Understanding the Drug situation in your hospital/ dispensary/health centre

(Note : To help you prepare for participation in the CHAI Workshop on "Towards a People-oriented Drug Policy" given hereunder is a check list of questions which you should go through along with other members of your team especially those who prescribe or dispense drugs. This list is not exhaustive but covers the main issues which will be discussed during the Workshop).

1. Range of Drugs

How many drugs are available in your centre?

Do you have a complete list?

Are these classified into groups?

Are there any duplicate drugs? (ie., drugs of the same type but different manufacturers)

Do you stock combination drugs?

If so, what are the commonest combinations?

Do you stock non-allopathic medicines? Which ones?

2. Drug Selection

Who selects drugs in your institution?

Is this a formal/informal process?

Do you have a selection committee?

If so, who does it consist of?

What are the criteria for selection?

Cost? therapeutic consideration? Cultural?
Availability? Packing? Any others
Efficacy? medical representative?

3. Dispensing

Who all dispense drugs in your institution?

Do you have a trained pharmacist or any other staff trained in pharmacy?

Do you dispense drugs in situations other than out patient/inpatient?

Health centres? School/hostel infirmaries?
Mobile clinics? Rehabilitation centres? Any other

Do you have any guidelines for dispensing?

Are these different for different situations, types of staff and level of use?

4. **Purchasing**

How do you purchase drugs?
Wholesale? Retail? Through medical representative?
Do you purchase in bulk?
Do you purchase by generic names or brand names?
What sort of trade discounts do you allow/accept?
Do you prepare any medicines in the hospital/dispensary?

5 **Pricing**

How do you price your medicines?
Do you give medicines free or at concessional rates?
Are the 'free' or purchased medicines of the same type?

6. **Drug Information**

Do your staff get any kinds of information on therapeutic indications, dosages or side effects
Are these from medical representatives, drug companies or other sources?
Do you have a locally written—a) formulary

b) therapeutic manual

c) standardised drug regimes?

7. **Pharmacy Facilities**

Does your pharmacy have the following facilities?

a. basic library of reference books, bulletins and information filing system

b. special locked storage space

c. refrigerator

8. **Pharmacy Policy**

Do you have an institutional policy on

a. storage and administration of narcotics and dangerous drugs?

b. adverse drug reaction—monitoring and reporting

c. Ref Dealing with persuasive pressure tactics of sales representatives

d. Standardised drug distribution policies for

—ward stock

—prepackaged prescription

—protected drugs

—free drugs

e. standing orders for department/pharmacy

9. Expiry Dates

Do you have any policy about use of expired drugs?
If you use some beyond the expiry date, which are these?
For how long beyond expiry date do you use them?

10. Foreign Drug Donations

Do you get drugs donated from abroad?
Do you have a list of drugs? Sources?
Do they have instructions for use in a language your staff can understand?
If not, how do you get the information translated?
Do you have any in large quantities/or types which you cannot use?

11. Banned Drugs

Are you aware of the drugs banned by the government in July 1983?
Do you have a banned brand list?
Are your staff aware of the ban?
Have you weeded these drugs out of your practice.

12. Problem Drugs

Look at the list of problem drugs (p.)
Do you stock any of these in your pharmacy?
Which are the brands? What are the indications?

13. Placebos

Do you use any drugs as placebos?
Which are the commonest? and for what situation?

14. Initiatives

Have you taken any initiatives in recent years to rationalise your prescription/dispensing practices, in your institution?
What are they? How successful have they been?

15. Other information

Is there any other information about your pharmacy/dispensary or about drugs used in your centre which is relevant but is not covered by 1 to 14?

DR 30.2

Ethics of Drug Prescription

Fr. George Lobo, S.J.

Use of drugs to be regulated by the principles of ~~the~~ totality (overall good of the patient) and of double effect (the good ~~effect~~ effect overriding any hramful effect). Unfortunate situation of ~~many~~ overpricing, overprescribing and misprescribing of drugs-often untried and dangerous drugs are prescribed.

Reasons: technological model of health care leading to the manipulation of the patient, to the neglect of preventive health, herbal medicine and to the transgressing of legitimate bounds of human experimentation; desire for instantaneous relief of symptoms; creation of air of magic by the use of exotic drugs with esoteric names; capitalist system with an overemphasis on the profit motive; deep rooted cultural alienation, effect of neocolonialism, leading to the ~~maxprxdepreciation~~ depreciation of all that is indigenous and uncritical acceptance of all that is foreign; dependent status of developing countries allowing undue pressure from multinationals; drug prescription and medical research directed by the pharamceutical industry; bourgeois captialist values leading to the 'get rich quickly' ~~mx~~ mentality on the part of physcians.

Remedies: development of a person-centred and holistic approach to health care; physicians regaining true autonomy and ideals of the medical profession; countering capitalism, cultural alienation and the interference of foreign powers; massive movement against ~~the mxix~~ manipulation by drug companies; supporting well intentioned efforts of the government to check abuses in the production, distribution and use of drugs; reducing the list of pharacopia in hospitals; developing ethical values and understanding of right norms among all concerned.

DRUGS FOR PRIMARY HEALTH CARE

What is primary health care?

Primary health care is essential health care made available to individuals and families in the community and has to be

(1) accessible, assuring equitable access to all,
(2) acceptable, based on the life pattern of the people,
(3) effective, in providing an adequate level of care, and
(4) affordable, without the imposition of excessive burden on the individual, family or community.

It is the first contact care, where most of the usual, everyday health care needs can be met. Primary health care is an approach which integrates at the community level all the elements which are necessary to improve the health of the people. It is a response to the fundamental human need of being assisted in the actions needed to live a healthy life and when illness comes, get relief from pain or suffering and restoration of health.

Primary health care includes promotion of health, prevention of disease, cure of disease where possible, care and rehabilitation. Among the important factors in promotive and preventive measures are health education to lead a normal healthy life, avoiding risk factors, good nutrition, safe drinking water and sanitation. Food production in the country is adequate but it distribution is bad, due to poverty, unemployment and lack of education. Water supply is not safe, especially in the villages. There are still lakhs of villages which are classified as problem villages (those which do not have an assured source of drinking water within a distance of 1.6 km). Disposal of excreta lags far behind; only 2% of the rural population has been covered by satisfactory disposal, while a neighbouring country like Sri Lanka has had a remarkable progress in this area.

India, a signatory to the Declaration of the Alma Ata International Conference on Primary Health Care is committed to provide an acceptable level of health for all by the year 2000 AD. Primary health care has to be defined in terms of function and the scope and quality of care under each function. It is also necessary to decide what proportion of the GNP should be alloted to health care and what part of it to primary health care, though this can present problems[1]. An integral part of this commitment is the provision of all essential drugs to all those who need them, in adequate quantity and quality, and at affordable prices, wherever the person is. The ability to

meet the cost or to reach the place should not be considerations in providing the essential drugs.

Drug production

The production of pharmaceutical products in India is estimated to be Rs.18,000 million in 1983, If we compare our production with the production in affluent countries or even with the average world figures, it is extremely low. The world consumption of pharmaceutical products was estimated in the year 1981 to amount to Rs.763 billion. India's share comes to about one in five hundred while her population is about one in six.

Even this limited amount is wasted in the production, distribution and consumption of non-essential and useless drugs, a large proportion being vitamin combinations and tonics. Often they are spurious. There are over 25,000 formulations made by over 5000 production units. This compares with something like 3000 formulations in the Scandinavian countries.

What are the drugs required?

Drugs are required for prevention, cure and symptomatic relief. The World Health Organization has, in 1983, listed about 250 drugs as essential[2]. This is a large scale modification of the list prepared in 1977 and revised and updated in 1979. The objective of WHO action programme on essential drugs and vaccines is to ensure the regular supply to all people of safe and effective drugs and vaccines of acceptable quality at lowest possible cost in support of primary health care[3]. They have also given a list of 22 drugs for primary health care. These drugs "can be used effectively and safely by responsible individuals with little formal medical knowledge". The report also states "highly trained workers might use a wider range of drugs appropriate to their diagnostic skills" and advocated that where there is no scarcity of medical manpower, many potent drugs could be used. Primary health care is the involvement of the practitioner(doctor, nurse, medical assistant, auxiliary, or primary health worker), to whom a person first turns, when ill or seeking advice. This varies from country to country and even within the country. The W.H.O. expert committee observed "....the preparation of a drug list of uniform, general applicability and acceptability is not feasible or possible". The same is equally true for a vast country like India. In India, there is a reasonable ratio of trained doctors to population in the majority of places; in many situations, they will be the persons for primary contact; in others, these will be trained nurses, community health workers or others. Depending on who provides the health care in the first contact situation, the use of drugs will vary. I shall take the situation where a qualified physician is available; in other

situations, the list of drugs may have to be drastically curtailed, being nearer the twentytwo drugs listed by the expert committee of W.H.O.

Choice of drugs

The drugs for primary health care must be well-chosen. The choice has to be based on a survey of the mobidity pattern in the area or region. To ensure optimal benefits, the definition and determined implementation of clear national policies are required[3]. The steps to success in the choice and supply of essential drugs have been listed[4]. They are

(1) A comprehensive National Drug Policy
(2) Selection of essential drugs
(3) Drug production and procurement
(4) Logistics of supply
(5) Proper use of drugs
(6) Quality control
(7) Training of personnel.

National Drug Policy: There is an imperative need to have a comprehensive National Policy, based upon the socioeconomic, political and other options and the practical implication of that policy. There is need for a clear decision as to what diseases and symptom complexes come within the purview of primary health care. A purposefully determined regimen of treatment should be worked out for each disease and symptom complex, leaving the rarer treatment regimes to the specialists at the referral care. In declaring the bold New Drug Policy of June 1982, Bangladesh followed 6 precepts[5].

(1) Elimination of harmful and useless drugs. As follow-up, 1,700 such drugs were banned. (Similarly, in Philippines, about 6,000 out of an estimated 15,000 drugs in the country would be phased out during this year. In Mexico, over 10,000 drugs have been closely evaluated and many duplications, obsolete products and those with limited or doubtful benefits have been eliminated, reducing the number of drugs available to 329, in 583 combinations).
(2) Increased domestic production of essential drugs.
(3) Public distribution system of essential drugs.
(4) Bulk importation of pharmaceutical materials from different sources at competitive prices (Many countries have been able to do this, achieving economy. Tetracycline which used to be imported at 102 U.S.dollars per kg. before the Policy was imported at U.S.$ 27 per kg.).
(5) Use of generic names.
(6) Encouragement of locally organised applied drug research.

Selection of drugs should be based on the prevalence of morbidity in the

community. The list should be drawn up by a regional committee of doctors, pharmacists and others interested and involved in primary health care. Concise and yet comprehensive drug information should accompany the list. The common diseases in our country are infectious diseases, parasitic infestations, acute diarrhoeal diseases and malnutrition. India, in common with other less affluent countries, has a young population with about 42% under 15 years of age. Hence the diseases common among children have preponderance; drugs required for their care must have priority. Periodic revisions must be made to meet the changing needs or based on better assessment of the needs and the availability of more cost-effective drugs. It is better to have only one preparation for each indication, avoiding unnecessary duplication. The drugs, where possible, are better supplied in tablet form for ease of administration; they should also have keeping qualities under the existing and often exacting conditions of temperature and humidity. The packing must be efficient but not expensive. The choice of the drug should be based on

(1) proven efficacy; well tried drugs should be preferred to newer drugs whose efficacy, side-effects and adverse reactions have not been fully established.

(2) low cost, commensurate with efficacy; the cost of the whole treatment should be considered and not merely of single dose.

(3) safety in the hands of the user.

Drug production and procurement: The country should as far as possible become self-sufficient in the production of drugs for primary health care. Where imports are necessary, they should be obtained on the basis of bulk purchases on global tenders and selection with due regard to quality and cost. Considerable savings can be effected.

Even affluent countries have taken measures to contain the costs[6]. The nine countries in the European ~~countries~~ Community took steps to reduce the cost of drugs. Among them are

(1) Fixing of prices or limiting profits of pharmaceutical companies

(2) Limiting sales promotion activity

(3) Regulation of retail margins

(4) Circulation of information to doctors to encourage economical prescribing.

Logistics of supply: An adequate supply of the essential drugs must be ensured at all times, in all places and in suitable dosage forms including paediatric dosages. The challenge is to devise systems that will provide essential drugs where they are needed, matching the supply to the health care needs. It often happens that the essential drugs are not available at

all times, leading to shortages. This has happened often to the large scale treatment of tuberculosis, leprosy and other diseases. Sometimes it has happened because manufactures debiberately did not produce them or retailers refused to stock and dispense them, all clamouring for a larger margin of profit. Villages and regions may be cut off in certain seasons for a variety of reasons.

Quality control: It is most important that quality, stability and bio-availability are assured, through proper monitoring at different points in supply and use.

Regulating the drug trade: Social and economic damage is caused by the indiscriminate advertising and marketing activities[7]. We do not have well-organised and effective agencies like the Food and Drug Administration of USA. Even in advanced countries, promotional activities go far beyond what is reasonable, eg., the Benoxaprofen affair or the Opren scandal[8]: "A combination of an unserupulous pharmaceutical firm, feeble watchdogs and gullible doctors had been responsible for the use of an unnecessary and unsafe drug ..... key figures were extravagantly entertained at sponsored conferences in attractive venues".

Drugs for immunization: High priority must be given for immunization in primary health care. The commonly preventable diseases must be prevented. This is high technology and highly cost-effective. Everyone knows of the success story of small-pox eradication; it is estimated that about a billion dollars have been saved by giving up compulsory vaccination. Infectious diseases take a big toll in our country, especially of infants and children. The cost for treating the patients with these infectious diseases and the complications and sequelae are very high. Among the common infectious diseases which can be effectively prevented today are

diptheria,
poliomyelitis,
measles,
whooping cough,
tetanus.

Newer effective vaccines may be added, depending on the cost - benefit.

Drugs for cure: Some of the more essential drugs are listed; a few more will be needed, based on regional requirements and other factors.

Antimicrobials: Infectious diseases being the commonest, priority should be given for drugs to fight them. The proportion of the pharmaceutical

budget spent on antibiotics and antiparasitic drugs was 24% in India, compared to 4% in the Federal Republic of Germany and 15% in Britain[9]. Well - tried, cost-effective antimicrobials from among the many available, should be selected. This would necessarily include the penicillins (crystalline, procaine and oral) and ampicillin; one or two potent and safer sulphonamides could be included. Drugs like chloramphenicol and tetracyclines will also be useful. The misuse of antimicrobials is fraught with danger, especially the development of resistance. Antimalarials: Malaria is again becoming a major threat. From an all-time low annual incidence of 100,000 in 1965, it has risen to ~~many~~ some millions. Chloroquine is a good drug. Unfortunately, resistant strains have developed especially in the northeast and are spreading to other parts of the country. Primaquine may be provided for radical cure; quinine is also included. Antileprosy: Dapsone can still be the basis of treatment, though multidrug treatment with rifampicin, clofazimine and/or ethionamide is common now and probably cost-effective. Antituberculous: It is estimated that there are about 9 million people in India suffering from tuberculosis with about one-fourth of them being infective. About 50,000 die per year from pulmonary tuberculosis. The drugs required for standard therapy such as INH plus streptomycin plus PAS/Thiacetazone/ethambutal or the short course including rifampicin must be available. Antiamoebic: metronidazole; Antihelminthic: Mebendazole. Antianaemic : Ferrous sulphate; folic acid. Antizerophthalmic - Vitamin A. Antifilarial: diethylcarbamazine. Antifungal: griseofulvin; Antikala-azar (in regions where kala-azar is present).

Drugs for symptomatic relief

Analgesic and antipyretic: aeetylsalicylic acid; paracetamol; morphine in special situations. Inflammation: Glycerine and mag. sulph.; ibuprofen. Cough: Noscapine; pheniramine maleate. Diarrhoea: rehydration salt. Constipation: magnesium sulphate; senna. Vomiting: promethazine. Allergy: Chlorpheneramine. Asthma: ephedrine, aminophylline and salbutamol; adrenaline injections for an acute attack or status asthmaticus. Angina: glyceryl trinitrate; propranolol. Hypertension and congestive heart failure: hydrochlorothiazide; digoxin. Epilepsy and convulsive disorders: phenobarbitone; phenytoin. Sedatives and hypnotics: diazepam. Poisoning: atropine sulphate injections; activated charcoal; syrup of ipecac. Antacid: aluminium hydroxide. Colicky pain: Oxyphenonium bromide. [redacted] Diabetes mellitus: an oral hypoglycaemic like glibenclamide or metformin; insulin. Uterine bleeding: ergometrine; Oxytocin. Urinary tract infections: Cotrimoxazole..Ear infections: Choramphemicol/gentamicin drops (Other requirements for ear, nose and throat conditions will have to be met). Skin conditions: Disinfectant: chlorhexidine; gentian violet; iodine. Soothing

agent:calamine lotion. Ringworm and other fungi:Whitfields ointment (benezoic acid plus salicylic acid). Scabies and lice:benzyl benzoate.

Eye conditions: Topical antibiotics:chloramphenicol - 1% ointment; tetracyclines - 0.5% ointment (other materials, including spectacles will have to be provided).

Psychiatric conditions: Amitriptyline, chlorpromazine, fluphenazine. In addition to the drugs mentioned, there is need for intravenous solutions like normal saline and 5% dextrose, surgical dressings, suture materials and a local anaesthetic.

Malnutrition: The most important health - threatening condition in our country is malnutrition, mostly protein - calorie malnutrition, though specific deficiencies are also present. Adequate food intake is the solution. While there are many factors like lack of unjust distribution, poverty and lack of education, primary health care should ensure adequate intake of balanced food, with easily available foodstuffs.

Tobacco: The smoking epidemic should be of great concern in primary health care. While cigarette consumption is declining in many affluent countries, it is increasing in our country. The tragic effect is increase in lung cancer and cardiovascular and other diseases related to smoking. A campaign must be mounted as part of primary health care against smoking.

Alcohol: The alcohol problem is a growing threat to health. Between 1960 and 1980, alcohol consumption increased by 500% in Asia. Alcohol - related problems affect not only the individual drinkers but also their families and the general community and can be physical, mental or social in nature.

Chemicals in the environment: A class of substances are being added to the environment; these are synthetic chemicals. Many of them can be toxic and need to be dealt with in the same way as poisons and infections. Among them are pesticides and insecticides (example: highly toxic organo-phosphorus compounds); their metabolites; industrial effluents (an example is disease produced in people who ate fish rendered toxic by the presence of methyl mercury); herbicides (Agent Orange); Fungicides. All these call for prevention, recognition and management. There are an estimated 375,000 cases of human poisonings by pesticides in developing countries every year with some 10,000 deaths[10]. Lack of protein in the food of rural workers is an additional factor that makes these chemicals even more dangerous. Agricultural spraying (including aerial) is common in the countryside but its effects are not always known. India is proud to be the largest manufacturer of pesticidal chemicals in the whole of

South Asia and Africa, with a licensed capacity of 78,000 tornes[11].

Search for new drugs

Affluent countries are spending vast sums of money on the search for new products to counter diseases met commonly in those countries and which often do not have relevance to the morbidity and mortality in our country. Because the pharmaceutical firms do not have a ready market for some of the drugs required in our country, these transnational firms do not develop them. The large transnationals are not interested in the problems of a poor country. We must also catch up on the newer of natural products of "biodrugs". These drugs could be manufactured with the level of technology available in our country[12].; we have traditionally been producing these plants and their products and we should not have to import the finished products from the affluent countries.

It is necessary that we develop a research base. The Government must actively undertake and stimulate and encourage research into pharmaceutical preparations, essential to combat the diseases most important to our country. They should give sizeable grants to the Indian firms engaged in research and also make it obligatory for all pharmaceutical firms in the country to set apart and utilize a proportion of their sales turnover for research and development of new products, relevant for primary health care. The Government should also give sizeable grants to Universities, Medical Colleges and research institutions for search for new products and technology. Production of all essential drugs must be taken up by the Government, with the collaboration of voluntary nonprofit organizations; so also the distribution and supply of these drugs. There should be no scope for profiteering. The pricing policy should be such that the burden on the public is eased; there should be no excise and other similar duties on essential drugs or the raw materials. There is no need for high pressure salesmanship, with very large numbers of salesmen, free samples, gifts and free travel in the country and abroad for conferences or pleasure for those doctors who push the products. These should be banned as also advertisements in media for the public. All essential drugs should be free of patents and be known only by the generic name; at the same time the profession and the public should be assured of quality. This starts with good manufacturing practices and subsequent monitoring of quality through to utilization.

Drug information

Every drug is a poison. Drugs are prescribed because they give more benefit than harm. One must be careful of the adverse reactions and be especially

watchful in infants and children (particularly small-for-date babies, protein-calorie malnutrition, infections), elderly patients and pregnant women. Adequate information should be given to the patient about the drug. These would include

What is the dose; frequency of use; route; relation to meals?
Does it cure or give symptomatic relief?
What to do if the drug is not working? Is there a lag period?
How long to take? When to discontinue?
What are the side-effects? adverse reactions?
What are the precautions during work in the field or the factory?
How is it to be stored?

Evaluation

It is necessary to make periodical evaluation of the efficacy of primary health care including drugs. Measurements of health, morbidity and mortality, immunization, improvements in water supply and sanitation, consumer satisfaction and community invlovement will all form part of it. Changes must be made periodically in the drugs as needed for better health care.

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IN SEARCH OF APPROPRIATE MEDICINE-1

COUGH MIXTURES

Cough sedatives and expectorant mixtures are probably the most commonly prescribed preparations along with tonics, and the sale of these forms the butter on the bread of quite a few pharmaceutical firms. This study was prompted by our need for a cheap and effective anti-tussive.

INDICATIONS FOR COUGH SUPPRESSANTS

Cough is a protective reflex which helps to expel irritant matter from the respiratory tract. Indiscriminate arrest of cough is not desirable. If the cough is due to centre being too hypersensitive to reflex irritation from the upper respiratory tract (larynx and above) and where cough is of unproductive nature central depressants like opiates are indicated. In children sedation at night is more effective.

UTILITY OF COUGH EXPECTORANTS

Expectorants are used in the treatment of cough due to irritation of the respiratory mucosa below the epiglottis and respiratory conditions in which the secretion is thick and viscid needing liquifaction. Commonly used expectorants (Ammonium chloride, iodide, Ipecacunha, are supposed to stimulate output of respiratory tract fluid reflexly through irritation of gastric mucosa. For this, simple steam inhalation is much better, effective and reliable therapy.

It must be remembered that except for dextromethorphan and codeine (centrally-acting cough suppressants) experimental proof of effectivity of other drugs used in cough mixtures is totally lacking and rationale for their use can be debated.

With these facts in mind, we evaluated most of the cough mixtures available in the market today and found out some interesting facts.

1) Most of the proprietary preparations available as cough remedies generally contain a central cough suppressant, an expectorant, an antihistaminic and a brochodilator in pleasantly flavoured syrupy base. Combining the therapeutically incompatible cough suppressants and expectorants cannot be justified except for the fact that it enables the pharmacy to sale their product with a good margin of profit (cough sedative is costly due to codeine content), when sold in market as a cough remedy. It is interesting to find that a pure cough expectorant is not cheaper than a pure cough sedative or cough sedative-expectorant mixture. It is also interesting to find that the cough mixtures available in bulk (5 litre Jar) are only cough expectorants and these are the preparations dispensed by a private practitioner as a cough remedy in all cases of cough irrespective of their site of irritation (even if the site is above glottis)

2) The average daily cost of taking a cough remedy is:

Cough sedative-expectorant	- 1.50 to 2.25 Rs./day (40 ml. syrup)
Pure cough sedative	- about 1.10 Rs./day
Pure cough expectorant	- 1.25 to 2.25 Rs./day (40 ml. syrup)

Note:- The cost of cough mixtures with same ingredients varies as much as 50%.

...2

3) Many available commercial preparations contain drugs in either quite inadequate or excessive doses and some of them contain drugs which are out dated and no longer recommended.

These observations prompted us to evolve a sedative mixture and an expectorant mixture containing only the required drugs in adequate dose in a palatable base and which would be reasonably priced. As we have no access to the required drugs in their powder form which are available only in bulk, we arrived at approximate cost by using tablets available in the market, so that cost computed by us is necessarily higher than it would be for the drug companies who buy the drugs in bulk in their poder form. Still a difference can be made out between the market price of commercial preparations and the cost of the mixtures as prepared by us using tablets bought in retail.

HOW TO PREPARE COUGH MIXTURE ;

1) Cough sedative

i) Crush and make into powder
   a) 10 tablets of codeine phosphate (100 ml.) (10 mg.-6 paise each)
   +b) 5 tablets of ephedrine HCl (30 mg.-1.5 paise each)
   +c) 5 tablets of chlorpheneramine maleate (4 mg-2 paise each)
ii) Dissolve the powder in warm water and filter
iii) Dissolve 6 heaped teaspoonsful of sugar (66 gms. 20 paise) in ½ cup of boiling water and add 1 drop of pineapple flavour.
iv) Add 0.5 gm (flat teaspoonful) of Na benzoate as preservative to the filtrate and mix well with sugar solution to make it 100 cc. total. (1 teaspoonful flat = 2.2 gms.)

Dose : 10 ml/6 hrly for adult
5 ml/6hrly for children
Cost 55 paise per day.

2) Cough Expectorant (100 ml.)

i) Crush and make into powder.
   a) 5 tablets of chlorpheniramine maleate (4mg.-2paise each)
   b) 5 tablets of ephedrine HCl (30 mg-1.5 paise each)
   c) less than one flat teaspoonful of ammonium chloride (3gms-3 paise) (1 TSF flat= 4 gms)

ii) Dissolve in hot water and filter.
iii) Dissolve 6 heaped teaspoonful of sugar (60 gms-20 paise) in ½ cup of boiling water to which 2 drops of pineapple flavour are to be added.
iv) Add 500 mg (1/8 teaspoonful flat) of Na benzoate as preservative to the filtrate and mix it with sugar solution to make 100 cc

Dose: 10 ml/6hrly/day adult
cost: 16 paise per day.

Remember Na benzoate is added to avoid fungus overgrowth. Those who wish to utilise the drug within 48 hours, need not add the preservative. Please preserve in clean container to avoid fungus overgrowth.

Sanjiv Chugh
Medico Friends Circle
Sevagram

To be cyclostyled for Refresher course for Dr's + nurses - (Copy to Pharmacy Dept)

DR 30.5

Ichthanol in Glycerin

Ichthanol	500G
Glycerin	900G

Mix well.

Gentian Violet 1%

Dissolve 1G in warm water (Water should be boiled first & then if it is warm use it). make up the volume upto 100 ml with warm water

Acriflavin Solution

(Same as above)

Dissolve 1G in warm water make up the Volume upto 100 ml with warm water.

Normal Saline 0.9% I.P (1966)

Sodium chloride 9G

Water for injection Sufficient to Produce 1000 ml.

Dissolve, filter and immediately sterlise by heating in an Auto clave or in a Pressure Cooker.

Benzyl Benzoate Emulsion

Benzyl Benzoate	250 c.c.
Emulsifying Wax	20 G
Water q.s.	1000 c.c.

Weigh Wax, measure water and add water to Wax. Heat the water and Wax together until the Wax is melted. Take off the heat. Add Benzyl Benzoate and Stir vigerously until cool. Then Transfer the suspension in a jar and shake occationly until cool

Eusol Solution

Bleeching Powder	6 G	120 G
Boric Acid	6 G	120 G
Water q.s.	500 c.c.	10000 c.c.

Triturate the bleeching Powder with half of the Water add the boric Acid Powder. Transfer to a bottle & shake Well, add Water to volume Allow to Stand for at least half an hour And then filter or Decant

Boro Glycerin

Borax	12%
Glycerin q.s.	100%

Powder the Borax throughly & then triturate with Glycerin, Heat the mixture until the Borax dissolves. use the gentle heat. Take care not to over heat.

Procedures for Iteid various dilutions & Savolon various dilutions it is on the Container. Contact Hospital pharmacy (SSMCH)

Procedure Not available.

Mercurochrome

Corticosteroid ointment

Mixture for Cough & fever for children

Milk of Magnesia

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APPENDIX - 2

LIST OF ALLOPATHIC MEDICINES USED AT SUBCENTRE LEVEL

2.1 MEDICINES TO BE CARRIED BY HEALTH WORKER (MALE)

For Internal Use :

1. Aspirin, Phenacetin and Caffeine (APC) tablets
2. Belladonna and phenobarbitone tablets
3. Chloroquine tablets
4. Dried aluminium hydroxide tablets
5. Ergot tablets
6. Iron and folic acid tablets
7. Magnesium hydroxide tablets
8. Magnesium sulphate
9. Mepyramine (Antihistamine tablets)
10. Mist bismuth kaolin
11. Phthalyl sulphathiazole tablets
12. Piperazine citrate tablets
13. Rehydration powder
14. Tincture codeine co.
15. Triple-sulpha tablets
16. Vitamin A solution

For External Use:

17. Antiseptic lotion
18. Benzoic salicylic ointment
19. Benzyl benzoate emulsion
20. Gentian violet 2 per cent
21. Mercurochrome 2 per cent
22. Methyl salicylate liniment
23. Potassium permanganate crystals
24. Silver nitrate eye drops
25. Sulphacetamide eye and ear drops 10 per cent
26. Sulphanilamide skin ointment
27. Sulphonamide dusting powder
28. Tetracycline eye ointment
29. White vaseline

2.2 MEDICINES TO BE KEPT AT SUBCENTRE

For Internal Use

1. Biphenium hydroxy-naphthoate granules
2. Liquid paraffin
3. Mist. alkaline
4. Mist. carminative

..Contd/2-

5. Mist. sedative expectorant
6. Multivitamin tablets (A,B,C,D)
7. Syrup ferric ammonium citrate

For External Use

8. Boric acid powder
9. Calamine lotion
10. Methylated spirit
11. Tincture benzoin co.
12. Tincture iodine
13. Zinc boric dusting powder

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DR 30:7

ESSENTIAL DRUGS LIST FOR PRIMARY HEALTH *
CARE LEVEL.

1. Aluminium Hydroxide + Magnesium Hydroxide (Tab/Liquid, Antacid)
2. Antihaemorrhoidal oint.
3. Aspirin Tablet (Acetylsalicylic acid) for adults only
4. Benzoic acid + salicyclic acid ointment (Unguantum of Whitefield).
5. Benzly benzoate lotion
6. Calamine lotion
7. Charcoal Activated
8 Chloroquine Tablet
9 Chlorpheneramine maleate Tablet
10. Citremide + Chlorhexidine
11. Ethinylestradiol + Levonorgestral Tablet (low dose)**
12. Ferrous sulphate + folic acid Tablet
13. Folic acid
14. Gentian violet solution
15. Glycerine suppository
16. Iodised salt
17. Lysol/Cresol solution
18. Magnesium sulphate
19. Mebendazole Tablet
20. Oral Rehydration Salts

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* The above drugs can be used by Auxillary Nurse, Midwives, Public Health Nurses and adequately trained and supervised village workers.

** Proper training to be imparted to Family Planning workers to dispense contraceptive pills and follow-up.

21. Paracetamol Tablet and Syrup

22. Phenoxymethylpencillin Tablet

23. Simple cough linctus

24. Tetracycline eye ointment

25. Vitamin A Capsules and Tablet

26. Vitamin-C Tablet.

Source:
INTERNATIONAL CONSULTATION ON
RATIONAL SELECTION
OF
DRUGS

17th-21st July 1986
New Delhi

VOLUNTARY HEALTH ASSOCIATION OF INDIA

DR 30.7

ESSENTIAL DRUGS LIST FOR PRIMARY HEALTH * CARE LEVEL.

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17th-21st July 1986
New Delhi

VOLUNTARY HEALTH ASSOCIATION OF INDIA

DR 30.8

BAN INJECTABLE CONTRACEPTIVES -

INDIAN WOMEN DESERVE A BETTER DEAL

A campaign group has been formed in Bombay to protest against the Drug-controller of India approving NET-EN as a contraceptive. Two companies - UNICHEM and GERMAN REMEDIES - have been given licences to manufacture this drug.

Today's protest demonstration in front of Oberoi Towers, where the Family Planning Association is holding a closed door conference of 'experts' on NET-EN. We plan to continue with the campaign and expand it to include all long-acting contraceptives.

What are Injectable Contraceptives? Injectable Contraceptives (I C) prevent pregnancy more or less in the same way as oral contraceptives. But they are administered by injection and are long-acting. The best-known ones are Depo-provera and NET-EN Depo needs only one injection every 3 months and nET-EN, one every 2 months.

Population control enthusiasts consider injectables the ideal form of contraception for women in the third-world because of the ease with which they can be administered on a mass -scale and the low failure rate. To those who look at women in the third world as nothing but faceless factors to be considered in any strategx of population control they cook up, the benefits seem overwhelming and the 'risks' in terms of women's health negligible. There has been a concerted campaign lately to 'sell' the idea of I Cs through the media and elsewhere. The conference organised by the Family Planning Association on 28th and 29th December 1984 at Oberoi, is part of this 'marketing strategy'.

Depo-provera and NET-EN -the controversial contraceptives...

Depo-provera has been the centre of a fight between Health groups and women's groups on the one side and Pharmaceutical companies on the other since the sixties, when the Upjohn Co. of U S A sought approval for it in the sixties. Upjohn has fought a hard and long battle in the U S unsuccessfully. They desparately wanted approval before their exclusive rights on the drug expired. The campaign in the U S and elsewhere brought Depo-provera a 'bad name'. Approval for its manufacture has not been given by the Drug-controller of India. But neither has any explanation been given to the public or to interested groups about why it has not been approved. Meanwhile, NET-EN another I C about which not much is known has been approved in India and licence to manufacture it has been granted to two companies - Unichem and German Remedies.

Both Depo-provera and NET-EN have been used in India for several years now for research purposes. This research has been carried out maily on poor women by voluntary agencies who conduct community health programmes, under the supervision of the Indian Council of Medical Research. The reports of the studies have not been published till today

and ICMR has refused to make it available to anyone. All interested parties are supposed to take their word for it that while Depo is not so good, NET-EN is just fine. Past experience with contraceptives and other drugs does not inspire in us any such trust or confidence. We believe that we have a right to know the details of the research studies, to make our own investigations and to come to our own conclusions. We do not consider the masses of women mere pawns in population control strategies to whom contraceptives are 'sold' on the basis of incentives without prior information.

What we do know about ICs is quite disturbing. Upjohn Co., conducted two animal safety studies in the sixties - a seven year one on beagle dogs and a ten year one on monkeys. Within three and a half years of the dog study, all dogs on high doses and half on low doses were dead due to inflamation of uterine lining. (The two on low doses who survived had their uteruses removed.) All control dogs and survived except one which died of bite wounds and four which were sacrificed by the researchers. The dogs also developed cancer of the breasts, drug-induced diabetes and various other problems. At this point, Upjohn declared that beagle dogs were not the ideal animals to judge risks to human females. Later even the monkey studies in which cancer of the uterus occured were said to be 'irrelevant to human experience'. The history of this controversy has been marked with disinformation and a desparate desire on the part of the company to maximise profits without making sure first that the drug is safe.

Breast cancer, two types of uterine cancer, serious menstrual disturbances and masculinisation of female foetuses are some of the serious effects of Depo-provera. Others are depression, decreased libido, nausea, dizziness,(weight gain without any increase in nutrition)etc.

The W H O report on I Cs (1982) says that the majority of women on I Cs have their menstrual cycle disrupted. The extent of disruption is stunning. "Less than one third of women on Depo report having any normal menstrual cycle during the first year of usage' and 'approximately half the users (of NET-EN) reported at least one normal menstrual cycle during the first year'. Both the above quotes from the W H O report are examples of the concerted attempt to underplay the dangers of I Cs. In fact a significant number of women stop having their periods only to have severe bleeding after injections are withdrawn while others bleed every day of the month while on the drug. But everyone concerned seems to feel that it is a minor side-effect. For Indian women who hold the world record for anemia, it is a very very significant side effect.

There is far less information available about NET-EN on human metabolism, on infants exposed to them through breast-milk or about their carcinogenic properties. No one seems to know why the majority of women on these drugs suffer from menstrual chaos. No do they know why these women put on weight without more nutrition or why they are depressed.

Yet the advocates of I Cs, including the W H C, consider them an ideal form of contraception. Their favourite phrase is risk-benefit ratio. According to them if the benefit outweighs risk, the drug should be used.

But the risks are taken only by women. The benefits are mainly for the pharmaceutical companies, the population control experts and the Governments of third world countries.

There is a lot that is wrong with our family planning policies. Its always our families and their plans. A beginning must be made somewhere to correct them. Lets start with the newest strategy which is about to be imposed on the masses of Indian women. Lets struggle against the inundation of this country with I C S.

OUR DEMANDS: ;) Ban all long-acting contraceptives and withdraw approval for NET-EN.

2) Make public all studies in India on Depo and NET-EN. immediately.

3) Stop experimenting on third world women with hazardous drugs and contraceptives.

4) Institute a public enquiry on the controversial injectable and implanted contraceptives.

JOIN US IN OUR STRUGGLE FOR A BETTER DEAL FOR OUR WOMEN.

Campaign group against long-acting contraceptives.

1. Forum Against Oppression Of Women.

2) Women's Centre, Bombay.

3) Medico-friends' Circle.

4) Stree Mukti Sanghatna

5) Sangharsh Vahini.

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A SURVEY OF COUGH SYRUPS

Objective :

To study the various cough syrups and similar products used in the treatment of cough, to find out the rationality of their usage in therapy for cough, by doing a detailed analysis of the various ingredients of the mixtures and also finding out the cost/day's treatment.

Methodology : (June '86)

Eighty products listed by MIMS India, classified as expectorants, cough suppressants, mucolytics and decongestents were included in the survey.

They were analysed according to the rationality from therapeutic point of view under various categories A,B,C..... as laid down in the summary part.

To judge the effectiveness of a particular cough mixture following criteria should be considered.

As far as possible it should have a single ingredient which is proven to have the desired effect. e.g., (a) if the unproductive, dry cough is to be suppressed it may contain noscapine, codeine, etc., as single constituent.

(b) If the sputum is to be expectorated (brought out) it may contain an expectorant like Potassium Iodide as single constituent. However, steam is the best expectorant and administration of other compounds is not proven to be more efficacious for the expectorant action.

(c) In patients of asthma or chronic bronchitis where aim is to dilate the airways and help clear them of excess secretions it could contain bronchodilators like Salbutamol, ephedrine, etc., as single constitutent ingredients.

Whatever the ingredients are present, they should be in sufficient doses which would be therapeutically efficacious.

For therapeutic effects tablets are preferred over liquid preparations most of the times. However when a soothing effect on the pharyngeal mucosa (inside of throat) is desired, one could opt for alternatives like drinking hot fluids or simple sugar syrups or sucking a sugar cube, etc.

In case of multiple ingredients it is necessary to see that the ingredients do not antagonise each other's actions in any form.

e.g. A cough expectorant should not be combined with a cough suppressant or an antihistamine; a bronchodilator with an antihistamine or a cough suppressant., etc.

The cost of therapy with a particular formulation advised should be reasonable, i.e, as low as possible for the desired action - the therapeutic benefit.

In any case, one has to make sure that the cough syrup or whatever formulation is being used has the capacity to produce the action for which it is being marketed.

Summary of the survey findings :

The formulations are categorised as explained below :

Category

A	-	Only Antitussive (can suppress the cough reflex)
B	-	Only expectorant (which help in bringing out the sputum)
C	-	Only mucolytics (which is supposed to liquify the sputum)

contd.....2/-

Category

D - Only bronchodilator (which dilates the bronchi)
E - Only Antihistamine (anti-allergic compounds)
F - Expectorant + Antitussive
G - Expectorant + Bronchodilator
H - Expectorant + Mucolytics
I - Expectorant + Antihistamines
J - Having more than 2 of the A,B,C,D,E.
K - Bronchodilator + Antihistamine
L - Bronchodilator + Mucolytics

Table - 1

Break up of Categories

Total No. of formulations : 80

Category	Rational Formulation	Irrational Formulation
A	5	-
B	2	-
C	-	4
D	2	-
E	-	-
F	-	6
G	2	-
H	-	-
I	-	7
J	-	47
K	-	3
L		
	11 (13.75%)	69 (86.25%)

Table - 2

Type of formulation

Tablets/capsules	19	23.75%
Liquids/Syrups	56	70.00%
Other forms	5	6.25%
TOTAL	80	100 %

contd.....3/-

Table - 3

No. of Ingredients	No. of Formulations	%
1	9	11.25
2	11	13.75
3	20	25.00
4	11	13.75
5	13	16.25
6	7	8.75
7	2	2.50
8	5	6.25
9	1	1.25
10	0	-
11	0	-
12	1	1.25
	80	100.00

Table - 4

Cost/day for an Adult	No. of Formulations	%
Below Re. 0.50	1	1.36
Re. 0.50 - below 0.95	5	6.84
Re. 1.00 - Rs. 1.95	23	31.50
Rs. 2.00 and above	44	60.27
TOTAL	73	99.97

Conclusion :

The findings of this survey are left open to the people for discussion. But we would like to raise the basic issues such as the uselessness of the mixtures in cough therapy, especially the liquid preparations when compared to the medical benefits they are likely to have.

ANTACIDS

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1. Introduction
2. General Information
   a) Uses of Antacids
   b) Classification
   c) Individual Antacids : (1) Aluminium hydroxide (2) Aluminium phosphate (3) Other Aluminium compounds (4) Calcium carbonate (5) Magnesium hydroxide and oxide (6) Magnesium trisillicate (7) Magnesium carbonate (8) Magaldrate (9) Sodium bicarbonate (10) Sodium citrate (11) Tripotassium dicitrate bismuthate (12) Miscellaneous gastric antacids (13) Antacid combinations.
   d) Gastrointestinal Protectives and Abdosbents : (1) Simethicone (2) Kaolin (3) Activated charcoal (4) Pectin (5) Magnesium triscillicate.
3. Comparison of Antacids
4. Choice of Antacid
5. Dosages of Antacid
6. Evaluation of available preparations
7. Review of promotional literature
8. Practices and malpractices followed by G.P.s
9. Other antiulcer drugs and surgery
10. Role of gastric antacid in management of Peptic ulcer.
11. Dangers of antacids
12. Epidemiological aspects of peptic ulcer
13. Clinical aspects
14. Preventive aspects
15. Issues - Hyperacidity - Antacid pru
16. Action Plan
17. Conclusions
18. References

"The desire to take medicine is perhaps the greatest feature which distinguishes man from animals"

- Sir William Osler.

The human desire 'to take medicine' carries, however a price tag[1]. A desire to take Antacids in any 'dyspepsia', 'flatulance', 'gas', 'belching'. 'Borborygms' has made them one of the most abused drugs. Because of irresponsible advertising it has become misused drugs and public has started believing that man is constantly fighting a battle against acidity and every little belch or upper gastro-intestinal upset calls for an antacid. Who is responsible for such misuse of Antacids ? The answer is four 'P's :

(1) Power of Placebo : Many studies have revealed substantial incidence of placebo responsiveness of individuals with minor gastrointestinal upset.

(2) Physicians: The first weapon used by a physician for any abdominal discomfort is 'Antacid'.

(3) Pharmaceuticals: Irresponsible advertising has misguided physicians and public. In profit maximisation and adoption of management principle like 'foot-in-the door-phenomenon' has made antacids most abused drug. The drug proved effective for healing ulcer is promoted for indigestion[1].

(4) Public: They have started believing that they have to pay penalty in form of ulcer for their stressful life.

General Information of Gastric Antacids

Gastric antacids are agents that neutralises or remove acid from the gastric contents. They are indicated in following conditions :

(1) Peptic ulcer : Administration of antacids has been the major accepted form of treatment for peptic ulcer[3].

(2) Reflux Oseophagitis : Reflux of gastric contents through an incompetent lower oesophageal sphincter can lead to oesophageal inflammation and cause heart burn. Hiatal hernias can be seen on radiographs of patient with reflux oesophagitis. The medical therapy of patients with reflux is mainly aimed at reducing the quantity and acidity of the gastric contents available for reflux which is done by Antacids.

