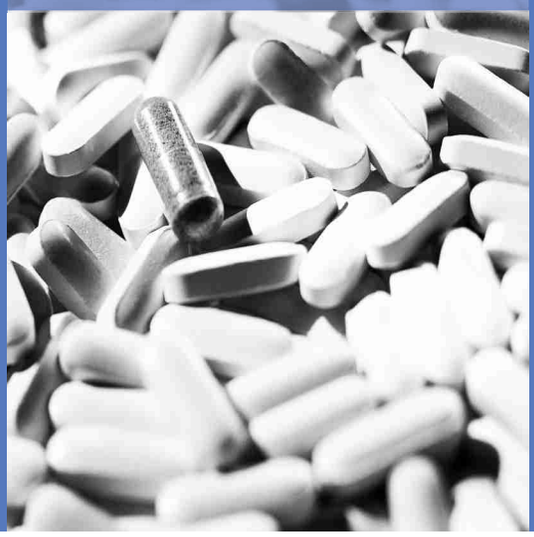

Promoting Rational Drug Use under NRHM

"Every physician should, as far as possible, prescribe drugs with generic names and he/she shall ensure that there is a rational prescription and use of drugs."

Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002.

The Problem

The widely pervasive irrational practice of medicine is a matter of serious concern, not only in India but across the world. No section of providers is untouched by this malaise, though there is evidence that it is more in the private sector relative to the public; is prevalent among formally trained doctors and somewhat greater amongst non-formally trained practitioners. It may take the form of irrational prescription of drugs, diagnostics, or therapeutic procedures including surgery.

Irrational practice leads to:

* unnecessary financial costs of medical care to the health service system
* unnecessary financial costs of medical care to the patient
* neglect of essential treatment components while the unnecessary are taken under conditions of resource constraints of patients
* neglect of essential treatment components while the unnecessary are administered under conditions of work over-load of care providers in public facilities
* side effects and diseases due to medical intervention, which form an increasingly large proportion of the burden of disease even in the developed countries

Out of Pocket Expenditure on Medicines at public facility (OPD)= 83% rural, 77% urban

Out of Pocket Expenditure by patients at public facility (indoor)= 56% rural, 47% urban

[Source: NSSO]

However, this need not necessarily be so. Universal access to low cost medicines is possible, and systems have been put in place in diverse settings to ensure this.

Components of Rational Use of Medicines

1. Availability of essential drugs
2. Access and affordability of medicines
3. Rationality of prescription

In a public health service system, free access of low cost medicines to all patients is an important element in ensuring implementation of Rational Drug Use guidelines.

Inputs for Rational Use of Medicines

Several States have undertaken initiatives in the past to promote rational use of medicines in the government health services with mixed results. However, with a few exceptions, these have not been sustained or made adequate impact. Three patterns can be seen in the states:

I. a) Free generic medicines available in adequate quantities for all patients, with
   b) low procurement costs of generics, and
   c) generic medicines prescribed by doctors, eg. Tamil Nadu, Delhi.

II. a) Generic medicine prescription, with
   b) negotiated low costs of generics, but
   c) free medicines only for the BPL therefore still dependence of patients on outside purchase of medicines, eg. Rajasthan.

III. a) Free medicines only for the BPL,
   b) inadequate quantities therefore patients still dependent on outside purchase &
   c) little use of generic medicines, branded drugs purchased by the public system and by patients at huge cost--As is the situation in most States.

What will it cost to provide free medicines to all patients in public facilities? The estimate below gives us some idea. Based on the cost of generic medicines currently adopted by the public health system in Chittorgarh, Rajasthan, it takes into consideration the increase in OPD attendance that such a provision will generate.

Estimated Drug Cost (OPD) for Rajasthan per year

Facilities	Cost (In Rupees)
Sub Centre & PHC	70,66,09,771
CHC	1,27,30,66,821
District Hospital	2,95,57,58,324
Total funds requirement	**4,93,54,34,916**
Total Population of Rajasthan 2008 (Projected)	6,46,41,000
Total cost of drugs (OPD)	4,93,54,34,916
Per Capita Cost	**76.35**

(Based on burden of diseases of Rajasthan, treatment cost for standard procedures and medicines procured on Government rates. The above cost includes immunization and temporary F.P. procedures.)
Source: Narendra Gupta, 2009, Prayas, Chittorgarh, Rajasthan

Continue to Page 4

PROMOTING RATIONAL DRUG USE

under NRHM

NATIONAL RURAL HEALTH MISSION
राष्ट्रीय ग्रामीण स्वास्थ्य मिशन

World Health Organization
Country Office for India

PROMOTING RATIONAL DRUG USE

Need For An NRHM Sub-Mission

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Contents

PROMOTING RATIONAL DRUG USE
Need for an NRHM Sub-Mission

Introduction: The Issues

Health system strengthening is a central mandate of the National Rural Health Mission. The number of doctors, nurses and paramedical staff in public facilities has increased markedly. So has the utilization of these facilities by the community. However the adequate availability of medicines and other consumables is still not fully ensured in all states. Even while states work to ensure this, expensive diagnostic tests and medicines are still being prescribed by the providers that have to be bought out of pocket by the patients. The social protection afforded to the poor by public expenditure on drugs and supplies would be lost if irrational prescription of drugs and prescription of costly branded drugs that need to be out of pocket from private pharmacies, continues to rise in parallel. Therefore along with developing systems for procurement and distribution of appropriate medicines and equipments, States need to popularize the use of essential and generic drugs and rational diagnostic, prescriptive and therapeutic practices.

Participation of users, involvement of communities, patient friendly facilities, accountability of institutions and providers are key elements and the very spirit of the NRHM. Accountability is sought to be institutionalized though the Rogi Kalyan Samitis, the district health societies and community monitoring processes. These structures can ensure accountability in decisions relating to aspects such as infrastructure, human resources, cleanliness etc. They are however unable to address issues related to clinical decisions or patient management approaches.

With the extreme information gap on clinical decisions between the users of medical services and the providers, it is extremely difficult to incorporate ac-

countability on this at the level of facility or provider - patient interaction. Providers may engage in over prescription of diagnostic tests, unnecessary medication and surgery, as malpractice or due to inadequate knowledge of scientific evidence or due to mis-information from commercial interests. Simultaneously, misconceptions about medical treatments among lay public, which act as a driver for irrational care, needs to be addressed. The demands of patients contribute in a significant way to providers practicing irrational medicine. Therefore along with dissemination and utilization of widely accepted guidelines for rational patient management, a larger public support for adherence to rational principles must be mobilized if such a policy is to be sustained. WHO has evolved guidelines for some areas of use of medical technology and an essential drug lists. This has to be suited to each epidemiological, health service and providers context. Therefore country and state specific preparation of essential drug lists, treatment guidelines, and production of educational materials are needed.

Why worry about medicines

- Drugs are essential to health care, to save lives, decrease suffering and improve health
- Drug availability promotes trust and participation in health services
- Drugs are costly to patients, household and Government
- Drugs are different from other consumer products since the prescriber and purchaser are often different.
- Inappropriate drug use can be harmful.
- Substantive improvements are possible in the supply and use of drugs.

However, even this will not be enough if the availability and access of medicines is inadequate. Availability and appropriate use of medicines play a central part in the attainment of an acceptable standard of good health. The effectiveness, credibility and attendance at health services depend to a large extent on patients being able to obtain relevant drugs at the right time. A good diagnosis is not much use if the patient cannot obtain the necessary treatment. Lack of drugs thus compromises, if not completely negates, the operation of a health care facility and of health care systems.

