PHARMACOVIGILANCE OF DRUGS OF INDIAN SYSTEM OF MEDICINE

Do we need evidence for:
- Efficacy
- Safety
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Consultant WHO Center for International Drug Monitoring, Uppsala, Sweden

Vice – Chancellor,

NIMS University

Jaipur
To produce its characteristic effects a drug must be administered in proper dosage form by proper route and must be present in appropriate concentration at the site of action. Many variables that effect transport across membranes influence absorption of drugs. Time of administration of drug i.e with relation to stomach being empty or otherwise, during day or at night and other factors may influence absorption. This is amply emphasized in Ayurveda that very medicine may be taken as properly administered which is capable to bring about disease free condition and that very physician as the best one who could relieve (the patient) of his disorder.
A drug, if unknown, is (fatal) like poison, weapon, fire and thunderbolt while, if known is (vitaliser) like nector. A drug unknown by these - name, form and properties (including actions) - and badly administered even if known are responsible for complications. Drawing attention to causation of adverse reactions by drugs and their treatment, Charak states that in case there appear thirst, mental confusion, giddiness and fainting during digestion of the drug, pitta - alleviating, sweet and cold measures are recommended.
Dusivisa (latent poison) produces pustules, kitibha and urticarial rashes due to disorders of blood. Thus poison takes away
**WHO**

Traditional Medicine is the sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in prevention, diagnosis, improvement or treatment of physical and mental illness.
Medicinal Plants for Primary Care

- 65 to 80% world population use traditional Medicine
- Use based on historical and anecdotal evidence
- Little data with regard to efficacy
Galen

"If you need a single drug of good quality which is not available, use a drug of lesser quality, for it would be less harmful then if you want to prepare a compound drug of which one single drug is unavailable, use the lesser quality drug double the weight of the original drug. Thus the efficacy of the drug would remain unchanged."
Maqala Fi Abdal Al-Adwiya Al Mustamala Fi
Al-Tib wa Al-Illaj (Kitab Al-Abdal)

"All the drugs required for the treatment are not available everywhere. So, if the physician is unaware of substitutes which may be used in place of the original drug, the objectivity and benefaction of this medical profession would cease."
Examples of compound drugs along with substitutes

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Principles of substitutions

Avicenna
- Substitute should only be used when original drug meant to be used is not available.

Avicenna
- No drug can be a complete substitute for another drug in all respects.

Rhazes
- Drug should be substituted for original drug for specific activity
  - Different drugs may be substituted for different action
  - Substituted drug should match the original in mijaz (Temperament)
Pharmacovigilance!

All drugs are dangerous some may also be useful

N Moore, BMJ, 2005, 330, 539-40
What is Pharmacovigilance!

"No drug which is pharmacologically effective is entirely without hazard. The hazard may be insignificant or may be acceptable in relation to the drug's therapeutic action. Furthermore, not all hazards can be known before a drug is marketed... "A report by EU experts"

All drugs are dangerous some may also be useful

Wednesday, 12 November 2014

Moore, BMJ, 2005, 330, 539-40
No medicinal product is entirely or absolutely safe for all people, in all places, at all times. We must always live with some measure of uncertainty.

Be vigilant......

मुहर्मुहुश्र रोगाणामवस्थामातुरस्य च ।
अवेक्षमाणस्तु भिषक् चिकित्सायां न मुद्यति ॥

च०चि० ३०/३०६
- **Medicinal Plants for Primary Care**
- **65 to 80%** world population use safety traditional Medicine
- Use based on historical and anecdotal evidence
- Little data with regard to efficacy
Pharmacovigilance

- Any thing herbal is safe!!?????
- Adverse drug reactions (ADR)
- Drug-drug interactions
- Herb-Drug interactions
- Toxicity of the isolated ingredients
- Traditional process (Shodhana)
India

Herbal Drugs

Widely Prescribed

Lack of Systematic Evaluation

Adverse Drug Reactions
Traditional Medicine

Why ADR Monitoring Difficult

♦ Theories of application are difficult
♦ Too many products to monitor
♦ Multiple ingredient formulations - numerous
♦ Herbal and allopathic drugs taken together
♦ Formulations change keeping same brand name
♦ Methods of preparations differ
♦ Quality checking is ambiguous
Health care system in India

- Allopathy – Disease oriented
- Ayurveda - (Holistic system)
- Unani - (Holistic system)
- Siddha - (Holistic system)
- Homeopathy Symptom based
Principles of Treatment are different

- **Ayurveda** - **VATA**
- - **Pitta**
- - **Kafa**
Mijaz (Temperament)

Drug could be
Hot + Dry
Hot + Moist
Cold + Dry
Cold + Moist

- Hot, Cold, Dry, Moist - each has degrees from 1-3
- A drug hot and dry in 1st degree be substituted with hot and dry 1st degree
Why is ADR monitoring of ‘Herbal’ drugs even more difficult?