(3) Use as prophylaxis for GI bleeding - The patients who are seriously ill especially admitted in intensive care unit are having risk of development of upper GI haemmorhage. Many of these patients have been treated prophylactically with either antacids or cimetidine to prevent haemmorhage. Studies have shown that antacids are more effective than placebo or cimetidine for this purpose (N.Engl.J. Med.302:426, 1980) Surg.Gynecol.Obstet.153:214,1981).

(4) Erosive gastritis which is also known as haemorrhagic gastritis or multiple gastric erosions is an important cause of upper GI bleeding. Once bleeding stops, a regimen of hourly antacids or cimetidine is the line of management.

Though these are the scientific usages of antacids, in practice, it is used in wide variety of conditions. Lay people use them as self medicament in almost any GI condition.

Classification[5]

Antacids are commonly divided into :

1) Nonsystemic antacids
2) Systemic antacids.

Nonsystemic antacids includes aluminium hydroxide, magnesium hydroxide, magnesium oxide, magnesium trisilicate, calcium carbonate, bismuth carbonate and calcium phosphate. These drugs are water insoluble, generally unabsorbable and are called nonsystemic because they do not produce systemic alkalosis.

Systemic antacids include compounds like sodium bicarbonate and sodium citrate which are absorbed into the systemic circulation and may cause metabolic alkalosis.

Individual Antacids[2]

(1) Aluminium Hydroxide : It is a weak antacid and generally is marketed with other antacids. Although it is considered to be nonsystemic, some absorption from the gastrointestinal tract occurs. The acid neutralizing capacity has been found to differ according to the process of manufacture, age of the product and it is varying from batch to batch in the case of given product. Pepsin activity is not significantly inhibited. Particles of wet aluminium hydroxide are somewhat adhesive and the compound is demulcent. The role that the demulcent action plays in the treatment of peptic ulcer is controversial.

Adverse reaction : Constipation, hypophosphaemia interfere with absorption of drugs like tetracyclines, iron salts, antichlolinergic drugs digoxin and PAS. Aluminium hydroxide may prevent the absorption of phosphate from the intestine which would result in hypophosphatemias and osteomalcia giving use to proximal myopathy. Encephalepathy might result in patients undergoing hemodialysia.

Other uses : It can be used to reduce intestinal absorption of phsophate ine case with phosphatic renal calculi and in chronic renal failure.

(2) Aluminium phosphate : It is sometimes prefered to aluminium hydroxide as it does not interfere with phosphate absorption. It has however no special advantages and it is an ineffective antacid.

(3) Other aluminium compounds : Basic Aluminium carbonate has its pharmacological property same as Aluminium hydroxide. However its capacity for neutralisation is greater. Amongst the aluminium containing Antacids it is best for the management of phosphatic nephrolithiasis.

Dihydroxyaluminium sodium carbonate combines in a single chemical entity, properties of both sodium bicarbonate and aluminium hydroxide. The drug is partially systemic antacid. It is claimed better than aluminium hydroxide however lacks the confirmatory data.

Dihydroxyaluminium aminoacetate is a basic salt of aluminium and glycene. Claims that the substance is less constipating than aluminium hydroxide are not objective, but there is less aluminium per chemical equivalent. The capacity for neutralisation is low.

(4) Calcium carbonate : It occurs as a white, odourless powder with a chalky taste. It was the first gastric antacid to be used. It has remained popular for a century and a half. Its antacid effects are rapid in onset and relatively prolonged in duration $CaCO_3$ has a high capacity for neutralising acid in vivo. It is inexpensive. It was * considered to be the most effective antacid for many years. However today, $CaCO_3$ is used much less frequently.

Adverse reactions : CaCO3 has long been considered to be a nonsystemic antacid. However enough is absorbed to cause systemic and renal effects in certain circumstances. A slight to moderate alkalosis occurs. Hyper calamia may result in patients having uremia. It may cause acid rebound, might be because of reactionof Ca++ on the small intestine to stimulate release of gastrin. It has tendency to produce constipation and fecal concretions. The administration of CaCO3 promotes positive phosphate balance and lead to hyperphosphatemia especially in patients who have developed milk alkali syndrome. Disturbance resulting from the liberation of carbondioxide may lead to belching in some individuals. Nausea is also an occasional complaint. Hypercaleiuria and alkalyria predispose to nephrolithiasis.

(5) Magnesium hydroxide and oxide : Magnesium oxide, a on contact with water is converted to magnesium hydroxide and then acts. Magnesium oxide is available as a light colourless powder insoluble in water, while Magnesium hydroxide is available as milk of magnesia containing 7 to 8.5% of magnesium hydroxide.

It is quick acting antacid and the action is prolonged. $Mg(OH)_2$ as milk of Magnesia has long been popular among the laity as an antacid and a cathartic. Acid rebound occurs. However it is insignificant.

Adverse reactions : It has mild cathartic action. It is contraindicated in patients having impaired renal function or it might cause hypermagnesimia. Although Mg(OH)3 is classified as nonsystemic antacids, 5 to 10 % of the magnesium can be absorbed.

(6) Magnesium trisilicate : It has too slow rate of reaction with acid, to be useful for the management of peptic ulcer. Even in a normal person it rarely elevates the intragastric pH above 2.7. As it becomes gelatinous in consistency it provides a protective coating to the ulcer crater.

Adverse reactions - laxation by high doses. Approximately 5% is absorbed any hypermagnesemia can occur in patients with renal insufficiency. Approximately 7% of silica may be absorbed which may lead to siliceous nephroliths. Intestinal concretions also occur. It is good absorbent which may interfere with absorption of dietary proteins and number of other drugs. It adsorbs pepsin also.

(7) Magnesium carbonate : This antacid has properties similar to those of magnesium hydroxide except that carbondioxide is liberated which may cause belching. It has been shown to be an excellent antacid in clinical practice.

(8) Magaldrate : It is complex hydroxymagnesium aluminate which reacts with acid in stages. The aydroxymagnesium is relatively rapidly converted to magnesium in and the aluminate to hydrated aluminium hydroxide. The aluminium hydroxide then reacts slowly to give a sustained antacid effect. Magaldrate more consistently buffers the gastric contents than do the mixtures. The PH is usually maintained between 3.5 to 4.0 Its systemic effects are those of $Mg(OH)_2$.

(9) Sodium Bicarbonate : It exerts immediate and rapid antacid action in the stomach because of its solubility, however it has short duration of action. It is a systemic antacid. Eructation of the carbon dioxide liberated during the process of acid neutralisation often gives the patient a sense of relief from abdominal discomfort. This is the basis of its reputed carminative action.

Adverse reactions : Chronic use of $NaHCO_3$ alone as an antacid (taking with milk) can cause milk alkali syndrome. Because of its sodium content it might lead to weight gain, volume expansion, increase in BP and may promote oedema. It may be hazardous in renal insufficiency, incipient or active hypertensives and in CCF patients. Continuous maintenance of raised pH by $NaHCO_3$ in stomach may lead to stimulation of gastrin and rebound acidity.

Other uses : (1) In metabolic acidosis
(2) In urinary tract infection to make urine alkaline and to prevent precipitation of substance like sulfonamide and uric acid, it is used.
(3) For topical application it is used as an antipruritic lotion, as an eyewash, mouth wash, douch to loosen wax in the ear and in enemata.

(10) Sodium citrate : Sodium citrate has properties similar to those of sodiumbicarbonate except that there is no liberation of carbondioxide. Effervescent preparation that 'fizz' consist of sodium bicarbonate and citric acid which react in solution producing carbondioxide and sodium citrate.

(11) Tripotassium dicitrate bismuthate (de-nol) : A colloidal bismuth preparation accelerates healing of gastric and duodenal ulcer. In a crossover trial, Lam et al found that colloidal bismuth subcitrate headed 85% cimetidine resistant ulcers whereas high dose of cimetidine headed only 40%[6]. Similar comparison was done with ranitidine and healing. Relapse of duodenal ulcer was compared. Though there was no statistical difference in healing at 4 wks and 8 wks with both these drugs there was difference in relapse rates. 74% and 84% of ranitidine beated patients developed relapse of duodenal ulcer after 4 months and 8 months respectively. In contrast to this, 41% and 55% of the patients treated with TBB developed relapse[7]. Similar results have been obtained by Martin DF[8].

Adverse reaction : It causes black discoloration of stools. Liquid preparation is less acceptable to the patient because of its odour. However TDB tablets can be given which are effective and acceptable.

(12) Miscellaneous gastric antacids : Gaviscon is mixture containing small amounts of $NaHCO_3$, $Al(OH)_3$, $Mg_2Si_3O_8$ and alginic acid. It makes foam (raft) which floats on top of gastric juice. It is intended that in gastro oesophageal reflux, the floating mixture is the first material to make contact with the oesophagus. However it has negligible effect on gastric acid below the raft.

The mineral hydrotalate ($Mg_6Al_2(OH)_{16}CO_3.4H_2O$) has an acid neutralising capacity 84% of that of $Mg(OH)_2$. Milk as antacid has very little effect.

(13) Antacid combinations : Antacids are combined for a variety of reasons and probably such combinations can be considered rational. Laxative and constipating compound can correct the disadvantage of each other, a fast acting ingredient can be combined with a slow acting ingredient to increase the total buffering time, the daily dose of a single entity can be decreased to reduce the risk of toxicity, patient compliance can be improved by combining agents, rather than by giving multiple separate preparations.

The most common mixture of antacids are those of $Al(OH)_3$ and $Mg(OH)_3$ in gravimetric ratio of 2:1 or 1:1.

Gastrointestinal Protectives and Adsorbents : These are discussed here because they are used in combination with Antacids.

1. Simethicone : It is a common ingredient in the antacid combinations. It is included to defoam the gastric juice in order to decrease the tendency towards gastro-oesophageal reflux.

It is light gray, translucent liquid of greasy consistency. It is a mixture of liquid demethylpolyolloxanes with antifoaming and water repellent properties. It is promoted as an adjunct in the treatment of conditions in which gas is a problem, such as flatulence, functional gastric bloating and postoperative gaseous destension. It has also been used to reduce gas shadows in radiography of the bowel to improve visualisation in gastroscopy clinical studies in support of these recommendations are not convincing. Simethicone is used in combination with antacids, antispasmodics, sedatives and digestants.

2. Kaolin is a native hydrated aluminium silicate powdered and freed from gritty particles by elutrication. It is used internally and externally for its adsorbent properties.

3. Activated charcoal : It is an odourless, tasteless fine black powder which is residue from the destructive distillation of various organic materials, treated to increase its adsorptive power. The adsorptive capacity of various brands of activated charcoal differs enormously. It has broad speetal adsorptive activity and is rapid in action. It is used in emergency treatment of oral drug poisoning.

4. Pectin : It is a purified carbohydrate product obtained from fruits and chemically consists of chiefly polygalacturonic acid. It is claimed to be an adsorbent and demulcent.

5. Magtrisilicate : It is an effective gastrointestinal adsorbent but a weak antacid, discussed earlier.

Comparisons of various Antacids

The ideal antacid should have following characteristics[3]:

1. It should be potent in neutralising acid
2. Inexpensive
3. Should not be adsorbed from the gastrointestinal tract.
4. Should contain negligible amount of sodium
5. Sufficiently palatable.
6. Readily tolerated and free from side effects.

Although the ideal antacid is yet to be developed, a number of preparations are available which can be used for the treatment of patients with duodenal ulcer.

One of the ways by which we can compare the antacids is by comparing the buffering capacity of individual antacids. This buffering capacity is expressed in form of mulliequivalent of acid neutralised per gram or per ml. of antacid. Western literatures of various proprietary brands of antacid suspension and tablets and their buffering capacity is available. However such data is leading for Indian brands of antacids. Following chart of western brand antacid is given to give an idea of their buffering cppacities according to their ingredients.

Antacid	Buffering capacity meq/15 ml.	Sodium content meq/15 ml.
1.AI (OH)3 Amphogel	20	0.9
2.AI(OH)3+Mg(OH)2 Maalox Therapeutic concentrate	95	0.11
Maalox plus (containing simethicone)	40	0.18
3.CaCO3 Tums tablet	19.5 per 2 tab.	0.125
4.AI(OH)3+Mg(OH)2+CaCO3 Camalox	54	0.33

(Chart from Manual of Medical Therapeutics - 24th Edition p. 251).

It is evident that maximum buffering capacity is of Antacids containing $Mg(OH)_2$.

Choice of Antacid

1. In general liquid antacids are more effective then tablets[4]. Tablet preparation of magnesium hydroxide and/or aluminium hydroxide possess little acid neutralising capacity and are not recommended in the treatment of duodenal ulcer[3].

2. Magnesium hydroxide is a potent antacid but large, frequent dose can cause severe diarrhoea. For this reason it is combined with $Al(OH)_3$. In most popular preparation, this antacid however would be contraindicated in patients with severe renal disease.

3. Aluminium hydroxide has moderate buffering activity and is hardly used alone as an antacid.

4. Calcium carbonate though effective in expensive and well tolerated antacid, it produces a genuine acid rebound. Again it might lead to hypercalcemia, hypercalciuria and milk alkali syndrome and that is why not preferred.

5. Magnesium trisallicate which is included in various antacid mixtures is a slow acting and weak antacid.

Dosage of antacids

Antacid dosage should be based on multiequivalents of neutralising capacity rather than on volume or number of tablets[9]. An 80-100 mEq dose of antacid is usually prescribed for patients with ulcer disease. This dosage varies from 30 ml. of magnesium and aluminium hydroxide containing antacid to 45 ml. of an aluminium hydroxide contqining antacid. As in India the neutralising capacity of various proprietary brands of antacids is not available, scientific recommendation about the dosage is difficult to make.

In Western set up where three meals per day is taken, recommended dose of antacid is 80 - 100 mEq of liquid antacid. 1 and 3 hours after meal and at bed time 4,9,10. This means a person has to take antacid 7 times in a day. If the most potent antacid is used it means that person has to drink 210 ml. of liquid antacid. If the stomach is empty, antacids must be taken frequently. In treating fasting patients, for example, patients in intensive care units it may be necessary to give antacids every 30 to 60 min. to achieve adequate reduction of acidity.

In Indian set up we take meals twice in a day. Thus 5 dosages logically may be sufficient. However this needs confirmation.

Evaluation of available preparations

I have tried to analyse the antacid preparations listed by MIMS- India (Vol. 2 November 10)[11] and have come to following conclusions.

1. 34 brands of antacids is listed.

2. Of these 34 brands 15 are marketed in the form of liquid, and tablets both. 15 are marketed only in tablet form and 4 are marketed only in liquid form.

In view of less rationality of tablet preparation, to have 30 brand out of 34 in tablet form of which 15 are marketed in tablet forms only seems concernable.

3. I have tried to designate a commercial preparation 'pure antacids' for preparation having a single and/or combined ingredient in form of antacid without having combination of gastrointestinal adsorbents or anticholinergics, for the evaluation purpose.

	out of 34 listed
1 pure antacids (as defined earlier)	5 preparation
2 having added simethicone (dimethyl polysiloxanes)	23 preparations.

Thus if I want to prescribe an antacid for a patient of Duodenal ulcer and I do not want simethicone to be given to him I would have only choice of these 5 antacid preparations.

5. If we analyse still further these 5 antacid preparation none is suitable for my patient of duodenal ulcer. Demerits of these 5 antacids are as below -

1. Aiucinol - is basically aluminium containing antacid and thus would be a weak antacid.
2. Alludrox - contains only AI(OH)3. The alludrox MH contains AI(OH)3:Mg(OH)3 in ratio of 3:1 - ideal ration being 1:1.
3. Eugastrid - 4 antacids are combined of which 3 are weak antacids.
4. Gelusil - Magtrisillicate and aluminium hydroxide - both are weak antacids.
5. Magsil - 4 antacids combined.

6. Gelusil in India contains Magtrisillicate and aluminium hydroxide while in United States of America Gelusil-1 contains AI (OH)3 and Mg(OH)3.

7. Most liquid preparations are available in very small packing e.g. Almagel in 175 ml, Allugel in 210 ml, Digene Gel in 210 ml, Diovol in 175 ml, Gelusil in 175 ml. This would be hardly sufficient for (1) day! This itself suggests that most antacid are working as placeto rather than antacids.

8. If a liquid preparation is prescribed 45 ml x 7 times in a day for 6 wks, a person may require 12600 ml. of antacid meaning that he has to buy 60 bottles of 210 ml packing.

9. If antacid containing methylpolysiloxane is prescribed for CDU than a person would be taking and paying for 63000 mgm of methylpolysiloxane extra. A person taking 3/4 kilo of methylpolysiloxane without any benefit (antacid contains average 25 mgm/5 ml and if requirement is 12600 ml of antacid it would come to 63000 mgm).

Review of Promotional literature

As I mentioned in the starting of this paper (quoting the standard textbook of pharmacology) that because of irresponsible advertising, antacids are most abused drugs. This state of affairs is not present only in India but all over the world. 'Rennie' one of the most popular brand of antacid available on the counter in UK writes 'Digestif Rennie - for on the spot relief' . This tablet contains 680 mgm of calcium carbonate and 80 mgm of light magnesium carbonate. The other caption which is written on the package is 'Digestif Rennie relieves acid indigestion, heart burn, nervous indigestion, acidity, flatulence upset stomach and dyspepsia'.

As it is with this Rennie tablets most of the antacids are promoted as the drug for antiflatulence. No where it is written that antacid relieves the flatulence on the contrary antacids like NaHCO3, MgCO3 liberate CO2 which might produce belching.

The other common finding is almost all antacid preparations are promoted for variety of conditions.

However scientific indications of antacids are few and specific. Many a times it is promoted for indigestion. How are the antacids going to improve the digestion , As mentioned by Kurt Kroenke in his article on polypharmacy that pharmaceuticals adopt foot in the door policy. The drug like antacids was marketed and accepted by the medical science as antiulcer drug had a foot inside and thus it is now promoted for indigestion.

Practices and Malpractices followed by the GP

Physicians are not less responsible for misusing the antacids. Most of the times it is prescribed to give placebo effect. When a patient comes to a doctor for pain in abdomen, something has to be prescribed and that is in form of antacids. In the indicated patients it is prescribed in smaller doses. Many a times because of lack of time knowledge and diagnostic skill antacids are prescribed which is moreso by the unscientific doctors. Again there is a belief that antacids are harmless and thus they are prescribed for a very long time. Such belief is common among the doctor and also in public. Many Indian patients are fussy about their habit of passing stools every day in the morning. They find magnesium containing antacids useful for their bavel habits. This feeling is reinforced by the doctor by saying that 'you are passing stools because you get better digestion with help of the pills'.

Other antiulcer drugs and surgery in the management of peptic ulcer

H2 receptor antagonist cimetidine is now widely used in the treatment of duodenal ulcer. 84 % patients develops healing in the ulcer by cimethidine therapy[12]. The other H2 receptor antagonists like ranitidine and Omeprezol have also been tried in the management of duodenal ulcer.

Anticholinergics have been used for many years to decrease gastric acid secretion. Because of their side effects and advent of H2 receptor antagonists they are used much less frequently as anti-secretory agents. Recently a selective antimuscarinic type of anticholinergic PIERENZEPIN has been developed[13].

Surcalfate (carafate) a drug that coats ulcer crater them from acid and pepsin is also been used. Prostaglandin E2 is also under experimental stage.

Current medical treatment of duodenal ulcer, be it with cimetidine, ranitidine, sucralfate, deNol, prostaglanotin or antacids is successful in not more than 75-80 %[14] of patients and thus surgery would be required in the rest .

Role of Gastric antacid in the management of peptic ulcer

What share antacid has today in the management of peptic ulcer , Today we have so many new drugs especially H2 recepter blocker drugs. The Goodman-Gillman's text book writes 'The status of antacid is presently in a stage of evolution. The use of cimetidine will undoubtedly decrease but will not abolish the need for antacids'[2].

I have an opinion that antacid has a very little role today in the management of peptic ulcer. Treatment with cimetidine is much more convenient, is advantageous in that bavel function is not altered and is no more expensive[2].

Hollander and Harlan did not find any significant difference between antacids and placebo in its effectiveness in a double blind trial[15]. In contrast to this another double blind clinical trial showed that large dose antacid regimen had statistically significant better ulcer healing rates in comparison with placebo(ulcer healing occured in 45% receiving placebo while in 78% treated with antacid)[10]. Though antacid efficacy is proved by this study and is accepted by most text books also the question is that if ulcer healing is occurs in 45% of patient with placebo why to give antacid , Again the same article has proved that ANTACID WAS NOT MORE EFFECTIVE than PLACEBO IN RELIEVING ULCER SYMPTOM.

Antacid therapy can be useful in patient who has cimetidine resistant duodenal ulcer. Most studies show that H2 receptor antagonists heal about 85% of duodenal ulcer after 2 months, but relapse rates on withdrawal of the drugs are very high[16]. A multicentric trial of cimetidine versus intensive antacid therapy for duodenal ulcer showed similar rates of healing with both the form of therapy. 80% of cimetidine beated patients became asymptomatic by week 4, as did 63% of antacid treated patients (P 0.1)[17]. In pregnant patients antacid is preferred to cimetidine therapy.

Dangers of Antacids[2]

The presence of an antacid in the gastric contents increases the volume of gastric juice secreted and the output of HCl. An elevated pH induces the pyloric antrum to release gastrin. In patients with duodenal ulcer this is more marked. Acid rebound is known to occur with many antacids like CaCO3, Mg(OH)2, NaHCO3. Gastric alkalinization may lead to increased susceptibility to various acid sensitive microbial pathogens such as Brucella abortus,. Antacids like Mg(OH)2 and CaCO3 can cause significant elevation of urinary pH and predispose to UTI and urolithiasis. Antacid interact with other drugs by pH related and other mechanisms.

Epidemidogical aspects of peptic ulcer

The absolute prevalence is not known. For duodenal ulcer, estimates have ranged from 6 to 15 per cent. This variation may be related to the population examined, differences in study design, diagnostic method and perhaps to actual changes in frequency of duodenal ulcer disease. It is suggested that 10% of the population has a clinical evidence of duodenal ulcer at sometime in their life time.

It seems that duodenal ulcers are declining[18]. Susser and Stein reported decline in death rates in England and Wales after 1950 due to peptic ulcer[19]. Similar finding is from Germany[20]. The same fact was observed by Sonnerberg in Switzerland. He compiled mortality figures as follows[21].

Country	G.U.	D.U.	Population	G.U.	D.U.	Population
	male			female		
England and Wales	35.3	52.1	23,881,300	35.5	29.1	25,186,100
West Germany	59.3	29.6	29,348,400	34.0	11.8	32,205,000
Switzerland	36.8	28.1	3,074,700	35.0	16.6	3,228,100

The figures refer to the averages of the period 1971-80. The death rate of gastric ulcer and duodenal ulcer are expressed per million living men or women per year.

As far as epidemiology of peptic ulcer in India is concerned following differences are noted[22].

1. Peptic ulcer affects maximum subjects a decade earlier than west.

2. Duodenal ulcer is more prevalent than gastric ulcer.

Significant difference is noted in the incidance of peptic ulcer in southern and northern parts of India and is believed by some th t the incidence is more in soyth in comparison with north. Many studies have correlated this difference with food habits and customs. However no conclusive proof is evident. In India peptic ulcer also affects those in poor socio economic strata[22].

Brief clinical aspects of Peptic Ulcer

Peptic ulcer is a term used to refer a group of ulcerative disorders of upper gastrointestinal tract, which appear to have in common participation of acid pepsin in their pathogenesis. The Zollinger Ellison syndrome (gastrinoma) may be considered a form of peptic ulcer.

Epigastric pain of burning or gnawing character is the most frequent symptom which occurs from 90 mm to 3 hour after eating which is relieved by food and antacids. Change in the character of pain often indicate the presence of combinations. The complications of peptic ulcer includes bleeding, gastric outlet obstruction perforation, penetration and lutractability.

New studies have demonstrated following facts which have important bearings in the management of peptic ulcer. They are :

1. Ulcer symptoms may resolve even though the ulcer is not healed.

2. Many patients with active disease have no ulcer symptoms and may present with complications.

3. Many patients with ulcer like symptoms may have no evidence of an ulcer even after careful readiographic and endoscopic examination.

Preventive aspects[23]

1. The prevelance of duodenal ulcer disease is higher in aggregate smokers than in non smokers. The frequency of the anodation apparently increases in proportion to the amount of smoking.

2. Alcohol, a gastric secretons stimulent should be avoided. It dameges the gastric mucosal barrier.

3. High dose of aspirin ingestion is anociated with an increased incidence of gastritis and gastric ulcer and should be avoided in patients with an active or healed peptic ulcer. Other drugs, such as respine, indomethacin or phynylbutazone may cause epigastrine distress but there is no evidence that they cause peptic ulceration[4].

4. Coffee, tea and meat extractives are to be avoided for the same reason[23].

5. There is no evidence that Bland diets are beneficial in beating ulcer disease. Therefore regular diet should be prescribed. Milk is a poor buffer and its protein and calcium content promotes acid secretion.

6. Reduction of stress some patients have undue stress at work or at home and sometimes modification of the work or home situation cum reduce anxiety[4].

Issues : I could bring out five issues from this paper, they are :

1. What is role of antacids in todays management of peptic ulcer disease when we have their better drugs available ?

2. Which is the best antacid ?

3. What should be dosage of antacid in Indians situation where we take meals twice in a day

4. What is hyperacidity

5. What is role of pris antacids

The first three issues I have discussed earlier and I have presented my view. The last two are discussed below.

What is HYPERACIDITY

This is very common diagnosis made by general practitioner and a physician, however a question would arise whether such condition really exist ? Textbook of medicine and journals mentiona about peptic ulcer but no where the clinical entity like hyperacidity exists. Many a times Hyperacidity is taken as symonyms for Peptic ulcer. Againa any patient having upper abdominal discomfort is stamped having hyperacidity and then he is loaded with antacids. Does Hyperacidity exists without an ulcer ? Many pharmaceuticals literature writes in indications of antacid therapy peptic ulcer and hyperacidity separately.

It is described by the workers that many patient with ulcer like symptoms may have no evidence of ulcer even after careful radiographic and endoscopic examination.

A dilemma exists especially for the Indian situation where diagnostic facility of endoscopy and radiology is available to an average middle class Indian patient, is so small that confirmation of diagnosis by endoscopy or radiology and then starting management would be impracticable and costly. Nevertheless healing patient under broad umbrella of hyperacidity means we are misusing antiulcer drugs especially antacids.

Role of pru Antacids

In USA antacids are taken in pru form. This means when patient has pain they would take antacids. Such practice is also observed in India. However there is no evidence on the effectiveness of antacid prn to prevent ulcer recurrence.

The other question is does antacid relieve the pain of peptic ulcer ? In a multicentric double blind while accepted clinical trial it was shown that antacid regimen was not more effective in relieving ulcer symptoms and pain so I feel that placebo can do same job as what antacids are doing.

Action plan suggested to LOCOST

1. Education of lay public, general practitioners and physicians to give correct idea of antacid therapy. They should be informed that ANTACIDS ARE NOT FREE FROM DANGERS AND IT HAS NOTHING TO DO with DIGESTION.

2. Counter sale of antacids should be discouraged.

3. If LOCOST desires to manufacture antacids it should be liquid preparation of $Mg(OH)_2$ and $Al(OH)_3$ in ratio of 1:1 (without adding simethicone) which would have high neutrilising capacity. The preparation should be like Maalox which is very popular in west.

4. To find out neutralising capacity of various antacid brands available in India.

5. To find out whether adding of simethicone increasing toxicity decreases the effectiveness and increases the cost of available antacids in India.

CONCLUSION

On concluding this paper I feel that antacids are more misused than used moreso in Indian situation. Again we are lacking in many scientific details. Regarding present paper I have shown my personal view which may be biased and I am open to correction.

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DRUGS IN PULMONARY TUBERCULOSIS

The treatment of pulmonary tuberculosis presents a fascinating challenge to the respiratory physician since modern chemotherapeutic agents offer the near certainity of cure, provided that a proven regimen of treatment is applied assiduously for a sufficient length of time. The difficulty lies in maintaining treatment with a combination of potentially toxic drugs for a long time, since the regimens which embody "standard" chemotherapy require sustained treatment for 9 to 18 months, although the efficacy of shorter regimens lasting 4 to 6 months is being investigated.

Objectives of combination chemotherapy (essential in TB) :

1. to prevent emergence of resistance
2. to eradicate the infection in the shortest possible time
3. to reduce the incidence of ADR.

IMP : 1. To keep the no. of drugs to minimum which can achieve above objectives.

2. For successful anti TB R_x, regular surveillance throughout the course of treatment by an experienced health care team so as to reduce the total dosage or duration of Rx.

Anti - TB drugs

"First-line" drugs

INH
Rifam.
Etham
SM
Pyrazinamide

Most effective
Least Toxic.

"Second-Line" drugs

Used in Rx of infection resistant to the first-line drugs.

PAS
Thiacetazone
Ethionamide
Cydoserine
Capreomycin
Viomycin
Kanamicin

* . bacteriostatic for "resting" bacilli but bactericidal for rapidly dividing micro.

. Tuberculostatic conc : 0.025 to 0.05 8/m.

. Penetrates cells easily effective against intracellular org.

FIRST-LINE DRUGS :

1. INH : Isonicotinic acid hydrazine, Isoniazid.

   - Highly effective, primary drug for chemo of TB.
   - bactericidal anti TB agent, mainstay of anti-TB R_x,
   - included in all current chemotherapeutic regimens against susceptible mycobacteria.

History : Observation that nicotinamide was tuberculostatic. Fortuitous discover (1945) - Chorine.

Chemistry:

- Hydrazide of isonicotinic acid
- Iproniazid - isopropyl derivatives of isonicotinic acid - too toxic for use in TB, used as MAOI.

* Mechanism to spedrum of Action :

- effective against actively growing mycobacteria but less so against resting organisms.
- mode of action precisely not known. Possibly inhibits synthesis of mycolic acids which are components of mycobacterial cell walls.
- Selective toxicity against myco. only because of the above mech. since mycotic acid is not present in mammalian cells or other micro-organisms.
- Spectrum - ∵ of mech. - only myco. Some atypical mycobacteria an resistant.
- If used alone myco. develop resistance against it very rapidly ∴ never used alone (except for preventive R_x in certain specific situations). Always used with one more agent atleast.

Clinical Pharmacology :-

- readily absorbed from the GIT - nearly always. administered by the oral route
- Aluminium containing antacids - interfere with absorption.

* There is no conclusive evidence of a difference in therapeutic efficacy or in the incidence of toxicity related to rate of acetylation of INH in Pts receiving the drug every day.

- a large oral dose → peak serum level of 10-15 µg/ml in 1-2 hr (GG - 3-5 µg/ml in 1-2 hr).
- widely distributed in all body tissues including pleural effusion and CSF.
- penetrates caseous tissue and macrophages, thus effective against intracellular organisms.
- t ½ - rapid inactivators - 0.5 - 1.0 hr. ◊ GG
  ◊ 70 min
  - slow inactivators - 2-4 hrs. ◊ 3 hr.
- Meta. In liver.

INH $\xrightarrow[\text{acetylation}]{\text{N-acetyltransferase}}$ Acetyl isoniazid →

excreted largely in the urine, small amount excreted unchanged.

Imp : In pts with severe renal failure (creatinine clearance 10ml/min.) and slow inactivators dosage modification necessary, monitor Plasma levels of INH.

It is not clear whether dosage adjustment is necessary in Pts with impaired hepatic function, although there is some evidence that serum isoniazid levels are increased in chronic liver disease.

* Importance of Genetic (Acetylator status).
In vitro - myco exposed to inhibitory concentrations of INH for 10 h or morelose viability. But ifbthe inhibition is short-lived they slowly recover the capacity to synthesise myctic acid. This observation may explain the loss of therapeutic effectiveness of INH in pts. who are rapid in activators and who are Rxed by intermittent dosage regimens. If the doses are spaced too far apart i.e. less often than twice weekly.

In contrast, the neurotoxic effects of INH are more likely to occur in slow inactivators who have a greater tendency to accumulate the drug, particularly those treated by high dosage intermittent regimens, and some authorities advocate the administration of prophylactic pyridoxine to all patients receiving INH therapy in order to prevent possible neuropathic side-effects.

It has been suggested that hepatotoxic metabolites are more likely to accumulate in rapid inactivators who would therefore be more liable to isoniazid induced hepatic necrosis, but measurements have shown that the actual exposure of rapid inactivators to the relevant compound, acetylhydrazine, is no greater than that of slow inactivators, and clinical studies confirm that there is no increased risk of hepatic toxicity among rapid inactivators of INH whether treated with INH alone or with a combination of INH and rifampicin.

Administration & Dosage :

Normally administered by mouth, either as tablets or as a syrup/elixir. Also IM / those who are vomitting or /inj. for unable to take oral R_x.

Dose in adults : 5 mg/kg - max. 300 mg as a single daily dose.

Children (since tolerate higher doses) 10-15 mg/kg.

For pts on twice weekly regimen : 15 mg/kg.

*(give 10 mg/g pyridoxine to all pts taking INH in order to avoid possibility of neuro-toxic side effects. - R.B. Cole) - personal view.

This precaution is particularly important in adults receiving large doses of 10 mg/kg or more of INH/d or in those who may be predisposed to peripheral neuropathies by other conditions such as alcoholism or malnutrition.

Slow release INH preparations (matrix INH) have been studied in an attempt to provide an effective once-weekly intermittent regimen, but these have proved unsatisfactory : the blood conc. achieved in rapid INH inactivators are inadequate except with doses which would be likely to cause toxicity in slow inactivators.

Toxic Effects :

. Neurotoxic effects - dose related, more likely to occur in slow than in rapid inactivators.

Peripheral neuropathy - due to pyridoxine def. of excessive excretion of pyridoxine in pts receiving INH -respond to pyridoxine R_x - tingling in legs/feet and occasionally in hands.

CNS effects - dizziness(related to high dose), insomnia, restlessness and memory loss (at ordinary dose), may ppt fits in previously stable epileptics, excessive overdosage --> acute psychosis, convulsions and coma. Occ - muscle pains, arthropathy, and "frozen shoulder".

Hypersensitivity reactions - not common - occasionally fever or skin rashes. It is one of the drugs which can induce the syndrome of SLE - though this is rare, anti-nuclear antibodies can be found in a substantial proportion of pts --> vasculitis.

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* Pyridoxine (15-50 mg/d) - especially in malnourished, predisposed to neuropathy, (i.e. elderly, pregnant women, diabetics, alcoholic and uremics) - G.G.

Other toxic effects : Haematological reactions (agranulocytosis, ecsinophilia, thrombocytopesia, methaine -globinemia, tinnitus, urinary retention (G.G.)

Most important reaction is hepatotoxicity Usually occurs as a reversible asymptomatic elevation of serum transaminase, occasionally manifests as clinical jaundice preceeded by GIT symptoms, rarely leading to massive hepatic necrosis. Hepatotoxicity may occur at any time during the cause of INH therapy in approximately 20% of individuals who receive the drug and in about 5% it has to be withdrawn ∵ of developing hepatocellular damage. In the great majority of pts the abnormalities subside without any alteration in the INH regimen, and it is usual to persist with treatment unless the serum glutamic oxalacetic transaminase (SGOT) value exceeds 5 times the upper limit of normal or if symptoms and signs of hepatitis develop.

The development of INH hepatotoxicity does not correlate with the plasma drug concentration and is probably unrelated to be due to an allergic phenomenon for which the exact mechanism is at present undefined. INH is commonly administered concurrently with other hepatotoxic antitubercular drugs, especially rifampicin, and most evidences suggest that rifampin hepatotoxicity is enhanced by INH, particularly in slow inactivators who have higher INH serum levels.

Drug Interactions :

Concurrent administration of INH inhibits the metabolism of DPH ---> increased serum levels ---> CNS toxicity (disorientation, drowsiness, lethargy, ataxia, nystagmus, psychotic behaviour and coma) INH interferes with the parahydroxylation of DPH which is the rate-limiting step in DPH metabolism, exact mech. is not known. Slow acetylators are more at risk, but not invariably so : In practice, dosage reduction of DPH from 300 to 100-200 mg daily is indicated if clinical signs of toxicity are encountered, and if facilities are available for measuring serum DPH conc. it is advisable to avoid levels > 20 µg/ml.

Clinical Use :

* Most widely used of the anti-TB agents ∵ of its

- effectiveness
- cheapness and
- relative lack of toxicity

It is part of most regimens for TB.

Use in prevention : Used as a single agent in the preventive R_x of TB (sometimes called "disease prophylaxis"), in which chemotherapy is given to individuals who show evidence of infection although there is no sign of disease at that time. The use of INH alone for chemoprophylaxis has only very rarely led to the emergence of resistant strains of M. tuberculosis. Based on the code of practice

recommended by the American Thoracic Society and the U.S. Public Health Service Centre for Disease Control joint statement

The indications for preventive therapy with INH can be categorised as follows :

1. Household contacts of an active case of TB.

2. Radiological evidence of apparently inactive TB.

3. Positive tuberculin reactors : either recently converted from negative to positive within the past two years or with increased susceptibility to the disease ∴ of complicating factors such as long term corticosteroid or immunosuppressive therapy, D.M. or silicosis, or below the age of 35 years who have not received BCG vaccine.

The reason for giving preventive INH therapy to positive reactors below the age of 35 years is based on the argument that these individuals have a relatively high risk of developing active disease but little likelihood of suffering INH hepatotoxicity, which occurs mainly in older age groups.

Single chemotherapy with INH also has a place in the Rx of progressive BCG infection, which rarely complicates BCG vaccination. Such cases are usually characterised by regional lymphadenitis and localised abscesses. Treatment with INH in the usual dosage for 3 months is sufficient to control the infection.

2. Rifampin (Rifampicin) :-

- Semi-synthetic derivative of the antibiotic rifamycin B, which was isolated from streptomyces mediterrance.
- Of established importance in anti TB chemotherapy.

∴ of its effectiveness in short-course treatment

- One of the main drawbacks - high cost.
- Besides TB, also useful in Rx of a wide range of bacterial infections and some systemic mycoses.

* Mechanism of action :

- bactericidal
- acts by inhibiting the activity of DNA-dependent RNA polymerase, which is the enzyme responsible for catalysing the polymerisation of certain ribonucleotides into RNA molecules, a step which transfers genetic data from DNA to RNA. The selective toxicity of rifampin depends upon the relative insensitivity of mammalian RNA polymerase to the drug.

. Bactericidal for both intracellular and extracellular org.

* Spectrum of action :

. Highly active against M. Tuberculosis and M.Leprae.

. active against gram positive cocci including penicillin and methicillin-resistant S. aureus and against Neisseria species.

. lower degree of activity against gram negative bacilli.

. potential synergistic action with trimethoprim against gram negative pathogens and with amphotericin B against fungi (under investigation).

Primary resistance to rifampicin is low but resistance develops rapidly during therapy among most microorganisms which are initially sensitive, usually resulting from a single, large-step mutation which alters the conformation of DNA-dependent RNA polymerases and prevents rifampin binding. In the therapy of TB, it is therefore always used in combination with other drugs.

* Clinical Pharmacology :

. readily absorbed from the G.I.T., but the presence of food diminishes absorption and rifampin is therefore usually administered on an empty stomach.

. A normal oral dose of 600 mg --> peak blood level of about 7 µg/ml after 1.5-3 hours and effective therapeutic levels are maintained for 12-24 hours.

. The drug is widely distributed in all body tissues including CSF and pleural exudate, and because it is lipid soluble it penetrates cells and kills intracellular microorganisms. About 85% is protein bound

. t 1/2 ~ 1.5 - 5 hrs, increased in presence of hepatic damage. Decreased in pts receiving INH concurrently who are slow inactivators progressive decreased t $\frac{1}{2}$ in first 14 days due to induction of hepatic enzyme.

. partly deacetylated in the liver and is excreted in the bile in both the deacetylated form and as the unaltered drug. The latter is reabsorbed and recirculates through the liver, but the metabolite is very largely excreted in the feces. Eventually about 60% of the drug is excreted in this way. Slight accumulation may occur in patients with hepatic dysfunction due to cirrhosis, suggesting that care should be exercised in the use of rifampin in the presence of liver disease.

. Rifampin induces hepatic metabolising enzymes, including those responsible for its own metabolism, leading to a gradual reduction in the serum half-life during the first week of therapy, but this is insufficient to alter the therapeutic effectiveness of the drug and no dosage adjustment is necessary.

. Rifampin and its deacetylated metabolite are also excreted to a lesser extent in the urine, but it does not accumulate in patients with impaired renal function and no reduction in dose is indicated.

* Administration and Dosage :

. Normally b given by mouth in a single daily dose in the early morning 1 hr before breakfast.

. Usual dose in adults is approximately 10 mg/kg body wt., often standardised to 450 mg/day in those weighing < 50 kg and 600 mg/day for the remainder. In children the recommended dose is 10-20 mg/kg upto a maximum of 600 mg/d.

. also used in intermittent twice weekly anti TB regimens using doses of 600 mg or 900 mg twice weekly.

* Toxicity :

Although rifampin can cause a wide range of adverse effects, they are relatively infrequent, and only rarely do they necessiate the withdrawal. They include the following:-

1. G.I. disturbances = nausea, abdominal distension, epigastric discomfort and diarrhoea which seldom require a change of therapy.

2. Drug-induced hepatitis. difficult to attribute specifically to rifampin: the drug is commonly used in combination with other hepatotoxic agents, notably INH.

. transient elevation in liver enzymes during early weeks or Rx, subsides spontaneously whether Rx is cont. or not.

. Occ. increase in serum bilirubin or clinical jaundice, sign for immediate withdrawal.

. Jaundice more likely to occur in elderly, in alcoholics or those with pre-existing liver damage, but the risk of hepatitis in patients with normal liver function appears to be slight.

3. Hypersensitivity reactions - rare. Rashes, urticania itching of skin, redness and watering of eye, may occ. require withdrawal. Anaphylatic shock can also occur.

4 Neurological symptosm = headache, drowsiness, dizziness, and ataxia - occ. rarely - acute psychosis.

Several other imp. adverse reactions are largely but not entirely confined to patients Rxed with high dosage intermittent regimens or who take their Rx irregularly with long intervals between doses.

These effects include the following :-

5. An influenza-like reaction ("Flu syndrome"), characterised by fever, chills, muscle aching, nausea and vomitting, may come on several weeks or months after the commencement of Rx, usually, ppted 1 or 2 hrs after the ingestion of a dose. It subsides spontaneously after a few hours but recurs with subsequent doses and is much more common in patients on once weekly regimens who are taking higher doses, i.e. 1200 mg or more. It is attributed to an

immunological reaction, preventable by cont. Rx which is thought to result ~~xhx~~ in neutralisation of rifampin antibodies. This can be avoided by reverting to daily administration.

6. Thrombocytopenia ——→ bleeding (with high-dose intermittent Rx, appears to have an immunological basis. Contra-indicated if thrombocytopenia observed.

7. Renal failure with intermittant Rx or when resumed after an interval. Usually due to acute tubular necrosis which may have an immunological basis, since high titres of antibodies to rifam have been observed. Withdrawal of rifam ——→ recovery of renal function, but further use of rifam is contra-indicated.

8. Potential teratogenicity unknown, best to avoid the use of Rifam during pregnancy. It crosses placenta.

9.*

Other biological effects :

(Which are of interest but which do not appear to affect the clinical use of the drug.)

- Immunosuppressive effects on both humoral and cell-mediated immunity, readily reversed after Rx is discontinued.
- Associated with light chain proteinuria in the majority of patients.
- Harmless reddish discoloration of the urine and faeces, sometimes also affecting tears, saliva and sweat (due to both active drug and metabolites) - warn the pt., in order to allay unnecessary anxiety.

* Drug Interactions : (appears after 5-8 days of admin. and persists for 5-7 days after stopped)

Rifam ——→ induction of hepatic microsomal enzymes responsible for drug metabolism ——→ increased rate of elimination of several important drugs if administered concurrently with them. They are -

1. Warfarin, leading to the need for an unusually high dose to maintain effective anticoagulation
2. Tolbutamide, digitoxin, quinidine, propranolol, metoprolol, clofibrate, ketoconazole
3. Corticosteroids.
4. Oestrogens ——→ menstrual irregularity and unwanted pregnancy in pts taking OC agents.
5. Concurrent admn. of PAS impairs the absorption of rifam ∴ careful spacing required (8-12 hrs).