Several States have undertaken initiatives in the past to promote rational use of medicines in the government health services. However, with a few exceptions, these have not been sustained or made any significant impact. Some recent attempts provide useful models to examine. Lessons learnt show that a simultaneous multi-pronged approach is necessary for concerted impact. Much work has also been done in this area at international and national level as well as by several non-governmental organizations and persons in India (for instance All India Drug Action Network, DSPRUD, VHAI, among others). Various professional medical specialist associations (for instance Indian Association of Pediatricians, FOGSI, etc.) are also engaged in developing standard protocols for patient management as well as health communication material for patients and the public. These resources can all be drawn upon to undertake an effective initiative for promoting rational use of medicines which would further strengthen the health service system under the NRHM.

Regarding medicines, any health service system has to address three critical areas - the access to essential drugs, the affordability of essential drugs and the rational or appropriate use of drugs. These are three inter-related areas, each of which pose several challenges to the achievement of health for all.

Section–I

Availability of Essential Drugs

Availability of drugs in the market is not merely about drug manufacturing and pharmaceutical industry and the policies to regulate them. In a far greater measure drugs availability depends on robustness and soundness of the public health systems and their ability to ensure provisioning of the essential drugs. And finally it depends on drug pricing that is determined by the penetration of private health sector in the country and the affordability of drugs in private sector pharmacy shops, since the number of pharmacy shops has undoubtedly increased by leaps and bounds and therefore for private health sector, it is only the question of affordability that limits access.

Under the Constitution of India both the Central Government and the individual States have concurrent legislative mandates for drug control, towards their safety, quality and efficacy. The two main objectives of India's health policy in the pharmaceutical sector have been firstly, to ensure the availability of reasonably priced and high quality drugs, and secondly, to promote the growth and development of a vibrant domestic drug industry. However one notes, that, pharmaceutical policy in India is perceived primarily as a part of industrial policy rather than that of the health policy (Modifications in Drug Policy, 1986), which is glaring in the fact that it comes under the ministry of chemicals and fertilizers, and not the health

ministry. Accordingly, the focus of pharmaceutical policy is around promotion of high growth rates and commercial profitability in this area, a focus that could potentially conflict with health goals of universal access to affordable essential drugs and phasing out irrational drugs.

The magnitude of expenditure incurred on drugs by households does not show a similar pattern in public expenditure.

The component of drugs and medicines in the overall budget of both the Central and State Governments is only a minor share, as salaries account for the bulk of the health sector expenditure in India. (S. Sakthivel,National Commission on Macroeconomics and Health, 2005)

This does not imply that the health sector salary expenditure is high but that expenditure on medicines is too low.

It is important to bear in mind that especially for the poor, and for many rural and remote areas, the public health system remains the only channel of access to essential drugs. Whether the public health system is able to provide adequate access depends largely on density of public health facilities and density of health human resources deployed in them. Further, it also depends on the proportion of public health expenditure that goes to drug expenditure, which though not the largest head of health expenditure is certainly one of the most important and difficult to manage. The three indicators that could thus most closely reflect the access of essential drugs to the poor are:

a) Density of facilities and skilled health care providers in the public sector.

b) Average cost spent out of pocket per patient per hospitalization episode.

c) Per capita public health expenditure on drugs and proportion of health budget that is spent on drugs.

If we take Tamil Nadu as a benchmark for these indicators (even though Tamil Nadu is well below the international norms for this) we would see that almost all states fall well below the modest benchmark. This comparison is shown in Appendix 1. Tamil Nadu has a density of 110 providers per 100,000 population, an average out of pocket expenditure on drugs of Rs 250 (national average is Rs 1200 per hospitalization) and a Rs 31 per capita public drug expenditure. It is pertinent to mention that World Health Organisation recommends a skilled health care provider density of 230 per 100,000 population, an average zero direct out-of-pocket payment per hospitalization episode, and a per capita public expenditure on drugs as $1 or approximately Rs 50.

Section–II

The Access and Affordability of Drugs

While all health costs are rising steeply, the component whose costs have risen most steeply and almost invisibly is the cost of drugs.

The rising prices of drugs is a considerable drain on the pockets of the entire population, but it affects the poor most. It is estimated that each year 20 million Indians fall below the poverty line because of indebtedness due to expenditure incurred on healthcare. This is worrisome given the fact that more than two-thirds of the country's population is already either poor or living at subsistence levels. Patients have to make out-of-pocket payments for seeking private health services at the cost of other essential needs such as nutrition, housing, education etc. In most poor households, health care ends up being the second highest item of expenditure, second only to food.

The rising prices of drugs is a considerable drain on the pockets of the entire population, but it affects the poor most. It is estimated that each year 20 million Indians fall below the poverty line because of indebtedness due to expenditure incurred on healthcare.

Passive privatization, the process by which the private sector share of health care grows rapidly while public health expenditure remains stagnant, has been one more reason for increasing costs of health care and increasing out–of-pocket payment on drugs.Increasing costs are also due to newer products being introduced under a changed patent regime, the costs of new technology-based investigations

and therapeutic interventions that are becoming more common, and the rising incidence and increasing costs of treating chronic diseases and life-style related illnesses like heart diseases and of cancers. Also, some groups like senior citizens that are more vulnerable to rising drug costs, are facing faster rate of increase in costs of drugs they use.

The rising price of drugs in the private sector thus limits access to the drugs for a majority of the population. But the impact of increasing prices are not only on individuals and households; they also act on health systems. As drug prices rise faster than the rate of inflation, the increase in the budget provided for drug procurement becomes insufficient to treat patients who seek care within the public health system. This in turn gets reflected in increased prescription by doctors of drugs not available in the facility's own stored, forcing them to buy privately from outside, and leads to lower effectiveness of care and greater cost to patients and decreased access, even exclusion of the poorest from meeting their essential drug needs.

In the 1970s there was an effort to bring drug prices under regulation by the Drug Price Control Order. However, while the list of drugs that were brought under the Order were relatively few, there was ample scope for various ways of getting around the Order. Even that Order has been subsequently relaxed considerably and the list of drugs covered under price regulation has decreased even further, and so for all practical purposes there is almost no such Order in place now to address drug price control.

In most other products the market competition acts to regulate prices, that are dependent on the costs of raw material, the costs incurred in manufacture and the dynamics of supply and demand. However, this logic of the market-place does not quite apply to drugs since the consumers do not make the choice on which drug to consume, it is the doctors who make the decision on their behalf. What makes things worse is that most doctors do not know or care to know the costs of the drugs they prescribe since they are little affected by it; in most cases in any case they have poor knowledge of the comparative costs of different brands, which adds to the difficulty of their making a rational choice for their patients. On the other hand, most drug promotion by drug companies is based on branding of drugs and on brand promotion through the doctors. And since the drug companies are fully aware of the different dynamics of medicines as a commodity in comparison to all others, and they make full use of this to their advantage and to the disadvantage of the consumers, the patients, who have minimal control in this as explained above. Eventhough when the public hospital buys on the behalf of patients considerable control on prices is possible, but when the patient is an individual client facing the market, there is no way that that

individual patient could make a rational choice given the high degree of what is called "information asymmetry." It is for the same set of reasons why so much irrational drug use occurs making matters even worse, which we shall see in the next section.