Too many products to monitor?
Why is ADR monitoring of ‘Herbal’ drugs even more difficult?

There are single and multiple ingredient formulations.
Why is ADR monitoring of ‘Herbal’ drugs even more difficult?

The formulations can be changed at will keeping the same brand name.
Why is ADR monitoring of ‘Herbal’ drugs even more difficult?

Quality checking is ambiguous affecting the causality of an ADR.
Why is ADR monitoring of ‘Herbal’ drugs even more difficult? Herbal products are taken OTC by patients.
Why is ADR monitoring of ‘Herbal’ drugs even more difficult?

Herbal products are prescribed by all specialities i.e. Allopaths, Ayurveds, Homeopaths and RMPs
Why is ADR monitoring of ‘Herbal’ drugs even more difficult?

The ADR reporting terminology of multiple specialties can differ
Why is ADR monitoring of ‘Herbal’ drugs even more difficult?

Herbal and Allopathic drugs are taken together by the same patient.
PROTOCOL FOR NATIONAL PHARMACOVIGILANCE PROGRAMME FOR AYURVEDA, SIDDHA AND UNANI (ASU) DRUGS

National Pharmacovigilance Resource Centre, for ASU Drugs
Institute for P. G. Teaching & Research in Ayurveda, Gujarat Ayurved University, Jamnagar 361008, Gujarat

Department of AYUSH, Ministry of Health & Family Welfare, Government of India, New Delhi,
in collaboration with WHO Country Office for India, New Delhi

2008
Substitution of Drugs

National Pharmacovigilance Programme For ASU Drugs

National PV centre

8 Regional PV centres

30 Peripheral PV centres

IPGT&RA
JAMNAGAR

BHU

N

W

NIA

C

BHOPAL

S

THIRUVAN
TAPURAM

E

GUWHATI

S

CCRAS
NEWDELHI

SIDDHA
CHENNAI

UNANI
BANGALORE
Ibn Sina  
The Author of Al Qanoon Fil Tibb (Canon of Medicine)
Abu Bakr Mohammad bin Zakariyya al Razi (Rhazes)

- Born in Iran 240 hijri
  - Studied Indian Medicine
  - Chief Medical Officer in hospital of Baghdad
  - Became blind at 60
- 29 books written by Rhazes are available
MAQALA FI ABDAL AL-ADWIYA
AL-MUSTAMALA FI AL-TIB
WA AL-ILAJ

known as

KITAB AL-ABDAL
(Book on Substitutes of Single Drugs)
ABU BAKR MOHAMMAD BIN ZAKARIYYA
AL-RAZI (Rhazes) (865-925 A.D.)
(English Translation)

CENTRAL COUNCIL FOR RESEARCH IN UNANI MEDICINE
(Department of Indian Systems of Medicine & Homoeopathy)
Ministry of Health & Family Welfare, Government of India
NEW DELHI
"All the drugs required for the treatment are not available everywhere. So, if the physician is unaware of substitutes which may be used in place of the original drug, the objectivity and benefaction of this medical profession would cease".
## Examples of compound drugs along with substitutes

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## Principles of Substitutions

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Substitution (Abdal al-adviya) Drug of one origin can be replaced with drug of another origin.

Example:

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<td>Jund Bedastar (Animal)</td>
<td>Black pepper ($\frac{1}{2}$ by weight) (Plant)</td>
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<tr>
<td>Calcinated &amp; washed egg shell</td>
<td>Tarasis (Gummiferum)</td>
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One species of plant may substitute for another species

- Podina kohi (Mentha)  Podina Nahri (Panny Royal)

Another part of same plant may serve as substitute

- Margosa flower  Margosa leave or bark
- Sosan leaves (Lilly)  Sosan Root
- Banafsha
Substitution of Drugs in Ayurveda

- Not mentioned in Charak and Sushruta Samhita
- According to three Nighantus (Materia Medica)
- Bhavprakash
- Yogaratnakar
- Bhashjya Ratnavali
Substitution of Drugs in Ayurveda

If any drug is not available then another drug similar can be substituted

- RASA  Physical Properties
- GUNA  Pharmacological actions
- VIRYA  Potency
- VIPAKA  Effect on digestion and interaction
Main drug in any formulation should not be substituted.

Other drugs can be substituted appropriately (Pratinidhi Dravya)
Mile Stones for the launch of National Pharmacovigilance Programme for ASU Drugs:

Consultative Committee meeting:

at AYUSH, New Delhi

29th & 30th of August 08

under the sponsorship of WHO, India Office

Protocol was finalized.
Adverse Reaction Terminology

औषधि प्रतिकूल प्रतिक्रिया शब्दावली
(For Physicians of Indian Systems of Medicine)

Society of Pharmacovigilance, India