* Suppresses T cell function and cutaneous hypersensitivity tuberculin. Immunosuppresseht observed in animals but not delitarious effect in humers.

* Clinical Uses :

- Primary role in Rx of mycobacterial infections in combination with other chemotherapeutic agents.
- rifampicin - INH combination - essential element in most of the successful short-course regimens.
- Used in Rx of pts who did notreceive the drug during initial therapy, in Rx of extra-pulmonary TB i.e. TBM, Rx of Inf. due to atypica mycobacteria like M. Kansasii.
- Not used in Rx of pulmonary infections due to strepto/staph though effective . . of availability ofo thereffective antibiotics, ∴ its use can → delay in Δ of underlying TB or → development of resistant bacteria.
- Legionnaire's dis. that fails to respond to erythromycin or tetracycline since Legionella pheumophilia is highly susceptible.
- multiple-resistant pneumococcal pheumonia
- resistant staphylococcal endocarditis
- preventive Rx of nasopharyngeal carriers of meningococci.
- Leprosy.

3. Ethambutol :

- The value of ethambutol in the initial treatment of TB is wall established and the drug is used in most of the current standard regimens.
- Synthetic, tuberculostatic agent, discovered in 1961
- Adv : relatively cheap, low toxicity, effective by oral administration.
- M/A - uncertain, thought to inhibit RNA synthesis by mycobacteria.

* Spectrum of Activity :

- limited to mycobacteria only
- primary resistance of M. tuberculosis to Etham is low, but increased when used alone. ∴ used in combination with one or more other effective anti-TB agents.

* Clinical Pharmacology :

about 80% absorption orally, remainder excreted unchanged in feces.

- P.O. 25 mg/kg → max. serum conc. of 2-6 µg/ml after 2-4 h → 0.4 ug/ml at 10 hr. elimination half-time - 4 h. in pt with normal renal function.

- 70% of ingested dose excreted unchanged by the kidneys and upto 15% metabolised to inactive compounds excreted in urine.

- Widely distributed in body tissues but therapeutic conc. achieved in CSF only in presence of meningeal inflammation Hammalian conc. in RBC 1-2 times more than in plasma, thus RBC serve as a depot for Etham.

- preferentially, concentrated in RBC and about 20-30% protein bound.

* Administration and Dosage :

- Administered by mouth in a single daily dose of 15-25 mg/kg body weight in adults and children $>$ 10 years $<$ 10 years $\rightarrow$ 35 mg/kg in order to achieve peak serum conc. of $>$ 2 µg/ml. (Note: in this dose the risk of ocular toxicity and the difficulty of recognising it in small children must be remembered).

- Commonly used in the first 2 months of combined anti-TB Rx in a dose of 25 mg/kg body weight and is then either stopped or in some regimens maintained at a lower dose of 15 mg/kg throughout the continuation phase of Rx in order to decrease the risk of ocular toxicity which is dose related. Still to be on safer side, use 15 mg/kg dose even during initial therapy, since it has proved to be clinically effective (R.B. cole).

- Modification of dosage essential in pts with renal failure $\therefore$ elimination is largely dependent upon renal function.

- This can be achieved by giving the usual dose of 25 mg/kg at interval of

  - 36-48 h when creatine clearance 10-50 ml/min.
  - 48 h or large if creatine clearance $<$ 10 ml/min.

estimation of serum ethambutol conc. desirable as a guide to dosage - aim at obtaining (max. not $>$ 5 µg/ml at 2 h, declining to 0.5 µg/ml before the next dose.

- Clearance increased by peritoneal and haemodialysis

  $\therefore$ dosage supplementation necessary.

* Toxic Effects :-

- M IMP adverse effect - Retrobulbar Neuritis.

  $\rightarrow$ progressive loss of peripheral vision or impaired visual acuity, particularly to green, $\rightarrow$ central scotoma

Optic neuritis - incidence 1% when dose is 25 mg/kg initially for 2 months and then 15 mg/kg or maintenance (customary regimen), 5% when higher dose continued for 6 months.

- changes usually but not always reversible on withdrawal of the drug

- Good to carry out a comprehensive optholmomological examination periodic check up and monitoring of vision, reporting of any visual disturbance promptly.

. Other complications - rare

- peripheral neuropathy independent of INH Rx.

- nephrotoxicity, reversed on withdrawal.

- Hyperuricemia - quite common ∴ of decreased renal clearance of uric acid ⟶ occ. pptn. of ac. gout.

- allergic skin reactions.

** * Clinical Uses :

. important component of combination Rx, especially in the initial phase of therapy in standard ~~xf~~ 9 month regimen.

. If does not contribute significantly to 6-month short course chemotherapy, and in this role it is less effective than pyrazinamide in preventing relapse.

. effective in twice-weekly interminent chemotherapy when combined with INH after a 2 or 3 month initial phase of daily triple therapy.

. usually INH alone is used for chemoprophylaxis, but some clinicians prefer to use a combination of INH and Ethambutol, especially in pts from a community in which prevalence of INH resistance is high i.e. Asians. In the chemoprophylaxis of contacts of patients with INH-resistant TB it has been suggested that ethambutol may be used as an alternative preventive agent.

. Ethambutol is effective in Rx of TB infections resistant to other chemotherapeutic agents and is used successfully in treating some atypical mycobacterial infections, such as those due to M. Kansasii.

4. Pyrazinamide*

* sythetic pyrazine derivative of nicotinamide.

. bactericidal in vitro at a slightly acidic pH.

. though bacteriostatic activity of Pyrazinamide was recognised as long ago as 1952, until recently its use has largely been confined to the Rx of infections resistant to the standard drugs, ∴ of its low in vitro activity and significant record of hepatotoxicity. But in the last few years there has been increasing clinical evidence to suggest that pyrazinamide can make an effective contribution to 6-month regimens possibly by using it only during the first two months of

** Other toxicity : pruritus, joint pain, GIT upset, abdominal pain, malaise, headache, dizziness, mental confusion, disorientation, hallucination.

combined Rx. The role of PZ therefore is undergoing reappraisal, and it appears that the risk of hepatitis from the use of PZ in these short-course regimens is much lower than was suggested by earlier studies, in which larger doses were used for longer periods.

- PZ - a synthetic derivative of nicotinamide.
- No antimycobacterial activity at neutral pH, but it is effective against phagocytosed living tubercle bacilli, presumably due to the acid pH within macrophages.
- effective only against M. tuberculosis which rapidly develops resistance to PZ unless the drug is used in combination with other effective anti-TB agents.

* Clinical Pharmacology :

- readily and nearly completely absorbed from GIT.
- single oral dose of 20 mg/kg ——→ C max of 65 ug/ml within 2 hours. (45 mg/ml at 2 h, 10 ug/ml at 15 h) - GG.
- $t\ ^1/_2$ = 6 h.
- penetrates into liver, kidneys, lungs, therapeutic levels in CSF in TBM.
- active drug and meta (pyrazinoic and 5-hydroxypyrazinoic acid) filtered by glameruli. Nearly all of the unchanged drug reabsorbed from renal tubules while meta excreted in the urine. Urinary conc. 50-100 ug/ml for several h. after a
- pyrazinoic acid decreases tubular secretion of uric acid which leads to hyperuricemia and occ. to clinical gout.
- accumulates in jaundiced pt, suggesting that it is metabolised in liver.

* Administration and Dosage :

- Early trials - daily dose of 40-50 mg/kg ——→ Unacceptably high incidence of hepatitis ——→ clinicians discarded it as a first line drug.
- more recent assessment ——→ revision of view. Risk of hepatic toxicity is small when lower doses are used in 6-month regimens of combined chemotherapy (Hong-Kong trials).
- Now adult daily dose 20-35 mg/kg. in 2-3 divided doses. 0.5 gm tablets available. commonly 1 g. bd or 0.5 g tds.
- In intermittent regimens, 40-60 mg/kg 2-3 times a week or even 90 mg/kg once a week without serious incidence of side effects.

* Toxicity :

- MIMP adverse effect of PZ is its tendency to cause hepatitis. Effect-dose related. Symptoms of hepatitis, liver enlargement and rarely death due to hepatic necrosis

in pts Rxed for 3-6 months with PZ in the dose of 40-50 mg/kg/d i.e. 3 g/d.

. Incidence of hepatitis decreased with dose of 20-35 mg/kg although an increase in hepatic enzyme levels in upto 9% pts.

. If is sensible to -

- avoid use of PZ in people with impaired hepatic function
- withdrawal the drug if SGOT increase very much during the course of Rx.
- advise pt to report prompty all S/S suggestive of hepatic toxicity.

. Arthralgia - mainly of shoulders, knees, fingers - common. Increase serum uric acid in patients on daily therapy. Usually improves spontaneously after a few weeks, aspirin appears to be more effective than allopurinol in Rxing it symptomatically.

. Concurrent PZ and probenceid affects tubular excretion of uric acid and may enhance urate retention.
Others: anorexia, nausea, vomiting, dysuria, malaise, fever.

* Clinical Uses :

. Use of PZ in primary Rx of TB with modern short-course chemo. regimens throughout the world both with daily and intermittent Rx, highly encouraging and the incidence of troublesome or serious toxicity has been small with dosage used now.

. More evidence on the drug's toxicity is needed to show whether PZ has a place in routine anti-TB regimens.

. At present PZ is occ. used in the technically advanced countries for the Rx of TB infections resistant to more effective and less toxic agents. In developing countries where drug-resistant TB is more common, satisfactory results have been obtained in Rx regimens using PZ in various drug combinations with ethionamide and cycloserine and with PAS and streptomycin.

5. Streptocycin*

.. Until the introduction of rifam. and etham. into routine anti TB Rx within the last few years, SM with INH and PAS provided a standard chemotherapeutic regimen which was reliable and highly effective.

* First clinically effective drug to become available for Rx of Mist. TB - from 1947-52 - only effective agent available to Rx TB.

- Usual course was all 3 for initial 2-4 months, stop SM at this stage, cont. remaining 2 until a total duration of 18-24 months.

- Now Rifam + INH + Etham. But SM still used -

  1. When oral drugs cannot be administered

  2. In Rx of infections resistant to other drugs but sensitive to SM.

  3. In Rxing large pulmonary lesions with cavity.

  4. In some short-course regimens.

  5. In some completely supervised twice-weekly regimens especially when the administration of the injection provides an excuse or supervision of concurrent oral therapy in out-patients who cannot be relied upon to take medication.

- Need for IM inj. ◊ Sufficiently serious drawbacks of SM toxicity ◊ to discourage its use for Rxing

  pulm TB when the other drugs arereadily available, but amongst poorer population and in developing countries where cost is a highly important consideration in the choice of Rx, SM still appears to play a useful and relatively inexpensive part in short course and supervised intermittent regimens.

6. Thiacetazone :

- Although more toxic and rather less effective than the others, TZ currently has a place among the first-line anti TB drugs in developing countries ∴ of its cheapness.

- A thiosemicarbazene, fairly active against M. tuber.

- Toxicity - considerable variation in different communities - due to differing standards of observation or interpretation.

- Resistance emerges during course of Rx, unless TZ is used in conjunction with atleast one other effective anti TB agent.

- Well absorbed from the gut. 150 mg P.O. Cmax of 1-2 µg/ml in 4-6 h. 20% excreted unchanged in the urine.

* Administration and Dosage :

- adult dose - 150 mg as single daily dose, administered with INH (300 mg) as a single tab. Twice weekly (intermittent regimen) dose = 450 mg TZ + INH 15 mg/kg twice a week.

* Toxicity :

. Incidence of toxicity low in above doses.

. Commonest side effects - anorexia, nausea, vomitting and occ. diarrhoea. Ototoxicity dizzness and rarely to ataxia. BM depresion agranulocytosis & anaemia. Allergic skin reactions (not usually serious) but occ. Steven - Johnson syndrome & exfoliative dermatitis which necessiate withdrawal of drug. Hepatitis also reported but may be due to companian drug i.e. INH.

* Clinical Uses :

. The only indication for using TZ in the primary Rx of pulm TB is in developing countries where cost is the predominant factor in determining the choice of TB Rx programme.

. Widely used in Africa and Asia, usually combined with INH in a daily oral regimen lasting 18 months with SM for the first 4-8 weeks. ∠ 90% success with this regimen (∠ greater than) in East Africa, but less effective in Singapore, and more toxic.

. TZ has a possible role in twice weekly interminent Rx of pulm TB, but ineffective in short course regimen.

SECOND LINE DRUGS :

. More toxic and generally less effective than the first-line drugs .·. use largely confined to the Rx of infections which are resistant to the usual anti TB drug.

. As with the other drugs, resistance is likely to emerge during Rx unless atleast one other effective drug is used concurrently.

1. Para-aminosalicylic Acid (PAS) :

. Until recently PAS was an essential component of the "classical" antituberculosis regimen, which also included SM and INH, but it has now been displaced from standard chemotherapy in the developed countries by Etham and Rifam, which produce fewer side effects and fewer interruptions of Rx.

. bacteriostatic, effective only against M. tuber. and occ. strain of M. Kansasii. MTC - 1 ug/ml.

. m/a - competitive antagonism with PABA ---> inhibition of synthesis of microbial folate ---> inhibition of mycobacterial growth. (similar to sulfonamides) - specific for myco.

. Well absorbed from gut, widely distributed in the body including the pleural fluid and caseous tissue.

4 g ---> 75 µg/ml in 1.5 - 2 h.

. $t\frac{1}{2}$ - 0.75 h acetylated in liver, excreted in urine.

- $t\ ^{1}/_{2}$ increased in presence of impaired renal function, avoid in severe renal failure.

- Usual daily dosage in adults - 12 g given in 2 divided doses, often combined with INH.

* Side Effects :

- Major - GIT irritation - anorexia, nausea, vomitting, abdominal pain, diarrhoea in 25-40% of cases, decreased when taken with food, this effect - decreased pt compliance.

  Others : generalised malaise, joint pains, sore throat, skin eruptions of various types, leucopenia agranulocytosis, eosinophilia, lymphocytosis, thrombocytopesia, ac. haemolytic anaemia.

- Hypersensitivity reactions - Fever, rashes lymphadenopathy, eosinophilia, in 5% pts.

- Hepatitis hepatic necrosis may occur.

- Others - BM depression, hypokalemia, (secondary to GIT disturbances) and goitre.

2. Cycloserine :

- an antibiotic with a bacteriostatic effect against mycobacteria and some other organisms i.e. E.Coli.

- m/a - inhibition of bacterial cell wall synthesis.

- Well ~~abser~~ absorbed from gut, widely distributed through out the body tissues, including CSF.

- Excreted in the urine - $^{2}/_{3}^{rd}$ as unchanged and $^{1}/_{3}^{rd}$ as unidentified metabolites.

- Accumulates in pts with impaired renal Fn. needing dosage adjustment if necessary.

- Usual dosage in adults - 250 mg bd, increased to 500 mg bd in seriously ill pts - but higher dose may not be tolerated due to nephrotoxicity.

  Toxicity can decreased by adjusting the dose to give plasma levels not $\angle$ 30 µg/ml. greater than

- MIMP ADR : on CNS - headache, insomnia, ~~tremors~~, convulsions, various psychotic disturbances, incidence of mental/neurological toxicity - 16% in pts receiving 500 mg/d. (Hong-Kong study). Rarely peripheral neuropathy.

- Contraindicated in epileptic pts, use cautiously in those with mental disturbances such as depression or anxiety. Toxic symptoms resolve when cycloserine is discontinued.

3. Ethionamide * :

- derivative of isonicotinic acid
- bacteriostatic against mycob. tuber but little activity against other mycobacteria.
- well absorbed after oral administration and widely distributed in tissues, reaching significant conc. in CSF.
- largely metabolished in liver, 1% excreted unchanged in urine.
- available as tabs of 125 & 250 mg. Usual adult dose 250 mg bd, which may be increased to a maximum of 1.0 g/d. depending on the pt's ability to tolerate the GIT side effects. This can be minimised by taking with means or as a single bedtime dose.

* ADR. Others : Severe postural hypotension.

- Most common - anorexia, nausea and vomiting, metallic taste.
- depression, psychological disturbances - quite common.
- Neurological symptoms - headache, restlessness, visual and olfactory disturbances, tremors, convulsions, and peripheral neuropathy have been reported.
- Allergic skin reactions, gynaecomastia, alopecia,
- hepatitis - particularly in diabetics.
- teratogenic in animals .: avoid during pregnancy.
- C max - 20 µg/ml in 3 hr. after 1.00 g P.O.
- Propionamide - n-propyl derivative of ethio, with similar anti TB activity and equivalent toxicity, no advantage over ethionamide.

4. Capreomycin :

- Polypeptide antibiotic derived from streptomyces capreolus.
- bacteriostatic action against M. tuber with some in vitro activity against other mycobacteria.
- effective against organisms resistant to the more commonly used anti TB drugs.
- cross resistance between capreomycin and viamycin is the rule , and it frequently occurs between capreomycin and kanamycin.
- oral absorption unsatisfactory, .·. administered by I M inj.
- Adult dose of 1 gm ——> Cmax of 30 µg/ml in 2 hrs.

- 50% excreted unchanged in the urine - remainder meta but mode 2 site of inactivation unknown.
- daily dose - 15 mg/kg (adult 1 g) by a single IM inj., usually for a period of 4-6 months.
- dosage reduction advisable in pts with renal dysfn.

* ADR :

- rather similar to those of SM
- Nephrotoxicity - protein, casts and cells in urine, uremia and renal K^+ loss hypokalemia.
- totoxicity - vertigom tinnitus, deafness. More likely to occur in the elderly.
- allergic reactions - eosinophilia, fever, rashes.

5. Viomycin :

- bacteriostatic against M. tuberculosis which is 1/4M - 1/2 that of Streptomycin.
- obtained from stepto. puniceus.
- effective against SM - resistant organisms, exhibits cross resistance with capreo. and Kana.
- Dose : by IM , daily dose of 1-2 g, for a period of 2-3 weeks and thereafter in doses of 1-2g, 2 or 3 times per week.

* ADR :

- vesticular disturbances, deafness.
- nephrotoxicity
- allergic reactions.

Note:- avoid the use of viomycin in conjunction with other ototoxic or nephrotoxic drugs, such as kanamycin and capreomycin, although it has been used successfully with SM.

- Therapeutic efficacy of viomycin appears to be low.

TREATMENT OF PULMONARY TUBERCULOSIS :

- Before the availability of Etham and Rifam, the "Classical" regimen of chemotherapy for TB included - SM, INH & PAS.

  SM - daily by inj for 2-3 months with INH & PAS. then INH + PAS in twice daily regimen for period upto 18 months, for 12 months in mild infections and 2 years in case of severe cavitary disease.

- This type of therapy provided -

  (1) guard against chance resistance of organisms against one of the drug.

2) conformed with the concept of two phases in chemotherapy - an initial period of intensive drug therapy when the bacillary population is large, followed by a less intense phase of continuation therapy when the number of organism has substantially decreased.

. This regimen was highly successful when properly supervised and it has been the standard against which modern regimens have been measured.

. Disadvantages :

- I.M inj. of SM
- lengthy dependence on pt compliance and
- significant toxicities of PAS & SM

. In developing countries - similar regimen was used where 150 mg of TZ substituted PAS as a comparion drug to INH '.' of its relative cheapness.

. Benefits of Etham. & Rifam.

- greater efficacy
- relative lack of toxicity

} permitted introduction of shorter and less toxic.regimens.

Also led to the introduction of a wider variety of regimens of Rx which allow greater flexibility in circumventing adverse effects, improving supervision by means of intermittent administration and shortening the duration of therapy.

. Cardinal rules of therapy - unchanged i.e.

- requiring careful attention to detail in the application of an approved regimen and
- skilled supervision throughout the duration of therapy to ensure that drugs are taken as prescribed.

* Standard Chemotherapy :

In U.S.A. - daily oral INH + Etham for 18 months + daily IM of SM for first 3 months in the case of extensive cavitary lesions or if the pt comes from an area where drug resistant infection is prevalent.

Accepted modifications :-

1. For extensive dis. - oral rifampin & INH may be used throughout instead of the 3 drug regimen.

2. If parenteral therapy is necessary during the early stage of Rx, a combination of SM and INH may be used for the first 3 months (Strepto-erbazide).

3. PAS is preferable to etham as a companion drug to INH in young children '.' of the difficulty of recognising visual toxic symptoms in this age group.

4. INH with Etham is the preferred combination for the R_x of TB in pregnancy, of possible teratogenic effects of Rifampin.

- In Australia : a rather similar regimen, initially daily 3-drug therapy with INH & Rifam + either SM or Etham. given for 2-4 months, followed by continuation Rx with INH and Rifam to complete 18 months.

- In Britain : 9-month short-course regimen. (see below)

* Intermittent Chemotherapy :-

- The main indication for intermittent chemo is in the Rx of individuals who cannot be relied on to take daily Rx unsupervised but who can be interviewed once or twice weekly and watched while they take their drugs.

- generally speaking intermittent regimens are less toxic than daily ones, and they can be combined with short course chemotherapy (see below) to produce regimens which are highly effective in urban populations where every dose is supervised.

- Intermittent chemo can be successful, if given throughout the course of Rx, even in short-course regimens of only 9 months, but at present most authorities favour an initial phase of intensive daily therapy followed by a twice-weekly continuation regimens.

- some drugs, such as INH, are unsuitable for once weekly administration, and twice-weekly regimens are currently considered safer and more effective. The advantage of three-weekly schedules have yet to be defined.

- Recommended intermittent regimen in USA :

  - daily conventional Rx for 1-4 months, followed by twice weekly INH 15 mg/kg orally + 25-30 mg/kg IM or INH 15 mg/kg + Etham 50 mg/kg - both orally - maintained for 18 months.

- Recent reports show that prolongation of intermittent regimen beyond 1 yr is unnecessary when fully supervised.

- The twice weekly combination of INH 15 mg/kg + Rifam 600 mg with or without an initial phase of daily Rx, has produced good results with a low level of adverse effects, although intermittent rifampin in higher dosage is more likely to cause systemic reactions.

* Short-Course Chemotherapy : Advantages (Fox & Mitchison)

- reduction in cost of Rx

- reduction in chronic drug toxicity ∴ total quantity of drug used is less.

- improvement in patient cooperation

- improvement in surveillance of Rx

- diminished likelihood of relapse if pts default early from the Rx.

Various experimental studies to determine and compare the frequency of bacteriological relapse in chemotherapeutic regimens ranging from 4-12 months.

Recommendation : (adopted in UK)
INH 300 mg + Rifam 450-600 mg — daily for 9 months
Etham 15-25 mg/kg or Strepto — daily for 1st 2 months

Note:- The use of strepto instead of etham for the initial phase of Rx is equally effective but leads to a greater incidence of side-effects.

- Shorter regimens lasting 6 or 4 months have shown considerable promise and are particularly relevant in developing countries where the problem of cost and the difficulties of lengthy supervision are overriding considerations.

- Streptomycin + INH + Rifam + PZ daily for first 2 months, followed by a continuation phase of daily INH + Rifam for 4 months — Singapore trial, highly successful.

  When cont. phase reduced to 2 months, relapse rate 8-24%.

- Most recent development - in order to decrease the costs, inconvenience and toxicity of anti TB chemo has been the trial of 3-month and 2-month regimens of daily SM + INH + Rifam + PZ for the Rx of pts for whom the diagnosis of pulm TB seems likely on clinical and radiological grounds but for whom microscopy sputum reveals no AFB. Observations after 1 year of follow-up suggest that those with negative cultures show a very low incidence of subsequent relapse if Rx is stopped after 2 or 3 months, but in those with positive cultures the incidence of relapse was at a level which would generally be regarded as unacceptable.

- The potential of these observations lies in the possibility of safely stopping Rx at 3 months if the initial cultures have proved negative, but a longer period of observation will be needed before reliable conclusions can be drawn.

- Combination of intermitent Rx with short-course chemo provides an alternative choice of regimen which minimises the total drug load and permits full supervision of every dose.

  A high level of effectiveness has been obtained by giving SM + INH + Rifam + PZ daily for an initial phase of 1-2 months followed by a continuation phase consisting of twice weekly SM + INH + PZ to a total Rx duration of 6-8 months.

- USA trial - unsupervised

  INH 300 mg + Rifam 600 mg — daily orally for 1 month

  followed by

INH 900 mg
Rifam 600 mg } twice weekly for a further 8 months.

Further work necessary to demonstrate the superiority of this type of regimen over others.

* Management : of Pulm TB

. Objective - eradication of infection in every person with active disease by administering a therapeutic regimen of proven efficacy for its full duration. The objective should be to achieve success with the least possible disturbance in the normal life of the pt or his family.

Major management problems to be considered are -

(1) Choice of regimen

(2) Selection of patients for hospital Rx

(3) Supervision of therapy and

(4) Retreatment chemotherapy.

* Choice of Regimen :

In the routine management of pulm TB the initial regimen is customarily a standard schedule of Rx which has been shown by trial and experience to be effective in that population. Preliminary assessment is necessary to identify any factors which may give rise to modification of the standard regimen.

Such common factors :-

Modifying factors	Modification recommended
. Previous anti TB chemo	. Retreatment regimen, if poss possible with-hold Rx until sensitivities of the infecting micro ascertained.
. Pt originates from an area where resistant organisms common.	. Always use 3 drugs in the initial phase of therapy, or until sensitivities ascertained.
. Unstable social background due to psychiatric domestic or financial difficulties	. consider fully supervised interminent chemo regimen.
. Pregnancy	. Avoid rifampin during the first trimester.
. Serious disturbance of vision young children, and the aged.	. Avoid ethambutol.

. Impaired renal function	. Modify dosage of SM, Etham. & PAS, or avoid use.
. Impaired hepatic function	. Avoid rifam or monitor hepatic enzyme conc.

- Once the decision is made the patient should be fully informed of the nature and duration of the therapeutic regimen to which he is submitting himself, including the possibility and character of adverse effects, so that he can adjust to the constraints which will be placed on him and learn the importance of strict adherence to the Rx schedule.

* Selection of patients for Hospital Treatment :

. Hospital admission at the start of therapy is not necessary for the routine management of pulm TB, but certain categories of patients are best treated in hospital initially. They include the following :

1) Very ill patients requiring supportive therapy and nursing care

2) Uncooperative patients - with unfavourable social or domestic circumstances, h/o poor cooperation, mental disturbance, alcoholism, or drug addiction. Hospital admission is usually necessary for the duration of the intensive initial phase of Rx which preceedes a fully supervised out-patient intermittent continuation phase.

3) Patients with drug resistant disease who require Rx with second-line drugs of high toxicity.

4) Infectious patients with highly susceptible domestic contacts such as tuberculin-negative children or family members with impaired immunological defence mechanisms.

Imp.: There is strong evidence to show that the risk of infection to contacts is minimal once the index case has started Rx.

. The choice between hospital and out-patient therapy must depend on the individual circumstances of the patient and the facilities which are available in the ca location for safe and efficient ambulatory case.

* Surveillance of Therapy :

Imp : The aims of treatment supervision be clear -

1. To ensure adherence to the recommended regimens.

2. To detect evidence of adverse effects as early as possible, and take corrective steps if indicated.

3. To monitor recovery by regular examination, smear, and culture examination of sputum, including sensitivity testing if compliance is suspect, and radiographic examination of chest.

4. To terminate Rx as soon as the approved regimen has been completed.

. Most physicians with experience, develop their own schemes for treating pulm TB for achieving these objectives which suit local circumstances.

. Follow-up of the patients is a must, because the maintenance of an unbroken therapeutic regimen becomes increasingly important as treatment schedules are shortened and the total number of doses is progressively reduced.

. It is probably safe to discharge the patient from further follow-up, once an approved regimen of Rx is completed, provided that the physician is satisfied that compliance has been good and there is adequate bacteriological, clinical and radiological evidence of successful treatment.

. Only patients who are known or thought to have had irregular chemotherapy or an inadequate duration of Rx should be followed for a limited period, but routine chest radiography, or sputum cultures rarely lead to the detection of reactivation disease, almost all cases presenting with symptoms. The discharged patient must therefore be encouraged to return to the clinic promptly if he develops symptoms that might indicate a relapse.

* Retreatment Chemotherapy :

Recurrence of infection during or after a course of anti TB chemotherapy calls for a careful reassessment to determine the reasons for treatment failure.

Causes of Treatment Failure in Pulm TB

Failure	Cause
. Infection with resistant micro-organisms	. - previous ineffectual Rx - primary resistance, most common in developing countries.
. Choice of an inadequate regimen	. - Single drug therapy - One or more drugs given in insufficient dosage - Inadequate duration of Rx.

- Failure of adherence to the prescribed regimen
  - Inadequate explanation and/or supervision of therapy.
  - Intolerable side effects.

- Therapeutic errors such as single drug Rx, insufficient dosage, or inadequate duration of therapy are common in developing countries and have led to a substantial pool of resistant organisms in some countries.

- Primary resistance to one or more anti-TB drugs occurs overall in / 10% of infections in the highly /less tha developed countries but the rate is considerably higher in developing countries and immigrant populations from such countries.

- A much more important reason for treatment failure is lack of cooperation with the recommended regimen, and the great majority of failures is found among individuals of low intelligence, vagrants, alcoholics, and drug addicts.

- In planning the retreatment of patients who have had previous chemotherapy it is therefore necessary to take account of the ethnic and geographical origins of the individual, the social background, and the precise nature and duration of earlier treatment. The current sensitivities of sputum cultures should be obtained to enable the optimal drug regimen to be determined, and in general no Rx should be given until the results of reliable resistance tests are available.

The following principles provide a guide to the successful chemotherapy of patients with resistant infection :

1. Patients should be assessed prior to Rx for possible increased risk of hepatic or renal toxicity, and close monitoring for adverse effects should be maintained throughout, including measurements of plasma drug levels where necessary.

2. Treatment should begin with atleast 3 drugs to which the organisms are known to be sensitive, using the most effective of the available drugs and taking into consideration their potential for toxicity in any given patient.

3. Drugs should be administered under strict supervision, initially in hospital. A parenteral drug is useful when patients progress to outpatient therapy since it provides an opportunity for supervising pill swallowing when the patient attends for injections.

4. Frequent tests of sputum microscopy culture and drug susceptibilities be made during Rx.

5. Prolonged therapy for more than 18 months may be required and adjunctive surgery is occasionally indicated.

. Since most patients with drug-resistant disease have acquired it ·.· of failure to adhere to previously recommended Rx, the success of Rx depends to a very large extent upon the establishment of a sympathetic relationship between doctor and patient.

(Paper prepared for Rational Therapy Cell of LCCOST)

DR 30.12

DR

41st ANNUAL CONVENTION

CATHOLIC HOSPITAL ASSOCIATION OF INDIA

23-26 NOVEMBER 1984

WORKSHOP THEME:

towards a people-oriented drug policy

'Eternal vigilance is required to ensure that the health system does not get medicalised, that the doctor-drug producer axis does not exploit the people and that the abundance of drugs does not become a vested interest in ill-health'.

---ICMR/ICSSR Health for All Report.

Venue: ST JOHN'S MEDICAL COLLEGE, BANGALORE 560034

SIGNIFICANCE OF THE THEME

THE Workshop is to help participants understand the issues relevant to drug prescribing, drug distribution and pharmacy policy in our institutions in the context of the ICMR/ICSSR warning and to challenge them to participate in the growing national response to the problem.

WHAT does the 'abundance of drugs' mean to the millions of the poor in our country who struggle in life to make both ends meet? Can they ever have access to the modern health care system which has become a business today, rather than remaining at the service of humanity at large? Do they have essential and life saving drugs at their reach within a price range they can afford?

IS our drug policy today more profession-oriented, drug industry-oriented rather than patient-oriented? Whose interests are we serving in our institutions?

HOW can we move towards a more people and patient-oriented drug policy?

THESE are some of the QUESTIONS which we shall respond to in our Workshop.

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"Community Health is a process of enabling people to exercise collectively their responsibilities to maintain their health and to demand health as their right. Thus it is beyond mere distribution of medicines, prevention of sickness, and income generating programmes".

--CHAI new vision

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OBJECTIVES

1. TO CREATE AN AWARENESS OF:-

   the health situation in India, the role of drugs in health care, the pattern of drug production in India vis-a-vis the people's health needs, the dynamics of the drug industry, the pattern of drug distribution and availability in the health system, the national drug policies and laws.

2. TO CREATE AN AWARENESS OF:-

   irrational use, over use and misuse of drugs by health personnel.

3. TO DISCOVER

   the social, economic, political, cultural and other factors responsible for this problem.

4. TO DISCOVER

   how all of us are part of the problem at a personal level.

5. TO CONSIDER

   the various responses at national/regional levels in the areas of :-- consumer awareness and people's movements; continuing professional education; pressure group on policy makers; search for low cost alternatives; individual/group action; institutional policy changes.

6. TO DISCOVER

   ways and means by which we can respond to this situation at individual, institutional and regional/national levels.

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PROGRAMME HIGHLIGHTS

Sessions on:

Understanding the problem
Drugs and the healing ministry
Towards rational therapeutics
What to do to tackle the problem
Some initiatives in the country
The people's medicine

Group discussions on:

What/why the problem in our health institutions?
What can we do to tackle this problem?

Liturgy

Reflecting on our calling and the faith dimension of our response

Exhibition on:

Socio-political dimensions of Health and Drugs
Rational Drug Therapy
Home remedies and Herbal medicines

Studies on:

Drugs for a Community Health Center
Understanding the injection/tonic culture
Use/misuse of drugs in surgery
Drug situation in small rural hospitals
Cost of treatment

Cultural Programme

Understanding the problem from the poor man's point of view.

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SYNOPSIS OF PAPERS

Drugs for Primary Health Care (C M Francis)

An integral part of our commitment to primary health care is the provision of essential drugs to all those who need them, in adequate quantity and quality and at affordable prices wherever the person is. The various aspects of the drug problem needing our attention include production, what drugs are required, choice of drugs, National Drug Policy, selection of drugs, drug production and procurement, logistics of supply, quality control, regulating the drug trade, drugs for immunization, drugs for cure, drugs for symptomatic relief, search for new drugs, drug information and the need for evaluation of the efficacy of primary health care including drugs.

The Ten Commandments of the Drug Industry (Augustine Veliath)

1. Thou shalt have tens of thousands of drugs
2. Thou shalt not question the price of a drug
3. Thou shalt not tamper with nature's garden
4. Thou shalt respect they doctor more than thyself
5. Thou shalt betray thy people and thy nation for petty rewards
6. Thou shalt not covet, court, or subscribe to any other system of medicine
7. Thou shalt never reveal company secrets
8. Thou shall first seek remedies for fashionable ailments
9. Thou shalt be a dumping ground for banned drugs
10. Thou shalt be a guinea pig for new and untried drugs.

The Ethics of Prescribing (George Lobo, sj)

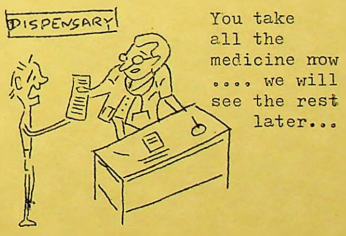
Discusses reasons for the unfortunate situation related to drugs prevalent today, viz., technological model of health care leading to manipulation of the patient, search and demand for instantaneous cure of symptoms, mystification of medicine, profit motive and 'free enterprise' of the pharmaceutical industry, a deep rooted cultural alienation from the people, exploitation of dependent developing countries, decreasing emphasis being given to preventive medicine and other systems of medicine.

The use of drugs should be regulated by the principles of totality (overall good of the patient) and of double effect (the good effect overriding any harmful effect). It suggests remedies for the development of a person-centred and holistic approach to health care.

Professionals in the Church - an introspection (George Joseph)

Serious questions have been raised about the institutional witness of the church in India, particularly its relevance in the social context of today. In the case of the Healing Ministry there is urgent need to critically look at our priorities and commitment and our style of functioning in the light of the gospel. The role of the professionals have to be reassessed as part of an overall effort to bring back the true spirit of 'Diakonia' into this ministry.

The whole issue regarding the need for evolving a 'rational drug policy' has to be seen in this perspective.



What is Rational Drug Therapy? (Mira Shive)

Rational drug therapy means practice of socially conscious, relevant, concerned and yet scientifically sound medicine. It recognizes the non-role of drugs in certain conditions, the role of alternative systems of medicine and recognizes the limitations of Western Medicine in our social context.

It emphasises selective use of drugs based on essentiality, efficacy, safety, easy availability, easy administration, quality drugs preferably of indigenous production.

Rational Drug Therapy recognizes the concept of essential drugs and the concept of graded essential drug lists for different levels of health personnel. It recognizes the right of health personnel and consumers to drug information and its effective communication.

It is taking of a conscious decision to boycott certain drugs and use others only when needed. It means prescription with awareness, to avoid as far as possible -- iatrogenesis (drug induced problems, drug interactions, adverse drug reactions and emerging drug resistance).

It is understanding the role of drugs and rational drug therapy in the emerging health movement.

What can be done at a pharmacy level (Alan Cranmer)

(a) Management of Pharmacy Services include involving the users of the service; the Pharmacy Committee -- its constitution and functions, viz., implementation of hospital policy, selection of medicines, sources of medicines, cost versus quality, basic drugs and formulations, medicines banned in India and abroad, medicines from other systems; stock control; prescribing discipline and pharmacy discipline.

(b) Good dispensing services involve need for good professional service to patients, proper presentation of patient's medicines, preparation of medicines in the pharmacy compared to purchase, medicines in the pharmacy and at clinic level.

contd.....

(c) Relationships with suppliers, ie., with representatives in the pharmacy and an assessment of products offered and their sources.

(d) Educational requirements - basic courses, legal requirements, course content, continuing education for pharmacists.

(e) Relationships with hospital colleagues.

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INITIATIVES IN THE COUNTRY

(1)

Arogya Dakshata Mandal, Pune has been raising awareness about drug related issues among medical professionals and the lay public since the past 8 years. They publish a monthly--'Pune Journal of Continuing Health Education'--on drug issues and are also bringing out a book 'Rational Drug Therapy' in December 1984.

They launched a movement called 'Operation Medicine' in 1977 against irrational prescription of vitamins, tonics and tinned foods.

(2)

All India Drug Action Network: A number of groups have been working in the field of drug related issues at various levels during the past 3-4 years. They have been in contact with each other and have been working informally together sharing information, putting forward a memorandum (demanding a Rational Drug Policy), participating in campaigns, lobbying with government etc. In August 1984, they felt the need to have a more organized base and have formed the All India Drug Action Network. CHAI is also a member of the Network.

(3)

Lok Vigyan Sanghatana, Maharashtra, or the People's Science Movement have launched campaigns about anaemia and irrational anti-anaemia drug preparations and also about over the counter drugs. They organise jathas, hold district/town seminars, write in the mass media etc.

(4)

Kerala Sastra Sahitya Parishad is a voluntary non-government organization consisting of scientists, doctors, engineers, social scientists, teachers, students, workers, peasants, technicians who are committed to popularising science and channelising it for social revolution. The KSSP has recently decided to take up the Drug issue and initiate a big campaign to expose the anti-people and exploitative tactics of the Multinational Drug Companies. The questions of essential versus non-essential and dangerous drugs, the inadequacy of drug safety control measures, the rising prices of life saving drugs and the non-implementation of the Hathi Committee recommendations are the highlights of the programme.

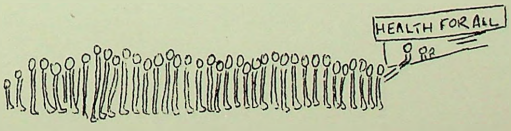
(5)
LOCOST or Low Cost Standard Therapeutics is a collective voluntary enterprise for rational therapeutics. LOCOST aims to promote low cost, scientifically tested medicine under generic names. LOCOST is a response to a growing demand and challenge of the voluntary health sector to meet the needs of the deprived sectors of the society for not only low priced but also good quality medicine. LOCOST includes procurement, quality testing and control, distribution and educational efforts, and is located in Gujarat.

(6)
Bangarapet Mission Tablet Industry in Karnataka is a successful small scale venture providing low cost, good quality formulations to some mission hospitals in the country.

(7)
Low Cost drugs and Rational Therapeutics Cell of the Voluntary Health Association of India, New Delhi, has been instrumental in bringing together various groups in India on the issue of drugs. They have been providing informational backing to these groups, organizing meetings, informally coordinating some actions etc.

(8)
medico friends circle is a group of socially conscious individuals, interested in the health problems of our people. Through their monthly bulletin, they discuss drug issues among others. They have formed a Rational Drug Policy Cell and have launched a campaign on anti-diarrhoeals.

(9)
The Kurji Holy Family Hospital Formulary is the result of the accumulated experience of the hospital over the last 10 years. It gives a comprehensive list of drugs to treat 98% of the hospital admissions. It also gives the generic name, dosage, indications, contra-indications and side effects of these drugs. Information about comparative cost of treatment is also provided.



(10)
State Forums: During the past year drug action forums have been active in Andhra Pradesh and West Bengal. Drug Action forums are also being initiated in Gujarat and Orissa.

(11)
The Pharmacology Department of the Post-Graduate Institute of Medical Education and Research, Chandigarh, provide unbiased technical information on drugs and therapeutics through a monthly publication 'The Drugs Bulletin'.

(12)
Others: The following organizations have also been involved in drug related issues and are part of the All India Drug Action Network:

Consumer guidance Society of India, Bombay
Consumer Education Research Centre, Ahmedabad
Federation of Medical Representatives Association of India
Health Services Association, Calcutta
Delhi Science Forum, New Delhi
People's Participation in Science and Technology, Madras/Bangalore
Centre for Science and Environment, Delhi
Centre of Social Medicine and Community Health, J N University, New Delhi

What we can do ?

-- Support them

-- Join them

-- Keep them informed about what you are doing

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RESOURCE MATERIALS

- People, Pills and Prescriptions, column in MEDICAL SERVICE since May-June 1984.
- Objectives of the Workshop, a handout.
- Understanding the Drug situation in our Hospitals, a check list.
- Towards a People-Oriented Drug Policy, Special Convention Issue of MEDICAL SERVICE (October-November 1984) and a supplement to this issue will be distributed during the Workshop.
- Drugs awareness and Action, mfc BULLETIN Special Issue No.107 November 1984.
- DECCAN HERALD Supplement on the Workshop.

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"What people really need, first and foremost is clean drinking water, latrines, school and land, not urban hospitals with their wonder drugs".

-- Planning Commission

AN INSPIRATION

Reading

The story of the sickman
at the pool of Bethsaida

John 5: 1-9

Reflection

The action of Jesus in bypassing the pool is an invitation to us to look more critically at our own health care system. Thanks to our emphasis on curative health care, we have grown accustomed to thinking solely in terms of the health needs of the individual rather than addressing ourselves to the community as a whole. While concentrating on the symptoms, we have failed to take into account the environment and other social factors. Poor sanitation, polluted water supply, the superstitious beliefs and taboos of the community are also related to sickness and disease.

Further, the miraculous pool in its ineffectiveness is a symbol of our own ineffective health care system despite the highly qualified doctors and nurses, well equipped private and public hospitals, medical research centres and multinational drug industry.

The poor man in the gospel story lived very close to the pool, yet he was helpless because of his poverty. In like manner the poor in our midst remain helpless in the shadow of an expensive, curative health care system that is geared exclusively to the service of the rich.

Source: The Bible: Aspirin or Dynamite
by Cedric Rebello s.j.

DR-33-13

PGIS

PRESCRIPTION GUIDANCE AND INFORMATION SERVICE

LOCOST
a voluntary effort
for the use of the correct
medicine

Low Cost Standard Therapeutics (LOCOST) was founded with the goal of promoting rational drug therapy. We seek to promote this by two major activities : (a) supply of good quality essential drugs under generic names and (b) educational efforts.

The Prescription Guidance and Information Services (PGIS) of LOCOST is an educational effort to promote awareness about the correct use of medicines. PGIS is therefore for the benefit of both prescribers as well as patients.

WHY THIS SERVICE ?