Generic drugs are less expensive than brand-name drugs: Generic drugs, which are the drugs that are usually produced when a branded drug loses its patent, approximately 20 years after the drug patent application was registered, can tremendously increase the availability, affordability and efficient use of medicines. . Price appears to be the real difference between most brand and generic drugs since generic drugs are held to the same quality standards for safety and performance as the brand names, yet can sell for 30-80% less, and in fact on an average, most generic drugs are approximately half the price of their brand name counterparts. However, prices of even the generic drugs are being manipulated by larger drug companies which have been acquiring smaller generic companies, and keeping the generic drugs prices high to discourage their use. These changes result in reducing the price difference between branded and generic products, thus keeping their sale and profits of former intact and letting them earn more even from generic drug sales, leading to disproportionate profiteering by them, while the people may not get the benefit of savings through use of generic drugs despite the end of patent on them.

It is extremely important that the generic drugs be protected from price manipulations and also that they be used in public health care system as it would drastically bring down the drug expenditure of government, allowing more money to be spent on other areas of healthcare that would otherwise be neglected with the higher price of medicine.

Price variation of Drugs Generic (G) vs Brand (B)

Name of the Medicines/ Tab/Cap.	CIPLA		CADILA		BLUE CROSS			
	G	B	G	B	G	B	G	B
Roxithromycin (150 mg)	4.41	9.75	4.46	10.90	-	-	10.90 Torrent	-
Omeprazole (20 mg)	1.77	3.60	-	-	1.33	3.50	1.99 (Mankind)	
Norfloxacin (400 mg.)	4.70	-	1.31	4.60	-	-	4.50 (Ranbaxy)	
Cetrizine (10 mg.)	2.50	-	0.27	2.31	0.74	2.10	2.55	-
Ciprofloxacine (500 mg)	2.45	7.89	2.50	6.63	-	-	8.47 (Ranbaxy)	
Nimesulide (100mg)	0.45	-	1.99	-	0.32	1.80	0.99 (Mankind)	

Price (Generic) Variation of the Same Drug Manufacured by Different Campanies

Manufacturer	Name of different Drugs				
	Nimesulide	Omeprazole	Sparfloxacin	Ciprofloxacin	Cetrizine
Cipla	0.45	1.77	11.03	2.45	2.50
Cadilla	1.99	-	-	2.50	0.27
Torrent	-	-	-	-	2.55
Ranbaxy	-	-	22.50	8.47	-
Blue Cross	0.32	1.33	-	-	0.74
Glaxo	-	-	-	-	2.67
Panacea Biotec	2.90	-	-	-	-
Mankind	0.99	1.99	-	3.49	0.55
Dr. Reddy's	-	3.95	-	-	2.72
Sun Pharma	-	-	25.75	-	2.61
Alembic	-	-	26.00	-	-

Section –III

The Rational Use of Medicines

Irrational, Non-essential and Hazardous drugs in the market

While the pharmaceutical industry has witnessed tremendous transformation since the 1950s leading to their increasing profits, at the same time huge numbers of irrational, non-essential and hazardous drugs have flooded the market.

It needs to be clearly understood that as little as about 300-400 pharmaceuticals are capable of providing all the useful therapeutic value that any medicine can provide for any type of illness. This is what is really the "essential drugs" list. Even if we include a number of drugs which are safe and efficacious but which duplicate the effects provided by one of these 300 chemicals, still we should have maximum 750 to 1000 drugs on essential drugs list. Yet, it is estimated that there are as many as 70,000 formulations available in the market today. This is a source of tremendous confusion for both the doctors and the patients, since in any case the patients would have little knowledge of what drug has been prescribed to them and even doctors would not easily be able to interpret the prescription of another doctor. It is estimated that as many as 90% of the drugs sold in the market today and consumed by people be the same essential drugs being sold under

It needs to be clearly understood that as little as about 300-400 pharmaceuticals are capable of providing all the useful therapeutic value that any medicine can provide for any type of illness. This is what is really the "essential drugs" list. Yet, it is estimated that there are as many as 70,000 formulations available in the market today.

different brand names, or they may be inessential drugs, or worse, they may even be irrational/unscientific or hazardous drugs.

What then are these other drugs?

Most formulations are brand names given by companies for the same drug.

Another large set of formulations are what are called fixed dose combinations of one or more of the essential drugs amongst themselves or with inessential ones. It must be noted that except for about 10 drug combinations where there is a pharmacologic synergy in combining the drugs in a certain dose, most fixed dose combinations are irrational and inadvisable. This is because dose of each one of drugs in the combination may have to be altered at different rates at different times, or because the combination is with an inessential or even hazardous drug.

Combinations of allopathic drugs with AYUSH drugs, almost all of which are neither tested nor certified, form another major group of irrational drugs.

Another large set of formulations are made of drugs which have no therapeutic value, or have much less value than generic preparation of the active ingredient. A large number of cough syrups, tonics, gripe waters, digestives, energizers and so on are examples of this category. It is worth noting that it was found that of the top 10 selling formulations three were of such combinations - an irrational vitamin combination, a cough syrup and a liver capsule. (ORG Retail Sales Audit, June 1995)

Another large set are basically drugs which are minor and less effective drugs, or more hazardous drugs, or more costly variants of other active drugs available for that purpose. Most of these drugs comprise of antibiotics, vitamins and anti-inflammatory analgesics. There are also, surprisingly, a number of drugs that have been clearly banned by the Drug Control Authority of India, but which still continue to be available in the market and they continue to be prescribed/used. Most of them are there through some weakness in the banning order or some technical device that has been used to contravene the order. But there are also drugs that are in the market illegally - a reflection on the poor state of drug control and regulation.

A list of banned and bannable drugs was published by VHAI in 1986 in the book "Banned and Bannable Drugs: Unbiased drug information, essential drugs and rational drug policy" highlighting these issues and the need for strengthening the regulatory mechanism. This list has been periodically updated- the latest being the 5th updated and revised edition of august 2004.

Types of Irrational Prescriptions

Irrational drug use is not merely an issue of drug manufacturers and drug control. Since almost all drugs consumed are being prescribed, one has to understand why doctors prescribe such drugs. The problem of irrational or inappropriate prescription by doctors, though may be caused by the manipulation of market forces by drug companies, that in its turn it actually contributes to the irrational

drugs being marketed and used. Therefore, the issue of irrational or inappropriate drug prescription must be seen as much larger than the availability of irrational drugs.

Various prescription audits and monitoring and evaluation studies done in India show a wide variety of irrational drug uses that arise from prescription practices adopted by doctors:

- The use of too many medicines prescribed per patient (poly-pharmacy); often these result in cross reactions between different drugs prescribed;
- Inappropriate prescription of antimicrobials, often in inadequate dosage, for non-bacterial infections;
- Over-prescription of injections when oral formulations would be more appropriate;
- Failure to prescribe in accordance with clinical guidelines: wrong choice of drugs, or inadequate dosages, or incorrect frequency of administration of drug or improper duration of therapy, or failure to observe drug contra-indications;
- Under-use of life-extending drugs for illnesses such as hypertension, heart disease, asthma, and other chronic illnesses. Usually these are situations where a small dose of the drug has to be taken in a fixed low periodicity, lifelong;
- Choice of more expensive drugs when less expensive drugs would be equally or more effective;
- Prescription of drugs which have no use - only for their placebo effect or for impressing the patient or for vested interests in the prescribed drugs;
- Inadequate consulting time, very short dispensing time and poor communication of information regarding drugs to patient in verbal or written form leading to incorrect use by patients is of great public health concern too. Worldwide more than 50% of all medicines are prescribed, dispensed, or sold inappropriately, while 50% of patients fail to take them correctly.
- Inappropriate self-medication, often of prescription-only medicines;

Impact of irrational use of medicines: Massive detrimental effects

a) Ineffective treatment leading to serious morbidity and mortality, both in infections and in chronic diseases, such as hypertension, diabetes, epilepsy and mental disorders. This would affect those more who are sicker or who are more vulnerable due to childhood, old age or other morbidities.

b) Iatrogenic diseases - diseases caused by the choice of hazardous drugs or

Definition of rational use of medicines
Patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community. (WHO, 1985).

