G A P

► Pharmacological expertise needed

and

► Availability of pharmacologists
G A P

- Type of specialized pharmacological expertise needed

and

- Type of pharmacological expertise available
GLOBAL LEADERSHIP

► Drug discovery

► International health care

► Clinical trials

► Traditional medicine research
DRUG DISCOVERY

► New molecules coming from Indian laboratories

► 40+ molecules at different stages of clinical trials in India

► Interesting leads sold to the foreign companies

► Essential to have drug development expertise in India
TYPES OF PHARMACOLOGICAL EXPERTISE NEEDED

► Immunopharmacology
► Biochemical pharmacology
► Pharmacogenetics
► Molecular pharmacology
## INTERNATIONAL HEALTH CARE

### Cost of Carrying Out

<table>
<thead>
<tr>
<th>Procedure</th>
<th>USA</th>
<th>India</th>
<th>Thailand</th>
<th>Singapore</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary artery bypass surgery</td>
<td>$70,000-$133,000</td>
<td>$7,000</td>
<td>$22,000</td>
<td>$16,300</td>
</tr>
<tr>
<td>Bypass surgery with heart valve</td>
<td>$75,000-$140,000</td>
<td>$9,500</td>
<td>$25,000</td>
<td>$22,000</td>
</tr>
<tr>
<td>replacement</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hip replacement</td>
<td>$33,000-$57,000</td>
<td>$7,200</td>
<td>$12,700</td>
<td>$12,000</td>
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<tr>
<td>Knee replacement</td>
<td>$30,000-$53,000</td>
<td>$7,200</td>
<td>$11,500</td>
<td>$9,600</td>
</tr>
<tr>
<td>Prostate surgery (TURP procedure)</td>
<td>$10,000-$16,000</td>
<td>$3,600</td>
<td>$4,400</td>
<td>$5,300</td>
</tr>
<tr>
<td>Gastric bypass</td>
<td>$35,000-$52,000</td>
<td>$9,300</td>
<td>$13,000</td>
<td>$16,500</td>
</tr>
<tr>
<td>Face lift</td>
<td>$10,500-$16,000</td>
<td>$4,800</td>
<td>$5,000</td>
<td>$7,500</td>
</tr>
</tbody>
</table>
CLINICAL TRIALS

Why India?

► Availability of a large population of patients
► Large variety of diseases prevalence
► Availability of naive patients, 299 medical colleges, competent clinicians with fluency in english
► Greatly reduced cost for carrying out clinical trials
► Relatively strong drug regulatory agency
CLINICAL TRIALS IN INDIA

► BOON – Ethical transparent trials

or

► BANE – Unethical trials exploiting poor and illiterate
PREPARATIONS BY ICMR FOR DRUG DEVELOPMENT / CLINICAL TRIALS

Advanced Centres

- NIRRH, Mumbai – Reproductive Toxicology
- NIN, Hyderabad – Toxicology
- JIPMER, Pondicherry – Genotoxicology
  - Reverse Pharmacology
- Regional Research Institute, Jammu – Standardization
PREPARATIONS BY ICMR FOR DRUG DEVELOPMENT / CLINICAL TRIALS

Advanced Centres

► RMRC, Belgaum – Traditional medicine
► Himalayan Institute, Palampur – Cultivation of medicinal plants
► Bose Institute, Kolkata – Plant genome research
CLINICAL TRIAL CENTRES

► NIZAM’s Institute, Hyderabad - Pharmacodynamics
► CMC, Vellore – Centre for evidence based medicine
► Vivekananda Yoga Kendra – Effect of yoga
► Nair Hospital, Mumbai – Clinical Trials
► KEM Hospital, Mumbai – Clinical Trials
CENTRES FOR CLINICAL TRIALS OF TRADITIONAL REMEDIES

► AIIMS, New Delhi
► PGIMER, Chandigarh
► BHU, Varanasi
► Medical Colleges – Cuttack
  - Trivandrum
  - Chennai
  - Kottayam
INSTITUTE ETHICS COMMITTEE

► To protect patient/public from exploitation
► Committee needed at all centres where clinical trials are being carried
► No trial to be carried out till proposal cleared by Ethics Committee and
► Placed in Register of Clinical Trials, ICMR
CLINICAL PHARMACOLOGIST in Institutional Ethics Committees