The average patient suffers from a lack of information. In addition he/she perceives the doctor as a high priest of a magic cult. The patient also has almost unquestioning faith in the power of drugs, tonics and injections. The doctor on the other hand, has his/her own compulsions and limitations, compulsions which make doctors yield to social/peer pressures and current fads of prescribing certain types of drugs. Quite often even senior doctors from reputed institutions are known to respond : " Dr. X gives this drug to his patients. I know it is irrational but if I do not do the same, I will lose my patients ". A scientific attitude to healing is thus sacrificed and that too at the expense of the patient.

An added limitation is that doctors quite often do not have the time to update their medical and pharmacological knowledge. A major source of drug disinformation are the drug companies. Through various subtle and not so subtle means, they use medical representatives/agents to persuade doctors to prescribe quite often, irrational brand name combinations. Again the patient as the end user is the one who suffers by way of irrational (and sometimes harmful) prescriptions. PGIS is an attempt to restore this gross imbalance in the healing process, a process in which the patient is more an active than a passive participant.

Two main aspects of PGIS being proposed are :

(1) Information dissemination to doctors who write prescriptions, and
(2) Guidance to the patients regarding the correctness and use of medicines prescribed in a particular condition.

THE PGIS CELL

LOCOST has identified a number of expert doctors in the Baroda Medical College and a few from outside also. At least two experts in each of the common specialities have been included in this cell. They will respond to the various requests through LOCOST.

LOCOST
1st Floor, Premanand
Sahitya Sabha Hall,
Opp. Lakadi Pool,
Dandia Bazar,
BARODA-390 001

PRESCRIPTION INFORMATION

It is often found that the person who is prescribing the medicines does not have enough access to the latest information regarding the disease and related drugs. The PGIS cell will respond to requests for information relating to the use of a particular drug. In all such cases, it will be assumed that the diagnosis made by the prescriber is correct, unless the prescriber specifically requests for assistance in diagnosis also.

THE APPROACH TO PRESCRIPTION INFORMATION

The individual requests should be routed through LOCOST office. Only in cases of emergency, the Coordinator, PGIS, may be contacted directly. Attempt should be made to send the requests in writing to LOCOST. The PGIS Coordinator and the experts concerned will be in turn consulted by LOCOST. The names of the persons concerned i. e. the doctor who sends the request and the experts who give the advice will be kept completely confidential, if required.

An attempt will also be made to approach the doctors working in institutions. Prescriptions from such doctors, if requested, will be discussed in person or at group meetings organised by the institution. One or more experts from the PGIS cell will attend these meetings and the pros and cons of a particular prescription will be discussed in detail. In such cases we would prefer, if the prescriptions to be discussed along with other related information is given well in advance. (In case a group meeting is being held, LOCOST will require a notice in advance)

PRESCRIPTION GUIDANCE

The objective here, is to help the patient, the end user of medicines to know the correctness of the medicines prescribed. The PGIS will give comments on following aspects of the prescription : corract medicine for a particular diagnosis, adequacy of the treatment, the uselessness or harmful effects of any medicine, the side effects of the medicines required, the dosage, alternatives available both in terms of cost, quality and nature of medicines, etc. Whereever possible, other aspects of the therapy will also be explained.

This will help the patient by developing an understanding regarding the treatment given to him/her. This will also equip the patient and relatives or friends to questionand to ask for more information from prescribers in future. Thus the ultimate aim is to build up consumer awareness and initiative to bring about a change towards more rational therapy.

THE APPROACH TO PRESCRIPTION GUIDANCE

1. The patient (or the relative/friend) sends the prescription with relevant details to LOCOST. (See Box below).

2. The prescription will be critically studied by LOCOST's PGIS cell. The PGIS cell consists of a group of expert doctors who are conscious of rational therapy practices.

3. The PGIS Cell will send its comments on the prescription to the prescriber for his/her reactions. Modificatons if necessary, will be made based on the prescriber's reactions. If no response from the prescriber is received within 10 days of sending comments, then the comments will be passed on to the patient.

4. The copy of the final comments will also be sent to the prescriber. (Note : Suitable modifications of the above procedure will be made as and when. For instance, if the patient does not want the comments and his/her identity revealed to the doctor the PGIS Cell may defer the comments to the doctor by say one to two months However, requests by patients that the doctor be not informed at all, will not normally be acceded.)

INFORMATION NEEDED FOR PRESCRIPTION GUIDANCE

While sending the request to LOCOST the patient would be required to give the following information :

(a) Name and address of the patient;

(b) Name and address of the prescriber to whom a copy has to be sent;

(c) Age, sex, history of the patient and symptoms at the time of consultation of the doctor;

(d) Diagnosis (preferably written on the prescription in the doctor's own hand);

(e) List of medicines with dosage taken before the current prescription (past six months);

(f) Details of laboratory tests, x-ray tests, special procedures and medicines prescribed by the current prescriber, those taken by the patient and results of the same;

(g) Any other relevant detail/document (copy to be enclosed);

(h) Original prescription or photostat copy.

(i) Present condition of the patient.

A COLLECTIVE EDUCATION

In conclusion, PGIS is a person-to-person service that would hopefully lead to collective awareness about the correct use of medicine. The collective awareness could then result in collective action and programmes in many other areas of drug policy and other issues in health.

LOCOST is aware of the limitations of PGIS : Personal examination of the patient may not be feasible, the scope of PGIS may not cover all diagnostic situations as also the fact that a large number of 'successful' treatments may not be touched, and so on and so forth. The service may not be useful for the patient as it will take at least 10–15 days to give a balanced view on the prescription. However, queries by doctors for information can be attended to faster. In cases of exceptional emergency, the PGIS coordinator will decide about the mode of response and communication depending on the merits of each case

HHWL

LOCOST is keen on not encouraging legal battles between the patient and the doctor. PGIS is a beginning, a collective effort to facilitate awareness, education and action. Action towards more rational therapy and towards conserving scarce resources of patients as well as that of the community.

AN INVITATION

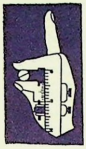
LOCOST is also prepared to facilitate prescription/medical audits of hospitals, dispensaries and community health projects, if so requested. You may be a like minded doctor, a patient or a person simply interested in social change. We seek your cooperation and collaboration. Please spread this idea. Put patients and doctors in need in touch with us. Write to us with your views.

Contact us at : *Prescription Guidance and Information Service (PGIS)*

LOCOST
Ist Floor, Premanand Sahitya Sabha Hall
Opp. Lakadi Pool, Dandia Bazar
Baroda–390 001.

LOCOST is a non-profit trust Other major programmes of LOCOST include : (a) Supply of generic drugs to voluntary groups. (b) Promotion of quality awareness among prescribers and users. (c) Research on issues in community pharmacology. (d) Documentation and dissemination of information on community health issues.

Product Information Sheet



Locost

LOW COST STANDARD THERAPEUTICS
G. P. O. Post Box No. 134, Vadodara - 390 001.

Generic Name : Mebendazole.

Some Brand Names : Wormin, Idibend, Mebex, etc.

Presentation : Tablets of 100 mg.

Pharmacological action : Broad spectrum anthelminthic drug effective against most of the common worm infestations. Acts by inhibiting glucose uptake irreversibly in worms. It does not alter the glucose level in host.

Therapeutic indications : Single or mixed worm infestation with round worm, hook-worm, thread worm and whipworm. For hydatid cyst with prolonged treatment.

Dose in adults : In roundworm, hookworm and whipworm infestations : 1 tablet two times a day for 3 days continuously. It may be repeated after 3 weeks if necessary.

For threadworms, 1 tablet once only. To be repeated after 2 weeks.

Dose in children : Remains same as above.

Use in pregnancy : Should not be used in first 3-4 months of pregnancy.

Use in lactation : Quite safe.

Use in Hydatid cyst : 400-500 mg. 3 times a day for 21-30 days.

Precautions : Should not be used in patients allergic to Mebendazole.

Contraindications : None.

Adverse reaction : No systemic toxicity. Transient abdominal pain, nausea and diarrhoea may occur with massive infestations.

Instructions to patients : No fasting or purging is necessary before or after treatment. Personal hygiene instructions must be given.

Note : All possible contacts may also be treated for worms.

Overdose : No overdose toxicity.

Significant interactions : None.

References :

1. Goodman, Alfred Gilman et al : **The Pharmacological Basis of Therapeutics,** Macmillan Publishing Co. Inc. New York. 1980, Sixth Edition.
2. Lawrence, D. R. : **Clinical Pharmacology,** 1980, Fifth Edition.
3. Satoskar, R. S. et al : **Pharmacology and Pharmacotherapeutics,** Popular Prakashan, Bombay 1983, Eighth Edition.

This medicine has been tested for quality by LOCOST in a reliable and independent laboratory.

DR 30.15

DR

(COVER STORY)
HEALTH ACTION

RATIONAL DRUG USE

The Problem

Drugs are the hallmark of Modern Medicine. The 'healing professions' throughout the ages have always used 'natural' or 'synthetic' products for their medicinal value, to treat various common ailments of people. Drugs, however, have never in the past dominated the medical scene as they have done in the second half of this century. Today, the 'pill for every ill' culture is well established. It has ensured that we are probably the most 'drugged generation' of all times. Not a very healthy thought!

Throughout the centuries, philosophers, social activists and concerned doctors have warned against the dangers and problems of overuse, of misuse, of drugs by doctors and the people.

"The physician who sets about to treat a disease without knowing anything about it is to be punished even if he is a qualified physician; if he does not give proper treatment, he is to be punished more severely; and if by his treatment the vital functions of the patient are impaired, he must be punished most severely."

--Koutilya Arthashastra

"Physicians prescribe medicine of which they know little, to cure diseases of which they know less in human beings of which they know nothing."

--Voltaire, 18th century

"The incidence of disease cannot be manipulated and so increased sales volume must depend at least in part on the use of drugs unrelated to their utility or need or in other words improperly prescribed. Human frailty can be manipulated and exploited and this is fertile ground for anyone who wishes to increase profits."

--Kefauver Committee Hearing on Drugs, USA

"I believe that Modern Medicine treatments for disease are seldom effective and they are often more dangerous than the diseases they are designed to treat.

I believe that modern medicine has gone too far by using in everyday situations extreme treatments designed for critical conditions.

I believe that more than ninety percent of modern medicine could disappear from the face of the earth--doctors, hospitals, drugs--and the effect on our health would be immediate and beneficial.

--Dr Mendelsohn, Confessions of a Medical Heretic, 1980

"There are two types of physicians--those who promote life and attack diseases; those who promote diseases and attack life.

--Charaka Samhita

THE INDIAN SITUATION

The Indian Council of Medical Research and the Indian Council of Social Sciences Research set up a joint study group to study the health situation in India and evolve an alternative strategy for our commitment to 'Health for All by 2000 AD." This high powered expert committee had some very interesting things to say about the present situation of drugs and prescribing practices, in their Report published in 1981.(1)

*

"There is now an over-production of drugs (often very costly) meant for the rich and well-to-do while the drugs needed by the poor people (and these must be cheap) are not adequately available. This skewed pattern of drug production is in keeping with our inequitous social structure which stresses the production of luxury goods for the rich at the cost of the basic needs of the poor.....

* One of the most distressing aspects of the present health situation in India is the habit of doctors to over-prescribe glamorous and costly drugs with limited medical potential. It is also unfortunate that the drug producers always try to push doctors into using their products by all means--fair or foul. These basic facts are more responsible for distortions in drug production and consumption than anything else.

* Eternal vigilance is required to ensure that the health care system does not get medicalised, that the doctor-drug producer axis does not exploit the people and that the abundance of drugs does not become a vested interest in ill-health."

These warnings are a serious indictment of the medical profession and the drug industry in the country. It confirms the growing evidence that drugs are being

pushed on an unsuspecting public by devious methods which masquerade as 'sales promotion' of drug companies and 'professional prescribing practice' by doctors and health workers. All of us who are committed to 'Health' need to be concerned about this situation. The promotion of a 'Rational Drug Use' by the medical profession and health workers and ultimately by the consumers--the patient community and the public is an important item on the agenda of HEALTH ACTION.

Irrational Drug Use--some dimensions

To understand the principles of Rational Drug Use, one needs to first identify and appreciate the elements of irrationality in the present situation. A spate of reports appearing in our newspapers and periodicals highlight these elements. Of all of them, however, the report of the recent 'Lenten Commission' and its shocking findings are the most telling.

Irrationality in drug use arises out of three sets of factors:

A. Irrationality in drug production, marketing and availability

B. Irrationality in prescribing practices of doctors and health workers

C. Irrationality in drug use by the consumer public.

All these taken together result in the situation we find ourselves today.

A. Irrationality in drug production, marketing and availability

* Industrial policy

Drug policy continues to be part of the industrial policy and not part of the health policy. Industrial growth and profit margins determine the policy and not health needs of the people.

* Over abundance

There is a plethora of drugs produced in the country. The Hathi Committee recommended 116 as essential and the WHO says 200 are necessary. At present there are over 45000 formulations in the country.

* Quality of drugs

Twenty percent of the drugs available in the country are substandard and spurious. Many are adulterated. Many are old and being sold after the expiry dates are over.

Turmeric powder in tetracycline capsules and poor quality intravenous fluids have been reported. The substandard glycerol' in J J Hospital highlighted by the Lenten report is another example.

* Unwanted Drugs

The formulations available include the following:

i. Banned drugs: Drugs which have been banned in many countries such as Lomotil and Clioquinol.

ii. Irrational combinations: Formulations which have combinations that are antagonistic or irrational. The Hathi Committee had suggested weeding out of atleast 23 such groups of preparations. These were finally banned by a gazette notification in July 1983 but continue to be available.

(See Dangerous drug list--page)

iii. Hazardous or Bannable drugs: Hazardous drug which should not be available without prescription or adequate medical supervision. Preparations containing analgin, oxyphenbutazone and cortico-steroids are the commonest example

(Refer A to Z of Drug use - page)

iv. Drugs promoted for indications that are not clinically proven or are potentially dangerous, eg. Promotion of EP Forte combinations for pregnancy testing and induction of abortion even when there is well documented evidence that risk of foetal deformity is increased by the use of these preparations.

v. Costly Drugs: Drugs which are inflated in cost by inclusion of costly, additional, often unnecessary ingredients or by cosmetic embellishments in manufacture and packaging. Tonics and high protein foods especially baby foods are good examples.

* Wrong Priorities

There is over-production of unimportant drugs or drugs for the rich while drugs for some common health problems are in short supply. Tonics, vitamins, hormone preparations and high protein substitutes are being produced in wasteful abundance while drugs for leprosy and tuberculosis

(two major public health problems) are produced at one third and one fourth of actual requirements. Similarly Vitamin A and many vaccines urgently required for child care programmes are frequently in short supply.

* Over-the-counter sales

Sale of drugs over the counter without doctor's prescriptions or the necessary statutory checks are not at all uncommon. This results from inadequate drug legislation and even more inadequate drug controls. Over-the-counter unauthorised sales of prescription drugs, which now-a-days do not even have the precautionary product information make the situation even more hazardous.

* Escalating Prices

Price control policies have been both inadequate and ineffective and hence the cost of drugs has been constantly escalating. With liberalization policies of the present government, this is bound to increase further. The purchasing power of majority of our patients is limited. With increasing prices, patients are forced to buy only part of a prescription or go in for substandard alternatives promoted by the drug shops.

B. Irrational Drug Prescribing

Doctors, nurses and health workers often prescribe or administer drugs irrationally.
The types of irrational drug prescribing has been classified as follows: (4)

Type of irrational drug use	Occurs if a drug is prescribed when:
1. Extravagant prescribing	- a less expensive drug would provide comparable efficacy and safety - symptomatic treatment of mild conditions divert funds from treating serious illness - a brand name is used where less expensive equivalents are available.
2. Over-prescribing	- the drug is not needed - the dose is too large - the treatment period is too long - the quantity dispensed is too great for the current course of treatment

3. Incorrect prescribing	- the drug is given for an incorrect diagnosis - the wrong drug is selected for the indication - the prescription is prepared improperly - adjustments are not made for co-existing medical, genetic, environmental or other factors.
4. Multiple prescribing	- two or more medications are used when one or two would achieve virtually the same effect. - several related conditions are treated when treatment of the primary condition will improve or cure the other conditions.

5. Under prescribing
- needed medications are not prescribed
- dosage is inadequate
- length of treatment is too brief.

(4)

Taken from Managing Drug Supply, Management Sciences for Health, Boston, Massachusetts, USA

How does such prescribing take place?

There are many background factors which lead to such prescribing practices.

a. Inadequate training

Doctors, nurses, pharmacists and health workers may be inadequately trained in the use of drugs. The training may be theoretical and not geared to the practice of prescribing in the real life situation. Technical minutiae may be stressed at the cost of information on cost, social context and hazard.

b. Inadequate continuing education

The doctor, pharmacist, nurse or health workers in field practice are inadequately supported

by a process of continuing education by their professional associations and training institutions. Once graduation is over, there is little opportunity to refresh one's knowledge of drugs and medical matters through unbiased sources of information.

* c. Unethical medical advertising

Medical advertising of drugs has more often than not found to be full of unproven claims of efficacy. In addition, promotional literature all over the world by the same company for the same drug has been found to be vastly different. Facts are withheld or modified. Statistics are used in a biased manner. Drug company sponsored misinformation is not uncommon.

Drug: Tetracycline (antibiotic used against various infections; Lederle Laboratories)

	Caution against use	Adverse reaction publicized
U.S.A.	By infants, children; during pregnancy; liver or kidney impairement (latter can be fatal) or if overly sensitive to light.	Vomiting, diarrhoea, nausea, stomach upset, rashes, kidney poisoning; can poison fetus.

	Caution against use	Adverse reactions publicized
Mexico	By infants, children; during pregnancy or if overly sensitive to light.	vomiting, diarrhoea, nausea, stomach upset.
Brazil	By infants, children, during pregnancy	vomiting, nausea, stomach upset, rashes
Argentina	None	None

Courtesy: Mother Jones, USA

d. Prescribing for prestige/power

Doctors especially often prescribe extravagantly as a sign of 'prestige' and 'power'. In India people often consider a good doctor to be one who gives a long, costly prescription, in keeping with his list of degrees. Many doctors succumb to this cultural status symbol. A vicious cycle is maintained thereby.

Patient, why do you take so many drugs?
I take them since the doctor has prescribed it.

Doctor, why do you prescribe so many different, similar and expensive drugs?
I prescribe them because the patients expect them.

e. Busy outpatients

Many of our institutions are understaffed especially those run by the government. The queues at the out-patient clinic are long and there is a heavy rush. Lack of time to make a good clinical judgment often results in an irrational prescription including drugs for all eventualities.

f. Inducements by medical companies

Misinformation is not the only method by which doctors are made to prescribe irrationally by medical companies. Sales promotion includes a host of practices such as unethical trade discounts, bribes, gifts, sponsorship for conferences and travel. The commercial proposition induces many doctors to prescribe unethically.

g. Unauthorised prescribing

Health workers and practitioners of other non-allopathic systems of medicine are often by virtue of their training unauthorised to prescribe all the drugs in the medical armamentarium. Health worker may be trained to prescribe only a few drugs. Too often they get a larger number of drugs and dispense them to get the community's approval and get greater prestige. Many traditional medicine practitioners, dispense allopathic drugs with little background training or knowledge.

h. Drugs as a substitute for caring

Drugs have become a symbol of the new medical culture, where treatment is primarily drug oriented and all other aspects of 'caring' and nursing of the patient are relegated to the background. When simple home remedies like hot water gargles and nursing procedures can provide relief to many symptoms of the patients, doctors prefer to prescribe symptomatic drugs instead, thus increasing drug consumption irrationally.

h. Commercialization of the medical profession

There was a time not so long ago when the doctors' profession was a vocation. Aspirants to the profession saw service to the sick and ailing as more important than the financial rewards they would get, if at all from their grateful patients. Today the situation has changed drastically. Parents are willing to pay lakhs to get their children into medical school. No such investment would be made if the returns were not equally rewarding. Aspirants today therefore see medicine as a business investment. In such a social ethos 'irrational prescribing' for pecuniary benefits would not at all be frowned upon. In fact it may even be seen as a stepping stone to success.

C. Drug use by Consumer Public - irrational dimensions

i. Self-medication: Medication by patients themselves is not an uncommon problems. Either they are too poor to consult doctors or because of the easy availability of drugs they medicate themselves, encouraged by the pharmacists, advertisements, peer group information or advise of family members. A survey conducted by the National Institute of Nutrition in the twin cities of Hyderabad and Secunderabad covering 10 percent of the 330 retail

pharmaceutical shops showed that self-medication rate was an alarming 46 percent.

ii. Use of unutilized drugs

It is a very common habit among the consumer public to take a medicine, not as the doctor has directed but just enough to feel better. This is often the case with antibiotics and particularly for children. Unused medicine is kept in the home pharmacy and given to one or other of the children or family member who gets the same symptoms, next. Unused or unutilized portion of prescribed medicine is often kept beyond expiry date. If proper storage precautions are not taken, it may also get denatured. Use of such medicines is a major cause of untoward reactions.

iii. Inadequate labelling or storage of medicine

Medicines prescribed by doctors are often inadequately labelled by the dispensing pharmacist. Storage instructions are are not very clearly explained to the patient. The medicine cupboard is often a source of irrational drug use. Children may have access to it and this may lead to accidental poisoning.

iv. Peer-group exchange

Consumers of drugs often advise relatives, friends and neighbours about the benefits a particular

prescribed drug has given them. They are advised to take these drugs for what is thought to be a similar complaint or disease. This peer group exchange is often the cause of much irrational drug use by the lay public.

v. Status-symbol drugs

Capsules, injections and tonics have become status symbol drugs. They are thought to be more effective and also being costlier are considered to be of greater prestige value. Patients often demand or pressurise their doctors to prescribe one or more of these and doctors often comply with the request to retain the patient and family in their practice.

vi. Multiple consultations

Patients often go to many doctors seeking quick relief of their symptoms. The doctors are not often aware that consultation with them is one of many such concurrent events. Generalists and Specialists may both be consulted. Practitioners of different systems may be consulted simultaneously. Different medicines given by different doctors are then consumed with the hope of getting relief. When relief does occur it is not easy to decide which medicine brought it about.

Multiple prescriptions then become a way of life when symptoms reccur. Many drugs may potentiate one another. Others may work at cross purposes. When the consultation is of plural systems, the confusion is worse.

vii. Inadequate Consumer Awareness

Probably one of the key factors for irrational drug use by consumers is the absence of awareness of drug use, misuse and the effects of overuse. Consumer education is next to absent in India. Due to loopholes in the existing laws, precautionary product information is not supplied with the medical products. The media, the medical profession, the educational system and the social welfare agencies concentrate on the misuse of psychotropic substances and drug abuse. Misuse, overuse or abuse of commonly prescribed drugs is not considered to be an adequately serious problem for consumer education. The problem is further compounded by a large illiterate population and for the need of such efforts to be in multiple languages when they do get organized.

RATIONAL DRUG USE - PRINCIPLES

The irrationalities and predisposing factors promoting unsafe drug use in our country have been described. The challenge that faces all of us today is How to counter this phenomena? Health for All by 2000 AD would be an empty slogan if we did not join and participate actively in a consumer and professional movement to tackle the 'irrational drug use' problem. In the absence of prompt efforts in thisdirection, we would probably arrive at a situation--overabundant drugs and ill-health for all by 2000 AD. What could be our prescription for action?

A thorough understanding of the situation would lead us to appreciate the following principles.(3)

Rational Drug Use

* means practice of socially conscious, relevant and scientifically sound medicine
* emphasises the selective use of drugs based on
  - essentiality
  - efficacy
  - safety
  - easily availability

- low cost
- ease of administration
- adequate quality
- preferably of indigenous production

* recognises the concept of essential drugs and the concept of graded lists for different levels of health personnel

* recognises the non-role of drugs in certain conditions, the role of alternative systems of medicine in some other conditions and recognises the overall limitations of allopathic medicine in our economic, social and cultural context.

* accepts a conscious decision to boycott certain drugs which are hazardous or bannable or banned and use all others only when they are really needed.

* means prescription with awareness, to avoid as far as possible iatrogenesis which includes--
  - drug induced problems
  - drug interactions
  - adverse drug reactions
  - emerging drug resistance

* recognises the rights of health personnel and consumers to unbiased drug information and its effective communication.

* understands the role of drugs in the emerging health movement.

(3)

~~Source: Rational Drug Use, Mira Shiva, CHAI Workshop~~

For all of us concerned about the increasing medicalising of health action and the 'over abundance of drugs' becoming a 'vested interest in ill health' there is a phenomenal challenge in making the above principles of Rational Drug use ~~both~~ - common knowledge
- common practice
- common commitment.

In conclusion, drugs have allayed pain and suffering over the centuries. They have helped many live more comfortable, productive and meaningful lives. All of us committed to the health movement must ensure that drugs should continue to

to play their limited but useful role in the medical service. However, the use of drugs knowingly and unknowingly, to make profit out of human health must stop.

And it will only if

Governments;

drug industry;

planners;

health professionals;

medical colleges;

pharmacy colleges;

nursing colleges;

drug controllers;

pharmacists;

journalists and medica persons;

teachers and educators;

social development activists;

consumer groups;

and

the public

commit themselves to promoting a Rational Drug Use.

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1. ICMR/ICSSR (1981)
Health for All--An alternative Strategy.

2. VHAI (1986)
Banned and Bannable drugs

3. Shiva Mira (1985)
Rational Drug Therapy
Medical Service, Vol. 42, No.1, January 1985.

4. Management Sciences for Health (1982)
Managing Drug Supply
Boston, Masachusetts, USA

5. Narayan Ravi (1984)
Consumer Alert--Consumer Action
Medical Service, Vol 41, No.9, October-November 1984

6. Werner David & Bower Bill (1982)
Helping Health Worker's Learn
Hesperian Foundation, USA.

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All India Drug Action Network (AIDAN)

All India Drug Action Network (AIDAN) is a coordinating body of Voluntary Health, Consumer, Science Organizations and individuals actively involved in this field, from different parts of India; set up to :

i Work towards a Rational, Pro-people Drug Policy in India and to

ii Exchange ideas, experiences about different aspects of alternative practices at grass root level pertaining to the production, distribution, use etc. of Rational Drugs.

PERSPECTIVE

AIDAN realizes that the health of people depends primarily on nutrition, sanitation, living and working conditions, social culture..etc and that availability of health services especially of drugs, has only a secondary role to play. But at the same time, in India, where infectious diseases predominate, drugs can save large-number of lives and remarkably reduce sufferings. The Rational Drug Policy, can therefore, play an important role as part of a Rational Health Policy. However, during the last thirty years, along with a rapid increase in the range and volume of drug-production, there has been a more rapid rise in the irrationalities at all levels of the drug policy (i.e. Research, Production, Distribution, Marketing, Education and Use) due to a lack of scientific approach coupled with the profiteering by the drug industry. Secondly even 39 years after independence, the multinational drug companies continue to dominate the drug scene in India; self-reliance continues to be a dream. As a result, essential drugs are in short supply, out of the reach of the majority of the people who need them; whereas there has been a plethora of high-cost, useless, hazardous drugs in the market.

There is, therefore, a dire need to work for a Rational Drug Policy which should have the following objectives:

A Assessing the real drug-needs

1 To identify the real drug needs in consonance with the health need of the people, particularly those required for primary health-care; to prepare a graded essential and priority list of drugs for different levels of health-expertise in keeping with actual health needs of the people.

2 To eliminate irrational, useless and hazardous drugs. (This has become one of the most important problems today).

B Production, Price and Quality-control

1 To produce and make rational drugs available at low prices to the people, particularly the essential and priority drugs. Adequate supply of free drugs to the poor people through the state health system.

2 To ensure strict quality control of all drugs.

C Drug Distribution

To establish a national corporation for the distribution of drugs; retailing of drugs through appropriate channels and government's health infrastructures.

D Drug Information & Ethical Marketing

1 To ensure a drug information system for health personnel and consumers.

2 To ensure ethical marketing

3 To abolish brand names and introduce generic names of all (drugs)

E Self-reliance

1 To develop self-reliance in drug technology.

2 To foster and encourage the growth of the Indian Sector and to provide a leadership role to the public sector.

3 To aim at quick self-sufficiency in the output of drugs with a view to reducing the quantum of imports.

F Research and Development

1 To promote research and development for self-reliance and to meet the real health needs of the Indian people.

2 To evolve strictly ethical mode of medical research.

G Legislation and Administration

1 To provide comprehensive drug legislation and administrative support to deal effectively with and implement all the above aims and objectives.

2 To ensure smooth Centre-State relations and inter-departmental coordinations for effective drug production, drug control and drug supply.

H Human Power Development

To fulfill the needs for the above Rational Drug Policy, different types of technical personnel (e.g. druggists, paramedics technicians etc) need to be adequately and appropriately trained in adequate numbers.

Some elaboration of these objectives (A to H) has been published in the form of a 16 page pamphlet "Rational Drug Statement" of AIDAN and is available for Rs. 1-50 from Dr. Mira Shiva, Coordinator, AIDAN. A substantial document "A Rational Drug Policy" (see at the end) gives much more detailed account.

EVOLUTION & ACTIVITIES

Some groups and individuals concerned with misuse of drugs came together in 1981 and launched a campaign against the high dose combination of estrogen and progesterone. The campaign proved to be effective and the Government had to ban this combination. Encouraged by this success, attempts were made to rouse public opinion against irrational and hazardous drugs. Through the interaction during these campaign, it was felt that there was a need for a regular network to co-ordinate this work; to lobby for a rational drug policy as a whole and not only about hazardous drugs. A loose co-ordinating network was formed in 1983. A series of prolonged and intense discussions were held amongst those who had been consistently active in this collective work during those couple of years and a Rational Drug Policy Statement (RDP Statement) was prepared outlining our basic common understanding briefly elaborating the points enumerated above.

Within the perspective of this RDP Statement, member organisations & individuals have tried to create public awareness through various means

(articles in periodicals, pamphlets, meetings..etc.) On different aspects of the drug policy, particularly the relationship between plethora of irrational drug combinations and the paucity of essential drugs and that between high prices of drugs and the domination of multinational drug companies. (At the end, a list of publications in English on the drugs issue by member organisations has been given.)

From 1984, a new drug policy by the Government was quite in the air and hence AIDAN as a collective focussed its attention on this new policy. A detailed critique of the report of the steering committee of the new National Drugs and Pharmaceutical Development Council (NDPDC) was submitted to the Government; a spate of newspaper articles were written, concerned parliamentarians were appraised of our perspective and demands by providing substantial material. A signature campaign amongst doctors enlisting medical demands about new drug policy was carried out in different parts of the country.

After the announcement of the New Drug Policy on 18-12-86, its anti-people, pro-industry, irrational character is being exposed in the eyes of the public.

Apart from lobbying about the policy issues at the National level, some member organizations of AIDAN have been active in educating doctors, paramedics and the lay people about Rational drug use in their practice. For example:

★ "Drugs Diseases Doctors" by Drug Action Forum, West Bengal, is a periodical for doctors which is almost exclusively devoted to rational use of drugs and to highlight misuse of drugs.

★ Voluntary Health Association of India has been training their paramedics in rational drug use and has published health related booklets.

★ LOCOST has been trying to evolve a method of supplying good quality generic name drugs at cheaper rates, to the voluntary sector and promoting rational use of drugs.

WHAT YOU CAN DO FOR AIDAN

1 To become an active member of AIDAN please write to the co-oridnator on the following address. Dr. Mira Shiva C-4/14, S.D.A. New Delhi 110 016.

2 To study the substantial material published during last few years by AIDAN members or by other fraternal groups; and to write in various periodicals with the help of this material.

Please do not forget to send a copy of the cuttings of published material to the AIDAN Co-ordinator.

A list of such publications is given at the end of this brochure.

3 To sell this material to appropriate groups, socially conscious doctors, activists, Journalists...etc.

4 To foster Rational Drug Policy Cells in your area or within already existing appropriate organizations to carry out the above work of lobbying as well as to promote rational knowledge and use of drugs in your area. For example, a local group can launch a campaign amongst doctors as to why they should not accept any drug samples from any drug company, or why they should not use hazardous drugs like E.P. forte, Analgin, Butazones, Anabolic Steroids, Clioquinol, Combination of strepto-

mycin with chloramphenicol or with penicillin...etc.

Campaign amongst the people about primary importance of oral Rehydration in diarrhoea; and try to start "diarrhoea-treatment centres" by paramedics under the guidance of a doctor and about the wastage of money involved in the use of most of the highly advertised over-the-counter drugs and the alternative to these brands.

Lobby with the Government on the basis of awareness amongst the people about-

★ The urgent need to make available measles vaccine on a priority basis in the Government-centres or to shelve the plans to give NET-EN injections to women.

Lobby with the professional bodies like in Indian Academy of Paediatrics, IMA to

★ promote rational use of medicines amongst its members; to conduct seminar on the new drug policy;

★ to pressurize the Government to immediately make available the measles vaccine in its programme.

★ to prepare and distribute health-educational material for parents on child-health and about do's and don'ts about drugs.

Only a couple of illustrative examples have been given above about some of the types of activities that you can take up. Many such instances and also other types of activities are possible depending upon resources.

5 If you are interested and are in a position to do academic work; this will also be helpful. If you are a doctor, you can contribute to the above mentioned periodicals or you can prepare a study of various formulations belonging to any one of the groups of drugs (cough mixtures, haematinics, antacids.. etc) that are available in the market to assess their rationality. Studies conducted by the Medico Friend Circle (see at the end) offer such examples and have proved to be very useful in re-education of doctors.

If you are an economist or sociologist, you may study from that angle, various aspects of a rational drug policy-for example, the real needs of the Indian people about different drugs for example, how much of isonex-the antitubercular drug-would be required to treat all the TB-patients in India? How much money is wasted, concretely speaking, on irrational drugs? What is the impact of the new drug policy on the ex-FERA companies, Indian monopoly drug companies, medium size companies?... etc. If you are an artist, you can draw posters, cartoons, prepare songs, make a slide show...!

This is a movement and different types of people with different skills can make valuable contributions. Let us all together work towards a 'Rational Drug Policy".

LITERATURE ON DRUGS IN ENGLISH PUBLISHED BY AIDAN MEMBERS

I AIDAN Materials:

i Rational Drug Policy statement: pp 16, Rs. 1.50, VHAI (see below)

ii A Rational Drug Policy; pp.162, 2nd edition 1986, Rs. 20.00 (This book and C1 – see below-are very substantial resource books on different aspects of Drug Policy) Published by Voluntary Health Association of India for AIDAN

40, Institutional Area, South of I.I.T. New Delhi-110 016.

iii Critique of the New Drug Policy, April 1987 (under preparation) available at VHAI and CED).

iv Drug Alert-Hazardous Drugs, pp 52, Rs. 6/-

II Material Published by AIDAN Members:

A **Arogya Mitra Mandal** 2117, Sadashiv Peth, Pune 411 030 — Our Health, Our Medicines, Rs. 10/-

B **Catholic Hospital Association of India** (CHAI) PB 2126, 157/26 Staff Road, Secunderabad 500 003

1 Health Action — a monthly published by Health Accessories for All (HAFA) propagates Rational Drug Therapy and Critical approach on Health Care delivery.

Subscription Rate:

Life Membership	: Rs.	1000/-
Annual — Individual	: Rs.	60/-
Annual — Institutional	: Rs.	80/-
Foreign-Annual	: US$	50/-
Foreign-Life	: US$	500/-
Single copy	: Rs.	7/-

Themes covered by past issues in 1988 include Immunization, Infectious diseases, Tuberculosis, Nutritional Anaemia, Diarrhoea, Acute Respiratory Infections, Antenatal Care, Rational Drug Therapy, Nutrition, Leprosy, Addictions and Blindness.

1989 — Sports and Health, Growing Child, Hypertension, Mental Health, Accidents and Poisoning, Diabetes, Community Health, Allergies, Dental Health, Universal Immunization Programme, Cancer and Shelter (Housing).

2 Buyer's Guide —
A purchase guide to Health Care products and services — useful for Hospitals and Dispensaries.
Price Rs. 175/-

3 Herbal and Home Remedies — Loose Leaf format. Photographs and sketches of herbs used commonly as home remedies.
Price Rs: 40/-

4 Mini-manuals in Hindi (set of 10 titles) — Illustrated guide to deal with common health problems in a simple and rational way, giving both allopathic and home remedies. Topics covered are Scabies, Pneumonia, Tuberculosis, Polio, Care of Eyes, Ears and Teeth.
Price: Rs. 15/- for whole set.

C **Centre for Education & Documentation,** 3 Suleman Chambers, 4 Battery Street, Behind Regal Cinema, Bombay-400 039

i Aspects of Drug Industry in India, M Bhagat, pp. 130, 1982. Rs. 19

ii Brief List of the Literature on Drugs and Drug-related issues available at C.E.D. with facility for xeroxing and sending by post. Most of the literature in this list is available for sale with C.E.D. and V.H.A.I.

iii Injecting NET-EN into India, Mira Savara, June 86 Rs. 5.

D **Delhi Science Forum,** B-1, IInd floor, 'J' Block, Saket, New Delhi-110 017

i Drug Industry and the Indian people, Dr. Amit Sen Gupta, (ED.) co-publisher-F.M.R.A.I. Patna, pp 333, 1986, Rs. 40-00, Harbdound Rs. 100-00

E **Drug Action Forum** West Bengal

i Drug Disease Doctor (Quarterly); Ed. Dr. P.K. Sarkar, P. 254, Block-B, Lake Town, Calcutta-

700 089. Annual Subscription Rs. 12-00.

ii Poster: Drugs for the people or People for the Drugs, Rs. 3/-

F Kerala Shashtra Sahitya Parishad (KSSP) Parishad Bhavan, Marvencheri Lane, Trichur 680 002.

i A decade after Health Committee, Ed. Dr. B. Ekbal, Rs. 35/-

ii Drug Alert-Hazardous Drugs (AIDAN) pp. 52, Rs. 6/-

iii National policy for Universal salt Iodization-A critique, Dr. K.P. Arvindan, Rs. 3/-

G Medico Friend Circle Rational DrugPolicy Cell,50, LIC quarters, University Road, Pune-411 016.

i "Tonics how much an economic waste?" by Dr. Kamala Jaya Rao, xeroxed 6 page article from MFC Bulletin: Rs. 5-00 (available free of charge with V.H.A.I)

ii "Scientific Scrutiny of some over-the-counter-drugs" by Dr. A.R. Phadke, xeroxed copy of the reprinted article in "Medical service" Oct-Nov. 1985, 7 pages: Rs. 6-00

iii "Multinationals in the Indian Drug Industry" by Dr. A.R. Phadke, xeroxed copy of the 5 page article from MFC bulletin, Rs. 4-00 iv) Dipyrone, Hoechst and the Boston Study, Wilbert Bannenberg, reprint from MFC Bulletin No 123, December 1986, 4 pp. Rs. 2-00

v Drug Alert-Hazardous Drugs, pp 52, Rs. 6/-

H Pondicherry Science Forum

i Issues involved in drug policy. (A brief account of some of the issues discussed in I,II and Di published by Chennai Books; 6, Thayar Sahib Street, II Lane, Madras 600 012, pp 56; revised edition, Februrary 1987 Rs. 10-00

I Voluntary Health Association of India (VHAI) 40, Institutional Area, south of IIT, New Delhi-110 016

i Banned and Bannable Drugs, pp. 67, Rs. 15-00

ii Drug Information pack; Rs. 15-00

iii The use of Essential Drugs (reprint from WHO) Rs. 10-00 (for other books, see 'I' in beginning)

iv "Do you really need all these", a leaflet, Rs. 2-00

v Reprints from: "Where there is no Doctor", Right and wrong uses of modern medicine: Re. 1/- Instructions and precautions for Injections: Re. 1/-. The uses, dosage and precautions of common medicines, Rs. 2-50

vi Leaflets of Rs. 0-50 each: The declaration of Alma Ata, Drugging of Asia, WHO essential drugs, Bangladesh drug policy, Hazardous bannable and dumped drugs, Our concern about drugs, Essential drugs, The Courageous Bangladesh.

vii Posters: Murder in the name of medicine, profits before the people Rs. 5-00 each 'Can you understand the small print', Ban Bannable drugs, Drugs can be dangerous too. Don't judge a medicine by its packaging, Rs. 3-00 each.

For a list of other publisher's books on drugs available at VHAI, please write to the publication officer, VHAI.

For mode of payment, postage.. etc, please write to individual publishers listed above.

DRUG ACTION—FACT SHEET

WHO - Essential Drugs

Policies for providing essential drugs

The selection of essential drugs. Technical Report Series 615. WHO, 1977. Excerpt.

"While drugs alone are not sufficient to provide health care, they do play an important role in protecting, maintaining and restoring the health of people. In recent years, there has been a tremendous number of pharmaceutical products marketed; however, there has not been a proportionate improvement in health.

Many pharmaceutical products are marketed with little concern for the differing health needs and priorities of individual countries. Promotional activities of the manufacturers have created a demand greater than actual needs. Since up to 40% of the total health care budget in developing countries may be spent on drugs, the result has been an increase in the cost of health care or a reduction in funds available for other health services. The cost has affected even the affluent nations, and their governments are increasingly worried by the rising expenditure on pharmaceutical products. In developing countries, the problem is magnified by limited economic resources, shortage of trained health personnel, and lack of organised drug policies. In the least developed countries, where communicable diseases and lack of elementary health care are the major medical concerns, large segments of the population are in urgent need of essential drugs.

It is clear that for the optimal use of limited financial resources the available drugs must be restricted to those proven to be therapeutically effective, to have acceptable safety and to satisfy the health needs of the population. The selected drugs are here called 'essential' drugs, indicating that they are of the utmost importance, and are basic, indispensable and necessary for the health needs of the population.

Drugs included in such a list would differ from country to country depending on many conditions, such as the pattern of prevalent diseases, the type of health personnel available, financial resources, and genetic, demographic and environmental factors.

Because of the great differences between countries, the preparation of a drug list of uniform, general applicability and acceptability is not feasible or possible. Therefore, each country has the direct responsibility of evaluating and adopting a list of essential drugs, according to its own policy in the field of health.

The list of essential drugs based on the guidelines put forward in this report is a model which can furnish a basis for countries to identify their own priorities and to make their own selection.

The notion that the number of necessary drugs is relatively small is supported by experience. Several developing countries that have adopted limited drugs lists report good aceptance, as well as favourable medical and economic results. Lists and formularies with a limited number of drugs are also successfully used in many developed countries.

A limited list may not provide for the needs of every person but certainly should meet those of the vast majority. Whether or not drugs or pharmaceutical products outside the list are available in the private sector should be a local decision.

Limited drug lists have several advantages:

1. Reduction in the number of pharmaceutical products to be purchased, stored, analysed, and distributed;

2. Improvement in the quality of drug utilisation, management, information, and monitoring;

3. Stimulation of local pharmaceutical industries;

4. Assistance to the least developed countries in urgent need of high-priority drug programmes to solve their primary health care problems.

An effective programme of drug selection coupled with

appropriate information and education may help to improve attitudes regarding the role of drugs in health and disease."

General principles for establishing a list of essential drugs

The following principles were considered by the Expert Committee to be a foundation on which to establish a list of essential drugs:

1. Adoption of a list of essential drugs is part of a national health policy. This implies that priority is given to achieving the widest possible coverage of the pop-ulation with drugs of proven efficacy and safety, in order to meet the needs for prevention and treatment of the most prevalent diseases.
2. Only those drugs for which adequate scientific data are available from controlled studies should be selected.
3. Each selected pharmaceutical product must meet adequate standards of quality, including when necessary bioavailability.
4. Concise, accurate and comprehensive drug information drawn from unbiased sources should accompany each list of essential drugs.

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DR 30.18

VOLUNTARY HEALTH ASSOCIATION, KARNATAKA

Seminar on LOW COST DRUGS AND DRUG POLICY

REPORT

(1) Preamble

The following letter went out to all the Members of VHA (K) in early September.

"The V.H.A.I. goal has been and will always be a 'Healthy Community'. We seek 'to promote social justice in the provision and distribution of health care'. With the increasing emphasis on "Primary Health Care" we are all in an increasingly important quest for priorities. We are seeking clean water before antibiotics, food before vitamin pills, vaccination before kidney machines, mother's milk before powdered baby foods mixed with dirty water, and health for villages and slums before more hospitals for the affluent suburbs of capital cities. The dilemma before many of our members is how to shift priorities from our commitment to hospital systems to our increasing commitment to community health care systems.