Irrational or non-rational use is the use of medicines in a way that is not compliant with rational use as defined above.

of the side effects of essential drugs and inessential drugs. As the number of drugs prescribed increases the chances of adverse effects of drugs also increases.

c) Inappropriate use and over-use of medicines leading to high out-of-pocket payments by patients and resulting in significant patient harm in terms of poor patient outcomes and adverse drug reactions and needless and avoidable impoverishment of the patient.

d) Inappropriate use and over-use in the public sector facility, where the government pays the bills, leads to wastage of meager resources, and a shift of funds away from necessary expenditures to unnecessary areas.

e) Availability of too many not needed doubtful medicines in market leads to lack of consistent supply of needed drugs and variation of individual prescribing preferences and inconsistent prescribing leading to numerous prescribing and dispensing errors.

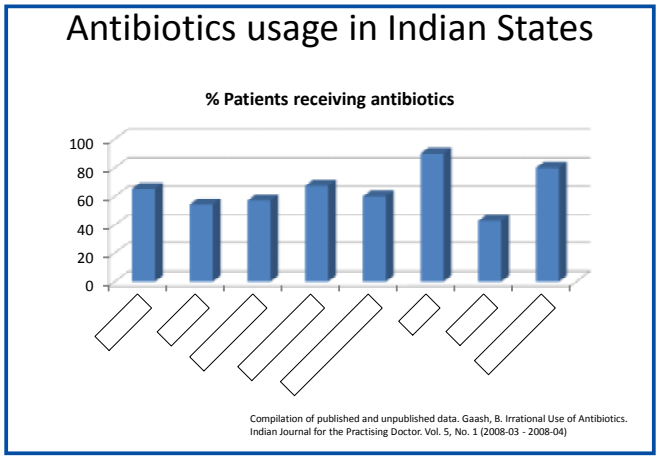
f) Irrational over-use of medicines can stimulate inappropriate patient demand, and lead to reduced access and attendance rates due to medicine stock-outs and loss of patient confidence in the health system.

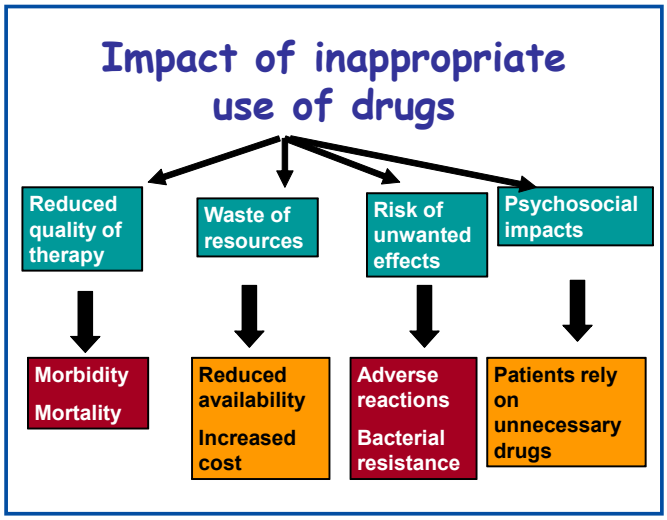
Inappropriate use of antimicrobials is leading to increased antimicrobial resistance. Antimicrobial resistance (AMR) is one of the world's most serious public health problems resulting in prolonged illness and hospitalization,

g) Increasing antimicrobial resistance: Inappropriate use of antimicrobials is leading to increased antimicrobial resistance. Antimicrobial resistance (AMR) is one of the world's most serious public health problems resulting in prolonged illness and hospitalization, which are costly and the use of drugs other than first-line drugs may increase costs 100-fold (see Figure 2) making them unaffordable for many governments and patients, especially in developing countries. Illustratively, cost of treatment of malaria is Rs. 10, and rises to Rs. 210 with quinine and to Rs. 972 for treatment with artesunate. Currently, antimicrobials are the most widely used of drugs in the world, accounting for over one-quarter of hospital drug costs. Utilization studies and prescription audits in various states in India reveal very high use of antibiotics both in outdoor and indoor patients and that antibiotics (with analgesics and antihistamines) were the most commonly used drugs accounting for 50-90% of the drugs prescribed and that 20-50% of antibiotic use is questionable. Currently use of the fluoroquinolone group is much higher than other antibiotic classes.

Development and spread of antimicrobial resistance is due to:

- Overuse, misuse, and irrational use by doctors;
- Non-compliance and self-medication by patients;
- Use in animal husbandry, aquaculture and agriculture.


Antibiotics usage in Indian States
% Patients receiving antibiotics
100
80
60
40
20
0
Compilation of published and unpublished data. Gaash, B. Irrational Use of Antibiotics. Indian Journal for the Practising Doctor. Vol. 5, No. 1 (2008-03 - 2008-04)


Impact of inappropriate use of drugs
Reduced quality of therapy
Waste of resources
Risk of unwanted effects
Psychosocial impacts
Morbidity
Mortality
Reduced availability
Increased cost
Adverse reactions
Bacterial resistance
Patients rely on unnecessary drugs

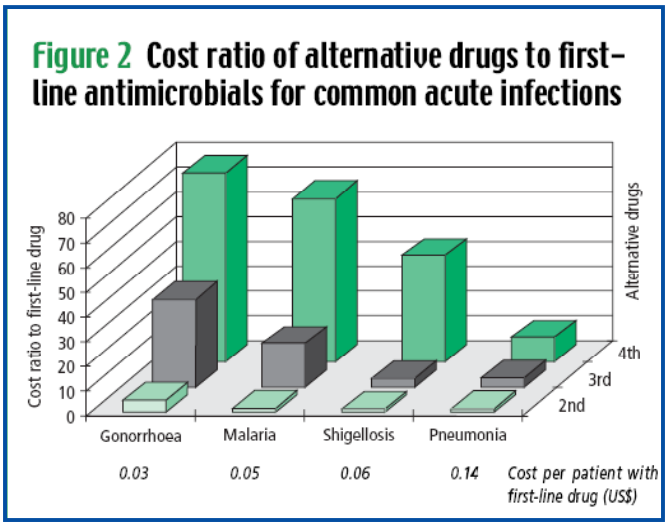


Figure 2 Cost ratio of alternative drugs to first-line antimicrobials for common acute infections
Cost ratio to first-line drug
80
70
60
50
40
30
20
10
0
Alternative drugs
4th
3rd
2nd
Gonorrhoea
Malaria
Shigellosis
Pneumonia
0.03
0.05
0.06
0.14
Cost per patient with first-line drug (US$)

Section–IV

Working towards Rational Use of Medicines

The history of promoting Rational Drug Use (RDU)

The problem of irrational drug use and the need for a rational drug policy came into public discussion in its current form in the 1970s. The Hathi Committee report of 1978 was a significant turning point, alerting not only India but the world to the problem of rational drug use. Another milestone was the Lentin Commission report of inquiry into deaths related to use of spurious medicines. At the international level, the programme to ensure global accessibility to quality assured and affordable medicines, particularly for the poorest among the world population, was initiated by the World Health Organization about 25 years ago. The first Model list of essential medicines of 1977 preceded the famous 1978 Alma Ata Declaration on Health For All and is widely regarded as one of WHO's most influential public health achievements.