► Informed Consent

► Use of Placebo

► Ownership of data

► Rights of patient after completion of trial
TRADITIONAL MEDICINE
Kolkata

► Col. R. N. Chopra
► Dr. B. B. Dikshit
► Dr. B. Mukherjee

School of tropical medicine,
Kolkata
<table>
<thead>
<tr>
<th>Region</th>
<th>Resources</th>
<th>Technology</th>
<th>Bio-diversity</th>
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</thead>
<tbody>
<tr>
<td>North</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>South</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
</tbody>
</table>
GOLD STANDARD
For Synthetic Drug

► Controlled
► Comparative
► Placebo
► Double-Blind
► Randomized
► Multi-centred
► Clinical trial
OTHER DESIGNS MAY BE APPROPRIATE FOR TRADITIONAL MEDICINES

- Observational pharmacology trials
- Open trials
- Single blind studies
- Sample of one trials
RATIONAL USE OF MEDICINES

ADVANTAGES

► Better therapeutics

► Reduction of side effects
  - Inappropriate dose
    - Inappropriate duration of treatment
    - Interactions

► Reduction in cost of medication
  - Individual
    - Family
    - Community
    - Country
THE DELHI MODEL

► Rajasthan

► Himachal Pradesh

► Uttar Pradesh

► Haryana

► Mumbai Corporation
OTHER ORGANIZATIONS USING CONCEPT OF RATIONAL USE OF MEDICINES

- Helpage
- Family Planning Association
- National Rural Health Mission
NEED FOR PHARMACOLOGISTS

► Development of drug policy
► Selection of drugs to be used in country
► Drug regulation
► Drug discovery
► Carrying out clinical trials
► Corporate and government hospitals
► Research in traditional medicines
► Pharmacovigilance
► Memberships/Chair – Ethics Committees
NEED FOR PHARMACOLOGISTS

Traditional role as professors of pharmacology in medical colleges and in drug research institutes and in drug regulatory agencies and in pharmaceutical industry
D.M. COURSE IN CLINICAL PHARMACOLOGY AT PGI, CHANDIGARH

Team: Professor Ranjit Roy Chaudhury
Professor V. S. Mathur
Professor P. L. Sharma
Dr. K. S. Raghavan
Dr. S. K. Garg

Collaboration: Professor P. K. Devi
Professor R. N. Chakravarty

Guidance and Support: Professor P. N. Chhuttani
Professor K. L. Wig
Professor Santokh Singh Anand
D.M. CLINICAL PHARMACOLOGY

- Open to pharmacologists and clinicians after receiving first advanced degree
- Two year course
- Clinical attachment
WHERE ARE THEY – 36 TILL DECEMBER 2009

India and Abroad

► Professors of clinical pharmacology
► Medical Directors/Vice-Presidents in pharmaceutical houses
► Heads of drug regulatory agencies
► Heads of divisions in research institutes
► Academic staff of medical colleges
D.M.’S QUALIFYING EVERY YEAR

► PGIMER, Chandigarh - 2
► KEM, Mumbai - 2
► Nizams, Hyderabad - 2
► A.I.I.M.S - 1
► Others - 2

- 10

► DNB in clinical pharmacology – 4 to 5

TOTAL – 15 per year

► NEED - 100 per year
OTHER TRAINING PROGRAMMES

► Masters in pharmacology from colleges of pharmacy

► Masters course in pharmaceutical medicine run by KEM Hospital, Mumbai

90 trainees each year
WHY IS THERE SO MUCH NEED?

Healthcare Industry

- At present – 20 billion dollars

- In ten years – 45 to 63 billion dollars
  + 9.00 billion dollars
  If health insurance comes in

Clinical trial turnover
1.0 billion dollars by 2015
INTERNATIONAL HEALTH

Patients from Abroad

1999 – 10,000

2004 – 180,000

Annual growth rate – 25 to 30%

Example – Apollo Hospitals

In last five years – 60,000

from 55 countries
M.D. COURSE OF A.I.I.M.S
Contains

► Molecular biology in pharmacology
► Clinical pharmacology and recent advances
► Drug regulations
► Drug development process
► Clinical trials
► Therapeutic drug monitoring
AREAS WHICH COULD BE ADDED

► Drug delivery systems
  - Transdermal drug delivery
► Ocular pharmacology
► Pharmacovigilance
► Regulations regarding IPR
► Pharmacogenetics
► Genomic pharmacology
PHARMACOLOGY POSTGRADUATES

► More needed
  - Scaling up

► Different expertise needed
  - Broaden curriculum horizons

► NEED tremendous

► No time to lose