One of the big problems we are facing in our hospitals is the increasing cost of drug bills. Drugs are becoming the mainstay and main cause of expenditure in our hospital system. Any shift of priority can only result from a concerted action on our part to look at drug policy and drug costs and see whether we, as a group of voluntary health workers, can do anything to reduce the drug bills as a first step towards shifting priorities. Can we change our prescribing policies? Can we stock low cost drugs? Can we produce low cost drugs?

The ICMR/ICSSR study on "Health for all - an alternative Strategy" warns us that eternal vigilance is required to ensure that the health care system does not get medicalised, that the doctor-drug-producer axis does not exploit the people and that the abundance of drugs does not become a vested interest in ill health."

Can we V.H.A. Members do anything about this individually and collectively?

To find an answer to this growing problem we have organised a seminar for all members on October 3rd, at St John's Medical College, Bangalore.

Join us to discuss the following issues !

- The pattern of drug production should be oriented to the disease pattern in India, with an emphasis on the production of essential and basic drugs. If we agree, what can we do about it?

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- We cry for drugs needed by poor and underprivileged groups which should be produced in adequate quantities and sold at cheapest possible prices. How may we bring about this?

- One of the most distressing aspects of the health service today is the habit of doctors to overprescribe or to prescribe glamorous and costly drugs with limited medical potential. Can the medical profession in our hospitals be made more discriminating in prescribing habits?

- The small scale drug industry needs to be encouraged and expanded subject to strict quality control. Can we produce low cost alternatives in our hospitals, health projects and village communities?

- Fifteen thousand branded drugs are on sale in India. But a Government Committee on Drugs and Pharmaceuticals Industry (1975) believes that health needs can be met by only 116 drugs. Can we agree to a simple standardised low cost pharmacopia for the Voluntary Health Sector?

- A Government Committee looking at drug costs has recommended acceptance of
  - A basic drug list
  - Generic Prescribing practice
  - Bulk purchasing
  - Local formulations
  - Use of indigenous drugs

Taken separately, each policy is a powerful weapon for change; taken together, they build into an integrated strategy. Can we consider these and accept them to change the drug scene in our hospitals?

These are many of the issues we will discuss together in the workshops. Please send representatives from your hospital/health centre institution to share with us your experiences and ideas. The Seminar is open to all Health Administrators, Doctors, Nurses, Pharmacists, Paramedical Workers and Voluntary Workers associated with Voluntary Health Care Agencies.●

(2) Participation

Over_____Members and____local invitees registered on 3rd October 81 for this seminar. Important among the local participants were the Deputy Director (Pharmacy), Directorate of Health and Family Welfare and the Deputy Drug Controller and represenative of the Drugs Testing Laboratory of the Government of Karnataka.

(3) RESOURCE PERSONS

Mr Alan Cranmer, Consultant Pharmacist CMAI based in Holdsworth Memorial Hospital, Mysore and Dr Ravi Narayan, Asst. Professor of Community Medicine, St John's Medical College,

Bangalore, were the key resource persons. Dr Thangam Joseph, Professor of Pharmacology, St John's Medical College, Dr CV Rama Rao, Professor of Community Medicine, St John's Medical College, Dr Premananda Shetty (Dy Director, Pharmacy), Dr Dara S Amar, Assoc Prof of Community Medicine, St John's Medical College, Dr Manohar, Physician of St Philomena's Hospital, Bangalore, Dr Sylvia Babu, Paediatrician, Baptist Mission Hospital, Bangalore, were additional resource persons who chaired the sessions and group discussions. Dr K E Peters and Dr P S Rai were guest speakers on 'Homeopathy' and 'Ayurveda' respectively during a session on the Role of these two systems in Health Care.

(4) Programme Highlights

9.00 am	Registration	
9.30 am	Introduction to Seminar	: Dr Sylvia Babu
	Self-introduction by participants	
9.50 am	Session I - Chairman: Dr Thangam Joseph	
	Keynote paper I	
	- Low Cost Drugs and Drug Policy (an overview)	: Dr Ravi Narayan
	Keynote paper II	
	- Hospital Pharmacy Policy for Low Cost Drugs (some perspectives)	: Mr Alan Cranmer
	DISCUSSION	
11.15 am	C O F F E E	
11.30 am	GROUP DISCUSSION	
Group A-1 (Room No.116)	Outlining a Prescribing Policy	: Chairman: Dr Manohar
Group C-1 (Room No.117)	-do-	: Chairman: Prof CV Rama Rao
Group B-1 (Room No.119)	Outlining a Pharmacy Policy	: Chairman: Dr K Premananda Shetty
12.30 pm	L U N C H	

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1.30 pm	GROUP DISCUSSION II	
Group C-2 (Room No.117)	Case Study on Management of Diarrhoea	: Chairman: Prof SV Rama Rao
Group A-2 (Room No.116)	-do-	: Chairman: Dr Sylvia Babu
Group B-2 (Room No.119)	Drawing up list of basic/essential drugs	: Chairman: Dr Dara S Amar
2.30 pm	Session II	
	Role of Ayurveda and Homeopathy	: Chairman : Prof SV Rama Rao
	1. Homeopathy	- Dr K E Peters
	2. Ayurveda	- Dr P S Rai
3.30 pm	T E A	
3.45 pm	Session III	- Chairman: Dr Thangam Joseph
	CONCLUSION	
	Group Reports by Rapporteurs of Groups A-1 & 2, C-1 & 2 and B1 & B-2	
	RECOMMENDATIONS	
	Vote of thanks	: Fr Bernard Morus Hon. Secretary, VHA (K)

(5) Main points of Keynote Addresses

(a) Low Cost Drugs and Drug Policy

An overview of the issue concerned with the Seminar theme was presented by Dr Ravi Narayan taking four publications as resource material. These were :

i. the Hathi Committee Report (1975);

ii. the Earthscan publication, Drugs and the Third World, by Anil Aggarwal

iii. the ICMR/ICSSR Study on Health for All - an alternative Strategy

iv. Health for the Millions, April-June 1981 issue on Medicines as if people mattered

He presented some facts on the Drug industry in India highlighting the following points:

1. Too many branded preparations;

ii. Too many companies--mostly private with a strong profit motive;

iii. Skewed consumption of drugs between urban/rural areas.

iv. Overproduction of drugs meant for illnesses of rich;

v. Drug colonialism; and

vi. absence of clear cut government policy.

He then highlighted the characteristics of the prescribing policy of the medical profession stressing on the unfortunate tonic and injection practice of doctors, irrational combinations, high pressure advertising tactics, including those of monetary and material inducements, drug misuse and over and under prescription. He also stressed the problem of improper medical training and near absent continuing education.

Among the many alternatives recommended by W.H.O. and National Committees, he outlined the pros and cons of :

a. essential drug list;

b. generic prescribing;

c. indigenous medicine;

d. non-drug therapies.

Finally he set out components of an alternative policy for group discussion.

(b) Hospital Pharmacy Policy for Low Cost Drugs

Mr Alan Crammer shared his perspectives gained over years of consultancies for CMAI and CSI group of hospitals.

He outlined the needs for a low cost pharmacy policy for drug supplies to the Health Care Delivery Systems at 3 levels or tiers.

1st tier: Medicines for Community Health Workers which should be cheap, effective symptomatically, easy dosage regimens, without problems of side effects or drug resistance. A list of 18 had been recommended by the ICMR study.

2nd tier: Medicines for the Primary Health Centre

In addition to those used by Community Health Workers, medicines at this tier would include long term therapies like TB and Leprosy, Anti-biotics, emergency drugs and related materials for preventive services like vaccines etc. Facilities for refrigeration would be essential. Health Education and Family Welfare Counselling would be additional priorities.

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3rd tier: Low Cost Medicines in the Hospital Pharmacy

He stressed the need for a Pharmacy Committee outlining its objectives. He discussed the importance of proper inventory procedures, storage facilities, seasonal stocking and group purchasing. He also dealt on the possible hospital based drug production including i.v. solutions, rehydration powders, injection solutions, skin preparations and so on. He then went on to outline questions which should be considered while evolving a Pharmacy Policy.

(3) Group Discussion

The participants were divided into three groups for small group discussions. Groups A & C discussed components of a prescribing policy and later discussed the treatment of diarrhoea as a case study. Group B discussed components of a Hospital Pharmacy policy and later discussed the criteria necessary in evolving an Essential/Basic drug list. For the assistance of the groups the following four sets of questions/guidlines were drawn up and circulated.

1. Outlining a Prescribing Policy

How many of the following components of an alternative PRESCRIBING POLICY can we accept as a group committed to 'Health for All'?

If yes, why? If no, why not?

(1) Accepting an ESSENTIAL/BASIC DRUG LIST for our practice

(2) Accepting GENERIC PRESCRIBING

(3) Accepting COST as an important criteria for selection of a remedy in addition to safety, efficacy and quality.

(4) Discouraging prescriptions of drugs whose only additional advertised value are:

a) Cosmetic embellishments;

b) Elegant packing;

c) Inadequate evidence of greater value;

d) Irrational combinations;

e) Imitative drug

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(5) Not accepting physician's samples and other monetary or material inducement which corrupts us to promote a companies product ie., we prescribe a product which we think is best suited for a condition, not because the company gave us the maximum material advantage.

(3) Other component which should be included:

a) Indigenous medicine;

b) Non-drug therapies;

c) Continuing Education of the Health Profession;

d) Promoting Primary Health Centre Priorities; and

e) Bare-foot pharmacy

2. Outlining a Pharmacy Policy

Questions to be pondered about:

(1) Can a Hospital devise a formulary of good quality, low cost medicines?

Can this be common for all Voluntary Hospitals?

(2) How can prescribers' compliance be ensured or is freedom of prescribing likely to make this impossible?

Can we ensure Health Workers' compliance with their formulary (medicine list)?

Will doctors also prescribe from this list?

Is it possible to prevent prescriptions to medical shops being given?

(3) Where simple low cost drugs will not be sufficient, how do we subsidise to all or those who need help most?

Should all patients contribute to the cost of medicines? If so, how?

(4) Will a Pharmacy Committee, including Doctors, Administrators and Pharmacists help in implementing cost control or quality control policy? (In most Hospitals medicines are the second largest item of expenditure.)

(5) Have we asked our pharmacists to research costs? If so, does he know how to do so?

Have we provided tools for the job? If so, what tools?

(3) Are bulk drugs purchases possible on a group of Hospitals-base? What methods can we devise for obtaining low cost drugs either for one or many Hospitals?

(7) Do we consider proper stock control, record keeping and auditing of medicines, purchase and distribution:

a) unnecessary expenditure; b) essential?

What are our reasons for our attitudes?

(8) In many Hospitals the Pharmacy is an important income producing section. Will a switch to low cost drugs raise cost or make it instead a burden on the Institution?

(9) Is the production of medicines in the Pharmacy :

a) too time consuming

b) too costly in terms of personnel or equipment

c) uneconomic?

(Broadly thinking of two types: non-sterile prescriptions and sterile prescriptions) How would you advise your Hospital Management?

3. Case Study on Management of Diarrhoea

Diarrhoea ranks highamong the morbidity and mortality figures for this country. The etiologic agents are most often food and water borne microbes and viruses. Mortality in this illness is most often due to loss of body fluids as a secondary effect of the diarrhoea.

Developed nations in contrast, have a relatively low prevalence of such infectious diarrhoeas—proper sanitation and protected water supply accounting for decreased prevalence and not better drugs to treat the infection.

In the past, when the markets were not flooded with innumerable drugs and drugs combinations, simple home remedies were used to contain diarrhoea.

Listed below are some of these simple home remedies and their basic ingredients.

(1) Dietary restriction to easily assimilate carbohydrates, rice, arrow-root, sego etc.

(2) Curds - lactobacilli

(3) Tea - Tannin

(4) Pomegranate - Tannin

(5) Poppy seeds - Opiates

(6) Tender coconut water - Hydration

(7) Bananas - Pectin

Scientific knowledge today supports the symptomatic treatment of diarrhoea with particular attention to maintaining hydration. While there is a definite place for use of APPROPRIATE ANTIBODIES in the treatment of diarrhoea, the most common occurrence today is inappropriate use of multiple antibiotics, further complicating the diarrhoea by severe alteration of normal gastro-intestinal flora.

Discuss some of the causes for this occurrence and suggest feasible solutions.

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4. Drawing up list of Basic/Essential Drugs

15,000 branded drugs are on sale in India. But the Government Committee on Drugs and Pharmaceutical industry believes that health needs would be met by only 116 drugs.

> Could we list out the CRITERIA which members of WHA could use in formulating a list of essential/ basic drugs to be used in their own institutions for hospital and health care?

(7) Session on Non-Allopathic Systems of Medicine

To widen the perspectives of the participants a special session on the role of Homeopathy and Ayurveda in Health Care was organised. Professor Rama Rao made preliminary introductory remarks on the importance of traditional medicine particularly in the light of these being an integral part of our cultural and historical traditions.

Dr Peters outlined the history of Homeopathy and mentioned how Dr Hahnemann accidently noticed the symptoms that cinchona bark produces in a healthy person and struck upon the idea that 'like is cured by like' - similia similibus curruntur. He then outlined the main importance of this system of medicine. In answer to a question he added that among the many cases that were being referred to him by Allopaths now-a-days the most important for which Homeopathy had good cures were plantar warts, hydrocele and hernia especially in child-hood, migraine, cervical spondylitis, hyperacidity, hypertension and heart disease.

Dr PC Rai outlined the philosophy and main principles of Ayurveda. He too, in answer to a question, mentioned the conditions of Jaundice, Leucorrhoea, Rheumatism, Asthma and Hypertension as the main diseases which were being referred to them by Allopaths and wherein the Ayurvedic system had good cures.

The frankness and humility of both speakers were very impressive and we hope members of WHAI will be more open to these systems in their future work.

CONCLUDING SESSION

Recommendations

The participants of the WHA (K) Seminar on LOW COST DRUG AND DRUG POLICY recommended that through a process of continous dialogue and discussion each member hospital, dispensary or health centre through its medical and pharmacy staff should—

a. appoint a THERAPEUTICS or PHARMACY COMMITTEE consisting of doctors, pharmacists and other members of a hospital or health centre team involved with

administration of drugs.

b) Formulate a list of Basic/Essential drugs (Formulary)

i. The WHO drug list could be taken as a basic document to work on. The list would be prepared on the basis of disease groups and include diagnostic agents, vaccines etc., within this group the arrangement will be alphabetical.

ii. The listing should be generic as this clearly indicates the drug being administered. This may also contribute to reducing costs.

iii. In case bioavailability is a problem, either a patent name may be included or the manufacturers name given. As bioavailability studies are not available for most drugs in India, this will be on the basis of clinical judgement.

iv. The list of approved suppliers for drugs in the formulary must be set out by the Pharmacy Committee. This will ensure quality and continuity of supply.

v. Strength of injections and other medicines to be stated also minimum and maximum doses and paediatric doses.

vi. Treatments of toxic reactions, poisoning and other emergencies to be set out.

vii. Prescribing policy and rules to be included in the front of the formulary. Where specific drugs demand special prescription, this is to be indicated by the item concerned.

viii. To whom should the formulary be given - doctors, nurses, nursing stations. Amendments can be issued for these only to the holders who are responsible for adding to their copies.

c) Involve a consensus among 'prescribing staff' towards the following policies in prescribing:

i. Generic prescribing;

ii. Rational drug therapy which emphasises efficient, safe, easy to administer, low cost drug

iii. Discouraging prescription of drugs whose only additional advertised value are -

- cosmetic embellishments;
- attractive/elegant packing;
- inadequate evidence of greater value;
- irrational combination;
- imitative or me-too drug

d) Evolve a consensus among 'prescribing staff' and 'pharmacy staff' about the unethical nature of the material and monetary inducements provided by medical companies including free physician samples especially if these are modifying or deciding our prescribing policy--and decide on action to counter the high power advertising pressure tactics of medical companies.

e) Accept cost as an important criteria in selecting a drug for prescription. This is in addition to safety, efficacy and reliability.

f) Introducing proper stock control, record keeping, auditing of medicines, purchase and distribution because we think these are essential and not unnecessary expenditure.

g) Consider the production of simple pharmaceutical preparations in the hospital pharmacy on a cost-effective basis to bring down drug costs for the patients. These could include mixtures, ointments, rehydration powder, iv fluids and many paediatric preparations.

h) Promote a greater openness and understanding of the indigenous non-allopathic traditions of medicine like Ayurveda and Homeopathy and non-drug therapies like Yoga, Naturopathy and Acupuncture so that their use and efficacy can be further researched and they could be used in our future programmes in an integrated way.

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i) Promote the priorities in Primary Health Care in all our programmes some of which are -

- clean water before anti-biotics;
- food before vitamin pills;
- vaccination before kidney machines;
- mother's milk before powdered baby foods;
- health for villagers and slum dwellers before more hospitals for affluent suburbs of capital cities and so on.

j) In addition to all the above (a) to (i), all WIA (K) members should be involved in a continous dialogue between doctors and pharmacists and be an active participant in continuing education on all the above issues to doctors, nurses, para-medical personnel, patients, students of medical professions, interns, junior doctors and all the members of the community.

k) In this task which we set for ourselves we request our Association, the WIA(K) to keep us informed of all aspects of this dialogue on drugs through our newsletter and any other means available to it like meetings/seminars etc.

l) All our efforts would be of not much use till we are able to get the Government especially the Director General of Health Services and Drug Control Department involved in studying varying aspects of the problems of low cost drugs and evolving an alternative policy. With this in mind we recommend that our Association initiate a regular dialogue with the State Government Health Authorities and help to evolve a policy whereby both Government and Voluntary Health Agencies can work in a meaningful partnership to achieve the goal: Health for All by 2000 AD.

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Resource for the Seminar
on
LOW COST DRUGS AND DRUG POLICY

1. Drugs and the third World - Anil Aggarwal—an Earthscan Publication.

2. Health for All - An Alternative Strategy -- ICMR/ICSSR Joint Report 1980.

3. Medicines as if People Mattered—Health for the Millions, VHAI, April-June 1981.

4. Report of the Committee on Drugs and Pharmaceutical Industry (Hathi Committee), April 1975.

5. SMASH NEWS, Dec. 1980

6. "Health for All by 2000 AD—Resources" by Dr CM Francis, Dean, St John's Medical College (ISHA Conference, 1980).

7. Pharmaceuticals, Drug Policy and Health Care. Bibile Memorial Lecture by Dr VHI Gunawatne, Feb. 1979.

8. Import of Technology and its impact on Development— Report of Seminar of Delhi Science Forum, May 1979.

9. The Pharmaceutical Industry - Drug Pricing Policy and Production — a study : K Jayaram: Economic Times, 10th May - June 1, 1976.

10. Myth and Reality of Drug Industry, Booklet (Standing Committee of the National Convention on Economic Independence and Perspective of Drug Industry).

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Needles And Noodles

IF you've graduated from the AFMC and have set up practice as a G.P. and are young and full of energy and enthusiasm, the world is a wonderful place to live in. Now all you have to do is sit by and rake it in as your practice begins to flourish while you try your hand at playing god — right?

Wrong — at least if you happen to be Manik Hiranandani. "I became disenchanted with the traditional methods of allopathic medicine early on in my practice," says Dr Hiranandani. "I found its limitations crippling. Allopathy has no really effective treatment for anything other than acute bacterial infections or accidents."

So Dr Hiranandani systematically set about acquiring skills in various fields of alternative medicine. This involved attending annual conferences abroad, seeking out experts and learning from them by observing their methods of treatment.

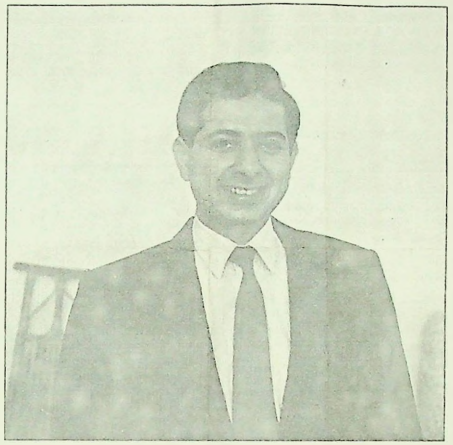
Confidence began to develop when his first case, an 87-year-old arthritic woman, made a remarkable recovery — and since then there has been no looking back. Today, the doctor has a vast practice and thousands of satisfied patients whom he has treated, using methods as diverse and strange-sounding as acupuncture, iridology and craniosacral osteopathy. Many of these have been people in acute suffering, "given up" by endless successions of practitioners.

Dr Hiranandani's resurrective powers have certainly brought him fame — but interestingly, he is widely known in many other quarters as well.

A prominent activist of the consumer movement, he possesses the distinction of having taken the FDA to court — and won; for having singlehandedly managed to get many harmful and unnecessary drugs off the market. "We all complain about the state of things. We all say that somebody ought to do something. So I did!" he smiles. "I have no liabilities so it wasn't difficult for me to stick my neck out and see that I won!"

Practical enough to identify a vacuum and move in with an original contribution, Dr Hiranandani's book on non-invasive acupuncture, the only one of its kind, is used as a text book all over the world. "Many patients dislike the thought of being pierced," he explains, "and today it is possible to dispense with needles using laser and ultrasound for acupuncture. When I first started using these techniques their inception was so recent that other doctors were unaware of how they worked and there was not even any literature to learn from. A book, explaining things, was needed desperately — so I wrote it!"

In keeping with his preoccupation with the consumer movement, a forthcoming book, *A Consumer's Guide To Good Health*, brings to the common man vital information, often inaccessible or neglected, such as how to choose a good doctor, the rights of a patient, home remedies for common ailments and many others.



Dr Manik Hiranandani: An acupuncturist, a consumer activist, a writer and a cook to boot.

Another book in the pipeline is to consist of a collection of his own recipes. As it turns out, Dr Hiranandani is an excellent cook — preoccupied not just with taste but health and food value as well. This consuming passion extends to shopping for the best and freshest of ingredients for each dish.

Widely travelled, he looks after his health by going on regular holidays — sometimes skiing or sailing, or simply retreating to an ashram. For one who lives a life so suffused with leisure and variety, the quantum of his tangible achievements at work is impressive. His patients are, to coin a phrase, walking advertisements.

Roland Medeira, an Air India purser, is a classic example. Immobile for five weeks after suffering a slipped disc, Mr Medeira was hospitalised and an operation was imminent. "But I came to see Dr Hiranandani," he says, "and was restored sufficiently to be able to walk out of the clinic. Two more sessions and the pain was gone." Now, a total convert, he has directed many colleagues — for whom backache and slipped discs are routine occupational hazards — to Dr Hiranandani who has set them right again.

The word of these miracle cures has spread far and wide and today Dr Hiranandani splits his practice between two clinics in south Bombay where he lives for half the year. The other half he spends in Hong Kong as medical director of the Vital Life Centre, a centre where he intends to propagate the practice of integrated medicine — treating patients with techniques from various schools as per their requirement — and spread it to other parts of the world.

Sceptics abound. "I started off that way too," confesses the doctor, "but when I discover something that works, no matter how unconventional, I adopt it. I have learned a lot by just being receptive to seemingly strange ideas. People sometimes challenge me and that is perfectly natural, but I have no inclination to prove anything to them. They have the choice of being convinced by my results if they wish to."

Retired businessman N. R. Kamani, for instance, reluctantly decided to try out acupuncture when he was struck with excruciating toothache and his dentist was away. Today, Mr Kamani has his own acupuncture machine and when affected by a minor ailment, just phones in to Dr Hiranandani for instructions.

"The idea," the doctor explains, "is not just to cure patients and relieve them of their pain, but to ensure that they stay cured, become self-sufficient, and don't keep coming back to me."

For one who lives a life so suffused with leisure and variety, the quantum of his tangible achievements at work is impressive.

Patients who come for treatment are not just treated — they are also given some background and understanding of the procedure to which they are subjected. Logical explanations are provided whenever asked for. And for those that scoff at his unorthodox methods, Dr Hiranandani has merely a sympathetic smile. "You can argue with thousands of my satisfied patients," it seems to say.

SINGLED OUT

SAAZ KOTHARE

DR 30.20

DR

Voluntary Health Association of India

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New Delhi-110016

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New Delhi-110016
Telephones: 668071
668072

2-4/379(a)
CS/S/15/4/85

CONSUMER ALERT

WITHDRAWAL OF PHENYLBUTAZONE/OXYPHENBUTAZONE

(INFORMATION RECEIVED FROM CONSUMER INTERPOL)

After throrough and careful reexamination of all past and presently available evidence on the therapeutic value and medical use of BUTAZOLIDIN (phenylbutazone) and TANDERIL (oxyphenbutazone) Ciba-Geigy Pharma has taken the following decisions :

1. The indications for BUTAZOLIDIN will be further restricted to the treatment of only four classical froms of rheumatic diseases

   - active ankylosing spondylitis
   - acute gouty arthritis
   - active rheumatoid arthitis
   - acute attacks of osteoarthritis

2. The medical use of BUTAZOLIDIN in these four indications will be recommended only for cases where other therapeutic measure, including other non-steroidal, anti-inflammatory drugs, have been tried and found unsatisfactory. BUTAZOLIDIN will thus become a drug of second choice.

3. Sales of TANDERIL will be discontinued world-wide.

The implementation of these decisions will begin immediately and will be completed in the third quarter of 1985. National health authorities have been informed. Physicians and pharmacists are again requested not to exceed our specific recommendations concerning the use of both products. There is no imminent health hazard to patients under treatment. It has to be remembered that both drugs have been standard medications in long and widely accepted medical use for decades.

Early in 1984, on the basis of a comprehensive benefitrisk evaluation conducted on its own initiative, Ciba-Geigy Pharma had already severly curtailed the use of BUTAZOLIDIN and TANDERIL.

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It recommended time limites for use, cautioned prescription for certain patients and stopped sales of pediatric forms and combination products altogether. The restricted field of indications was in line with clinical evidence demonstrating the efficacy and safety of both products under just those limited conditions. This step was supported later on by corresponding decisions of most national health authorities. A sharp decline of sales resulted during 1984 on a worldwide scale, as had to be expected.

Subsequently, Ciba-Geigy Pharma carefully surveyed the usage of both drugs. It turned out that the limiting conditions set forth for the use of BUTAZOLIDIN have been respected to considerable degree. This was far less the case with TANDERIL, following traditional patterns of use. In order to ensure drug safety to the best possible extent, we have therefore decided to still further limit the recommended usafe of BUTAZOLIDIN and to discontinue offering TANDERIL in our product range. In many individual cases a specific need for the treatment of patients with BUTAZOLIDIN which have not responded to other therapies in the limited range of its indications, still exists. Responding to such need by a continued offering of BUTAZOLIDIN for proper medical use is thus in the best interest of patients suffering from serious rheumatic disease. Ciba-Geigy Pharma will further monitor BUTAZOLIDIN in order to assure its appropriate use.

In its search for today's proper medical place of BUTAZOLIDIN and TANDERIL, Ciba-Geigy Pharma had also discussed its position with consumer representatives. Together with opinions of medical experts expressed in scientific literature their arguments have been taken into due account. With our decisions of today we intend to make again a major contribution to drug safety both in industrialized and developing countries.

. . .

IDENTITY OF PRODUCT OR SUBSTANCE

Use of the product : Non-steroidal anti-inflammatory drug

Generic or common name : (i) Phenylbutazone (ii) Oxyphenbutazone

Brand(s) : (i) Butazolidin (ii) Tanderil

Manufacturer/Distributor: Ciba-Geigy

(There are also other brands of phenylbutazone and oxyphenbutazone containing drugs manufactured by Ciba-Geigy and othe companies. This Alert refers specifically to Butazolidin and Tanderil).

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DR 30.21

British Journal of Clinical Practice

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Pg. 22-25

A symposium supplement

A review of childhood pyrexia and the therapeutic options for the 1990s

Warwick Castle
2 April 1990.

A MEDICAL TRIBUNE
UK LTD PUBLICATION

A double-blind comparison of ibuprofen and paracetamol in juvenile pyrexia

J SIDLER, B FREY*, K BAERLOCHER, Ostschweizerisches Kinderspital, St Gallen, *Kinderklinik, Lucerne, Switzerland

Introduction

The pyrexia which frequently accompanies childhood illnesses is thought by some clinicians to be a relatively innocuous component of the body's defence against disease. However, parental and medical concern increases with the extent of the rise in body temperature and the length of time over which a grossly abnormal temperature is sustained, and it has been demonstrated that these factors increase the likelihood of complications such as febrile convulsions. During a febrile illness the child's status is dull and his/her catabolism is increased.

The catabolic effects of infectious illness which are largely attributed to fever are reduced when fever is lowered, and there is an advantage in maintaining a near normal body temperature during an infection in that the patient feels better and eats better.

Fever is the result of many stimuli, either of an endogenous or an exogenous nature. Bacteria, virus, fungi, antibody-antigen reactions and various drugs can induce it. It is thought that it may be due to the production by leucocytes of an endogenous pyrogen, a low molecular weight protein nature, which probably acts on the thermosensitive neurones in the pre-optic hypothalamic region. Although not totally explained, the action of the endogenous pyrogens seems to be connected to the release of mediators such as serotonin and the prostaglandins E_1 and E_2, which are considered to be the central mediators or modulators of the onset of fever. That is why the inhibitors of prostaglandin synthesis are antipyretic.

In this study a double-blind comparison was undertaken of ibuprofen syrup and paracetamol syrup in the treatment of juvenile pyrexia.

Ibuprofen and paracetamol are both analgesic antipyretic drugs, ibuprofen being a propionic derivative and paracetamol a para-aminophenol derivative. With regard to indications, ibuprofen has been traditionally used as an anti-inflammatory and analgesic and paracetamol as an antipyretic, although recently ibuprofen has also been used as an antipyretic. This fact is due among other things to:

- Pharmacological evidence of its antipyretic properties. Already in 1970, Adams had shown the antipyretic activity of ibuprofen to be 20 times greater than that of acetylsalicylic acid in rats with fever induced by yeast.
- Better knowledge of the pathology of fever and the implication of prostaglandins in its onset. Substances with similar pharmacokinetics the one which shows a greater capacity for inhibiting prostaglandin synthesis has the most potent antipyretic effect.
- The good tolerability of ibuprofen proved by controlled trials and confirmed by the wide use of the substance as an anti-inflammatory and analgesic, particularly since it has become available in some countries without need of a doctor's prescription.

Aims

This study was designed to extend investigations with ibuprofen in children admitted urgently to hospital for the treatment of a variety of fever-producing conditions and had the following aims:

- To compare the antipyretic efficacy of ibuprofen (at two different strengths) and paracetamol.
- To compare the incidence and severity of side effects.

Study details

The study, a double-blind, parallel group, multipledose trial, was conducted at two centres in Switzerland.

Suitable patients for the study were children of either sex in an age range of five months to 13 years, weighing between 7 and 36 kg and having a rectal temperature of 38.5°C or more.

Details of the study were explained to the parent or legal guardian before informed consent was obtained for the child to take part in the study.

Children with severe systemic diseases including a bleeding disorder, a history of peptic ulceration, chronic dyspepsia or chronic gastrointestinal bleeding, or a history of asthma were excluded from the study. Also excluded were those receiving immunosuppressive treatment, those receiving treatment likely to interact with the study medication, those considered by the investigator to be unsuitable for entry, those allergic to the study medication or related compounds, those suffering from hepatic, renal or cardiac disease and those unable to tolerate a rectal probe.

Ninety suitable hospital patients were allocated to one of the following treatments by random distribution in blocks of three such that there were initially the same number of patients in each group:

- A single dose of ibuprofen syrup at 7 mg/kg body weight (formulation 20 mg/ml).
- A single dose of ibuprofen syrup at 10 mg/kg body weight (formulation 30 mg/ml).
- A single dose of paracetamol syrup at 10 mg/kg body weight (formulation 30 mg/ml).

Patients received the first dose of study medication at baseline (Hour 0), providing medication likely to affect the assessments had not been taken in the preceding four hours. A second or third dose of the medication could be administered only at eight-hour intervals, and only in cases where the rectal temperature was 38.2°C or more.

Demographic data recorded at entry to the study comprised age, sex, body weight, presumptive diagnosis and concomitant drug therapy.

Data recorded

Patient body temperatures were recorded at 10 minute intervals for a minimum of 12 hours and a maximum of 24 hours after the first dose of study medication using a rectal sound connected to automatic data logging equipment. Additional written records of body temperatures were provided at Hours 0, 0.25, 0.5, 1, 2, 3, 6, 8, 12, 16, 20, and 24. Changes in the clinical condition of the patients were recorded on a five-point scale (1 = much worse to 5 = much improved) at Hours 3, 6, 8, 12, 16, 20 and 24.

Details of withdrawals, side effects and any changes in concomitant drug therapy were rcorded.

Quality of data

The timing of a number of assessments was not at the scheduled time. In such cases assessments were taken to the nearest scheduled time. If as a result two or more assessments represented the same scheduled time, the assessment nearest to the scheduled time was used in the analysis and the other assessments were disregarded.

Analysis of data

The treatment groups were assessed for comparability with respect to baseline information. Clinically significant differences were allowed for in the subsequent analysis.

Reasons for and times of withdrawal/drop-out were reported and the frequency of complaints reported on each treatment were tabulated.

The principal measures of efficacy were the reduction of body temperatures three hours after dosing. The measures were analysed using a paired t-test and 95 per cent confidence intervals were calculated for the mean differences. The body temperature three hours after dosing was also analysed by analysis of covariance with the pre-treatment value as covariate. Differences between treatment groups in the proportion of patients with a drop in body temperature of 1°C or more at three hours were compared using a chi-squared test.

Results

At this stage the results for the automatic data logging are not available. The data presented here are those recorded by hand.

Withdrawals

Of the 90 patients recruited to the study, one patient was excluded from the efficacy analysis (prescribed Ponstan on the day prior to entering the study).

Eighteen (20%) of the 89 eligible patients withdrew from the study–three taking the 7 mg/kg ibuprofen medication, four the 10 mg/kg medication and 11 the paracetamol medication. The main reason for withdrawal was lack of response (Table 1).

Table 2. Summary of side effects.

	Treatment group		
	Ibuprofen 7 mg/kg	Ibuprofen 10 mg/kg	Paracetamol 10 mg/kg
Vomiting	1	—	2
Abdominal pain	1	—	—
Rash on forearms	1	—	—
Got cold at 35.5°C	—	1	—
Total number of side effects	3	1	2

Side effects

Six patients suffered side effects: three in the 7 mg/kg ibuprofen group, one in the 10 mg/kg ibuprofen group and two in the paracetamol 10 mg/kg group (Table 2).

Reduction in temperature

The reduction in temperature at three hours was significant for all three treatment groups: ibuprofen 7 mg/kg, —1.64°C; ibuprofen 10 mg/kg, —2.09°C; paracetamol, —1.29°C.

Twenty-six (90%) patients in the ibuprofen 10 mg/kg group had a decrease in temperature of 1°C or more. The corresponding numbers of patients in the ibuprofen 7 mg/kg and paracetamol groups were 23 (79%) and 20 (74%) respectively. There were no statistically significant differences between treatment groups in the proportion of patients with a decrease of 1°C or more.

Patients in the ibuprofen group had a significantly lower mean temperature (Fig 1) than patients in the paracetamol group ($p \leq 0.05$ for the 7 mg/kg group, $p \leq 0.01$ for the 10 mg/kg group). The covariate age had no effect on the temperature at three hours, the ibuprofen being more effective across the whole age range of 5 months to 13 years.

Table 1. Summary of withdrawals.

Withdrawals	Treatment group			Overall
	Ibuprofen 7 mg/kg	Ibuprofen 10 mg/kg	Paracetamol 10 mg/kg	
Yes	3	4	11	18
No	27	25	19	71
Complete recovery	—	—	2	2
Lack of response	2	4	5	11
Patient vomited	—	—	1	1
Second dose of medication not taken	1	—	—	1
Squirrel temperature defect	—	—	1	1
Unknown	—	—	2	2
Total number of patients	30	29	30	89

DR 30-21

Fig 1. Mean temperature up to three hours by treatment group.

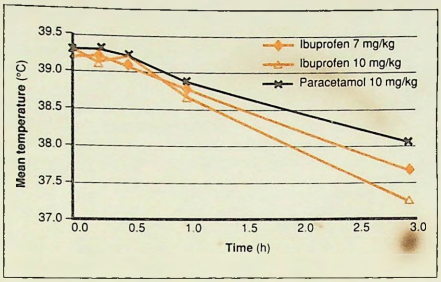
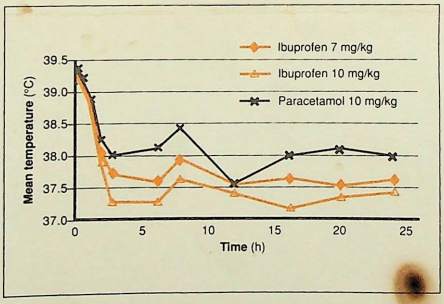


Fig 2. Mean temperature over time by treatment group (adjusted for age and baseline temperature).



The analysis of temperature over time (Fig 2) showed that there were significant differences between the treatment groups, with the overall mean temperature for the two ibuprofen groups significantly lower than for the paracetamol group. There was a significant treatment group by time interaction, suggesting the magnitude of the differences between the ibuprofen and paracetamol groups varied over time. The paracetamol temperature curve only came down to the ibuprofen 7 mg/kg curve at 12 hours after 59% of patients in the former group received a second dose of paracetamol at eight hours (Fig 2). The differences were greatest between three and eight hours and 16 and 24 hours.

Analysis of clinical condition at three hours and over time showed there were no significant differences between the treatment groups. Less than half the children required a second dose to control fever in the ibuprofen groups. (38% in the 7mg/kg group, 44% in the 10mg/kg group), whilst just over half the children (59%) required a second dose in the paracetamol group.

Conclusions

- *Treatments were efficacious.* All three treatment groups showed a significant reduction in temperature from baseline to three hours and the temperature remained lower over the 24 hours of the study.
- *Temperature reduction was greater in the ibuprofen groups.* There was a significantly greater reduction in temperature at three hours in the ibuprofen groups than in the paracetamol group, with a larger number of patients showing a decrease of 1°C or more.
- *Temperature reduction was fastest in the ibuprofen 10 mg/kg group.* Patients in the ibuprofen 10 mg/kg group had a significantly lower mean temperature at three hours than patients in the paracetamol (10 mg/kg) group.
- *Mean temperatures for ibuprofen groups were lower than for paracetamol group.* The overall mean temperatures for the two ibuprofen groups were significantly lower than the corresponding paracetamol group mean. The magnitude of the differences varied significantly over time.
- *Clinical condition improved more rapidly for ibuprofen groups.* Whilst there was no significant difference in overall clinical condition between the treatment groups, the rates of improvement were greater at three hours in the ibuprofen groups.
- *Good tolerability.* All doses of study medication were well tolerated, with only six patients reporting side effects.

DRUG References

DR 30.22

1. Feedback on Prescribing - Lancet Editorial 11th Feb '84

"According to Sir William Osler, one of the first duties of the physician was to educate the masses not to take medicine. Perhaps the remedies have improved since his day, but the pressure to prescribe is as high as ever - not least from patients, who may be reluctant to leave surgery or clinic without a prescription. At a time when the drug bill continues its expansion and the adverse effects of drugs are increasingly in the public eye, we should be looking very critically at our prescribing in the hope of improving performance."

St Mary's School Team Study

"whether or not general practitioners alter their prescribing habits if they are given information about their own prescriptions, an opportunity to discuss it with other general practitioners and access to any further reasonable facilities"

Analysis of Prescription Pricing Authority PPA
- PPA2 - Personal prescribing frequency + cost
- PPA8 - Individual prescribing pattern of each GP.

Findings

1. Older doctors changed their prescribing more than younger ones
2. Greatest potential for financial savings lay in use of six drugs - Nitrazepam (Mogadon) Aldomet (methyldopa
   Valium (Diazepam) Lasix (frusemide
   Indocid (indomethacin Inderal (propranolol.

Prescriptions ↓ 2-8 fold in favour of generic prescrip^{n}.

Lancet 21st Jan 1984 p142

Greenfield Report - Department of Health and Social Security - Effective prescribing - Report of an informal working group - DHSS London - 1983.

— X —

① Pharmacist & patient counselling

IJHP Jan Feb 84 Vol XXI No 1 pp 35-

② Drugs & Human Welfare: Hopes & Hindrances

The Indian Scene. Dr Nitya Anand

IJHP Jan Feb '84 Pg 9

NUCLEAR ISSUES - REFERENCES

(1) Before it is too late: the challenge of Nuclear Disarmament. Geneva world council of churches 1983 $13.95

Drugs

(1) Drugs in pregnancy + lactation
A reference guide to fetal + neonatal risk
Gerald G. Briggs, B Pharm; Thomas W Boclendorfer, Pharm D.
Roger K Freeman, MD, Sumner J. Yaffe, MD
1983 / about 400 pages / illustrated / 105") - 3 /
about - $ 36.00 / about - $ 43.25 outside the US

(2) Monitoring Adverse Reactions to Drugs (MARD)

Dear Dr.

The Dept of CH/MACH has started a project for MARD under the supervision of Dr A Jayanti MD (Pharmacology)

Drug reactions as you are aware, may be due to idio-syncrasies, toxicity, patient susceptibilities, interaction with other drugs simultaneously taken etc. We request you to extend your cooperation + support + report to same to us.

A suggested proforma is given below.

1. Patients name
2. Address / Area of residence
3. Age + sex of patient
4. Nature of drug (trade + generic name)
5. Type of reaction - details to be given
6. Degree of reaction - mild, moderate, severe.
7. Dosage, duration of the drug given.
8. The action taken by you in treating the reaction
9. How long did the reaction persist with your treatment or without treatment
10. Did the reaction occur following the administration of the same drug, similar drug of any other company or any other drug
11. any history of asthma, migraine, eczema, allergy, epilepsy, skin disease in the family or in the past
12. Is the drug given alone or in combination with other drugs; if so what are they

Please report to us such reactions as and when they occur. We are in the future as this is a continued programme

Addl. Director Superintendent
VHS.

3. Toxic effects of water soluble vitamins.
Nutrition Reviews Feb 1984 Vol 42 No 2.

Drugs - References

(1) Feprazone withdrawn in UK. - Feprazone (Methrazone, WB Pharmaceuticals) has been withdrawn from the UK market after a review by the Committee on Safety of Medicines. The CSM is said to have been unhappy about the drug's overall adverse reaction profile, in which skin reactions were prominent.

Lancet, April 7, 1984, pp 808

(2) Licence granted for Depo-Provera

Upjohn Limited, manufacturers of the long term injectable contraceptive 'Depo-Provera', have been granted a long term licence by the Dept. of Health & Social Security following a report by a panel appointed by the licensing authority. The panel found Depo-Provera to be an acceptable & effective method of contraception where other methods were contra-indicated. This announcement reverses the Dept's earlier decision not to grant such a licence.

Lancet, April 21, 1984, pp 920.

(3) Lancet, March 24, 1984 - ~~Withdrawal of~~ Althesin discontinued. Duncan Flockhart have informed anaesthetists & the DHSS that the Glaxo group have decided to discontinue the sale of 'Althesin' (alphaxolone/alphadolone), a steroid anaesthetic agent. The solvent polyoxyethylated castor oil, has proved to have disadvantages, notably an association with anaphylactoid reactions. Efforts to reformulate althesin with other solvents have been unsuccessful.

(4) Non-steroidal anti-inflammatory drugs: Have we been sold for choice Lancet, January 21, 1984

During the past 2 years, 3 new non-steroidal anti-inflammatory drugs (NSAIDs) - benoxaprofen, indoprofen, & zomepirac, and a novel formulation of indomethacin, 'osmosin' - have been withdrawn from the UK market. This unprecedented number of withdrawals in one therapeutic class in such a short time raises important questions. Has the CSM adopted a tough line with compounds for which there are apparently safer alternatives? Are the withdrawals connected with the aggressive way in which NSAIDs have been promoted, so that prescribing has been heavy & often inappropriate in terms of age, dose, & condition, hence the spate of reports of toxicity? What about phenylbutazone & oxyphenbutazone which are still widely used & about which the CSM continues to receive reports of adverse reactions, sometimes fatal, including blood disorders & gastrointestinal intolerance & bleeding? Should serious consideration be given now to withdrawal of these two drugs from general use?