The Hathi Committee report of 1978 was a significant turning point, alerting not only India but the world to the problem of rational drug use. Another milestone was the Lentin Commission report of inquiry into deaths related to use of spurious medicines.

By the turn of the century over 150 countries had a national list of essential medicines, and over 100 countries had a national medicines policy. Although initially aimed at the developing countries, the concept of essential medicines is

increasingly seen as relevant for middle- and high-income countries as well. Most medicine budgets in developing countries are below $3per person per year, with 38 countries having less than $2 per person per year. Hence, it is vital that the countries work both to increase drug financing within overall health financing, and to apply the essential medicines concept to achieve the best possible health outcomes within available resources.

Throughout the eighties and nineties, a number of civil society organizations in India like the All India Drug Action Network (AIDAN), and the National Coordination Committee on Drug Policy (NCCDP), the Delhi Society for Promotion of Rational Use of Drugs (DSPRUD) and Health Action International (HAI) played a major role in keeping this issue alive and in the public consciousness.

In the nineties the Tamil Nadu Medical Services Corporation (TNMSC) set a national and international benchmark in the rational use of drugs in the public sector, especially as regards procuring, logistics and capacity-building.

In the nineties the Tamil Nadu Medical Services Corporation (TNMSC) set a national and international benchmark in the rational use of drugs in the public sector, especially as regards procuring, logistics and capacity-building. Indeed the goal of universal access to essential medicines is nearest achievement in this state because of the progressive policies of this unique institution. However as of today despite such sustained efforts a rational drug use policy is not in place in most other states of India.

Twelve core interventions to promote rational use of medicines

The 12 core interventions that would constitute a rational drug use policy are as under:

1. Essential medicines list and drug formulary based on that list
2. Standard Treatment Guidelines
3. Drugs and therapeutics committees in districts and hospitals
4. In-service continuing medical and nursing and pharmacy education
5. Rational drug use in undergraduate curricula
6. Supervision, monitoring, audits
7. Independent prescriber information on medicines
8. Public education about medicines and awareness of essential drug concepts
9. Procurement and logistics within the public health system
10. Appropriate and enforced regulation
11. Sufficient public health and public drug expenditure.

Essential Medicines List

Essential medicines are those that satisfy the priority health-care needs of the population. They are selected with due regard to disease prevalence, evidence on efficacy, safety and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford.

Implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; exactly which medicines are regarded as essential remains the responsibility of states within a national framework.

Essential drugs are neither to be understood as only consisting of life saving drugs nor as medicines for treatment of rare diseases. Essential drugs concept includes all the drugs needed for most commonly encountered diseases including life saving conditions. The concept was mentioned in one of the ten points of the 1978 Alma Ata Declaration on primary health care.

A limited range of carefully selected essential medicines leads to

- better health care
- better drug management and health outcome (including procurement, storage and distribution, and improved quality of prescribed medicines),
- cost effective use of health resources

The availability of and accessibility to essential drugs is so crucial for the correct functioning of the health services that it is in a way a pre-condition for the success of any health reform. Several studies have documented the impact of clinical guidelines and lists of essential medicines on the availability and proper use of medicines within health care systems, for example in Delhi, Tamil Nadu, Orissa, Chhattisgarh. This is even more important in resource-poor settings where the availability of drugs in the public sector is often erratic. Under such circumstances measures to ensure a regular supply of essential medicines will result in real health gains and in increased public confidence in the health services.

No public sector or health insurance system can afford to supply or reimburse all medicines that are available in the market. Therefore, lists of essential medicines also guide the procurement and supply of medicines in the public sector, schemes that reimburse medicine costs, medicine donations, and local medicine production.

Essential drugs have a profound impact on:

Health – Effective drug treatments now exist for most leading infectious diseases as well as leading non-communicable diseases such as diabetes, ischemic heart disease and cancer.

Cost-effectiveness of health expenditure – Since expenditure on medicines represents the largest household expenditure, and public pharmaceutical expenditure is second only to spending on staff costs, by focusing on drug expenditure

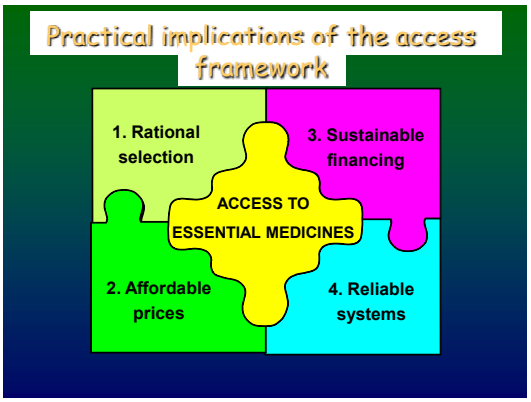
on essential drugs, the cost-effectiveness of government and out-of-pocket drugs expenditure can be enhanced and health impact heightened.

Health system effectiveness – Since essential drugs are high value commodities, their availability draws patients to health facilities, where they can also benefit from preventive services. Moreover, if drug procurement is efficient and transparent, the confidence of government and donors in the country's health system increases, and provision of resources is thereby encouraged.

Considering the diverse nature of India, its population size and socio-cultural characteristics, and as health care is a state matter, each state should have their own State Essential Medicines List (which could be divided into levels of care) and also clinical guidelines both of which must be regularly reviewed and updated. Many Indian States have developed their own respective lists. Delhi State developed its first list in 1994 and is being revised every two years and the last revision took place in 2007.

Key policy issues

1. Access to essential medicines depends on four factors: rational selection; affordable prices for government and consumers; sustainable financing through equitable funding, and reliable health systems.
2. The selection of essential medicines, preferably linked to evidence-based standard clinical guidelines, is a crucial step in ensuring access to health care and in promoting rational use by health professionals and consumers. For this the establishment of systematic, transparent and consultative procedures for defining the national/State list(s) of essential medicines is a must. The selection criteria be explicit based on efficacy, safety, quality, cost (which will vary locally) and cost-effectiveness and it must fit with the standard treatment guidelines.
3. Official adoption of the essential medicines concept identifies priorities for government involvement in the pharmaceutical sector in general, and for medicine supply in the public sector and medicine benefits as part of health insurance in particular.



