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*Swagatham*

# GENERAL GUIDELINES FOR METHODOLOGIES ON RESEARCH AND EVALUATION OF TRADITIONAL MEDICINE

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# WHO developed and issued Technical Guidelines

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- 1991    a.    Research guidelines for evaluating the safety and efficiency of herbal medicines
- b.    Guidelines for clinical research on acupuncture
- 1997           Draft guidelines for methodologies on research and evaluation of Traditional medicines
- 2000 -        General guidelines for methodology on Research and Evaluation of traditional medicines

# The guidelines focus on

- Æ Debates on safety and efficacy of traditional medicines
- Æ Raising and answering questions concerning evidence base
- Æ Clarifying certain commonly used under definitions
- Æ Presents national regulations for evaluation of HM
- Æ Recommends new approaches to carry out clinical Research

# Traditional Medicines

Sum total of knowledge, skills and practices based on theories, belief and experiences indigenous to different culture.

Used in the maintenance of

- Ø Health
- Ø Prevention
- Ø Diagnosis
- Ø Improvement
- Ø Treatment of physical and mental illness

# Methodology for research and evaluation is broadly divided into two

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## 1. Herbal medicine

## 2. Traditional procedures based therapies

- ö Manual therapy
- ö Yoga, Naturopathy
- ö Acupuncture
- ö Chiroprathy
- ö Osteopathy
- ö Mind & Body therapies etc.

# Purpose of Guidelines

1. Harmonize the use of certain accepted terms in traditional medicines
2. Summarise key issues for developing methodology for research and evaluation
3. Improve the quality and value of research
4. To provide appropriate evaluation methods

# Methodology for Research & Evaluation.

## Basic principles to be followed

- Æ Should guarantee safety & efficacy of traditional medicines and traditional procedure based therapies
- Æ They should not become obstacle to the application and development of traditional medicines



# Definitions

**Herbs** - Crude plant or plant parts/entire fragmented or powdered

## Herbal Materials

- Herbs, fresh juice, gums, fixed oils, essential oils, resins, dry powder of herbs processed by steaming, roasting, prepared in honey alcoholic beverages etc.

# Definitions

## Herbal preparations

- Finished herbal products powder, extracts, tinctures, fatty oils, etc.
- Produced by fragmentation purification, concentration or other physical or biological process.

## Finished Herbal Products

- Products made from one or more herbs.
- Contains excipients in addition to active ingredients

*“Chemically defined active substance or synthetic compounds and/ or isolated constituents if added to above is not considered as herbal”.*

### **Therapeutic activity**

- Successful prevention
- Diagnosis / treatment
- Improvement of symptoms of illness
- Beneficially alter/regulate the physical and mental status of body

# Definitions

## Active ingredients

Æ Ingredients which have therapeutic activity

Æ *If identified and separated should be standardised to contain defined amount of active ingredients, if adequate analytical methods are available'*

# Botanical verification and quality consideration

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- 2 Identification of plant
- 2 Botanical verification  
(Synonyms, vernacular names,  
Latin binomial names)
- 2 Parts used for the preparation
- 2 Instructions for agricultural  
Production & collection condition  
(G.A.P)

# Research and Evaluation of safety and efficacy

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- Ø Herbal medicines with out a long history of use or which have not been previously researched – should follow WHO's "Research Guidelines".
- Ø HM with documented history of use - the following procedures may be followed

# Review of Literature

## 1. General

- Reference books
- Review articles
- Systemic surveillance
- Data base searches
- In-vitro in-vivo data

## 2. Theories & Concepts

- Traditional medicines may be using medicine along with procedure therapies + behavioural rules + Healthy diets and habits

All must be taken into account

# Review of literature .....

- 3 Review of Safety and efficacy literature
- 2 Current level of evidence for safe and effective use of HM
- 4 Study designs
  - Ä Number of patients
  - Ä Specific diagnosis
  - Ä Dosage
  - Ä Duration of administration
  - Ä Criteria for evaluation
  - Ä Absence of simultaneous therapies
  - Ä Valued statistical analysis



# Safety .....

## when to conduct toxicological studies

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1. Report shows a herb or its closely related species, constituents and its preparations have side effect
2. When there is no documentation of long historical use of that medicinal
3. When doubts exist about its safety

# Efficacy....

## Proof of efficacy

- Documentation required to support the indicated claims

- For minor disorder
- Non specific indication
- Long historic of use
- For prophylatic use
- Supportive –  
pharmacological data

Less stringent  
& Requirements  
Eg. Observational  
studies

# Efficacy Grading

- A - Requires at least one randomised controlled trial
- B - Requires availability of well conducted clinical studies but no randomised clinical trial
- C - Requires evidence from expert committee / clinical experiences of respected authorities.

Well defined randomised controlled clinical trial provide highest, level of evidence for efficacy

# Clinical trial

## Scope and Design

- Based on information obtained from literature
- Or by consulting a traditional practitioner

## If

- New herbal medicines
- New Indication
- Different dosage
- Different route of administration

WHO's Good clinical  
practice protocols

# Problems and solutions

## Randomisation (to avoid biases)

Ethical issue, Technical problems

### Placebo

- Strong smell & taste of HM
- Patient who has already undergone such treatment

### Solution

- Low dosage of same drug or proper selection of control group.

# Study Design - Solutions

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- Single Case Design
- Back Box Design
- Observational Design
- Ethnographic Design

# Control group selection

- ö Well established treatment
- ö Non treatment
- ö Different dose of same treatment
- ö Placebo treatment
- ö Minimal treatment
- ö Alternative treatment

## Blind assessment

- ö Problems - Difficult in procedure based therapies – manual treatment, Pizhichil, Kizhi, Yoga etc.
- ö Solution - ?

# Evaluation of quality of life

Traditional medicines may not cure patients with certain illness such as cancer, aids etc. But may help to improve the quality of life.

- Æ Physical domain – Pain, energy & fatigue, Sleep & rest,
- Æ Psychological – Positive feelings, thinking, self-esteem, negative feelings
- Æ Level of independence – mobility, activities, working capacity
- Æ Social relationship – Social support



# Ethics & Surveillance

## Ethics

International ethical guidelines for biomedical research involving human subjects

- Justice
- Respect for patients
- Beneficence

Declaration of Hel-sinki

## Surveillance system

To monitor research activities at state & national level needed.

**Well established, randomised controlled clinical trials provide the highest level of evidence for efficacy. Such studies facilitate the acceptance of Ayurveda in different regions and in people with different cultural traditions.**



*Thank you*