More than 2 decades experience with a large number of NSAIDs has shown that, while the incidence of individual adverse reactions varies between drugs & some book p2>

safer than others, the overall profile of toxicity is similar (2)
particularly including blood dyscrasias, gastrointestinal intolerance & bleeding, liver damage, neurological symptoms & skin reactions. Even ibuprofen, now available in Britain without prescription, has been claimed to be associated with aplastic anaemia & hepatocellular necrosis, although the CSM presumably judged that such reactions were acceptably rare with a low dose formulation. The increased hazard of toxic effects from these drugs in elderly patients, due at least partly to pharmacokinetic changes with increasing age, has been recognised for many years, yet studies in the USA showed that more than a third of patients receiving phenylbutazone were over 60 years of age, & that the average duration of treatment was 2 weeks rather than the recommended upper limit of one week. In the UK adverse reactions to benoxaprofen were seen particularly in patients over 70. When, therefore, a new NSAID is introduced, we do well to assume that it has the adverse effects associated with its predecessors (and perhaps others as well) & that elderly patients are at special risk. For detecting such ill-effects the new system of prescription event monitoring might seem to be appropriate, but there is a limit to the number of prescriptions that it can handle, & there is a minimum period over which a realistic picture of a drug's safety will appear: the system failed us c̄ benoxaprofen. A case could be made, therefore, for restricting - - -

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The osmosin episode has emphasised that new formulations of old drugs, designed to reduce peak plasma levels & prolong their effective concentrations, should be assumed to possess the adverse reaction profile of their predecessors until proved otherwise. Indomethacin has a bad record of gastrointestinal toxicity, & there is no reason to think that the small intestine is less susceptible than the stomach to its mucosally injurious effects - jejunal ulceration & subsequent stricture after long term treatment having been described more than 10 years ago. A preparation that releases indomethacin throughout the lower small intestine cannot be assumed to be any safer therefore, than one that releases it in the upper gastrointestinal tract. A similar lesson has been taught by the various slow release formulations of potassium chloride.

Although the CSM, the pharmaceutical industry, & adverse drug reaction assessment bodies such as Inman's prescription event monitoring drug surveillance research unit have their own particular responsibilities

the biggest risks with the prescribing doctor. As we concluded with the benoxaprofen affair, "doctors are too often either ignorant of the hazards of a particular drug or incapable of making a reasoned judgement" concerning its risks + benefits." Among its less controversial + so less publicised recommendations, the Greenfield report on drug prescribing advocated increased education for doctors, both undergraduate + post graduate, in clinical pharmacology. If, as seems inevitable, prescribing doctors are going to be offered a continuing choice of NSAIDs, as well as numerous drugs in other therapeutic classes, then the profession must give high priority to continuous education in the process of choosing the most suitable drugs + prescribing it in safe + effective quantities

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Phenylbutazone + oxyphenbutazone: FDA considers petition for ban in USA

A petition for an immediate ban on two anti-inflammatory drugs, phenylbutazone + oxyphenbutazone, has been under consideration by the US Food + Drug Administration. Ciba-Geigy started to sell phenylbutazone 31 years ago + it has been marketing oxyphenbutazone for 23 years. The petition was filed by the Health Research Group, sponsored by Ralph Nader. Dr Sidney Wolfe, director of the organisation, estimated that worldwide, probably more than 10,000 patients had died as a result of taking the drugs. He said that 3000 of those fatalities were in the USA. Dr Wolfe arrived at his estimates by extrapolating from the company's own estimates of 1182 deaths worldwide the number given in a Ciba-Geigy memorandum. Dr Wolfe cited evidence showing that the fatalities may have been greatly under-reported. Dr Wolfe stated his case against the drugs in a letter to the Secretary of the Dept of Health + Human Services. He gave the leading causes of the drug-induced deaths as aplastic anaemia, agranulocytosis, leukaemia, + gastrointestinal bleeding or peptic ulceration. Other deaths were attributed to hepatitis, thrombocytopenia + renal failure.

Mr Joe Boyd, director of public relations for Ciba-Geigy at its US headquarters, contested Dr Wolfe's appraisal. Some of the numbers in the company's estimate were "soft". The drugs had been used in treating 180 million patients worldwide, + if 1182 of those died the drugs record would be no different from that of competing non-steroidal anti-inflammatory agents. Ciba-Geigy, he said, opposed pro

a ban, but did believe that the labelling on the drugs should probably be made more restrictive in Europe: the labelling in the US, he added, was already satisfactory.

(5) Wheezing reputation fails., Lancet, March 31, 1984

Child Health

References

(1) The health of children in South Africa: some food for thought
A. Moosa - Lancet April 7, 1984. pp 779

(2) Discussion papers by the Royal College of General Practitioners (RCGP continuing education programme) on
'Healthier children: Thinking prevention (July 1982) & Promoting Prevention (May 1983)
in Health for All & Medical schools - letter by CA Pearson Nigeria in Lancet April 21, 1984 - pp 910

(3) April issue of Tropical Diseases Bulletin echo's theme of WHO Day - Children's Health - Tomorrow's Wealth - a collection of abstracts of papers relating to children's health in tropical countries - from the Bureau of Hygiene & Tropical Diseases, Keppel Street, London over the last 18 months
Individual copies of the bulletin are available from the bureau (£5 - $12.50) by surface mail

Lancet, April 28, 1984.

Non-communicable Diseases - References

1) Third World Smoking - The new slave trade
Editorial - Lancet. January 7, 1984. pp 23

Medical/Health Journals

① Indian Drugs -
Scientific publication from the Indian Drug Manufacturers Ass.

② Communicable disease bulletin (quarterly)
National Institute of communicable diseases
22, Shamnath Marg
Delhi - 110054
editor - Dr R N. Bose.
Asst. Ed - Dr R.L. Ichhpujani.

③ The Bulletin of the voluntary Health Service Adyar
TTTI, Adyar P.O. Madras 600113.
(MAC Institute of Community Health
Dr A. Lakshmipathy unit for research in Indian Medicine

④ The Indian Journal of Hospital Pharmacy (IJHP)
official bimonthly publication of Indian Hospital
Pharmacists Association)
Annual subs: Rs 70/-
The Editor
IJHP.
R/566, New Rajinder Nagar
New Delhi 11-060

A selection of items providing information on preventing coronary heart disease based on WHO recommendations is available from the Flora Project for Heart Disease Prevention, 25 North Row, London W1R 2BY (01-499 0414). Advice on diet, blood pressure, obesity, fitness + stress is clearly set out and a cookery book Eating for a Healthy Heart is included in the kit.

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CISRS
Christian Institute for the Study of Religion + Society
P.O. Box. 4600, 17 Millers Road, Bangalore 560046.
Their Journal: Religion + Society Quarterly
Sarah K. Chatterji Richard W Taylor J. Victor Koilpillai
MM Thomas J. Paranjoti-Augustine

Social Action - a quarterly review of social trends
Indian Social Institute, Lodi Road, N Delhi 110003.
April-June '84 issue on social activists + people's movements

Review of sociological studies on TB - implications for health education: Dr AB Hiranandi + AK Bhatia
Source - Indian Journal, Feb 1984, pg 41
Central Health Education Bureau,
Kotla Marg, N. Delhi - 110002.

Journal of the CMAI: The CMAI office, Christian Council Lodge, Nagpur - 1, Maharashtra Annual Sub Rs 25/-
Editor - Dr S. Joseph MD
Mar Geevarghese Dionysius Memorial Hospital
Devagiri P.O
Kangazha 686535,
Kottayam, Kerala

TRADITIONAL MEDICINE / HEALING – Reference

Shamans, mystics + doctors : A psychological enquiry into India & its healing traditions
Sudhir Kakar Delhi. Oxford University Press 1982
PP x + 306 Rs 125.
reviewed : Social Action Oct-Dec '83 pp 457

PPST NEWSLETTER

Vol.2, No.1 February 1984

Concern about health care, drugs policy and suitability of modern medicine in developing countries has been expressed in various forms. Exploitation by multinational drug companies, aided by the 'ignorance' of the medical profession and apathy of the governments have made medical care expensive and ineffective. The lack of adequate nutrition has made the use of powerful drugs dangerous.

In this newsletter we present an interview with Dr. Zafrullah Chowdhury, one of the founders of the Gonoshasthya Kendra, Bangladesh, during his visit to Madras in December 1983. The Gonoshasthya Kendra (People's Health Center) was set up'to provide adequate health service in the rural areas of Savartharma , increase the independence and bargaining power of women and to bring about a change in the infrastructure and thereby allow for the economic and social development of poor villagers, i.e. 90% of the population of Bangladesh'. The main activity of the Kendra is a health programme involving training in rural health care, curative care through rural centers, preventive care, family planning, a health insurance scheme, a pharmaceutical plant and publication and distribution of literature to assist medical practitioners in rural areas. In addition vocational training and classes in literacy and 'conscience-raising' are given to villagers.

The Kendra was also actively involved in the formulation of the Bangladesh Drug policy which has resulted in the banning of over 1700 drugs. As a result, tremendous pressure has been put upon the Bangladesh Government by various Western countries including USA, UK, Holland, etc.

In view of the relevance of these issues to the situation in our country, we are reproducing here the interview contributed by Madras Group.

Dr. Chaudhury started by presenting a brief account of the People's Health Centre:

In 1971, a group of doctors from England came to Bangladesh during the War of liberation and worked in the liberation army. At that time we got a new perspective on health. All of us went back to England after the war, but some of us came back to Bangladesh in 1972. We started a primary health centre. We realised that poverty and malnutrition cannot be tackled just by doctors alone but

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a doctor could be a leader for a team of health workers who tackle major issues. We selected women from villages who had had 5-10 years of schooling and trained them as health workers. They give curative care, do all family planning, including operations, like abortions and sterilization, do pathological investigation (with slides, urine, etc.). One or two are trained to take ECG. They have high technical competence and have been checked by experts from WHO, Harvard, Johns Hopkins, etc. Women were also trained in handicrafts and other crafts such as welding, carpentry, etc. - functional education was given to provide a source of income. Education is very important: Kerala has a good health system due to education and a good public distribution system. School children can in fact act as teachers. Our lessons on oral rehydration for diarrhoea are very effectively taken home by school children.

Recently we have gone into the production of drugs. Our drugs are 1/3 to 2/3 cheaper. All our health services are paid for. We have a Health Insurance Scheme under which the poor people get all the care for 50 P. Middle class patients pay 10 Takas/year and 2 Takas/visit in addition to charges for pathological examination etc. The rich pay 25 Takas/year and 5 Takas/visit. This leaves us with a deficit of 50% in our budget, which we meet by local and foreign donations. Our pharmaceutical unit will break even this year and from next year we will make profits. We intend to use a part of this money to increase production and a part to support research and services.

In our center we train medical students in a brief two-week course. We talk about nutritional status of Bangladesh and several relevant social and economic factors that the regular medical course does not touch upon. We also train traditional birth attendants.

PPST : What is the strength of your group?

ZC : We are a trust with 4 local health centres. We have 500 full time and 500 part-time workers.

PPST : How does the medical community react to you?

ZC : Generally the profession is angry with us for our role in the drug policy and several other things. When we started the two-week course for medical students some medical college staff protested. But students who have gone through our course support us. They also dislike our training of paramedics for operations etc. We find that the present medical education is irrelevant to Bangladesh. We are trying to make it in Bengalee. This is also opposed. We are branded as communists.

At present Bangladesh has about 14,000 doctors. Over 5,000 of them are abroad. We have nine medical colleges producing 1200 doctors every year. In rural areas there is only one doctor for every 50,000 people though the government claims that there is one for every 7,000 people. 6000 of our doctors are in the major cities. In addition, villages have several unqualified 'quacks' (over 30-40,000). There are about 17,000 pharmacies and over 20,000 unregistered pharmacists.

PPST : What are the government health facilities available to the people?

ZC : Government hospitals are like in India. There is a primary health centre for every 150 - 350,000 people which are given 30,000 taka/year for drugs. Over half of this is sold outside. They are very ineffective and what they offer is mostly curative care. We have all our four centres in rural areas. We are also thinking of covering urban slums.

PPST : What is the present status of the drug policy?

ZC : There is great pressure from USA to revise it. The 'review committee' has made some concessions. The major concession is that third party licensing continues till present licence runs out, i.e., a company can sell a right to produce a brand name drug to another. Two American companies have a contract till 1985.

The government is not insisting that the 45 drugs sold in PHC's should be sold by generic names alone. The medical profession often says that brand names are used in India, after all they are also scientific etc. The fundamentalists also oppose us since 65% of all our health workers are women and they ride bicycles etc.

Some of the drugs banned here are coming in through India. Several countries have tried such bans earlier and failed. Sri Lanka wanted to rationalize its drug policy and failed under pressure from US government and companies. Bhutto tried it in Pakistan but had to withdraw the order since over 90% of their drugs are made by multinationals.

In our case, when the government asked us to formulate the drug policy, I did not think a military government could do it. We explained to Gen. Ershad the problems faced by Sri Lanka etc. There was no 'popular pressure' as such, but the government had some backing since we had commenced production of some vital drugs. We were also backed up very well by other countries, voluntary organisations, and social organisations. There has been tremendous pressure on the government.

In India an 'aura' has been built up about drugs. India is among the top ten drug producers. Here the national bourgeosie has joined hands with the international bourgeosie.

PPST : Why is the drug industry reaping such huge profits?

ZC : Tobacco, arms and drugs are making the highest profits. There are many reasons for the profitability of drugs. Firstly the doctor is ignorant - our curriculum is not preparing us well. We assume that multinationals produce quality drugs. In fact they are terrible. I saw the Glaxo factory in Bombay. I think it should be closed. The 'paying client is different from the doctor who prescribes. Consumer awareness is also poor. In countries that have National Health Service like Britain, the patient is not the buyer. When Margaret Thatcher asked the NHS to buy generic drugs, immediately the prices came down by 7 - 42%.

Our own pharmaceutical company is run by a trust. There are no share holders who stand to gain by increased profits. As per our charter our profits cannot exceed 15%. We encourage people to visit our quality control department.

PPST : What are your relations with the government? Do you also advertise? How do you counter the propaganda of drug companies?

ZC : Multinationals bribe our government heavily, which our company does not - so many are unhappy. Initially we wanted to supply only to the government. We had to popularise our drugs and we did it through local language. We do have medical representatives. All our literature is in Bengalee so that the public would read it. There was a hue and cry over this. We promote our drugs only by generic names. The passage of time is helping us. Doctors are learning to live without Novalgin and once a bureacracy siezes upon a government decision to act, it is not an easy task to change it.

We also write articles in major national dailies to counter the propaganda of major drug companies.

We have not yet started any alternate schools. We have not supported the revival of 3-year trained doctors since it would create a feeling of being second class doctors.

PPST : What is your attitude to traditional health systems?

JC : In our new curriculum we are integrating traditional health system. We have examined (i.e. a panel has) over 80,000 ayurvedic drugs. Only about 25,000 have been retained. For example, for pneumonia we accept 3 ayurvedic drugs. There are about 3-4,000 ayurvedic physicians though 'they' claim over 40,000. Also about 3,000 Unani physicians. Most of the village doctors are quacks.

PPST : What is your approach to family planning?

JC : It is to be linked to the whole issue of development and women's emancipation. We sterilize only if a couple has at least three children (with youngest at least 5 years) and with 4 kids if both husband and wife consent.

The government has over 40,000 workers for family planning. Tubectomy gets priority. The use of Depo Provera has not been stopped. In 1974 I was responsible for getting Depo Provera into Bangladesh. We were naive at that time and got taken for a ride. The government is pushing sterilization with gifts etc.

PPST : Can paramedics degenerate into quacks?

ZC : In isolation they cannot do much curative work. People like paramedics better - they are more concerned.

PPST : Do you think of traditional systems of medicine purely as a drug alternative? They might offer an entirely new perspective on health. For example, what should be taken as indicators for health? Rather than infant morality, etc., should we not aim for increased awareness, interest and participation in our health?

ZC : Yes. We have to give increased knowledge about health. We encourage families to improve their own health. We have translated Werner's book ('Where there is no Doctor' by David Werner) into Bengali.

The last part of the meeting was a general discussion on the attitude towards traditional health systems (specifically Ayurveda). It was suggested to Dr. Chowdhury that different health systems have their own criteria to understand and expalin drug action. Hence it may not be correct to 'evaluate' ayurvedic drugs, but they have to be observed in operation. This view however was not accepted by Dr. Chowdhury who felt that the criteria of modern medical system could indeed be used to check the efficacy of and 'standardize' all the drugs.

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Regulations
DR 30.24

DETAILS REQUIRED TO BE FURNISHED ON NEW DRUGS

If any part of the information is in a foreign language, an accurate and complete translation shall be appended to such part (together with the originals).

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For the purpose of this questionnaire, the term 'New Drug' shall have the meaning as specified in the Explanation under Rule 30-A/69-B/75-B of the Drugs and Cosmetics Rules and would also include :- (a) A drug which has been approved for use under certain conditions and for administration in a specific manner and which is now proposed to be indicated for new conditions or in a different manner; (b) a combination of two or more drugs even though each may have been approved separately.

1. (a) The chemical description of the drug and a declaration of the internationally or nationally accepted generic name if any (name of the country or the name of the pharmacopoeia in which this has been accepted as the generic name may be mentioned) or if it has no proper name, the name under which it is proposed to be sold;

(b) If the chemical composition of the drug is not known, such other details as are known.

2. The description of the pharmaceutical form/forms in which it is proposed to be marketed and the route of administration, the proposed dosage and the claims to be made for such a drug.

3. A detailed statement of the composition of the drug giving the amount of each ingredient whether active or not, contained in a stated quantity of the drug as for example per tablet per millilitre etc.

4. Details of the method of manufacture; the details should include the raw-materials used in various stages in (a) the synthesis of the pure drug if it is synthesized; (b) process of preparation if it is obtained from natural resources such as plants, animal tissues, or by growth of micro-organisms etc.; (c) the manufacture of the finished products containing the new drug(s) as the active ingredient(s), the precautions taken to see that these raw-materials intermediates,

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etc., are not present as impurities in the final product may be given. In the case of inert ingredients the specifications for acceptance for the manufacture of the finished product may also be stated.

5. Analytical specifications of the new drug and its preparations containing the drug. The details should include the tests for proper identity, purity, quality and the method for assay.

In the case of a preparation containing only one active ingredient, the analytical methods suggested should be capable of assuring its identity and determining its strength within a reasonable degree of accuracy either in presence of or after removal of other inert ingredients. In the case of a combination containing 2 or more active ingredients, the analytical methods should be capable of identifying and determining wherever possible the strength of all the active ingredients individually. The specifications should also include limits for impurities. The information may preferably be in the form of a monograph in a pharmacopoeia.

6. Details of the stability studies, the date of expiry proposed to be assigned to the drug or its formulations and special storage precautions to be observed, if any.

7. Details of investigations that have been made to show whether or not the drug is safe and effective for use :- If possible data as to how the new drug compares, under identical experimental conditions in respect of efficacy and safety, with other drugs known to be used for same indications may also please be given.

(a) Efficacy: Full reports of adequate in vitro and in vivo studies by at least two methods reasonably applicable to the type of drug under investigation for assessing its efficacy;

(b) Pharmacological studies: Details of pre-clinical investigations including studies made on laboratory animals in which methods used and the results obtained are clearly set forth. The animal studies may not be considered adequate unless they give proper attention to the conditions of use recommended in the proposed lebelling for the drug

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or to the conditions of clinical trials planned with the drug. The information should also include pharmacodyanamic studies on important physiological system, such as cardiovascular system, respiratory system, central nervous system, the urinary system and autonomic nervous system.

(c) Biochemical Studies : Details of biochemical studies showing the absorption and wherever possible the distribution, metabolism and excretion of the drug. The information whether any metabolites were identified, if so, their excretion and whether they have any effect on the activity or toxicity of the drug may also be given if techniques are available for these studies.

(d) Toxicological Studies: Toxicity should be studied in several species, two or more in both acute experiments and long term investigations. One of the species should be non-rodent. Both sexes should be studied. Animals used should be of healthy stock and adequate precautions taken during study to avoid extraneous infections. Adequate numbers should be used at each dose level. In atleast one of the species selected, the drug should, if possible, have an activity related to the expected therapeutic effect. Studies should include administration by those routes recommended for use or for clinical trials. At least one should be systemic. The details should cover acute, sub-acute and chronic toxicity studies. Adequate control groups administered all constituents of the drug other than the active substance should be included in all these studies. The over-all toxicological data should fully reflect the nature of new drug such as for example whether the drug is for short or longer administration or whether it is to be used in infants, children, pregnant women or menopausal women etc.

In case, some of the observed changes are considered to be unrelated to the drug, the basis on which such a conclusion is drawn be clearly explained.

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(i) Acute toxicity : Two or more routes of administration, one of which should at least be systemic if the drug is intended for systemic use, should be used in atleast two or more species mentioned above. Several dose levels should be used. LD-50 value with limits of error should also be included.

(ii) Sub-acute and chronic toxicity: Two or more species should be taken for long term studies and both sexes should be selected. Whenever possible the species chosen should be used and at least one experimental group should receive a dose that is toxic to some animals.

The details and duration see table laid down in Appendix I.

Chronic toxicity:- Duration of toxicity studies pending on the nature of the drug and species of the animal used should conform to the requirements laid down in Appendix I.

The parameters studied should cover changes in appearances and behaviour, rate of weight gain or loss, urine stool and blood analysis including hematology, liver and kidney functions tests. Detailed post mortem studies should include weights and microscopic comprehensive histological examination of all important organs. Local response of the tissues at the site of drug administration should also be recorded.

(iii) Where the nature of the drug indicates such a possibility special studies for assessing carcinogenicity and drug dependence should be conducted.

(iv) Teratogenic studies: Should be carried out if the drug is to be studied in women of child bearing age. These should be in atleast two species of animals, rats or mice and another species in which the incidence of spontaneous abnormalities in reproductive physiology are reasonably well known and in which there is a placental transfer of the drug. The studies covering single generation be conducted to evaluate the effect of the drug on fertility, implantation of the ova, development of the embryo and fetus, resorption, abortion, delivery, number of live births, size of litters, teratogenesis, viability of the new born, growth of the young, etc. Any deformities or abnormalities observed

should be clearly stated. These studies should be carried out at a dose level which will not be toxic to the mother.

C In case the application is for clinical trials, details of the nature of the trials planned may be indicated.

Phase I: Studies should be carried out in healthy volunteers or patients with mild degree of disease who volunteer for this study. Phase I trials start when the 'New Drug' is first introduced into man and only animal and in vitro data are available. This investigation is carried out with the purpose of determining human toxicity and pharmacological action including any untoward effects, preferred route of administration and safe dosage range.

Phase II and would extend to initial trials on a limited number of patients for specific disease control or prophylactic purposes. This study shall also include mode of absorption and excretion and where possible distribution of the drug.

Clinical trial or phase III trial is for assessment of the drug's safety and effectiveness and optimum dosage schedule in the diagnosis, treatment, or prophylaxis of groups of subjects involving a given disease or conditions.

In all the above cases, a reasonable protocol formulated on the basis of facts accumulated in the earlier studies belonging to the plan of investigation shall be submitted. The plan of investigation should indicate the number of patients to be treated with the drug, the number to be employed as controls, if any, clinical uses to be investigated; route of administration of the drug; proposed dosage; the kind of clinical observation and laboratory tests to be undertaken prior to, during and after administration of the drug, the estimated duration of the investigation; whether any other drug is also intended to be given alongwith the new drug under investigation and copy of report forms to be used to maintain an adequate record of the observations and the tests and results obtained. If it is a comparative trial, what other drugs are intended to be used for comparison, their dosage, route of administration etc.

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9. Combination of drugs:

The combination of drugs should generally fall into four broad groups.

1. The first group of combinations are those where one of the active components is a new compound.

(a). Clinical trials.

(b). Marketing permission.

This group of combinations should be treated on the same lines as any new drug, and the data which needs to be the same as described under guidelines for new drugs.

2. The second group of combinations would be where individually marketed drugs are combined for the first time and where the individual drugs have potent pharmacodynamic actions on vital organs.

(a) Clinical Trials:

In such cases an adequate summary of pre-existing information from pre-clinical and clinical investigations with the individual active components, results of clinical studies of the combination if carried out in other countries pertinent reports on side effects, contra-indications and limitations of the components, rationale of combining the drugs in the stated proportion, toxicity (acute toxicity with LD 50 values of the individual components and the combination under identical experimental conditions) and pertinent pharmacological studies should be submitted to obtain permission to carry out clinical trials.

(b) Marketing permission

Results of clinical trials in India and if available from abroad, should be submitted before a marketing permission can be granted.

3. In the third group would fall already marketed combinations wherein only modifications in proportion of individual ingredients is considered, or where new claims are made.

(a) Clinical trials:

For such combinations appropriate rationale should be submitted to obtain clinical trial permission.

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(b) Marketing permission:

Results of human studies should be submitted for marketing permission.

4. The fourth group of combinations including drugs whose individual active components have been widely used for several years and where the manufacturers do not claim any extra advantage other than those of a physical combination and convenient administration. Some of the examples in this group are (a) Vitamins,(b) minerals,(c) digestive enzymes, (d) nutritional products,(e) antacids,(f) non-specific anti-diarrhoeals, (g) laxatives, (h) analgesics,(i) certain topical preparations other than those containing steroids.

For this group of drugs no animal or human data is required and marketing permission may be granted straight away.

10. Copies of published or unpublished reports of clinical trials pertinent to an evaluation of the safety and effectiveness of the drug.

11. Certificate of approval or free sale certificate issued by the Health authorities in the country of manufacture and the names of the countries where this drug is being marketed.

12. Drafts or specimens of label, package, literature etc. proposed to be adopted for marketing this drug in this country.

13. Information in the package insert, literature etc. must not contain incorrect statements, half-truths or unverifiable assertions about the contents, effects (therapeutic as well as toxic) or indications of the drug.

In describing the literature for medical profession, stress should be laid down on rendering factual data, general statements should be supported by adequate and acceptable scientific evidence. Promotional material should not be exaggerated or misleading.

A full description based on current scientific knowledge should include nature and content of the active ingredients with generic name per dose; action and uses; dosage; form of administration, mode of application, if any; side effects and adverse reactions; precautions

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and contraindications; treatment in case of poisoning and references to the scientific or professional literature.

14. Whether the drug is approved by the Food & Drug Administration U.S.A. or by the Dunlop Committee, U.K. If so, whether any restrictions are imposed on sale, way of labelling etc. (a copy of the literature including, if any, side effects, contraindications, precautions, warning etc., as approved by these authorities may be sent).

(CP=Clinical Pharm.; CT= Clinical trials ; MP= Marketing)

Category	Duration of Human Administration.	Phase	Subacute or chronic toxicity.
I. Oral or Parenteral	Several Days	C.P. , C.T., M.P.	2 species; 2 weeks.
	Upto 2 weeks.	C.P.	2 species; upto 4 weeks.
	Upto 3 months.	C.T., M.P.	2 species; upto 3 weeks.
		C.P.	2 species; 4 weeks.
		C.T.	2 species; 3 months.
		M.P.	2 species; upto 6 months.
	6 months to unlimited.	C.T., M.P.	2 species; 6 months.
II. Inhalation (General Anesthetics)		C.P., C.T., M.P.	4 species; 5 days (3 hrs./day)
III. Dermal	Short-term application.	C.P.	1 species; single 24 hrs. exposure followed by 2 week observation.
		C.T., M.P.	1 species; 20-day repeat exposure (intact & abraded skin).
	Long-term	C.P., C.T., M.P.	1 species; number of applications and duration commensurate with the preparation and the duration of use. The occlusive irritant test may be sufficient.

IV.	Ophthalmic Otic Nasal	Single application		Irritation tests graded doses.
		Multiple application	C.P., C.T.	1 species; 3 weeks daily applications, as in clinical use.
			M.P.	1 species; duration commensurate with period of drug administration.
V.	Vaginal or Rectal		C.P., C.T., M.P.	1 species, duration & number of applications determine by proposed use.

Animal toxicity requirements for different phases of evaluation

(C.P. = Clinical Pharmacology; C.T. = Clinical Trials;
M.P. = Marketing)

Category	Duration of human administration.	Phase	Subacute or chronic toxicity
Oral	Several days	C.P., C.T., M.P.	2 Species ; 2 weeks.
	upto 2 weeks.	C.P.	2 species;- 4 weeks.
		C.T., M.P.	2 species ;-3 weeks.
or		C.P.	2 species ; 4 weeks.
parenteral	upto 3 months	C.T.	2 species; 3 months
		M.P.	2 species; 6 months.
	6 months to unlimited.	C.T., M.P.	2 species; 6 months.
Dermal	Short term application	C.P.	1 species; single 24 hrs. exposure followed by 2 week observation
	Long term	C.T., C.P., M.P.	1 species; no, of applications and duration commensurate with the preparation and the duration of use. The occlusive irritant test may be sufficient.
Inhalation (General anesthetics)		C.P., C.T., M.P.	4 species; 5 days (3 hrs./day).
Ophthalmic Otic Nasal	Single application multiple application.	C.P., C.T.	Irritation tests graded doses 1 species; 3 weeks daily applications, as in clinical use.
		M.P.	1 species; duration commensurate with period of drug administration.
Vaginal or Rectal		C.P., C.T., M.P.	1 Species; duration and number of applications determined by proposed use.

DR 30-25

Drugs Required at Primary Health Care Organisation

OBJECTIVES

1. To enable the voluntary health projects/private dispensaries and hospitals to draw their own essential drug lists, suitable to their own requirements and thus suggest a policy for their availability to the patients.

2. To ascertain and draw a list of the minimum drugs required and give an idea of minimum level of competence and facilities that may be required to deal with the illness at a given health set up.

3. To provide a reference list of drugs to the doctor for making a rational choice of drugs in the given condition.

4. To provide a prioritised reference list for stepwise availability of essential drugs in a given health set up.

THE LISTS

List - A : List of drugs required at a health set up equivalent to a primary health centre. It may be a small community health project with not enough diagnostic facilities.

List - B : In addition to the drugs in List-A, List B drugs are required at secondary health organisations which has at least a qualified Medical Officer with some diagnostic facilities such as a small pathological laboratory. This may be a referal centre at town or taluka level.

List- C : In addition to the List A and List B, drugs, these drugs are required to be used at a tertiary level health set up i.e. a district level hospital, medical college and teaching.

List - D : These drugs can be handled by the para medical workers with adequate training.

List - E : All the deviations from the Essential Drugs list of WHO, as published vide their Technical Report series No.722 are included here alongwith the reasons for the deviation, in case of each of them.

PRIORITIES

The drugs in every list are divided into two Priority I drugs and Priority II drugs. This is from the view point that if the priority I drugs are made available at each set up, then they will meet the need for drugs most of the conditions. The priority II drugs serve as supplementary to the priority I list. It also indicates the priority for usage e.g. Aspirin & Paracetamol are classified as Priority I drugs at primary health organisation as analgesic and antiinflammatory drugs, - meaning thereby that in majority of the cases these two drugs should be able to take care of the need. Only a few cases may need Ibuprofen.

FORMULATIONS

An attempt is also made to suggest the strengths and forms of each drug to avoid the dilemma of choosing from hundreds of formulations for each drug.

LIMITATIONS OF THE LIST

1. The list does not suggest all alternative rational drugs which may be used in given condition. This implies that the drugs outside this list are not necessarily "non-essential" or "irrational." This list gives only the list of minimum priority drugs which have to be made available at particular health set up.

2. It is possible that it may be necessary to use the drugs outside this list in individual patients. A proper record of such cases may be kept. It should contain the detailed history, reasons why the present drugs cannot take care of the condition and what is the additional advantage of the other drug being chosen. Such a record will help in the improvisation of the list after proper review.

APPLICABILITY OF THE LIST

1. You may be a general practitioner or at a village level dispensary or in a hospital. These lists will give you a reference guide to examine the utility of the many drugs being stored or used at your institution.

2. Some institutions are faced with a situation where donors supply a big chunk of drugs, and the physician in charge is under pressure to use them even if he/she thinks such drugs as unnecessary. These lists can be used to act as a reference for both the donors and the administrators.

3. A LARGE NUMBER OF DOCTORS BELIEVE THAT THE LIMITED DRUG LIST WILL HARM THE PATIENTS' BEST INTERESTS. THESE LISTS CAN BE A STARTING POINT FOR CONCRETE EXPERIMENTATION IN THIS REGARD. A FEW CATEGORIES OF DRUGS CAN BE SELECTED AND AN ATTEMPT BE MADE TO PRESCRIBE THE DRUGS IN THESE CATEGORIES FROM THIS LIST. THE EXPERIENCES MAY BE RECORDED SYSTEMATICALLY AND OVER A PERIOD OF TIME - SAY ONE YEAR - A REVIEW CAN BE DONE WITH THE TEACHERS IN PHARMACOLOGY, COMMUNITY PHYSICIANS AND EXPERTS IN VARIOUS DISCIPLINE. THE RESULTS OF SUCH A REVIEW BE GIVEN WIDE PUBLICITY TO START HEALTH AND DRUG ACTION BY SO MANY CONCERNED INDIVIDUALS AND INSTITUTIONS.

4. The Govt. and a large number of public & private sector companies are giving health benefits to their employees. This list can serve as a guiding list to them and will help them to formulate their rational drug policy and other health benefits.

LIST - A

DRUGS REQUIRED AT PRIMARY HEALTH CARE ORGANISATION

Category No.	Sr. No.	Name of Medicines Priority 1	Priority 2	Formulation
1.		Anaesthetics		
1.1		General Anaesthetics and Oxygen		
	1.		Oxygen	Inhalation (Gas)
1.2		Local Anaesthetics		
2.		Analgesics, Antipyretics, Non-steroidal Anti Inflamatory Drugs and Drugs to treat Gout.		
2.1		Non Opioids		
	2.	Acetylsalicylic acid.		Tab. 300 mg.
	3.	Paracetamol		Tab. 500 mg. Syp. 125 mg/5 ml.
	4.		Ibuprofen	Tab. 200 mg Tab. 400 mg.
2.2		Opioids analgesics		
	5.	Codeine		Tab. 30 mg.
3.		Antiallergics		
	6	Chlorpheniramine Maleate.		Tab. 4 mg. Syp. 4 mg./5ml Inj. 10 mg /ml
4.		Antidotes and other substances used in poisoning		
4.1		General		
	7.	Activated Charcoal		50 gm sachets powder.
4.2		Specific		
	8	Atropine		Inj. 0.5 mg/ml.
5.		Antiepileptics		
	9.	Phenobarbital		Tab. 30 mg. Tab. 60 mg.
6.		Antiinfective Drugs :		
6.1		Anthelminthic Drugs		
	10.	Mebendazole		Tab. 100 mg.
	11.		Pyrantel Pamoate	Tab. 500 mg. Suspension 50 mg/ml.

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List A Contd.

Category No.	Sr. No.	Name of Medicines Priority 1	Priority 2	Formulation
6.2		Antiamoebic Drugs		
	12.	Metronidazole		Tab. 200 mg., 400 mg. Susp. 200 mg/5 ml.
	13.	Chloroquine Phosphate		Tab. 150 mg/Base Syp. 50 mg/5 ml(base)
6.3		Antibacterial Drugs		
6.3.1		Penicillins		
	14.	Benzyl Penicillin		Inj. 10 lac IU (Sodium, Inj. 50 lac IU potta-sium)
	15.		Procaine benzyl pencillin.	Inj. 3 lac IU
	16.		Benzathine benzyl Penicillin	Inj. 12 lac IU
6.3.2		Other antibacterial drugs		* sterate or Ethyl succinate)
	17.	Erythromycin		Tab. 250 mg. (as * Oral susp. 125 mg/ 5 ml.
	18.	Sulphadimidine		Tab. 500 mg
	19.	Sulphamethoxazole + Trimethoprim		Tab. 400 mg + 80 mg.
	20.	Tetracycline		Cap. 250 mg(hydrochloride).
	21.	Doxycycline		Cap. 100 mg (as hydrochloride)
	22.	Amoxyciline		250 mg (as trihydrate) 125 mg /5 ml = powder for oral susp.
6.3.3		Antileprosy Drugs		
	23.		Rifampicin	Cap. 150 mg, 300 mg.
	24.		Dapsone	Tabs. 50 mg, 100 mg.
	25		Clofazimine	Cap. 50 mg, 100 mg.
6.3.4		Antituberculosis Drugs		
	26.	Ethambutol		Tab. 200 mg, 400 mg 800 mg.
	27.	Isoniazid		Liquid 100 mg /5 ml. Tab. 100 mg, 300 mg.
	28.	Thiacetazone + Isoniazid		Tab. 150 mg + 300 mg
6.4		Antifilarial Drugs		
	29.	Diethyl Carbamazine		Oral Liquid = 50 mg / 5 ml. Tab. 50 mg, 100 mgm. citrate)

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List 'A' Contd.

Category No.	Sr. No.	Name of Medicines Priority 1	Priority 2	Formulation
6.5		Antifungal Drug		
	30.	Nystatin		Pessary of One lakh unit.
6.6		Antileishmaniasis Drugs		
6.7		Antimalarial Drugs		
	31.	Chloroquine		Tab. (Phosphate, Sulphate) 150 mg (Base). Syp. (phosphate, Sulphate) 50 mg/5 ml.
	32.		Primaquine	Tab.(as Phosphate) 7.5 mg.
6.8		Antischistosomal Drugs		
6.9		Antipanosomal Drugs		
7.		Antimigraine Drugs		
8.		Antineoplastic & Immunosuppressive drugs		
9.		Antiparkinsonism Drugs		
10.		Blood Drugs Affecting the		
10.1		Anti Anaemia Drugs		
	33.	Ferrous Sulphate		Tab. 200 mg
	34.	Folic acid		Tab. 1 mg.
	35.	Ferrous sulphate + Folic Acid.		Tab. 200 mg + 200 micrograms.
10.2		Anticoagulants and Antagonists		
11.		Blood products and Blood Substitutes.		
11.1		Plasma substitute		
11.2		Plasma Fractions for Specific uses.		
12.		Cardiovascular Drugs		
12.1		Antianginal Drugs		
12.2		Antidysrhythmic Drugs		
12.3		Antihypertensive Drugs		
12.4		Cardiac Glycosides		
12.5		Drugs used in Shock - Anaphylaxis		
	36.	Epinephrine		Inj. 1 mg/ml (hydrochloride)

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List 'A' contd.

Category No.	Sr. No.	Name of Medicines Priority 1	Priority 2	Formulation
13.		Dermatological Drugs		
13.1		Antifungal Drugs		
	37.	Benzoic Acid + Salicylic Acid		Oint./Cream 6% + 3%
	38.		Nystatin	Oint./Cream, 1 lac IU/gm
	39.		Miconazole	Oint/Cream, 2%
13.2		Anti Infective Drugs		
	40.		Neomycin + Bacitracin	Oint. 5 mg neomycin sulphate + 500 IU bacitracin zinc/gm.
13.3		Anti inflammatory and Antipruritic Drugs		
	41.	Calamine lotion		Lotion
	42.	Hydrocortisone		Oint./Cream 1% (acetate)
	43.	Betamethosone		Oint./Cream (Valerate) 0.1%.
13.4		Astringent Drugs		
13.5		Keratoplastic and Keratolytic Agents.		
	44.	Coal tar		Topical Soln. 20%
13.6		Scabicides and Pediculicides		
	45.	Benzyl Benzoate		Lotion, 25%
	46.	Lindane (BHC)		Lotion, 1%
14.		Diagnostic Agents.		
15.		Disinfectants		
	47.	Chlorhexidine		Solution, 5%
	48.	Iodine		Tincture, 2% and 7%
	49.	Gentian Violet		Topical Solution, 1%
16.		Diuretics		
17.		Gastrointestinal Drugs		
17.1		Antacids and other antiulcer Drugs.		
	50.	Aluminium Hydroxide + Magnesium (Trisilicate		Tab. 250 mg.+ 125 mg Oral Susp. 320 mg/ 5 ml. Oral suspension equivalent 550 mg of MgO/10 ml.

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Cat. No.	Sr. No.	Name of Medicines Priority 1	Priority 2	Formulation
17.2		Antiemetic Drugs		
	51.	Promethazine		Tab. 10 mg, 25 mg.
17.3		Antihaemorrhoidal Drugs		
	52.		Local anaesthetic, astringent and anti inflammatory drug combination.	Ointment.
17.4		Anti spasmodic drugs		
	53.	Atropine		Tab. 1 mg.
17.5		Cathartic Drugs		
	54.		Bisecodyl	Tab. 5.0 mg.
17.6		Diarrhoea		
17.6.1		Antidiarrhoeal (Symptomatic) Drugs		
	55.	Loperamide		Tab. 1 or 2 mg.
17.6.2		Fluid Replacement Solution		
	56.	Oral Rehydration Salt		Sodium Chloride 3.5 gm + Trisodium citrate dihydrate 2.9 gm + Potassium chloride 1.5 gm + Glucose 20 gm for 1 litre solution.
18.		Hormones		
18.1		Adrenal Hormones and synthetic substitutes:		
18.2		Androgens		
18.3		Contraceptives		
	57.	Oral Contraceptive pills.		Ethyl Estradiol + Norethasterale - 30 microgram + 1 mgm.
18.4		Estrogens		
18.5		Insulins and other Anti Diabetic Agents		
18.6		Ovulation Inducers		
18.7		Progestogens.		
18.8		Thyroid Hormones and Antithyroid Drugs.		
19.		Immunologicals		

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List 'A' Contd.

Cat. No.	Sr. No.	Name of Medicines Priority 1	Priority 2	Formulation
19.1		Diagnostic Agents		
19.2		Sera and Immunoglobulins		
19.3		Vaccines		
19.3.1		For Universal Immunisation.		
	58.	BCG Vaccine		Inj.
	59.	DPT Vaccine		Inj.
	60.	DT Vaccine		Inj.
	61.	Measels Vaccine		Inj.
	62.	Poliomyelitis Vaccine		Solution
	63.	Tetanus Vaccine		Inj.
		NOTE : All vaccines should comply with WHO requirements for biological substances.		
19.3.2		For specific groups of Individuals.		
20.		Muscle Relaxants and Cholinesterase Inhibitors		
21.		Ophthalmological Preparations		
21.1		Antiinfective Agents.		
	64.	Sulfacetamide		Drops 10%
	65.	Tetracycline		Eye Oint. 1%
21.2		Antiinflammatory Agents		
21.3		Local Anaesthetics		
	66.	Tetracaine		Solution 0.5%
21.4		Miotics and Antiglaucoma Drugs		
21.5		Mydriatics		
22.		Oxytocics		
	67.		Ergometrine	Tab. 0.2 mg (Maleate)
23.		Peritoneal Dialysis Solution		
24.		Psychotherapeutic Drugs		
	68.	Diazepam		Tab. 5 mg.
25.		Respiratory Tract, Drugs Acting on the		

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List 'A' Contd.

Cat. No.	Sr. No.	Name of Medicines Priority 1	Priority 2	Formulation
25.1		Anti Asthmatic Drugs		
	69.	Aminophylline		Tab. 100 mg
	70.	Ephedrine		Tab. 30 mg.
	71.	Salbutamol		Tab. 2mg, 4 mg Liquid 2 mg /5 ml.
	72.	Adrenaline		Inj. 1 mg/ml.
25.2		Antitussives		
	73.	Codeine		Tab. 10 mg.
26.		Solutions Correcting water Electrolyte, and acid base disturbance		
26.1		Oral		
26.2		Parenteral		
26.3		Miscellaneous		
	74.	Water for injection		in 2 ml, 5 ml, 10 ml. ampoules.
27.		Vitamins and Minerals		
	75.	Ergocalciferol		Tab/Cap. 50000 IU
	76.	Retinol (Vit. A)		Cap./Tab. 25,000 In Oral Soln. 1 lakh/ml. IU
	76.		Ascorbic acid	Tab. 50 mg.

LIST - B

DRUGS REQUIRED AT SECONDARY HEALTH CARE ORGANISATION

(The drugs in List - A should also be available).