In addition to the above policy guidelines, following actions are required to be taken:

- Not only should we engage support from medical opinion leaders, senior clinicians, training institutions, professional organizations, but we also need to consider training and sensitization of persons who could explain specific choices or exclusions and who are familiar with the discipline of evidence based decision making. The current trend to follow the authority of the senior-most in this, which retards the process of change, needs to discouraged without disturbing the hierarchy. This could be very difficult to achieve and may require technical assistance. Technical assistance should however not substitute for the process of consultation.
- Make the list of essential medicines, formulary manuals and clinical guidelines widely available in all health care facilities and to all health care providers in both printed and electronic versions. Print it every year and re-distribute it. Copies need to be on every clinical table in the public health system for at least three years in running if it has to make an impact.
- Issuance of enabling government orders for strict implementation in the public sector with provisions for dealing with violations, particularly to ensure use of generic names, and prescription and purchases only from within the list at every level, with powers for exemption being only at the highest level.
- Preparation of separate lists would be needed for different levels of health care (ASHA, sub-centers, PHCs, CHCs, District hospitals and tertiary care) based on local morbidity patterns to be drawn from the main list at the State level.
- Clarification of specific legal or administrative authority of the essential medicines list for - updating including feedbacks, trainings, monitoring implementation, and for public information.
- Consider establishing an administrative or budgetary safety valve for the limited supply and use of non-listed medicines, e.g. by certain specialist units. While tThe hospitals would toned to be instructed to spend 90% of their drug budget on essential drugs only, they could be allowed some flexibility, and especially the tertiary care and super-specialty hospitals could be provided with a discretionary budget of 10% to procure drugs outside the EDL for special situations. This is particularly needed in the initial months, when the concept is poorly understood and there is much resistance.
- Regular review and updation of the essential drugs list and the clinical guidelines every 2 years so that they reflects therapeutic advances, changes in cost, resistance patterns, past experiences and public health relevance. , on the

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basis of monitoring of their use and impact, while frequent and extensive changes must be discouraged.

The governments need to understand the reasons that could lead to failure of essential drugs policy, so that they could be systemically addressed:

- Lack of Credibility and resistance from medical professionals: Doctors would need to be reassured that this it does not restrict professional freedoms. For this processes may be evolved through which professional consensus on good treatment could be built, where the costs of drugs are also, taken into account, and for this professional leaders may be involved.
- Opportunity for pressure groups (pharmaceutical industry) to defeat the endeavor
- Selection is perceived as unrealistic e.g. when sophisticated drugs are ideal but unavailable or unmanageable drugs are listed inappropriately for that level of care. Sometimes this is done deliberately as a way of frustrating the whole plan.
- Lack of a drug formulary accompanying the essential drug list. The drug formulary lists each drug, lists its indications, its doses and formulations, and its side effects and contraindications and interactions with other drugs. This is usually made in the form of a pocket book. One way to do it is to download the WHO drug formulary and then edit out all the drugs which are not in the states essential drug list. The drug formulary is essential to facilitate use of the essential drug list.

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Clinical Guidelines or Standard Treatment Guidelines (STGs) and Formularies

Together with essential medicines lists and drug formularies, Clinical Guidelines, which include Standard Treatment Guidelines, and the prescribing policies, are the most powerful tools for promotion of rational use of medicines. The Clinical Guidelines consist of systematically developed statements to help prescribers make decisions about appropriate treatments for specific clinical conditions. Essential drugs lists, formularies, and Clinical Guidelines are interdependent and should be developed in a systematic way. Guidelines should be developed for each level of care (ranging from paramedical staff in primary health care clinics to specialist doctors in tertiary referral hospitals), based on prevalent clinical conditions and the skills of available prescribers. Their development is also a good opportunity to integrate the technical advice of different disease programmes into an overall training programme.

Key factors for successful implementation of Clinical Guidelines

Evidence-based clinical guidelines are critical to promoting rational use of medicines. Firstly, they provide a benchmark of satisfactory diagnosis and treatment against which comparison of actual treatments can be made. Secondly, they are a proven way to promote more rational use of medicines, subject to the following conditions:

Evidence-based clinical guidelines are critical to promoting rational use of medicines.

- Developed in a participatory way involving end-users, for their acceptance
- Easy to read, for their easier and better use
- Introduced with an official launch, training and wide dissemination
- Reinforced by prescription audit and feedback
- Evidence-based regular updation and treatment recommendations to ensure credibility and acceptance of the guidelines by practitioners
- Sufficient resources are available to meet cost of their development, including compensation/ reimbursements to all those who contribute to the guidelines, and to cover the costs of printing, dissemination and training.

Issues in implementation of Clinical Guidelines

It is pertinent to bear in mind that the development process of the Clinical Guidelines/ Standard Treatment Guidelines itself is more important than the end product, the Guidelines themselves. The most common failure in the implementation of CGs/ STGs is a lack of their credibility and acceptance, due to failure to involve wide range of experts and established institution in the production.

Although standard treatment guidelines need to be tailored to the needs of local health facilities but developing STGs for each level afresh may be an expensive waste of time, effort and money if they are not developed in proper manner: firstly, arriving at a consensus is difficult to manage, secondly, it is difficult to follow time-line, and thirdly, to achieve uniformity in the text with diverse non-sensitized contributors is a challenge. At present about 8 states have their own STGs for different levels of care including Delhi, Himachal Pradesh, Chhattisgarh, Karnataka, Maharashtra etc. A few of the STGs are widely accepted, therefore, instead of everyone developing their own guidelines it would be better to adapt available guidelines according to local needs. Some states such as Gujarat, Rajasthan, Uttaranchal have adapted STGs to their needs using available guidelines and disseminated free copies to all doctors working in the public sector. Some of the widely accepted STGs published are as follows:

i) Comprehensive STGs developed by the Delhi Society for Promotion of Rational Use of Drugs (DSPRUD), first developed in 2002 under India-WHO Essential Drugs Programme, which is in its 3rd edition giving standard treat-

ment approach for more than 320 priority diseases from primary to tertiary care;

ii) STGs developed by Armed Forces Medical College (AFMC, 2007), for 35 common conditions, selected on the basis of prevalent morbidity and across four levels of care. A special feature of this set of STGs is the estimation of costs incurred for providing services as per the STGs. Costs have also been computed for human resources, equipment, tests, medicines and systems. Also an abridged version of the diagnostic and treatment modalities of individual National Disease Control Programmes has been attempted here.

iii) STGs developed by Chhattisgarh for both medical officers and health workers lists an overview of approach to diagnosis for primary and secondary level health facilities. The special feature of these guidelines for health workers is that these are written in Hindi. This has been further developed upon, especially in the paediatrics areas, to produce the STGs for Maharashtra.

The next crucial point in the implementation of STGs is their dissemination. A clear, systematic and realistic distribution plan should be drawn-up so that a personal copy, if possible free of cost, should be made available to all health workers and introduced in pre-service and in-service training programmes. Further it has been observed that dissemination of the guidelines alone does not change practitioners' behaviour, and therefore a multi-faceted approach, including educating the patients, endorsement of guidelines by clinical groups, book reviews in journals and educational inputs at medical colleges (especially focusing on interns) should be arranged to increase acceptance and adherence to the guidelines.

Production & Use of Standard Treatment Guideline (STGs): Delhi Society for Promotion of Rational Use of Drugs (DSPRUD) Experience

STGs for primary health care level were first developed by DSPRUD in 1998 and included the 12 most common diseases in adults and 5 diseases in children.

Based on the experiences gained from the selective guidelines for PHCs, *comprehensive STGs* covering 320 priority diseases for hospitals from 11 clinical specialties were first published in 2002 following a lengthy process of consultation with a wide range of physicians and developed by respected clinicians with technical assistance from WHO. *One publication for all levels served as a complete reference for all recommended treatments.*

Distinctive features:

Simplicity and credibility.

According to various facility levels: These STGs provide treatment choices according to level of the facility starting from the lowest level up to tertiary care along with referral criteria and criteria for assessment of response to treatment.

