for large scale opt-in surveys and observational studies. Stanford University recruited over 10,000 participants into one of its cardiovascular health studies within 24 hours of their ResearchKit built platform being launched (Jardine, Fisher and Carrick, 2015). This platform launched in 2015 is now a mature platform for conducting research and its Android equivalent is ResearchStack (Kubben, Dumontier and Dekker, 2019). These frameworks offer novel ways of engaging in scientific research, whilst automating data acquisition, and actively engaging subjects within the opt-in and research (Kubben, Dumontier and Dekker, 2019). Any device with a bluetooth connection can be adapted to connect to the modern mobile phone via these 2 platforms, providing robust and extensible data monitoring and acquisition platforms for 99% of mobile phone users (Kubben, Dumontier and Dekker, 2019).

To answer the question, 'Did the intervention change the internal terrain of the patient in the direction we intended?' researchers and herbalists must ask:

- What data is collectible by the technology available?
- What study design is suitable to robustly collect the data and answer the questions framed within the exposure vs outcome vari-

ables methodology fundamental to modern scientific research (Ranganathan and Aggarwal, 2018)?

The researcher - herbalist conversation on the data collected and its possible meaning and relationships, is itself the critical element in developing robust methods of medical herbalist research. Systems biology may prove to be an invaluable bridge between the grasp of ancient wisdom based medical herbalist sciences and a modern scientific enframing of these perennial problems (Gu and Chen, 2014).

### ***Big-Data, Bio-Banks and Herbal Medical Research***

#### ***Herbal Medical Bio-Banks: Herbal Medical Research Meets Big-Data***

Herbal Medical Research needs to acquire the habit of collecting and curating health data into datasets which may be analysed specifically for their research and stand as research resources for future research and researchers. Our 'Internet of Things' driven capacity to remotely collect bio-data for health monitoring and research allow us to collect, curate and compare snapshots of environmental, physiological, behavioural and psychological data (Mohammadi, Shenavarmasouleh and Arabnia, 2022). We are able to combine both quantitative and qualitative research methods to give context and dimensionality to data.

We have to understand data as a critical resource for patient management and research, for this gives us curated data resources to which we may apply Machine Learning techniques, such as deep learning, natural language processing, reinforcement learning, etc. to generate inferential knowledge from the data, by both supervised and unsupervised methods (Mohammadi, Shenavarmasouleh and Arabnia, 2022). Big-Data is a research resource and the development of Herbal Medical Research and healthcare management Bio-Banks, for the collation and curation of these resources will provide (Kinkorová and Topolčan, 2020) a necessary part of the Infrastructure of the future. The Herbal Medical traditions are already personalised medicine frameworks with centuries of data, time tested strategies as well as phytomedicinal wisdom and experience.

#### ***Developing Digital Knowledge Structures: Machine Learning Meets Herbal Medical Wisdom***

Data driven research establishes data as a research resource however, we do not know how researchers will utilise the data in the future. A Herbal Medical DataBank provides a research resource built upon the basis of ancient personalised medicine traditions (Kinkorová and Topolčan, 2020). This provides a framework to begin-omics translations of the medicinal wisdom frameworks underlying Medical Herbalism (Gu and Chen, 2014). This is necessary to provide a translational framework capable of mutually benefiting Biomedical models as well as Medical Herbalism models. As indicated earlier, systems biology and its applications of network medicine is perhaps the most promising translational tool (Gu and Chen, 2014). Systems biology frameworks such as Stapleberg's Psycho-Immuno-Neuro- Endocrine (PINE) Network (Stapelberg et al., 2018), provide network based models of disease transition points, progression and processes, that have familiar dynamics for Medical Herbalist practitioners.

#### ***Systems Biology, Herbal Medical Wisdom and Ontological Databases***

The explosion of data over the last two decades leads quite logically to the idea of Bio-Banks (Kinkorová and Topolčan, 2020), which further leads to the question of how to represent data relationships, definitions, analysis and inferences, in a manner suited to computational systems, Machine Learning and Artificial Intelligence. It is here that ontological databases have emerged (Hoehndorf, Schofield and Gkoutos, 2015). Ontological databases facilitate the translational meta-data conversation between Network Biological Models, Phyto-Chemical biological activities and the other -omics libraries (Slater et al., 2020), in which it is possible to record and define developing models with the possibility of embedding logical and inferential relationships.

### ***Conclusion - Research Implications of the Bioinformatics of Medical Herbalism***

We will focus upon three areas which seem particularly pregnant with possibilities:

## Herbs

Faced with the poly-phytochemical nature of medicinal herbs and variability within subspecies, ontological databases are a good resource for defining and recording constituent quantity ranges of herbs and their subspecies, to build robust mappings of geographical, subspecies and other factors which may affect constituent quantity ranges. This enables identification of subspecies and geographical conditions which produce more effective phytochemical profiles for particular therapeutic uses. For example, this may go a long way towards explaining the varying usages of *Urtica dioica* subspecies in some traditions. This provides opportunities for the identification of particular phytochemical profiles which are effective in certain conditions, this could in turn benefit biomedical pharmaceutical research also.

## Pathological Patterns

The methodology of Traditional Medical Herbalism (TMH) which modulates multiple organ system targets, mapped through systems biology may provide insights into optimised multiple organ system target modulation patterns and their effectiveness in addressing pathology. This is capable of offering insights to Biomedical drug therapies that may increase their effectiveness, and may also offer Traditional Medical Herbalism insights in how to optimise interventions. The development of such a framework as a resource is likely to yield unlikely benefits.

## Identification of Pathological Tipping or Transition Points

Systems biology and complex, chaotic systems theory utilise the idea of tipping or transitions at which system order and stability shift to differing underlying orders (Stapelberg et al., 2018). TMH has its own system of understanding tipping points and the way that multitarget imbalances change the stability of health depending upon the phenotype (as defined within the TMH system). This offers interesting avenues of research, theorising and development which in conversation with biomedicine may change our collective understanding of disease progression.

## Conclusion

The approach focuses upon the effects observable in the patient and the data generated using Wearable Health Technology, with databases developed to facilitate translational interdisciplinary crosstalk. The practical development and engagement of a working framework is the way in which we perceive it best to proceed, as we explore the possibilities offered in this emerging field.

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