Category No.	Sr. No.	Name of Medicine Priority 1	Priority 2	Formulation
1		Anaesthetics		
1.1		General Anaesthatics and Oxygen		
	1.		Thiopental	Powder for Inj. 0.5 gm, 1.0 gm in amp.
1.2		Local Anaesthetics		Inj. 1%, 2% in vial of 30 ml.
	2.	Lidocaine		Inj. 1%, 2% + Epinephrine 1:1 lac in vial, topical forms 2-4% (hydrochloride).
2.		Analgesics, Antipyretics, Non-steroidal Anti inflamatory Drugs and drugs to treat Gout.		
2.1		Non Opioids		
	3.		Allopurinol	Tab. 100 mg.
	4.		Indomethacin	Cap. 25 mg.
2.2		Opioids		
	5.	Morphine		Inj. 100 mg/ml.
	6.	Pethidine		Inj. 50 mg/ml.
3.		Antiallergics		
	7.	Dexamethasone		Tab. 0.5 mg, 4 mg. Inj. 4 mg (Sodium Phosphate) in 1 ml. ampoule.
	8.	Epinephrine		Inj. 1 mg. (hydrochloride) in 1 ml. ampoule.
	9.	Prednisolone		Tab. 5 mg.
4.		Antidotes and other substances used in Poisoning.		
4.1		General		
4.2		Specific		
	10.		Sodium thiosulfate	Inj. 250 mg/ml in 50 ml amp.
	11.	Atropine		Inj. 1 mg/ml. 10 ml amp / vial.
	12.		Pralidoxime (PAM)	Inj. 1 gm. powder.

List 'B' Contd.

Category No.	Sr. No.	Name of Medicine Priority 1	Priority 2	Formulation
5.		Antiepileptics		
	13.	Diazepam		Inj. 5 mg/ml. 2 ml. Amp.
	14.	Phenytoin		Cap. 25 mg, 100 mg. Syp. 100 mg/5 ml.
	15.		Ethosuximide	Cap. 250 mg.
	16.		Carbamazepine	Tab. 200 mg.
	17.		Valproic Acid	Tab. 200 mg. Syp. 200 mg/5ml.
6.		Antiinfective Drugs		
6.1		Anthelminthic Drugs		
6.2		Antiamoebic Drugs		
	18.	Dilcxanide Furoate		Tab. 500 mg.
6.3		Antibacterial Drugs		
6.3.1		Penicillins		
	19.	Chloramphenicol		Cap. 250 mg. Syp. 125 mg/5 ml. Inj. 1 gm powder/vial.
	20.		Gentamicin	Inj. 10 mg, 40 mg/ml. 2 ml. vial.
	21.	Phenoxy Methyl Pencillin		Susp. 125 mg/5 ml. Tab. 250 mg.
	22.	Ampicillin		Cap. 250 mg, 500 mg. Powder for susp. 125 mg/5 ml. Inj. 500 mg/vial.
6.3.2		Other antibacterial Drugs		
	23.	Nitrofurantoin		Tab. 100 mg. Syp. 25 mg/5 ml.
6.3.3		Antileprosy Drugs		
	24.		Ethionamide	Tab. 125 mg, 250 mg.
	25.		Protionamide	Tab. 125 mg.
6.3.4		Antituberculosis Drugs		
	26.		Pyrazinamide	Tab. 500 mg.
	27.		Streptomycin	Powder for inj. 0.75 gm and 1 gm/vial.

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List 'B' contd.

Cat. No.	Sr. No.	Name of medicines Priority 1	Priority 2	Formulation
6.4		Antifilarial Drugs		
6.5		Antifungal Drugs		
	28.	Griseofulvin		Tab. 125 mg, 250 mg.
	29.		Nystatin	Tab. 5 lac IU
6.6		Antileishmaniasis Drugs		
6.7		Antimalarial Drugs		
	30.	Quinine		Tab. 300 mg.
	31.		Chloroquine	Inj. 200 mg/5ml.
	32.		Sulphadoxine } Pyrimethamine }	Tab. 500 mg + 25 mg.
6.8		Antischistosomal Drugs		
6.9		Antipanosomal Drugs		
7.		Antimigraine Drugs		
	33.		Ergotamine	Tab. 2 mg (as tartrate).
8.		Antineoplastic and Immunosuppressive Drugs.		
9.		Antiparkinsonism Drugs.		
10.		Blood, Drugs affecting the		
10.1		Anti anaemia Drugs		
	34.		Iron Dextran	Inj. equivalent to 50 mg. iron/ml. 2 ml. inj. or 10 ml. amp.
	35.		Hydroxocobalamine	Inj. 1 mg/ml. amp.
10.2		Anticaogulants and Antagonists		
11.		Blood products and Blood substitutes.		
11.1		Plasma Substitutes		
11.2		Plasma fractions for specific uses.		
12.		Cardiovascular Drugs		
12.1		Antianginal Drugs		
	36.	Propranolol		Tab. 10 mg, 40 mg.
	37.	Glyceryl Trinitrate		Tab. 0.5 mg.
	38.	Isosorbide dinitrate		Tab. 5 mg (sublinqual)
	39.		Verapamil	Tab. 40 mg, 80 mg.

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List 'B' Contd.

Cat. No.	Sr. No.	Name of Medicines Priority 1	Priority 2	Formulation
12.2		Antidysrhythmic Drugs		
	40	Propranolol		Tab. 10 mg, 40 mg.
	41.		Isoprenaline	Tab. 10 mg, 15 mg.
	42.		Procainamide	Tab. 250 mg, 500 mg.
	43.		Quinidine	Tab. 200 mg.
12.3		Antihypertensive Drugs		
	44.	Propranolol		Tab. 40 mg, 80 mg (Hydrochloride)
	45.	Reserpine		Tab. 0.1 mg, 0.25 mg.
	46.	Clonidine		Tab. 100 microgram
	47.	Methyldopa		Tab. 250 mg.
	48.	Hydralazine		Tab. 50 mg.
	49	Hydrochlorothiazide		Tab. 50 mg.
12.4		Cardiac Glycosides		
	50.	Digoxin		Tab. 0.25 mg. Oral Soln. 0.05 mg/ml.
12.5		Drugs used in Shock - Anaphylaxis		
13.		Dermatological Drugs		
13.1		Antifungal Drugs		
13.2		Antiinfective Drugs		
13.3		Anti inflammatory and antipruritic drugs		
13.4		Astringent Drugs		
13.5		Keratoplastic and Keratolytic Agents		
	51.	Podophylline		Solution 10-25%
13.6		Scabicides and Pediculicides		
14		Diagnostic Agents		
15.		Disinfectants		
16.		Diuretics		
	52.	Hydrochlorthiazide		Tab. 50 mg.
	53.	Furosemide		Tab. 40 mg.
	54.		Chlortalidone	Tab. 25 mg.
17.		Gastrointestinal Drugs		
17.1		Antacids and other antiulcer Drugs		
	55.	Ranitidine		Tab. 150 mg.

List 'B' Contd.

Cat. No.	Sr. No.	Name of Medicines Priority 1	Priority 2	Formulation
17.2		Antiemetic Drugs		
	56.		Promethazine	Tab. 10 mg, 25 mg Inj. 25 mg/ml 12 in 2 ml amp. Oral liquid 5 mg/5 ml.
	57.	Metoclopramide		Tab. 10 mg. Inj. 5 mg /ml in 2 ml amp.
17.3		Antihaemorrhoidal Drugs		
17.4		Anti spasmodic Drugs		
17.5		Cathartic Drugs		
17.6		Diarrhoea : Antidiarrhoeals (Symptomatic Drugs)		
17.7		Fluid Replacement Solution		
18.		Hormones		
18.1		Adrenal Hormones and Synthetic Substitutes		
	585	Dexamethasone		Tab. 0.5 mg.
	59.	Prednisolone		Tab. 5 mg
	60.		Hydrocortisone	Powder for Inj. 100 mg/vial.
	61.		Dexamethasone	4 mg/ml.
18.2		Androgens		
18.3		Contraceptives		
	62.		Norethisterone	Tab. 0.35 mg.
18.4		Estrogens.		
18.5		Insulins and other Anti Diabetic agents		
	63.		Leute Insulin	Inj. 40 IU/ml in 10 ml
	64.	Insulin Soluble		Inj. 40 IU/ml in 10 ml.
	65.	Glibenclamide		Tabs. 5 mg.
18.6		Thyroid Hormones and Anti- Thyroid drugs		
19.		Immunologicals		
19.1		Diagnostic Agents.		
19.2		Sera and Immunoglobulins		

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List 'B' Contd.

Cat. No.	Sr. No.	Name of Medicines Priority 1	Priority 2	Formulation
	66.		Tetanus Antitoxin (Human)	Inj. 50,000 IU in vial. Inj. 500 IU/vial.
	67.		Diphtheria Antitoxin	Inj. 10,000 IU " 20,000 IU in vial.
	68.		Anti Rabies hyperimmune serum	Inj. 1000 IU in 5 ml.
	69.		Anti Snake Venom	Inj.
	70.		Anti-D Immuno-globulin (Human)	Inj. 0.25 mg/ml.
19.3		Vaccines		
19.3.1		For Universal Immunisation :		
19.3.2		For specific groups of Individuals :		
	71.	Typhoid Vaccine		Inj.
	72.	Rabies Vaccine		Inj.
Note :		All vaccines should comply with WHO requirements of Biological substances.		
20.		Muscle Relaxant and Cholinesterase inhibitors		
21.		Ophthalmological Preparations		
21.1		Antiinfective Agents.		
21.2		Antiinflammatory Agents.		
	73.	Hydrocortisone		Eye oint. 1%
21.3		Local Anaesthetics		
21.4		Miotics and Anti-glucoma Drugs		
21.5		Mydriatics.		
22.		Oxytocics		
	74.	Ergometrine		Inj. 0.2 mg/ml (Maleate) in 1 ml ampoule.
23.		Peritoneal Dialysis Solution.		
24.		Psychotherapeutic Drugs.		
	75.		Chlorpromazine	Tab. 50 mg, 100 mg. Syp. 25 mg/5 ml. (as hydrochloride).

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List 'B' Contd.

Cat. No.	Sr. no.	Name of Medicines Priority 1	Priority 2	Formulation
25.		Respiratory Tract, Drugs acting on the		
25.1		Anti Asthmatic Drugs		
	76.	Aminophylline		Inj. 25 mg/ml.
	77.		Cromoglycic acid (Cromolyn)	Oral Inhalation (Cartridges) 20 mg/dose (Sodium salt).
	78.		Baclometnasone	Oral Inhalation 0.05 mg/dose.
	79.	Epinephrine		Inj. 1 mg/ml in 1 ml ampoule (as hydrochloride).
25.2		Antitussives		
26.		Solutions correcting water Electrolyte and acid base disturbances		
26.1		Oral		
26.2		Parenteral		
	80.	Potassium Chloride		Oral Soln. 05 gm/5ml
	81.	Glucose		Inj. Solution 5% Isotonic. 500 ml, 1000 ml. 50% in 25 ml amp.
	82.	Glucose + Sod. Chloride		Inj. Soln. 4% + 0.18%.
	83.	Sodium Chloride		Inj. Soln. 0.9% isotonics.
26.3		Miscellaneous		
27.		Vitamins and Minerals		
	84.		Pyridoxine	Tab. 25 mg.
	85.		Riboflavin	Tab. 5 mg.
	86.		Thamine	Tab. 50 mg.
	87.		Calcium Gluconate	Inj. 100 mg/ml. in 10 ml. amp.

LIST C

DRUGS REQUIRED AT TERTIARY HEALTH CARE ORGANISATION

(The Drugs in List 'A' and List 'B' should also be available).

Category No.	Sr. No.	Name of medicines Priority 1	Priority 2	Formulation
1.		Anaesthetics		
1.1		General Anaesthetics and Oxygen.		
	1.		Anesthetic Ether	Inhalation (gas)
	2.		Halothane	" "
	3.		Nitrous Oxide	" "
1.2		Local Anaesthetics		
	4.		Bupivacaine	Inj. 0.25% and 0.5% in 10 ml amp.
2.		Analgesics, Antipyretics, Non steroidal Anti Inflamatory Drugs and drugs to treat Gout.		
2.1		Non Opioids		
	5.		Colchicine	Tab. 0.5 mg.
	6.		Probenecid	Tab. 500 mg.
2.2		Opioids		
3.		Antiallergics		
4.		Antidotes and other substances used in Poisoning.		
4.1		General		
4.2		Specific		
	7.		Sodium Nitrate	Inj. 30 mg/ml in 10 ml. amp.
	8.		Sodium Thiosulfate	Inj. 250 mg/ml in 50 ml amp.
	9.		Deferoxamine	Inj. 500 mg in vial.
	10.		Dimercaprol	Inj. 50 mg/ml in oil, 2 ml amp.
	11.		Protamine Sulphate	Inj. 10 mg/ml.
	12.		Sodium Calcium Edetate	Inj. 200 mg/ml. 5 ml/amp.
	13.		D-Pencillamine	Cap. 250 mg.
	14.		Nalexone	Inj. 0.4 mg/ml.
5.		Antiepileptics		
6.		Antiinfective Drugs - Anthelmintic Drugs		
	15.		Tiabendazole	Chewable Tab. 500 mg.
	16.		Niclosamide	Tab. 500 mg.

List C Contd.

Cat. No.	Sr. No.	Name of Medicines Priority 1	Priority 2	Formulation
6.2		Antiamoebic Drugs		
	17.		Dehydro emetine	Inj. 60 mg in 1 ml amp.
	18.	Metronidazole		Inj.500 mg in 100 ml
6.3		Antibacterial Drugs		
6.3.1		Penicillins		
	19.	Cloxacillin		Cap. 500 mg. Inj. 500 mg in vial Syp. 125 mg/5ml
6.3.2		Other antibacterial drugs		
	20.	Salazosulphapyridine		Tab. 500 mg.
	21.	Erythromycin or Lactobionate		Inj. 500 mg in vial.
	22.	Cephalosporin		Syp. 125 mg/5ml. Cap. 250, 500 mg.
6.3.3		Antileprosy Drugs.		
6.3.4		Antituberculosis Drugs.		
6.4		Antifilarial Drugs		
6.5		Antifungal Drugs		
	23		Flucytosine	Cap.250 mg, Infusion 2.5 g in 250 ml.
	24		Amphotericin-B	Inj. 50 mg in vial.
6.6		Antileishmaniasis Drugs.		
6.7		Antimalarial Drugs		
	25		Quinine	Inj. 300 mg/ml in 2 ml amps.
6.8		Antischistosomal Drugs		
6.9		Antipanosomal Drugs		
7.		Antimigraine Drugs		
8.		Antineoplastic and Immunosuppressive Drugs		
8.1		Immunosuppressive drugs		
	26.	Azathioprine		Tab. 500 mg. Inj. 100 mg as sodium salt in vial.
8.2		Cytotoxic Drugs		
	27.	Bleomycin		Inj.15 mg as sulph in vial.
	28.	Busulfan.		Tab. 2 mg .

List C Contd.

Cat. No.	Sr. No.	Name of Medicines Priority 1	Priority 2	Formulation
	29.	Calcium folinate		Tab. 15 mg. Inj. 3 mg/ml in 10 ml amp.
	30.	Chlorambucil		Tab. 2 mg .
	31.	Cyclophosphamide		Tab. 25 mg. Inj. 500 mg. in vial.
	32.	Cytarabine		Inj. 100 mg in vial.
	33.	Doxorubicin		Inj. 10 mg and 50 mg in (as hydrochloride) vial.
	34.	Fluorouracil		Inj. 50 mg/ml. in 5 ml amp.
	35.	Methotrexate		Tab. 2.5 mg. Inj. 50 mg as sodium in vial.
	36.	Procarbazine		Cap. 50 mg (as hydrochloride).
	37.	Vincristine		Inj. 1 mg and 5 mg in vial.
9.		Antiparkinsonism Drugs		
	38.	Levodopa		Tab. 250 mg.
	39.	Levodapa + Carbidopa		Tab. 150 mg + 10 mg. Tab. 250 mg + 25 mg.
	40.		Thrihexyphenydyl	2 mg. tabs.
10.		Blood, Drugs affecting the		
10.1		Anti Anaemia Drugs		
10.2		Anticoagulants and Antiagonists		
	41.	Warfarin		Tab. 5 Mg.(Sodium salt)
	42.	Phytomenadione		Inj. 10 mg/ml 1 & 5 ml amp.
	43.	Heparin		Inj. 1000 IU) 5000 IU) 1 ml 20000 IU) amp.
	44	Protamine Sulfate		Inj. 10 mg/ml in 5 ml amp.
11.		Blood Products and Blood Substitutes.		
11.1		Plasma Substitute		
	45.	Dextran		Inj. 6%, 500 ml.
11.2		Plasma Fractions for Specific uses.		
	46	Albumin, human.		Inj. solution, 25% (dried).

... 4

List C contd.

Cat. No.	Sr. No.	Name of Medicine Priority 1	Priority 2	Formulation
			Factor VIII Concentrate Factor IX complex (Coagulation factors II,VII, IX,X) concentrate (dried)	All plasma fractions should comply with WHO Requirements of collection processing and Quality control of human blood and blood products.
12.		Cardiovascular		
12.1		Antianginal Drugs		
	47.	Propranolol		Inj. 1 mg in 1 ml amp. (as HCl)
	48.		Verapamil	Inj. 2.5 mg/ml in 2 ml Amp.
12.2		Antidysrhythmic Drugs		
	49.	Propranolol		Inj. 1 mg in 1 ml ampoule.
	50.	Lidocaine		Inj. 20 mg/ml in 5 ml Amp.
	51.		Procainamide	Inj. 100 mg/ml in 10 ml amp.
12.3		Antihypertensive Drugs		
	52.	Propranolol		Inj. 1 mg in 1 ml Ampoule.
	53.	Sodium Nitroprusside		Inj. 50 mg in Amp.
12.4		Cardiac Glycosides		
	54.	Digoxin		Inj. 0.25 mg/ml in 2 ml amp.
12.5		Drugs used in Shock - Anaphylaxis.		
	55.	Dopamine		Inj. (as hydrochloride) 40 mg/ml in 5 ml vial.
13.		Dermatological Drugs		
13.1		Antifungal Drugs		
13.2		Anti infective Drugs		
13.3		Antiinflammatory and Antipruritic Drugs		
13.4		Astringent Drugs		
13.5		Keratoplastic and Keratolytic Agents		
13.6		Scabicides and Pediculicides		

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List C Contd.

Cat. No.	Sr. No.	Name of Medicine Priority 1	Pariority 2	Formulation
14.		Diagonistic Agents		
14.1		Ophthalmic Drugs		
		Flurescein		Eye drops 1% (Sodium salt)
14.2		Radio Contrast Media		
		Meglumine Amido trizoate		Inj. 60% in 20 ml ampoule.
		Sodium amidotrizoate		" 50% in 20 ml. amp.
		Barium Sulphate		Powder.
		Iopanoic Acid		Tab, 500 mg.
		Propyliodone		Inj. 600 gm/l in 20 ml. ampoule.
			Iohexol	Inj. 300 mg in 5 or 10 ml ampoule.
			Iotroxate	Solution 8 gm (as iodine) in 100-250 ml.
15.		Disinfectants		
16.		Diuretics		
	56.	Furosemide		Inj. 10 mg/ml in 2 ml amp.
	57.	Spironolactone		Tab. 25 mg.
	58.	Mannitol		Inj. 10% & 20%
	59.	Triamterene		Tab. 50 mg.
17.		Gastrointestinal Drugs		
17.1		Antacids and other Antiulcer drugs		
	60.	Cimetidine.		Inj. 100 mg/ml in 2 ml amp.
17.2		Antiemetic Drugs		
17.3		Antihaemorrhoidal Drugs		
17.4		Anti spasmodic Drugs		
17.5		Cathartic Drugs		
17.6		Diarrhoea		
17.6.1		Antidiarrhoeals (symptomatic) Drugs.		
17.6.2		Fluid Replacement Solution		

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List C Contd.

Cat. No.	Sr. No.	Name of medicine Priority 1	Priority 2	Formulation
18.		Hormones		
18.1		Adrenal Hormones and Synthetic Substitutes.		
	61.		Fludrocortisone	Tab. 0.1 mg (acetate)
18.2		Androgens		
	62.		Testosterone	Inj. 200 mg (as enantate) in 1 ml amp. and 25 mg (as propionate) in 1 ml amp.
18.3		Contraceptives		
	63.	Depot Medroxy Progesterone acetate.		Inj. 150 mg in 3 ml vial.
	64.	Norethisterone Enantate.		Inj. 200 mg in vial.
18.4		Estrogens		
	65		Ethinylestradiol	Tab. 0.05 mg.
18.5		Insulins and other Antidiabetic Agents.		
18.6		Ovulation Inducers		
	66.	Clomifene		Tab. 50 mg (citrate)
18.7		Progestogens		
18.8		Thyroid Hormones and Antithyroid drugs.		
	67	Levothyroxine		Tab. 0.05 mg, 1 mg (sodium salt)
	68	Potassium Iodide		Tab. 60 mg.
	69.	Propylthiouracil		Tab. 50 mg.
19.		Immunologicals		
19.1		Diagnostic Agents		
	70	Tuberculin purified Protein derivative (PPD)		Injection
19.2		Sera and Immunoglobulins		
	71	Anti-D immunoglobulin (human)		Inj. 0.25 mg/ml.
	72	Immunoglobulin, human normal.		Injection.
19.3		Vaccines		
19.3.1		For universal Immunisation		
19.3.2		For specific groups of individuals.		

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List C contd.

Cat. No.	Sr. No.	Name of Medicine Priority 1	Priority 2	Formulation
20.		Muscle Relaxants and Cholinesterase Inhibitors		
	73.		Neostigmine	Tab. 15 mg Bromide Inj. 0.5 mg (Metilsulfate in 1 ml amp.)
	74.		Gallamine	Inj. 20 mgm/ml.
	75.		Suxamethonium	Inj. 50mg/ml in 2ml Amp. (Chloride)
	76.		Pyridostigmine	Tab. (bromide) 60 mg. Inj. (bromide) 1 mg. 1 ml. amp.
21		Ophthalmological Preparations		
21.1		Antiinfective Agents		
21.2		Antiinflammatory Agents		
21.3		Local Anaesthetics		
21.4		Miotics and Antiglaucoma Drugs		
	77.		Acetazolamide	Tab. 250 mg.
	78.	Pilocarpine		Solution (hydrochloride or nitrate). 2%, 4%
21.5		Mydriatics		
	79.	Homatropine		Solution (hydrobromide) 2%
22		Oxytocics		
	80.	Oxytocin		Inj. 10 IU in 1 ml amp.
23		Peritoneal Dialysis Solution		
	81.		Intraperitoneal dialysis solution	Parenteral solution.
24		Psychotherapeutic Drugs		
	82.	Amitryptiline		Tab. 25 mg. (Hydrochloride).
	83.	Haloperidol		Tab. 2 mg. Inj. 5 mg in 1 ml amp.
	84.	Imipramine		Tab 10 mg, 25 mg. (hydrochloride)
	85.	Lithium carbonate		Cap. or Tab 300 mg.
	86	Chlorpromazine (hydrochloride)		Inj. 25 mg/ml in 2 ml amp.

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List C contd.

Cat. No.	Sr. No.	Name of Medicine Priority 1	Priority 2	Formulation
	87.	Fluphenazine		Inj. 25 mg/ml amp. (decanoate or enantate).
25.		Respiratory Tract, Drugs acting on the		
25.1		Anti Asthamatic Drugs		
25.2		Antitussives		
26.		Solutions correcting water electrolyte acid base disturbances.		
26.1		Oral		
26.2		Parenteral		
	88.	Sodium bicarbonate		Inj. solution, 1.4% isotonic. (Na^+ 167 mmol/l HCO_3^- 167 mmol/l)
26.3		Miscellaneous		
27.		Vitamins and Minerals		

LIST D.

List of Drugs which can be used by the Village Level Workers with adequate training.

	Drugs	Formulations
1.	Acetylsalicylic Acid	Tab 300 mg.
2.	Activated Charcoal	Powder 50 gm. sachets.
3.	Antacid (Aluminium Hydroxide + Magnesium Hydroxide).	Tab 125 mg.
4.	An Antihaemerrhoidal drug.	
5.	Atropine	Tab. 1 mg (as Sulfate)
6.	Aminophylline	Tab, 100 mg.
7.	Benzoic Acid + Salicylic Acid	Oint.(Benzoic Acid 6% + Salicylic Acid 3%)
8.	Betamethasone	Oint.0.1%
9.	Benzyl Benzoate	Lotion., 25%
10.	Bisecodyl	Tab., 5 mg
11.	Calamine	Lotion.1% (Acetate)
12.	Chlorhexidine	Solution, 5% (digluconate for dilution)
13.	Chloroquine Phosphate	Tab. 250 mg
14.	Chlorpheniramine Maleate	Tab., 4 mg.
15.	Clofazimine *	Caps, 50 mg, 100 mg.
16.	Coal Tar	Solution, Topical 20%
17.	Codeine (As antitussive)	Tab. 15 mg., syp. 12 mg/ml
18.	Dapsone *	Syp. 12 mg/ml.
19.	Diethyl Carbamezine *	Tab.50 mg(citrate)
20.	Diazepam	Tab. 2 mg.
21.	Ephedrine	Tab. 30 mg.
22-	Ergometrine (for post partum Haemorrhage)	Tab. 0.2 mg(Maleate)
23.	Ethyabutol *	Tab, 200 mg/400 mg/800mg
24.	Folic Acid	Tab 5 mg
25.	Gentian Violet	Solution 1%
26.	Glycerine Suppository	Solution
27.	Iodine	Solution, 2.5%
28.	Iron	Tab., 200 mg. (as sulphate)
29.	Iron + Folic Acid	Tab.
30.	Isoniazid	Tab., 200 mg + 0.2 mg.
31.	Isoniazid + Thiacetazone	Tab.100 mg, 300 mg.
32.	Lindane	Lotion 75 mg + 150 mg,
33.	Loperamide	150 mg + 300 mg. Tab.2 mg.
34.	Mebendazole	Tab, 100 mg.
35.	Metronidazole	Tab. 200 mg.
36.	Myconazole	Oint. or cream 2% (Nitrate).

List D continued.

	Drugs	Formulations
37.	Neomycin + Bacitracin	Ointment 5 mg neomycin sulphate + 500 IU bacitracin Zinc/gm.
38.	Nystatin *	Pessary 1 lac I.U.
39.	Oral Rehydration Salt	W.H.O. Formula.
40.	Oral contraceptive pills (Ethynylestradiol + Levonorgestrel)	Tab. 0.03 mg + 0.15 mg.
41.	Paracetamol	Tab. 500 mg. Syp. 125 mg/5 ml.
42.	Promethazine	Tab. 25 mg (hydrochloride) Syp. 5 mg/5 ml (-do-)
43.	Rifampicin *	Cap 150 mg, 300 mg.
44.	Salbutamol	Tab. 4 mg.
45.	Sulphacetamide	Eye drops 10% (sodium salt).
46.	Tetracycline	Eye Oint. 1% (Hydrochloride).
47.	Vitamin A	Capsule 2 lac I.U.
48.	Vaccines +	

Note : * These drugs could be given under supervision and periodic monitoring by the doctor.

\+ They should be easily accessible all round the year either at the centre or in the village.

VARIATIONS FROM WHO E.D. LIST

Sr. no.	Category No.	Locost list	Name of Drug	Reasons for inclusion/ exclusion
1	4.2	C	Protamine Sulphate	Included because this is a specific antidote for heparin which is widely used at Tertiary health care level eg. heart surgery.
2	"	-	Methylthianinium Chloride	
3	6.1	-	Piperazine	Excluded because broader coverage as an anthelmintic drug can be had by use of Mebendazole and Pyrantel Pamoate
4	"	-	Praziquental	Excluded because this drug is used against Schistosomiasis which does not occur in our country at present.
5	6.3.2	-	Spectinomycin	Excluded because this is useful for gonorrhoea in multiple resistant cases which are still not common in India.
6.	6.4	-	Suramin Sodium	Excluded because the specific parasite is not reported to be occuring in India.
7	6.6	-	Pentamidine Sodium Stiboglu-conate.	Excluded because Leishmaniasis does not occur in India.
8	6.7	-	Amodiaquine	Excluded because Amodiaquine and Chloroquine belong to the same category of chemical group, sharing same actions, adverse effects, etc.
9	9	C	Thrihexyphenydyl	Included because it is more easily available in India.
		-	Biperidin	Excluded because W.H.O. has suggested Biperidine or any substitute drug of same group. Thrihexyphenydyl is suggested in this list.

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Variation from WHO E.D. List Contd.

Sr. no.	Category No.	Locost list	Name of Drug	Reasons for inclusion/ exclusion
10.	12.3	B	Clonidine	Included because it is easily available in India and cheap anti-hypertensive drug - a substitute for Methyldopa.
11.	12.4	-	Digitoxin	Excluded because not available in India.
12.	13.4		Aluminium Acetate	
13.	13.5	-	Salicylic Acid	Excluded because the combination of Benxoic acid and salicylic acid will suffice the use.
14.	14	C	Edrophonium	
15.	16	C	Triamterene	Included as a substitute for Amiloride.
		-	Amiloride	Triamterene as its substitute included.
16.	17.1	-	Calcium Carbonate	Excluded because other agents are available, and possibility of its adverse effects.
17.	17.1	A	Ranitidine	Included because of its advantages such as less incidence of adverse reaction and less dosage frequency, therefore selected as a substitute for cimetidine.
18.	17.6.1	A	Loperamide Tab.	Included because of its symptomatic use in emergency situation for adults.
19.	19.3.2	-	Influenza vaccine Meningococcal vaccine. Yellow fever vaccine	Excluded because of their non-feasibility in Indian context.
20.	21.1	-	Silver Nitrate Solution.	Excluded from Locost List because better antibacterials are available.

DR 30-26

REPORT OF THE PUBLIC BOARD OF INQUIRY ON DEPO-PROVERA
17 OCTOBER, 1984

FINDINGS OF FACT

I. DATA AVAILABLE ON THE LONG-TERM RISKS OF DMPA ARE INSUFFICIENT AND INADEQUATE TO PROVIDE A BASIS FOR A DECISION WHETHER THE BENEFITS OF THE DRUG AS A CONTRACEPTIVE OUTWEIGH ITS DISADVANTAGES UNDER CONDITIONS OF GENERAL MARKETING IN THE U S A

There are adequate data to assess the efficacy and benefits of DMPA as a contraceptive. There is also sufficient information on its short term side effects and risks. The drug is clearly a highly effective contraceptive with certain specific advantages, and it does not appear to pose any immediate irreversible serious side effects. However, the facts relating to the long term consequences of the use of the drug are inadequate and insufficient to provide a basis for risk assessment. This is a serious deficiency in light of the specific questions that have been raised that the drug may have major adverse effects following its long term use or that may become evident only after a latent period. Most important among these has been the concern over the drug's carcinogenic potential.

The long term consequences of the use of DMPA on neoplasias, in particular of the breast and uterus, as well as osteoporosis and atherosclerosis are of particular relevance for any risk/benefit assessment of the drug's use in the United States because of the susceptibility of the population in this country to these diseases.

In the absence of adequate data on the long term consequences of the drug it is not possible to arrive at any scientifically defensible conclusion whether or not the benefits of the drug, when used as a contraceptive, outweigh its risks for the average healthy individual in the United States. It also makes it impossible to compare the risk/benefit ratio of DMPA with that of other drugs available for contraception.

II. DATA FROM THE STUDIES OF RHESUS MONKEYS AND BEAGLE DOGS CAN NOT BE DISMISSED AS IRRELEVANT TO THE HUMAN WITHOUT CONCLUSIVE EVIDENCE TO THE CONTRARY. SUCH EVIDENCE IS NOT AVAILABLE AT THIS TIME. THEREFORE, THE FACT THAT MALIGNANT NEOPLASIAS DEVELOPED IN TWO SPECIES IN TARGET ORGANS OF SEX STEROIDS MUST BE CONSIDERED AS AN INDICATION OF A POTENTIAL OF PROGESTOGENS, INCLUDING DMPA, TO PROMOTE THE DEVELOPMENT OF MALIGNANCIES IN TARGET ORGANS

The findings from animal tests implicate DMPA as a potential promoter of neoplasias because:

1) Chronic administration of DMPA was associated with the development of malignant neoplasias in two mammalian species.

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2. Data are also inadequate to establish effect of MPA on bone and on the profile of plasma lipoproteins, information needed to evaluate whether the long term use of the drug will or will not predispose the individual to osteoporosis or to atherosclerosis. Our conclusions of Law do not rely on this finding.

2) The neoplasias developed in target organs of sex steroids.

3) There is good evidence to support the conclusion that in both species the malignancies were drug related.

4) There is no evidence to support the conclusion that the effect of the drug is to be attributed only to the administration of excessively high doses and that the effect of lower doses would differ qualitatively from those of higher doses.

Therefore, DMPA in these experiments exhibited the characteristics of a potential carcinogen according to generally accepted criteria. Under the circumstances, to dismiss the findings as irrelevant to the human would require conclusive experimental evidence of fundamental differences among the species in the basic mechanisms of action of the hormone or in the responses of target cells. There is as yet no such evidence at hand. Specifically, there are no data on the histogenesis of the neoplasias nor on the mechanism of action of progestogens on the presumed cells of origin of the neoplasias in the test animals. Therefore, there is no evidence to support the claim that the malignancies developed either in cell types unique to the species or as a result of a species specific response of target cells to progestogens. Conversely, data on women who have been exposed for prolonged periods to the relatively unopposed action of progestogens are inadequate to warrant the conclusion that their response to this hormonal state in terms of neoplasias would differ in some fundamental way from the two species of test animals.

III. THE DATA ON THE HUMAN ARE INSUFFICIENT AND INADEQUATE TO EITHER CONFIRM OR REFUTE THE IMPLICATION OF THE ANIMAL DATA THAT DMPA MAY INCREASE THE RISK OF CANCER IN WOMEN USING DMPA AS A CONTRACEPTIVE.

The available data on the human can not provide a basis for conclusing whether DMPA, used as a contraceptive, does or does not influence the incidence of carcinomas in general or of the accessory organs of reproduction in particular, because:

1) They fail to provide information on an adequate number of long term users of DMPA, or on ex-users who have been followed for a long enough period of time. There are only minimal data on subjects that have used DMPA for 5 years or longer with most of the data reported having been obtained from women who have used the drug for 2 years or less.

2) In the majority of the studies there were no controls followed in parallel with those using DMPA. In many studies from developing countries there is not even information on the background incidence of the diseases being studied in DMPA users that could serve as a basis for comparison.

3) In a number of the retrospective studies there is reason to question the adequacy of the record keeping on subjects receiving DMPA and, therefore, of the possibility

of retrieving the data subsequently for any valid analysis.

To obtain the direct evidence needed to resolve the issue would have required purposeful, systematic collection and recording of data on users of DMPA and appropriate controls with consideration of the natural history of the diseases being monitored. Not until recently have suhh studies been initiated. Until they are completed and full reports of them available their value as evidence is limited.

IV. IN CASE OF CONTRACEPTIVE FAILURE WITH DMPA, THE RISK OF A MOTHER GIVING BIRTH TO A MALFORMED CHILD IS UNLIKELY TO BE MEASURABLY GREATER THAN THAT POSED BY THE ORAL CONTRACEPTIVES; The chance IN EACH CASE CAN BE ESTIMATED TO BE SMALL ENOUGH NOT TO POSE AN OBSTACLE TO THE USE OF THE DRUG AS A CONTRACEPTIVE WHEN OTHERWISE INDICATED.

Data have not been systematically collected on offspring that have been inadvertently exposed to DMPA in utero. Conclusions, therefore, can only be based on the body of epidemiological data obtained on the effects of a variety of sex steroids, including progestogens, on the developing human fetus. In these cases, the drugs had been administered for a variety of indications and at various times during pregnancy. This is clearly a less than ideal data base. Nonetheless it can provide some general estimate of the magnitude of the risk.

According to these data the risk of various malformations attributable to protestogens for the various malformations implicated is low. The rate of contraceptive failure with DMPA when used appropriately is also low. Consequently, the chance of a mother bearing a malformed child following contraceptive failure can be estimated to be small. However, because DMPA is a long acting depot preparation, the exposure of any susceptible fetus to the drug is likely to be more prolonged than with oral contraceptives. Consequently, the range of critical and vulnerable events that may come under the drug's influence may also be expected to be greater than with oral contraceptives. It should be possible to counter balance this disadvantage of DMPA by ensuring that contraceptive failure is kept at a minimum and taking the necessary steps to avoid inuecting women already pregnant. As with oral contraceptives this risk should not, in itself, constitute a reasonffor not using the drug if otherwise indicated.

There have been no direct determinations of the concentrations of MPA in the blood of breast fed infants of mothers receiving DMPA as a contraceptive nor if the amount of the drug transferred passed onto the infant is sufficient to have a biological effect. This information is needed before advocating the use of DMPA as a contraceptive to lactating mothers in the postnatal period and before it is possible to conclude that the drug does not pose any risk of funotional teratogenicity.

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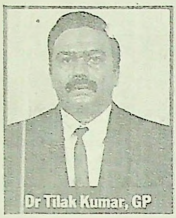
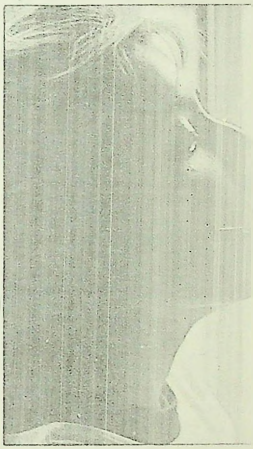
DR 30.27

PR

Who's winn


Dr Tilak Kumar, GP

With the increasing use — and abuse — of antibiotics, bacteria are learning to fight back against the deadly drugs



It is unfair to blame the GP alone for increasing antibiotic resistance. Patients should be educated against self-medication

You have the sniffles, you are running a temperature and your headache won't let you think. Your doctor sympathises with your desire to be back to normal for tomorrow's crucial event and prescribes an antibiotic. You wince at the price, but the next day, there is good news because you are already feeling fine. Good doctor, you think indulgently and spread the word to your friends.

Now for the bad news: the antibiotic could *not* have made you better. An antibiotic takes more than a day to even begin to effectively cure you — at least for most common infections.

Perhaps you didn't need the antibiotic anyway as you probably had a viral infection. And though doctors never bother to explain this to patients, antibiotics have no effect on viruses.

The truth is that antibiotics are among the most used and most abused of drugs today. By some estimates, more than ten per cent of all drugs prescribed in India are antibiotics. And because they are expensive, they account for almost half the value of all drugs sold in the market.

So what, you shrug, perhaps I took the wrong medicine. But I got better, didn't I?

Maybe you did. But maybe you also

Did you know? ◇ *Some little-known facts about antibiotics*

The beginning

Mass production of the first antibiotics began during World War II, when penicillin was found to have reduced a great number of amputations and casualties.

Then, since it was relatively cheap the use of antibiotics spread like wildfire.


Oh, what a lovely war!: the beginning of penicillin

And now...

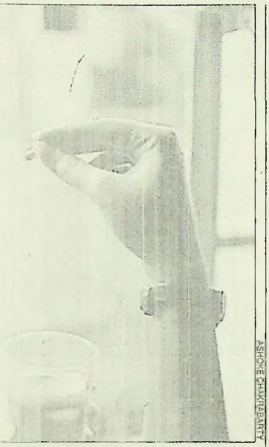
Take a look at these figures. Incredible as it may sound, today, the Indian drug market has 70,000 formulations available to doctors and patients — even though the World Health Organisation lists only 250 essential drugs.

With so many antibiotics in the market today with so many

Sunday 13-19 Nov 1993

ng this war?

Ram Shah, pharmacist



Antibiotic resistance

The more you take, the less it works

It goes back a little to the days when Alexander Fleming discovered penicillin, which led finally to the use of the first antibiotics in the Forties. Mass production of the first antibiotics, penicillin and streptomycin, began during World War II. Penicillin opened the flood gates to a variety of antibiotics that worked very effectively against disease-causing bacteria.

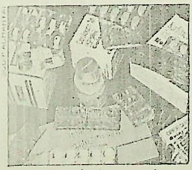
Since it was relatively cheap and easy to administer, and since they worked miraculously on the then life-threatening diseases like tuberculosis, typhoid and venereal disease, the use of antibiotics spread like wild fire.

Even today, newer antibacterials (for the purposes of this article, antibacterials and antibiotics are being used synonymously in terms of their action, i.e. inhibiting bacteria) are being created regularly by drug designers with a little tinkering of the organic chains of older drugs, or with other chemical jugglery. The potential for new drugs seems limitless.

Except for one thing. Even five decades after the first antibiotics were introduced, bacterial diseases remain a major cause of illness, and even death.

Bacteria evolve much faster than human beings. The only way out against them is to keep one step ahead through technical innovation

helped create more antibiotic resistant germs (pathogens) within your body. That could mean that someday, when your body *really* needs an antibiotic drug to fight a serious illness, the drug won't have the desired effect.



On the market: more than we need

variations, this leads to the dangerous abuse of drugs by an unsuspecting public.

Suffer the little ones

The overuse of antibiotics is particularly shocking when it is extended to children, who can develop resistant strains of bacteria in their systems which they pass on to other children. These children can then develop diseases for which commonly prescribed antibiotics provide no cure.

VIVEK DAS

The vulnerable ones: not all pediatricians care

Good news for the manufacturer

The economic problem has not stopped pharmaceutical companies from pumping a lot of money into the antibiotics research market.

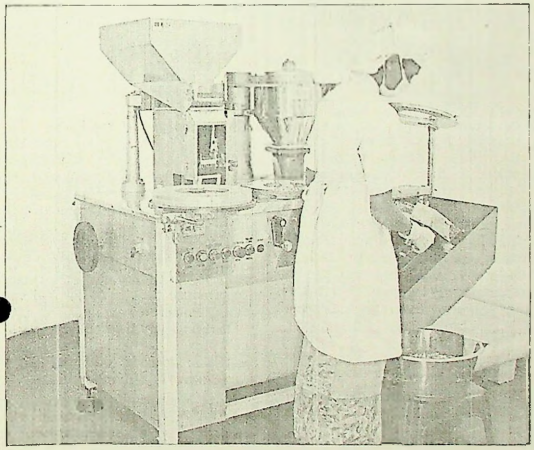
Cynics would say it is with good reason. The

son. The spiralling prices of newer drugs that are entering the market each day also mean better bottom lines for the drug industry. And the obsolesence of older, cheaper antibiotics is only good news for pharmaceutical companies. As doctors prefer to, or are forced to use higher order antibiotics to kill simple ailments, the bills that go up are the patients'.

Take a look at these figures. The Indian drug market has 70,000 formulations available to doctors and patients when WHO lists only 250 essential drugs and even the Hathi committee which went into the issue found only 116 drugs essential for India. The mind-boggling figure of 70,000 preparations includes many unessential and sometimes dangerous drugs that are in fact banned in many other countries.

antibiotics. Millions of dollars are spent to research, produce and market each new-generation antibiotic drug. And the pharmaceutical companies have to pass on the cost to the consumer. Which they do. That is why a newer antibiotic, such as Ceftum (which is a new antibiotic drug called cefuroxime) from Allenbury's costs around Rs 41 for one 500 mg tablet, whereas the middle-range antimicrobials like cephalexin costs Rs 9.50 for a 500 mg tablet. Compare that to sulphonomides, or cotrimoxazoles like Septran, which costs between 75 paise to Rs 1.50 per tablet depending on its strength.

And these are only the more common antibiotics. Some of the higher-order injectable antibiotics can cost upto Rs 350 per dose, whereas the higher-order tablets can reach upto Rs 90 per tablet.



At what price?

The bill that goes up is the patient's

The problem with overusing antibiotics of course, is quite special, due to the resistance factor. But there are other related problems as well. Price becomes a big factor in the introduction of newer

One of the ways of tackling resistance is to develop missiles that penetrate the shields that bacteria develop around them

And if the Dunkel draft agreement goes through, you can expect drug prices to go through the roof.

It is not just the price factor, however. There is also the question of side effects. While they have undoubtedly played a crucially important role in human health in the last 50 years, antibiotics have also been guilty of generating problematic side effects, most of which are commonly known, but some of which can even be deadly. For instance, the known side effects of the relatively new antibiotic, gentamicin, (available only as an injectable) are nephrotoxicity (which can lead to kidney damage) and ototoxicity, (which can cause deafness).