Patient-education section which provided information on various aspects of treatment to empower the patients, including precautions to be taken by them while on treatment, follow-up duration and interval, advice on prevention, and some do's and don'ts**Linked with essential medicines List and supply of medicines.**

Dissemination: Each doctor in Delhi was provided a personal copy of the manual.

Wide Acceptance: These guidelines have wide acceptance since have been developed by representative multidisciplinary group, recommendations based on scientific evidence and expert opinion, noting areas where either consensus could not be reached or scientific data is sparse. These STGs have now been extensively reviewed and adopted as reflected as government of Gujarat, Rajasthan, Uttarakhand and Department of Family Planning Maharashtra adopted supplied a copy of the STGs to all their doctors in public sector.

Adherence: Initial studies immediately after distribution showed that prescriptions adherence to STGs before dissemination was 31.7% and improved to 46.8% after dissemination in tertiary care hospitals. Most doctors, particularly the junior doctors, welcomed the STGs and reported that they followed the guidelines. The consultants use these guidelines for conditions other than their own specialty.

Process Guidelines: Developed using a participatory approach they helped to create ownership, and acceptance by the prescribers.

Regular update: Third edition brought out in 2009.

Development of Formulary

A government provided Essential Drugs Formulary for providers working in the public health system, provide independent information on all medicines in the List of Essential Medicines. STGs give an overview of treatment approach in the most commonly encountered diseases, but the STGs do not give details of medicine, its dosage, formulation, side effects precautions, contraindications etc, which are essential for deciding on treatment. Therefore, Essential Drugs Formulary serves as a complementary to Standard Treatment Guidelines providing comprehensive information on necessary information on medicines. Some states have taken initiative and developed a Formulary such as Delhi (1997 revised in 2005), Himachal Pradesh and Chhattisgarh. Chhattisgarh developed this formulary by downloading the WHO formulary one essential drugs and then editing out all drugs that were not on the Chhattisgarh list. This formulary also simplified the information, but kept to the design of a small pocket book that could easily fit into the doctors' coat or even trousers pocket- for ease of carrying it and using it. In the field this book was used quite intensively.

Drugs and Therapeutics Committees in districts and hospitals

A drugs and therapeutics committee (DTC), also called a pharmacy and therapeutics committee, is a committee designated to ensure safe and effective use of medicines in the respective hospitals. They have a great potential for the improving drug availability and use. Such committees are well-established in industrial countries as a successful way of promoting more rational, cost-effective use of medicines in hospitals.

DTC has a vital role in improving day-to-day care of patients and serves as an effective strategy for management of hospital formulary thereby having significant impact on the availability and accessibility to essential drugs and use of medicines. To be successful, the DTC should be appropriately located in the organizational structure, be representative of the stakeholders, have stakeholders ownership in the decision making process, use behavioural change models to implement decisions, and enthuse itself to break out of the "regulatory" mode to the "therapeutic leadership" role. Since appropriate medication use in a hospital is a multidisciplinary responsibility that includes representative of all the major specialties, nurses, pharmacists, administrators, support personnel, and patients.. A senior doctor would usually be the chairperson and the chief pharmacist, the secretary. Governments may encourage all district hospitals to have DTCs by making it an accreditation requirement to various professional societies. CHCs with less number of beds may join and 4-5 CHCs may have a common DTC.

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Responsibilities of a Drugs and Therapeutics Committee

1. Developing, adapting, or adopting clinical guidelines for the health institution or district where needed;
2. Selecting cost-effective and safe medicines (hospital/district drug formulary);
3. Promotion of rational use of drugs and implementation of Standard Treatment Guidelines. This includes providing on-going staff education (training and printed materials) and public information on this concept
4. Implementing and evaluating strategies to improve medicine use especially drug use evaluation, prescription audit and liaison with the antibiotic and infection control committees)
5. Controlling access to staff by the pharmaceutical industry with its promotional activities;
6. Monitoring and taking action to prevent adverse drug reactions and medication errors;
7. Providing advice about other drug management issues, such as quality and expenditure.

Along with managerial interventions such as making the lists of essential drugs and efficient procurement and logistics, DTCs can help tremendously in curtailing inappropriate drug use, reducing drug expenditures and increased availability and accessibility to essential medicines thus optimizing the value of limited government funds.

In India even where these committees exist, they are non-functional due to data deficiency, fragmented implementation and lack of operational clarity. Their performance should therefore be monitored and evaluated by their annual work reports on each of the 8 areas identified plus prescription audit report and drug use evaluation report.

Regular continuing in-service education – for doctors, pharmacists and nurses

Doctors: Continuing in-service medical education (CME) is a requirement for licensure of health professionals in many industrialized countries. CME is likely to be more effective if it is problem-based, targeted, personal, and is conducted with involvement of professional societies, universities and the ministry of health/ health departments. Printed materials that are unaccompanied by face-to-face interventions, have been found to be ineffective in changing prescribing behaviour. CME need not be limited only to professional medical or paramedical personnel, but may also include people in the informal sector such as medicine retailers. Often CME activities are heavily dependent on the support of pharmaceutical companies, as public funds are insufficient. This type of CME may not be unbiased**.** Governments should therefore support efforts by university departments and national professional associations to give independent CME. Education is the key to making progress with the prescriber population, therefore such programmes must be organized by the government on regular basis for all health professionals. The impact of training seems to be increased by employing multiple training modalities (lectures, group problem solving, role playing), repeaed sessions, focus on one clinical problem at a time, training at work site and using opinion leaders or district-level staff as trainers.

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Pharmacists: Training of pharmacists should emphasize the rationale of the essential drug list and restricting stocking to these drugs, It should also ensure that pharmacists are trained on effective inventory and stores management including prompt identification and removal of damaged or expired drugs.

An effective inventory management system apart from keeping track of receipts and issues of medical stores for discharge of an accounting responsibility acts as an instrument in improving health care.

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Nurses: Training on EDL and STGs are needed for nurses also: Medication administration errors, particularly in children, can threaten patient outcomes and are a dimension of patient safety directly linked to nursing care. Continuing education of nurses would stimulate the nurses to keep up with new knowledge and technology, to increase their skills and competency, and to be able to contribute to the health care team. DSPRUD has developed a module for training of nurses on rational use of drugs and a comprehensive programme for training of training of nurses has been jointly instituted with Rajasthan by Rajasthan Health Systems Development Project.

Pre-service problem-based training in pharmacotherapy in undergraduate curricula

The quality of basic training in pharmacotherapy for undergraduate medical and paramedical students can significantly influence future prescribing. Rational pharmacotherapy training, linked to clinical guidelines and essential medicines lists, can help to establish good prescribing habits. Training is more successful if it is problem-based, concentrates on common clinical conditions, takes into account students knowledge, attitudes and skills, and is targeted to the students' future prescribing requirements.

Specific exposure to irrational prescription and an understanding of why this takes place despite the teaching of pharmacology needs to be understood by students.

Supervision, Monitoring, Drug Use Evaluation and feedback

Supervision is essential to ensure good quality of care or resource utilization. Supervision that is supportive, educational and face-to-face, will be more effective and better accepted by prescribers than simple inspection and punishment. Drug use studies can be used to monitor and evaluate drug use patterns, identify drug use problems, or to measure the impact of strategies to improve drug use. Prescription audit and feedback consists of analyzing prescription appropriateness and then giving feedback. Prescribers may be told how their prescribing compares with accepted guidelines or with that of their peers through Drugs & Therapeutic Committees. Involving peers in audit and feedback (peer review) is particularly effective.