The rapid obsolesence of old drugs and the corresponding manufacture of new drugs also brings a sort of consumer culture into the drug industry. It only increases the misuse of medicine. Dr S. P. Tekur, an active member of the Drug Action Forum and of the Bangalore-based Community Health Cell, who himself runs a child health clinic, is very disturbed about the widespread irrational use of drugs.

There are so many antibiotics in the market today, with so many variations in side effects, half life and site-effectiveness that it is understandable that doctors themselves are confused. But sometimes, this leads to the dangerous abuse of drugs on an unsuspecting, ill-informed and apathetic public. Doctor Tekur cites the instance of Norfloxacin and Ciprofloxacin, which belong to the family of the recently introduced quinolones. "The recommended dosage per day is 400 mgs twice a day," he says. "They are not meant for children."

Quinolones are contra-indicated for children under 14 because they have been reported to cause damage to the joints of immature animals. "And yet," says Dr Tekur, "this antibiotic is available in 100 mg tablets, which tempt pediatricians to try them on children."

Shocking instances of antibiotic abuse like this expose the complete lack of coordination and implementation of the government's drug policy. But consumer awareness is the only really effective means to stop the misuse of drugs, and especially antibiotics. Because the vested interests of the manufacturer, the prescriber and the dispenser combine to perpetuate this misuse. And it is left to each individual to say, IT'S MY BODY, AFTER ALL. ◻

Rohini Nilekani/Bangalore

Draft By
Drug Action Forum, WB.
S-3/5 Sector III
Salt Lake
Calcutta 700 064
DR 30.28

ALL INDIA DRUG ACTION NETWORK

NATIONAL DRUG POLICY

AIDAN

All India Drug Action Network (AIDAN), the co-ordinating body of the individuals and organisations concerned with and engaged in the problems of health & drug, works towards the adoption and implementation of a Rational Drug Policy in India and sets out the following outline for the Drug Policy.

Health Policy & Drugs

Majority of the Indians suffer from the diseases of poverty and ignorance, i.e., communicable diseases, diseases due to undernutrition etc. Industrialisation, Modernisation and Urbanisation have led to spread of consequential diseases. Most of these illnesses are preventable and curable. What we need then, is adequate nutrition, safe water, universal sanitation, environmental protection and a primary medical service, available to all.

Role of Drugs

Drug is the most important element in medical care which, though constitute only a small part of the overall health care as stated above, is the most urgent, unavoidable, essential and priority need in the country where incidence of death and disability from diseases is high. So long the basic elements of health care is not made available universally, medical care will continue to be the priority service to reduce death and disability and in this context, drugs understandably assume a vital and priority role.

Present situation

But this life-saving function of drugs has been exploited by the drug industry in such a manner that the developing health culture heralds more harm than good. To the people, doctors and non-doctors alike, drugs appear as panacea for all ills. Health is still regarded as an individual or personal responsibility and it is believed that freedom from disease could be obtained by better & better and more & more drugs. Such a belief among educated and illiterate alike has led to a universal craze for drugs and this DRUG CULTURE has come to dominate the society. In this situation, drugs appear to be the best commodity for unlimited profit-making by the drug industry, since hardly any consumer ask for the necessity, utility, rationality, price-justifiability & harmful effects of a drug. It is not even asked whether a substance sold as Drug is actually a Drug at all. As a result, 60% of the drugs in the market are unscientific or harmful or substandard; a large

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number of them are not actually drugs; many drugs are consumed by those who do not need it; people die or are disabled from the effects of harmful drugs; drugs are sold at fantastically high prices; and most serious of all, life-saving and essential drugs are not available to those who need them most.

Objectives of Rational Drug Policy

Broad objectives of the rational drug policy should therefore be:

A. To authorise manufacture and marketing of only those drugs which are accepted or endorsed as drugs by the standard medical text books, eliminating all so-called drugs without scientific basis, from the drug market.

B. To ensure availability of safe, essential and quality drugs to all the needy - particularly who lack purchasing power.

C. To ensure drugs are sold at rational prices providing reasonable and known profit margin.

D. To attain self-sufficiency or self-reliance in priority drugs needed to combat dominating diseases afflicting majority of the population.

E. To ensure dissemination of all relevant informations regarding production, pricing, trade practices, efficacy, scientificity, limitations and adverse effects of drugs to the medical profession, health personnel and people at large.

F. To eliminate abuse of drugs at all levels.

G. To organise and build up peoples' movement in order to realise the above objectives.

In order to achieve the above objectives the following measures are necessary and in the process of phase-wise implementation, certain measures should be accorded priority.

For objective A.

1. National Drug Authority (Ref. Hathi Committee): Overall executive authority for National Formulary, Drug Registration, Drug Licensing, Drug information, Ethical Control, Quality control, Import & Export Policy, under the control of the Ministry of Health. This permanent body shall be composed of representatives of Health Ministry, Parliament, State Health Ministries, Medical profession, Trade Union, Industry, Trade, Pharmacists, Social Action groups on drug & health.

2. National Formulary shall be drawn up providing

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up-to-date pharmacological & therapeutic information.

3. Drug Registration: A separate body will ensure registration of only drugs having scientific basis and acceptance, thereby eliminating all so-called drugs having no pharmacological basis, from the Formulary.

4. Quality Control: A separate body to ensure quality functioning at all levels, e.g. production, distribution & consumption, and monitoring adverse reaction.

5. Legislation & Enforcement: NDA will recommend to the Ministry of Health for necessary legislation from time to time and supervise & monitor enforcement of those laws & regulations. The relevant fields are - Registration of drugs, labelling & advertisement, price-control, prescription control & sale of toxic/ poisonous/habit forming/dangerous drugs, deterrant penalty for violation of law, technology transfer, Import & Export, Drug Control Authority, Prosecution, etc.

6. All single ingredient drugs shall be registered & marketed in International Non-proprietory Names or suitable generic names.

7. R & D : Separate body to approve, guide and monitor all R & D activities on drugs on the basis of the actual need of Indian People. No R & D be allowed without prior registration and contious monitoring.

8. All these separate bodies, viz. 3, 4, 6 & 7 shall function at the state level, subordinate and accountable to NDA.

For objective B

1. Priority Drugs: An expert body under NDA shall identify, after studying & monitoring prevailing disease pattern, the priority drugs on the basis of greater mortality, greater morbidity, severe sequelae, national health programmes; select such drugs on the basis of efficacy, high therapeutic index, low cost, shelf-life & storage requirements, self-reliance, ease of administration, potential for misuse and bioavailability. It should also prepare graded essential drug lists required for different levels of medical care. This will be a continuing function according to changing needs & priorities, and ongoing scientific development.

2. Distribution: This is the most crucial problem of the drug policy.

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DR-30.29

Voluntary Health Association of India

40, Institutional Area,
(Near Qutab Hotel), South of IIT,
New Delhi-110016

Telegrams : VOLHEALTH
New Delhi-110016
Phones : 668071, 668072

ED-4(3) April 18,1988

Dear friends,

Since VHAI is venturing into some new areas of work, I felt you might like to get some orientation of these issues. Enclosed notes prepared by Dr.A.T.Dudani (Consultant VHAI), will give you some clear ideas on these issues.

Sincerely yours,

Alok Mukhopadhyay
Executive Director

Encl: as above

PESTICIDE PROBLEM IN INDIA

Pesticides are used in Agriculture to control various kinds of pests. In public health these highly poisonous organic chemicals are use to control disease carrying insects such as mosquitoes for Malaria.

Since pesticides are highly dangerous and harmful to human health it is necessary to know about their uses and also how to handle these with minimum danger to all concerned which includes the factory and farm workers. To add to this problem, pesticides get into the food through grains, fruits vegetables and even water. Once again through the feeds and fodder they get into milk both of animals and humans as also in the meat poultry etc thereby creating a vicious cycle through which these circulate.

The sprayers in the farms quite often get nausea, vomiting, headache a rash or other symptoms. The long term effects may be death from acute poisonings or leukemia or cancer for which well documented evidence exists.

By and large the pesticides use should be avoided by resort to good agricultural practices but where this is not possible careful use is the answer. Likewise the world is now turning to biological control of these insects. This involves use of pests which prey on the pests that are harmful to man. This is also being called Integrated Pest Management which is becoming popular world wide.

Unfortunately there are very powerful interests which thrive on manufacture and sale of these harmful chemicals irrespective of serious threat to ecology, environment and human health. There is very little or nill information in the country on the illnesses caused by the pesticides, many of which are sold in bags and paper envelopes without labels or loose. Data collection of cases of pesticide poisonings will help a great deal as also education for farm and factory workers and their families and highlighting the problem and working towards reduction and correct use of pesticides till these are can be totally eliminated through alternate methods of disease (plant and human) control.

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PROBLEMS CREATED BY JUNK FOODS AND RADIOACTIVITY IN FOODS THROUGH ENVIRONMENT

JUNK Foods briefly are foods of low or poor nutritional value which are finding an important place in the market.

An important factor of these is the attractive and expensive packaging in which these are sold at prices which have no relevance to their food value. Woven into the products which have flooded the market is aggresive advertising on the T.V. Junk foods are thus objectionable as these appeal to the vulnerable groups specially children. In our context these also divert the attention of the economically weaker sections or the have nots who like to imitate the well off.

The Junk foods are characterised by high saturated fat, high salt and sugar and limited nutritional value- such as candy, soft drinks, flavoured ices, french fries, and several other fancy products that are on the market. Some cereal foods fall in this category also. Instead there is need to promote the use of natural foods. In the USA Govt. have put curbs on Junk foods as these were replacing the natural foods in the school feeding.programmes for which US Govt. was spending some 3 billion dollars annually, to promote nutritious meals.

Many of the Junk foods need to be got analysed by our Laboratories and public educated vis-vis merits of nutritious foods and high prices. Instead there is need to promote consumption of fruits and vegetables. A part of the programme should be ban on advertising and price control of packaged products with some relation to nutritional quality as is being done in USA.

A new danger has come to notice in this country from the recent disclosures about radioactivity in butteroil and milk powder imported as Gifts from EEC after Chrnobyl disaster. Now the Govt.is embarking upon a programme of food irradiation which involves use of radioactive Cobalt 60 and Cesium 137. Results from exposure to radioactivity of Hiroshima and Nagasaki survivors and their off springs gives conclusive evidence of harmful effects of radiation even after 30-40 years in the form of genetic disease, leukemia and cancer. A close study, education and campaigning is needed in case of both the above problems which are assuming serious dimensions.

Informing, Advocacy and Influencing policy makers and decision makers for support programmes of common public interest through Parliament and Press

In the context of our democratic set up, we have access to the decision makers and policy makers either direct or through the parliament and the media.

Considering the high demands and limited public resources and heavy pressures that exist, for ensuring that the legitimate public interest causes such as those in the neglected health sector do not suffer due to lack of essential financial resources, it is necessary to use the accepted democratic norms as above.

1. Approach to highest level, the Minister/Prime Minister. This can be done either through writing or when possible and necessary through personal meetings or through delegations. In some cases it may also be possible to draw attention through arranging conventions/seminars/conferences and ensuring that the concerned Minister is the Guest of Honour.

2. However the procedure outlined at 1 above may not always be easy or convenient or applicable as the issues involved may not be of such vast magnitude or importance. In such a case we could influence policies and programmes and financial support by enlisting the help of M.Ps (or the M.L.A.s or Parishad members as the case may be) to raise the issue through questions in Parliament/State Assemblies/ Zila Parishad etc., as the case may be.

   This means active and close contrats with M.P.s who are willing and interested in raising the issues through questions or during Budget sessions or through other channels such as calling Attention and half hour discussions. It is also possible to raise issues through Supplementary questions even if the question has been raised by any other member but on a related issue.

   All this requires advance action and planning. Quite often it is advantageous if a news report can be arranged which draw attention to the problem in any place or community. Based on such a news report, it is easier to frame a question and have this put through the M.P.(etc).

   Framing the question is itself an art and a science but this can be learnt through practice. A look at the list of questions admitted in the Parliament would help in this direction. A question has to be put in some 22 days in advance for the date fixed by the Speaker for that particular Ministry in case of starred questions for the Lok Sabha for which discussion is possible through supplementaries. For a written reply, 11 days are required. For Rajya Sabha 11 days are required both for starred and written replies.

   The M.P.needs to be briefed and contacted if full advantage is to be obtained. After the reply is given, it is important that a copy of the reply is obtained on the same day and released to the helpful press for coverage.

3. Based on the replies in the Parliament, followup should be made by writing letter to the concerned Minister/Pm through an M.P. Once again copies of this letter may be released to the Press in order to build up public pressure and opinion. In short this is an unending cycle to the pursued till objective is attained.

DR

LOW COST DRUGS AND RATIONAL THERAPEUTICS

Workshops

Organised National Drug Policy, Trichy	May 1987
Drug and Health Policy, Panchgani	Feb.1987
CDMU Workshops in Siliguri	June, 1987

National Drug Policy Seminar
Indian Medical Association

* "Drugs and Cosmetics Act"

Indian Association of Public Health, Maulana Azad

* "Implications of the New Drug Policy in Primary Health Care"

National Campaign Committee for Rational Drug Policy
National Drug Policy Seminar
* "Hazardous Drugs"

Rational Drug Use in Paediatrics - AIIMS and WHO
* "Consumers Views on Drug Policy and Economics"

LEGAL

Banned Drugs Case appearance in Court of Justice Ranganath Mishra with Dr. Vincent Panikulangara in the Supreme Court.

EP Case - Appearance in the Public Hearings

Delhi Public Hearing (150 page submission made)	10th April 1987
Calcutta Public Hearing	10th July 1987
Bombay Public Hearing	14th July 1987

NATIONAL DRUG POLICY

Drug Price Control Order with the Kelkar Committee for formulation of Category II drugs

ALL INDIA DRUG ACTION NETWORK RELATED

AIDAN Annual Meet, Bombay	Feb. 1987
Launching of WIDAN, Bombay	Jan. 1987
Drug Action Network, Karnataka	August, 1987
Preparatory and Review meeting, Bangalore	Dec., 1987
Drug Action Forum, West Bengal meeting on Drugs, Calcutta	Jan. 1988

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* session taken

SCHOOL HEALTH RELATED

Teacher Orientation Programme on School Health, Nangloi
School Health Teachers Training Programme, Lajpat Bhawan

PRIMARY HEALTH CARE

VHAI orientation programme on "Primary Health Care" - August 1987, Jamkhed for programme staff and Executive Secretaries.

MISCELLANEOUS

1. MFC meeting, 1987 (Population Control) Jan.'88 (Child Survival)
2. People's Science Movement (Bhopal)
3. Gram Niyojan Kendra (Non health groups)
4. Role of Voluntary Organisation in Primary Health Care: National Institute of PHC - September 1987
5. Role of NGO's in Health Care, FRCH.

DRUG CAMPAIGN AT INTERNATIONAL FORUMS

World Consumer Congress, Madrid Sept. 87
Theme: Consumer Solidarity

* "Rational Drug Policy Dealing with the Critics"

-International Conference, Bielefeld, Oct. 87

Theme:Less Drugs Better Therapy

* 'Drug Issue Chaos and Crisis - views of the Third World"

Workshop - Need for International Controls

Action for Rational Drugs in Asia
Theme: "Drug Patents"

*"The Indian Patent Policy"

Consultation on Biotechnology and the Third world and its Socio economic impact on Health & Agriculture, Bogue, 87.

*session taken

Plans for 1988

ONGOING WORK

1. Follow up of the EP case
2. Follow up of the Drug Policy: specially in area of:
   i. Essential Drug List and the formulation of Category I & II drugs list.
   ii. Drug Pricing - Resist further rise in drug prices in area of Trade Commission, Excise Duty and Chemist fees

   Withdrawal of Hazardous drugs - 7 combination drugs recommended for being weeded out by DCC.

Besides the above work in the following areas will go on:

- Monitoring and control of unethical drug marketing practices
- Ensuring availability of unbiased drug information to doctors by way of updated National Drug Formulary on lines of British National Formulary.
- Demand for consumer caution and warnings for potentially hazardous drugs in regional language e.g. drugs contraindicated in pregnancy.
- Proper measures and clear dosage guidelines for paediatric medicines specially antibiotics.
- Drug Legislation reform and action against the violations of Drugs and Cosmetics Act eg. action on Lentin Commission report.
- Ensuring effective quality control and drug control.

The above will require formal informal meetings acquiring of information not easily available sending of consumer alerts use of the press and need to respond to crisis from time to time.

Workshops Planned

Rational Drug Use in Medical Education in collaboration with Kanpur Medical College - second half of 1988.

Rational Diarrhoea Care Western & Traditional concepts.

Four workshops on Rational Drug Use (responding to requests)

Consultation in workshops, seminars, discussions, dialogues, consultations and training programme on drugs will continue with

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other like minded organisations, social action groups etc.

- special focus of drug work will be Rational Drug Use in Children, Rational Drug Use in National Health Programmes, Women and Pharmaceuticals.

Preparation of material

Compilition of the update of -

- Banned Bannable drug List
- Rational Selection of Drugs
- Taste of Tears.

Summary of the Lentin Commission Report

The EP campaign and its outcome - summary report

Status report of the Drug situation in India for State of India's report.

Dr. Mira Shiva MD
Coordinator
Low Cost Drugs &
Rational Therapeutics

jg/22.4.1988

DR 30.30

DOSAGE SCHEDULE FOR ANTIMALARIAL DRUGS

Age	Presumptive treatment 4 AQ (chloroquine)	Radical Treatment for P V & P M: 4 AQ (chloroquine)	Radical Treatment for P V & P M: 8 AQ (Primaquine)	Radical treatment for P.f. cases: 4 AQ chloroquine	Radical treatment for P.f. cases: + Daraprim	Radical treatment for P.f. cases: OR Primaquine
0 - 1 year	75 mgm	75 mgm	+ nil	75 mgm	+ 12.5 mgm ($\frac{1}{2}$ tablet)	nil
1 - 4 years	150 mgm	150 mgm	+ 2.5 mg for 5 days	150 mgm)	+ 25 mgm (1 tablet)	OR 7.5 mgm for 1 day
				)		OR 15 mgm -do-
4 - 8 years	300 mgm	300 mgm	+ 5 mgm for 5 days	300 mgm)		
8 - 14 years	400 mgm	450 mgm	+10 mgm for 5 days	450 mgm)		OR 30 mgm -do-
14 & above	600 mgm	600 mgm	+15 mgm for 5 days	600 mgm	+ 50 mgm (2 tablets)	OR 45 mgm -do-

Action of Antimalarial Drugs

	Asexual stage	Sexual stage	P.T. Phase	Clinical Suppressors	Casual Prophy-loxis	Sporontocidal
4 AQ	+++ for all pv. & pm.	++	=	++	-	-
8 AQ	-	+++	+++	-	+	++
Pyrimetha mine (Daraprim)	++	++	-	+	+	+++
Quinine Sulphate	+++	+++	-	+	-	-
Progaunil	++	++	-	+	+	+

DOSAGE SCEEDULE FOR ANTIMALARIAL DRUGS

Age	Presumptive treatment 4 AQ (chloroquine)	Radical treatment for PV.&PM.		Radical treatment for P.f. cases		
		4 AQ (chloroquine)	8 AQ (Primaquine)	4 AQ chloroquine	+ Daraprim	OR Primaquine
0-1 year	75 mgm	75 mgm	+ nil	75 mgm	+ 12.5 mgm (½ tablet)	nil
1-4 years	150 mgm	150 mgm	+ 2.5 mg for 5 days	150 mgm)	+ 25 mgm (1 tablet)	OR 7.5 mgm for 1 day
4-8 years	300 mgm	300 mgm	+ 5 mgm for 5 days	300 mgm)		OR 15 mgm -do-
8-14 years	450 mgm	450 mgm	+ 10 mgm for 5 days	450 mgm)		OR 30 mgm -do-
14 & above	600 mgm	600 mgm	+ 15 mgm for 5 days	600 mgm	+ 50 mgm (2 tablets)	OR 45 mgm -do-

Action of Antimalarian Drugs

	Asexual stage	Sexual stage	P.T. Phase	Clinical supressors	Casual prophyloxis	Sprontocidal
4 AQ	+++ for all Pv.& Pm.	++	=	++	-	-
8 AQ	-	+++	+++	-	+	++
Pyrimetha mine (Daraprim)	++	++	-	+	+	+++
Quinine Sulphate	+++	+++	-	+	-	-
Progaunil	++	++	-	+	+	+

DOSAGE SCHEDULE FOR ANTIMALARIAL DRUGS

Age	Presumptive treatment 4 AQ (chloro-quine)	Radical Treatment for P V & P M		Radical treatment for P.f. cases		
		4 AQ (chloro-quine)	8 AQ (Primaquine)	4 AQ chloroquine	+ Daraprim	OR Primaquine
0 - 1 year	75 mgm	75 mgm	+ nil	75 mgm	+ 12.5 mgm (½ tablet)	nil
1 - 4 years	150 mgm	150 mgm	+ 2.5 mg for 5 days	150 mgm))	+ 25 mgm (1 tablet)	OR 7.5 mgm for 1 day OR 15 mgm -do-
4 - 8 years	300 mgm	300 mgm	+ 5 mgm for 5 days	300 mgm)		
8 - 14 years	400 mgm	450 mgm	+10 mgm for 5 days	450 mgm)		OR 30 mgm -do-
14 & above	600 mgm	600 mgm	+15 mgm for 5 days	600 mgm	+ 50 mgm (2 tablets)	OR 45 mgm -do-

Action of Antimalarial Drugs

	Asexual stage	Sexual stage	P.T. Phase	Clinical Suppressors	Casual Prophy-loxis	Sporontocidal
4 AQ	+++ for all pv. & pm.	++	=	++	-	-
8 AQ	-	+++	+++	-	+	++
Pyrimetha mine (Daraprim)	++	++	-	+	+	+++
Quinine Sulphate	+++	+++	-	+	-	-
Progaunil	++	++	-	+	+	+

DOSAGE SCHEDULE FOR ANTIMALARIAL DRUGS

Age	Presumptive treatment 4 AQ (chloroquine)	Radical Treatment for P V & P M		Radical treatment for P.f. cases		
		4 AQ (chloroquine)	8 AQ (Primaquine)	4 AQ chloroquine	+ Daraprim	OR Primaquine
0 - 1 year	75 mgm	75 mgm	+ nil	75 mgm	+ 12.5 mgm (½ tablet)	nil
1 - 4 years	150 mgm	150 mgm	+ 2.5 mg for 5 days	150 mgm))	+ 25 mgm (1 tablet)	OR 7.5 mgm for 1 day OR 15 mgm -do-
4 - 8 years	300 mgm	300 mgm	+ 5 mgm for 5 days	300 mgm)		
8 - 14 years	400 mgm	450 mgm	+10 mgm for 5 days	450 mgm)		OR 30 mgm -do-
14 & above	600 mgm	600 mgm	+15 mgm for 5 days	600 mgm	+ 50 mgm (2 tablets)	OR 45 mgm -do-

Action of Antimalarial Drugs

	Asexual stage	Sexual stage	P.T. Phase	Clinical Suppressors	Casual Prophyloxis	Sporontocidal
4 AQ	+++ for all pv. & pm.	++	=	++	-	-
8 AQ	-	+++	+++	-	+	++
Pyrimethamine (Daraprim)	++	++	-	+	+	+++
Quinine Sulphate	+++	+++	-	+	-	-
Progaunil	++	++	-	+	+	+

DOSAGE SCHEDULE FOR ANTIMALARIAL DRUGS

Age	Presumptive treatment 4 AQ (chloroquine)	Radical Treatment for P V & P M		Radical treatment for P.f. cases		
		4 AQ (chloroquine)	8 AQ (Primaquine)	4 AQ chloroquine	+ Daraprim	OR Primaquine
0 - 1 year	75 mgm	75 mgm	+ nil	75 mgm	+ 12.5 mgm ($\frac{1}{2}$ tablet)	nil
1 - 4 years	150 mgm	150 mgm	+ 2.5 mg for 5 days	150 mgm)	+ 25 mgm (1 tablet)	OR 7.5 mgm for 1 day
				)		OR 15 mgm -do-
4 - 8 years	300 mgm	300 mgm	+ 5 mgm for 5 days	300 mgm)		
8 - 14 years	400 mgm	450 mgm	+10 mgm for 5 days	450 mgm)		OR 30 mgm -do-
14 & above	600 mgm	600 mgm	+15 mgm for 5 days	600 mgm	+ 50 mgm (2 tablets)	OR 45 mgm -do-

Action of Antimalarial Drugs

	Asexual stage	Sexual stage	P.T. Phase	Clinical Suppressors	Casual Prophy-loxis	Sporontocidal
4 AQ	+++ for all pr. & pm.	++	=	++	-	-
8 AQ	-	+++	+++	-	+	++
Pyrimetha mine (Daraprim)	++	++	-	+	+	+++
Quinine Sulphate	+++	+++	-	+	-	-
Progaunil	++	++	-	+	+	+

DOSAGE SCHEDULE FOR ANTIMALARIAL DRUGS

Age	Presumptive treatment 4 AQ (chloroquine)	Radical Treatment for P V & P M: 4 AQ (chloroquine)	Radical Treatment for P V & P M: 8 AQ (Primaquine)	Radical treatment for P.f. cases: 4 AQ chloroquine	+ Daraprim	OR Primaquine
0 - 1 year	75 mgm	75 mgm	+ nil	75 mgm	+ 12.5 mgm ($\frac{1}{2}$ tablet)	nil
1 - 4 years	150 mgm	150 mgm	+ 2.5 mg for 5 days	150 mgm))	+ 25 mgm (1 tablet)	OR 7.5 mgm for 1 day OR 15 mgm -do-
4 - 8 years	300 mgm	300 mgm	+ 5 mgm for 5 days	300 mgm)		
8 - 14 years	400 mgm	450 mgm	+10 mgm for 5 days	450 mgm)		OR 30 mgm -do-
14 & above	600 mgm	600 mgm	+15 mgm for 5 days	600 mgm	+ 50 mgm (2 tablets)	OR 45 mgm -do-

Action of Antimalarial Drugs

	Asexual stage	Sexual stage	P.T. Phase	Clinical Suppressors	Casual Prophy-loxis	Sporontocidal
4 AQ	+++ for all pv. & pm.	++	=	++	-	-
8 AQ	-	+++	+++	-	+	++
Pyrimetha mine (Daraprim)	++	++	-	+	+	+++
Quinine Sulphate	+++	+++	-	+	-	-
Progaunil	++	++	-	+	+	+

DOSAGE SCHEDULE FOR ANTIMALARIAL DRUGS

Age	Presumptive treatment 4 AQ (chloroquine)	Radical Treatment for P V & P M		Radical treatment for P.f. cases		
		4 AQ (chloroquine)	8 AQ (Primaquine)	4 AQ chloroquine	+ Daraprim	OR Primaquine
0 - 1 year	75 mgm	75 mgm	+ nil	75 mgm	+ 12.5 mgm (½ tablet)	nil
1 - 4 years	150 mgm	150 mgm	+ 2.5 mg for 5 days	150 mgm))	+ 25 mgm (1 tablet)	OR 7.5 mgm for 1 day OR 15 mgm -do-
4 - 8 years	300 mgm	300 mgm	+ 5 mgm for 5 days	300 mgm)		
8 - 14 years	400 mgm	450 mgm	+10 mgm for 5 days	450 mgm)		OR 30 mgm -do-
14 & above	600 mgm	600 mgm	+15 mgm for 5 days	600 mgm	+ 50 mgm (2 tablets)	OR 45 mgm -do-

Action of Antimalarial Drugs

	Asexual stage	Sexual stage	P.T. Phase	Clinical Suppressors	Casual Prophyloxis	Sporontocidal
4 AQ	+++ for all pv. & pm.	++	=	++	-	-
8 AQ	-	+++	+++	-	+	++
Pyrimethamine (Daraprim)	++	++	-	+	+	+++
Quinine Sulphate	+++	+++	-	+	-	-
Proguanil	++	++	-	+	+	+

DOSAGE SCHEDULE FOR ANTIMALARIAL DRUGS

Age	Presumptive treatment 4 AQ (chloroquine)	Radical Treatment for P V & P M		Radical treatment for P.f. cases		
		4 AQ (chloroquine)	8 AQ (Primaquine)	4 AQ chloroquine	+ Daraprim	OR Primaquine
0 - 1 year	75 mgm	75 mgm	+ nil	75 mgm	+ 12.5 mgm ($\frac{1}{2}$ tablet)	nil
1 - 4 years	150 mgm	150 mgm	+ 2.5 mg for 5 days	150 mgm)	+ 25 mgm (1 tablet)	OR 7.5 mgm for 1 day
				)		OR 15 mgm -do-
4 - 8 years	300 mgm	300 mgm	+ 5 mgm for 5 days	300 mgm)		
8 - 14 years	400 mgm	450 mgm	+10 mgm for 5 days	450 mgm)		OR 30 mgm -do-
14 & above	600 mgm	600 mgm	+15 mgm for 5 days	600 mgm	+ 50 mgm (2 tablets)	OR 45 mgm -do-

Action of Antimalarial Drugs

	Asexual stage	Sexual stage	P.T. Phase	Clinical Suppressors	Casual Prophyloxis	Sporontocidal
4 AQ	+++ for all pv. & pm.	++	=	++	-	-
8 AQ	-	+++	+++	-	+	++
Pyrimethamine (Daraprim)	++	++	-	+	+	+++
Quinine Sulphate	+++	+++	-	+	-	-
Progaunil	++	++	-	+	+	+

DOSAGE SCHEDULE FOR ANTIMALARIAL DRUGS

Age	Presumptive treatment 4 AQ (chloroquine)	Radical Treatment for P V & P M: 4 AQ (chloroquine)	Radical Treatment for P V & P M: 8 AQ (Primaquine)	Radical treatment for P.f. cases: 4 AQ chloroquine	Radical treatment for P.f. cases: + Daraprim	Radical treatment for P.f. cases: OR primaquine
0 - 1 year	75 mgm	75 mgm	+ nil	75 mgm	+ 12.5 mgm ($\frac{1}{2}$ tablet)	nil
1 - 4 years	150 mgm	150 mgm	+ 2.5 mg for 5 days	150 mgm)	+ 25 mgm (1 tablet)	OR 7.5 mgm for 1 day OR 15 mgm -do-
4 - 8 years	300 mgm	300 mgm	+ 5 mgm for 5 days	300 mgm)		
8 - 14 years	400 mgm	450 mgm	+10 mgm for 5 days	450 mgm)		OR 30 mgm -do-
14 & above	600 mgm	600 mgm	+15 mgm for 5 days	600 mgm	+ 50 mgm (2 tablets)	OR 45 mgm -do-

Action of Antimalarial Drugs

	Asexual stage	Sexual stage	P.T. Phase	Clinical Suppressors	Casual Prophy-loxis	Sporontocidal
4 AQ	+++ for all pv. & pm.	++	=	++	-	-
8 AQ	-	+++	+++	-	+	++
Pyrimetha mine (Daraprim)	++	++	-	+	+	+++
Quinine Sulphate	+++	+++	-	+	-	-
Progaunil	++	++	-	+	+	+

DOSAGE SCHEDULE FOR ANTIMALARIAL DRUGS

Age	Presumptive treatment 4 AQ (chloro-quine)	Radical Treatment for P V & P M		Radical treatment for P.f. cases		
		4 AQ (chloro-quine)	8 AQ (Primaquine)	4 AQ chloroquine	+ Daraprim	OR Primaquine
0 - 1 year	75 mgm	75 mgm	+ nil	75 mgm	+ 12.5 mgm (½ tablet)	nil
1 - 4 years	150 mgm	150 mgm	+ 2.5 mg for 5 days	150 mgm)	+ 25 mgm (1 tablet)	OR 7.5 mgm for 1 day
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Action of Antimalarial Drugs

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8 AQ	-	+++	+++	-	+	++
Pyrimetha mine (Daraprim)	++	++	-	+	+	+++
Quinine Sulphate	+++	+++	-	+	-	-
Proguanil	++	++	-	+	+	+

DOSAGE SCHEDULE FOR ANTIMALARIAL DRUGS

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8 AQ	-	+++	+++	-	+	++
Pyrimetha mine (Daraprim)	++	++	-	+	+	+++
Quinine Sulphate	+++	+++	-	+	-	-
Proguanil	++	++	-	+	+	+

DOSAGE SCHEDULE FOR ANTIMALARIAL DRUGS

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8 AQ	-	+++	+++	-	+	++
Pyrimetha mine (Daraprim)	++	++	-	+	+	+++
Quinine Sulphate	+++	+++	-	+	-	-
Progaunil	++	++	-	+	+	+

DOSAGE SCHEDULE FOR ANTIMALARIAL DRUGS

Age	Presumptive treatment 4 AQ (chloroquine)	Radical Treatment for P V & P M: 4 AQ (chloroquine)	Radical Treatment for P V & P M: 8 AQ (Primaquine)	Radical treatment for P.f. cases: 4 AQ chloroquine	Radical treatment for P.f. cases: + Daraprim	Radical treatment for P.f. cases: OR Primaquine
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Action of Antimalarial Drugs

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8 AQ	-	+++	+++	-	+	++
Pyrimethamine (Daraprim)	++	++	-	+	+	+++
Quinine Sulphate	+++	+++	-	+	-	-
Progaunil	++	++	-	+	+	+

DOSAGE SCHEDULE FOR ANTIMALARIAL DRUGS

Age	Presumptive treatment 4 AQ (chloroquine)	Radical Treatment for P V & P M: 4 AQ (chloroquine)	Radical Treatment for P V & P M: 8 AQ (Primaquine)	Radical treatment for P.f. cases: 4 AQ chloroquine	Radical treatment for P.f. cases: + Daraprim	Radical treatment for P.f. cases: OR Primaquine
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Action of Antimalarial Drugs

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4 AQ	+++ for all pv. & pm.	++	=	++	–	–
8 AQ	–	+++	+++	–	+	++
Pyrimethamine (Daraprim)	++	++	–	+	+	+++
Quinine Sulphate	+++	+++	–	+	–	–
Progaunil	++	++	–	+	+	+

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BANNABLE DRUGS CAMPAIGN

Readers may have noticed that this year we stopped using a number of drugs that are still being freely sold in the chemists' shops. We do not feel that it is sufficient to add and subtract medicines from our armamentarium. People concerned should know why this is being done.

This education campaign was conducted at three levels. At first our staff read up on the use of these drugs and their side effects. Papers were presented during staff seminars and a pharmacology textbook in Tamil was bought. The seminar papers were cyclostyled and have been distributed to over 60 interested organisations and individuals around Tamilnadu.

The next step was to carry the message to our VLWs at their refresher courses and to the general public during street plays and public meetings. The Tamil monthly magazine 'Aakkam' has also carried one of our staff's articles on the danger of ANALGIN.

We also went one step further and carried the debate to the portals of the academic institutions. We asked specialists from the medical colleges the opinions on some of the controversial drugs. Nine teachers from Vellore, Chingleput and Madras Medical Colleges replied and their views have been compiled. We are also planning to translate their comments into Tamil.

We are cooperating with a consortium of five non-governmental organisations in Chingleput District who are arranging meetings on this issue in their area. Similarly we have supported a group of Ayurvedic and Allopathic medicos in Coimbatore who published information brochures and held meetings about bannable drugs. There are also a few individuals in Madras who are in contact with us on this issue.

What follows is a summary of the views of the experts on some of these drugs:

JN
13/7/88

THELMA & RAVI NARAYAN
326, IXTH MAIN, 1ST BLOCK,
KORAMANGALA
BANGALORE-560 034

Fixed dose combinations of Chloramphenicol and Streptomycin (for oral use):

This is not recommended - Pharmacology Professor, MMC.

"These combination medications have been stopped from being used by many advanced countries. Wonder why our country still continues to manufacture them". - Pediatrics Professor 1, Vellore.

	For	Against
General Medicine	1	3
Pediatrics	-	2
Pharmacology	-	1
Surgery	1	-
Other	1	-
	3	6

Fixed dose combinations of Penicillin and Streptomycin:

"(Found useful) in an animal model of staphylococcal endocorditis. Even here simultaneous administration of the two drugs in requisite dose is preferred to a fixed dose combination".
- Pharmacology Professor, MMC.

"Manufacturing licence should be withdrawn"
- Pediatrics Professor 2, Vellore

	For	Against
General Medicine	1	3
Pediatrics	-	2
Pharmacology	-	1
Surgery	1	-
Other	-	1
	2	7

Anabolic Steroids:

"Fracture in debilitated individuals; where improvement in debilitating disease is not satisfactory with other treatment".
- Medicine Professor, Chingleput

" To what extent they are beneficial is a moot question. Should not be used in Pediatric age group".
- Pharmacology Professor, MMC

"Should be used by only qualified Paediatric and adult endocrinologists".
- Pediatrics Professor 2, Vellore.

" Where there is excess protein breakdown in limited situations".
- Medicine Professor, Vellore.

"Can be used with reservation".- Medicine Asst. Prof, Chingleput.

	For	Specific Conditions	Against
General Medicine	-	3	1
Pediatrics	-	1	1
Pharmacology	-	1	-
Surgery	1	-	-
Other	1	-	-
	2	5	2

Oxyphenbutazone & Phenylbutazone:

"Only in ankylosing spondylitis where it is sometimes the only effective drug".
- Medicine Professor, Chingleput.

"Should be discontinued forthwith".
- Pediatrics Professor2, Vellore.

"Have to be used only be qualified physicians under medical supervision".
- Pharmacology Professor, MMC.

"For ankylosing spondilytis and acute phlebitis and rarely in rheumatoid arthritis"
- Medicine Professor, Vellore.

	For	Specific Conditions	Against
General Medicine	-	2	2
Pediatrics	-	-	2
Pharmacology	-	1	-
Surgery	1	-	-
Other	-	-	1
	1	3	5

Kaolin:

"Not necessary - I never use it"
- Medicine Professor, Chingleput.

"Has little actual benefit. Can be used as a non-specific anti-diarrhoeal agent. It is not a toxic drug".
- Pharmocology Professor, Madras.

"Is of no benefit whatsoever" - Pediatrics Professor 2, Vellore.

	For	Against
General Medicine	2	2
Pediatrics	-	2
Pharmacology	-	-
Surgery	1	-
Other	1	-
	4	4

Diphenoxylate:

"Useful in adults only where there is moderately severe diarrhoea. I use only 1 tablet dose in 6 hours".
- Medicine Professor, Chingleput.

"Contraindications: Allergy; Jaundice; Children below 2 years. Physiological and psychological dependence can occur if used in large doses over extended period because it is a member of the pethidine group".
- Pharmacology Professor, Madras.

"Useful when used with antibiotics in adults".
- Medicine Asst. Prof., Chingleput.

	For	Specific Conditions	No Comment	Against
General Medicine	1	1	2	-
Pediatrics	-	-	-	2
Pharmacology	1	-	-	-
Surgery	-	-	1	-
Other	-	-	-	1
	2	1	3	3

Loperamide:

"Not essential" - Medicine Professor, Chingleput.

"Of use only in specific situations and hence should be decided by qualified gastroenterologists only".
- Pediatrics Professor 2, Vellore.

"Fatal Paralytic Ileus and CNS manifestations (may result from its use in children)". - Pediatrics Professor 1, Vellore.

"Neurogenic & Functional Diarrhoeas".
- Medicine Asst. Prof., Chingleput.

"Used in Diarrhoea". - Pharmacology Professor, Madras.

	For	Specific Conditions	No Comment	Against
General Medicine	1	1	1	1
Pediatrics	-	1	-	1
Pharmacology	1	-	-	-
Surgery	1	-	-	-
Other	-	-	-	1
	3	2	1	3

Hydroxyquinolines:

"As it is potentially dangerous it should not be used as chronic amoebiasis in India is sometimes a life long disease".
- Medicine Professor, Chingleput.

"Some types of intestinal amoebasis and diarrohea".
- Pharmacology Professor, Madras.

"Orally for amoebic colitis" - Medicine Professor, Vellore

	For	Specific Conditions	No Comments	Against
General Medicine	1	1	-	2
Pediatrics	-	-	1	1
Pharmacology	-	1	-	-
Surgery	1	-	-	-
Other	-	-	-	1
	2	2	1	4

Analgin:

"Parenteral use is adviseable" - Surgery Asst. Proff., Chingleput.

"Can be sparingly used" - Medicine Professor, Chingleput.

"Its use as a routine analgesic is not recommended" - Pharmacology Professor, MMC.

"Never" - Medicine Professor, Vellore.

"Could cause renal failure, aplastic anemia" - Pediatric Professor1, Vellore.

	For	Rarely	Against
General Medicine	1	2	1
Pediatrics	-	-	2
Pharmacology	-	-	1
Surgery	1	-	-
Other	1	-	-
	3	2	4

Drug	For	Specific Conditions Rarely	Against	Conclusion
CHLOROSTREP	3	-	6	No
STREPTOPEN	2	-	7	No
ANABOLIC STEROIDS	2	5	2	Restrict
ANALGIN	3	2	4	Restrict or Ban
OXYPHEN + PHENYL BUTAZONE	1	3	5	No
KAOLIN	4	-	4	May Be
DIPHENOXYLATE	2	1	3	May Be
LOPERAMIDE	3	2	3	May Be
HYDROXY QUINOLINES	2	2	4	Restrict or Ban

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DETAILS OF SOME COMMENTS BY PHARMACOLOGY PROFESSOR - MMC

1. Fixed dose combinations of Chloramphenicol & Streptomycin (for oral use)

This is not recommended. Chloramphenicol is reserved for typhoid and has to be used with caution because of the danger of bone marrow depression. There are instances where it has produced diarrhoea. In intractable bacillary dysentery, the two may be used independently. There is no added advantage or a firm basis for such a combination.

2. Fixed dose combinations of Penicillin & Streptomycin.

Synergism invitro by a combination of Penicillin and Streptomycin has been demonstrated with staphylococcus aureus. Eradication of microorganism from infected vegetations was found to be more rapid in an animal model of staphyloccal endocarditis treated with this combination. Penicillin alters the structure of the cell wall end can markedly increase the entrance of aminoglycosides into these bacteria; this is the only condition where this combination is used. Even here simultaneous administration of the two drugs in the requisite dose in preferred to a fixed dose combination.

3. Analgin (Metamizole Sodium).
Preparations: (Dipyrone, Analgin, Novalgin) 500 mg tab tds used orally I.M or I.V.

It is closely related to aminopyrine and is documented for its ability to cause agranulocytosis. Hence, its use as a routine analgesic is not recommended. 'Shock' has also been reported after the parenteral use of this drug.

4. Oxyphenbutazone and Phenylbutazone.
Oxyphenbutazone: (Tanderil, Suganril) 100-200 mg tab tds
Phenylbutazone: (Butazolidine, Zolandin) 100, 200 mg tab tds

Both are anti-inflammatory agents and have to be used only by qualified physicians under medical supervision. Phenylbutazone has been banned in many countries. Oxyphenbutazone is the active metabolite of phenyl butazone. They have a number of adverse effects and are contra-indicated in blood, bone marrow diseases, allergy, peptic ulcer, hypertension and congestive cardiac failure.

Reference:

The Pharmacological basis of Therapeuticsed. Alfred Goodman Gilman et al 7th ed. 1985, Macmilan publishing Company.

Essentials of Medical Pharmacology K.D. Tripathi, 1985.
Jaypee brothers, New Delhi.

FURTHER COMMENTS BY PEDIATRIC PROFESSOR 2: VELLORE:

1. With regard to Anabolic steroids, my comments that it should be used only by qualified Paediatric and Adult Endocrinologists applys only to such preparations as oxandrolone. As you are aware there are many anabolic steroids available in the market and I wouldn't use any of them for any indications in endocrinology even. Oxandrolone is fairly specific for growth disorders and Oxymetholone is used for treatment for aplastic anaemia. Apart from these two drugs, I will not recommend any other anabolic steroids. I thought I must make my stand clear in this regard.

2. With regard to Loperamide, once again I would like to make it very explicit that the indications will be only in secretory diarrhoea where an infective aetiology is totally ruled out. And also only in cases of intractable chronic diarrhoea in children.