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Monitoring and evaluation of programme management and implementation should be integrated and programme impact evaluations to be undertaken on a continuous basis.

Indicators used for monitoring drug use

An indicator is a measurable characteristic of actual system performance that determines the extent to which desired outcomes are achieved, or the degree to which guidelines and standard operating procedures are adhered to. Indicators are used to monitor the quality or appropriateness of important clinical and management activities.

Health facility indicators and hospital antimicrobial indicators developed by WHO indicate general trends in prescribing. These are validated, widely tested, easy to use, can be used to compare performance of health facilities from time to time and across different levels and States.[1]

From records of procurement, pharmacy stock, and from patient records we could get:

- Pattern of Consumption of drugs: One could do an ABC or VED, analysis
- Medication error ADR reports
- Antimicrobial resistance surveillance reports

From prescription audits we could get an idea of prescriber specific indicators:

1. Average number of drugs prescribed per prescription
2. % prescription for antibiotics
3. % prescription for injections
4. % prescription for steroids, vitamins
5. % drugs prescribed by generic name
6. % drugs prescribed from Essential Medicine List

From prescription audit and from pharmacy we could get patient care indicators:

- Dispensing time
- % prescribed drugs dispensed
- % drugs prescribed that were unavailable in facility pharmacy
- % drugs prescribed that were clearly unnecessary or inappropriate by STP

1 See - How to Investigate Drug Use in Health Facilities, WHO/DAP/93.1
Managing Drug Supply. Management Sciences for Health in collaboration with WHO, 2nd edition, Kumarian Press, 1997

From pharmacy inventory we could get facility indicators:

- % availability of drugs in the EDL for that facility
- Availability of Essential Medicine List, Formulary at the health facility level

Drug Use Evaluation (DUE)

DUE indicates whether specific diseases are being treated with the correct medicine or whether specific medicines are being given for the correct indications. DUE could also assess which drugs are being used the most and whether this conforms to general pattern of illness.

Independent medicine information

Often, the only information about medicines that practitioners receive is provided by the pharmaceutical industry and this is often biased. Provision of independent and unbiased information is therefore essential.

Drug information centers (DICs) and Drug Bulletins are two useful ways to disseminate such information. Both may be run by government or a university teaching hospital.

Public education about medicines

Governments have a responsibility to ensure both - the quality of medicines and the quality of the information about medicines being available to consumers.

Without sufficient knowledge about the risks and benefits of using medicines and when and how to use them, often people will not get the expected clinical outcomes and may suffer adverse effects. Governments have a responsibility to ensure both - the quality of medicines and the quality of the information about medicines being available to consumers. This will require:

- Ensuring that all medicines are sold with adequate labeling and instructions and product information that are accurate, legible, and easily understood by laypersons. The information should include the medicine name, indications, contra-indications, dosages, drug interactions, and warnings concerning unsafe use or storage. Information should preferably be in the state language.
- Monitoring and regulating advertisements of medicines, which may adversely influence consumers as well as prescribers, and which may occur through television, radio, newspapers and the internet.
- Running targeted public education campaigns, which take into account cultural beliefs and the influence of social factors. Education about the use of medicines may be introduced into the health education component of school curricula or into adult education programmes, such as literacy courses. Post-

ers, leaflets, slogans, films have been developed by various agencies could be used. The focus of public education should be against common irrational beliefs about modern medicine and public pressures for irrational treatment - especially of injections, tonics etc.

Streamlining of Procurement & distribution

- Public sector procurement and distribution of medicines should be limited primarily to those medicines on the EDL, and it must be ensured that only those health workers approved to use certain medicines are actually supplied with them.
- Delays in procurement and poor logistics lead to non-availability of essential medicines thus in turn promote the use of nonessential medicines and irrational prescribing.
- The Tamil Nadu Medical Service Corporation (TNMSC) set up in 1994 is a pioneer in the current drug procurement and distribution system. The strength of TNMSC lies in its centralized drug procurement and distribution system supported by a computerized system of drug management. TNMSC procurement models clearly demonstrates that pooled procurement aimed at quality drugs and a transparent tender system with well defined pre-qualification criteria result not only in substantial reduction in procurement costs (thereby savings) due to economies of scale, but also in a better image and credibility, in addition to enhanced availability of drugs at health facilities. Today the states of Delhi and Kerala also have this model in place and many states are set to follow.
- Computerization simplifies and speeds up the complex tasks, increase accuracy, automate repetitive tasks, update and access information quickly, thus helping management information for decision-making. A linkage with all district warehouses with the state office is one of the features of TNMSC that created decentralized demand estimation but without losing the economies of scale of pooled procurement.
- The most impressive achievement of TNMSC however is with regard to the logistics. Every district always has a minimum of three months stock. Also, each facility has the same stock level. When the stock falls below the minimum threshold level, messages proceed to the district warehouse from the facility and to the state from the district triggering off an immediate supply. This occurs on a weekly basis. Every facility has an entitlement on quantity of drugs in terms of monetary value and a passbook is maintained where this is tracked. Only when the entitlement is exceeded would it go to an authority for approvals for further purchases/supplies.

Public sector procurement and distribution of medicines should be limited primarily to those medicines on the EDL, and it must be ensured that only those health workers approved to use certain medicines are actually supplied with them.

- **Tamil Nadu Medical Service Corporation (TNMSC) model for procurement & Distribution**
- Registered under the Company Act, 1956 on July 1, 1994
- Restricts procurement to drugs on the Essential Medicines List. At present less than 300 items are on the List accounting for 90% of the budget, leaving other drugs of small quantities to be purchased locally by the institutions from out of 10% budget.
- Pre-qualification criteria for manufacturers laid down by the corporation. All procurement is done from manufacturers.
- Established chain of warehouses in the districts with minimum level of stock at all times in order to ensure a regular supply of medicines.
- Each institution provided with an annual budgetary allocation within which it can freely draw drugs from the warehouse.
- Computerization/ Management Information System: There are district warehouses in very district and each district warehouse has a computer linked to the Head Office computer via internet. This innovation of the Government of Tamil Nadu in drug procurement and management has not only improved the availability of drugs in nearly 2000 health facilities but it has also resulted in savings in the outlay on drugs to the extent of 36% of the allocation. In addition, it has improved inventory management and cost control.
- Although, the corporation has been permitted by the government to spend 5% of the annual turnover on its overheads, it is only around 1.5% at present, with a better inventory management, MIS, and improved access to medicines.
- As a result of the confidence in the system and better utilization of drugs, Tamil Nadu has the highest public expenditure on drugs.
- More importantly, the NSSO 60th round shows that in Tamil Nadu per public sector hospitalization a patient spends only Rs 102 on drugs as against the all India average of almost Rs 976 and a figure as high as Rs 3000 in other states – like Rajasthan and Haryana.
- Every study that has been done shows an uninterrupted availability of all drugs in the Tamil Nadu public health sector.

Tamil Nadu: Per public sector hospitalization a patient spends only Rs 102 on drugs as against the all India average of almost Rs 976 and a figure as high as Rs 3000 in other states – like Rajasthan and Haryana.

Appropriate legal regulation and its enforcement

Regulation of the activities of all actors involved in the use of medicines is critical to ensuring rational use. If regulations are to have any effect, they must be enforced, and the regulatory authority must be sufficiently funded and backed up

by the judiciary. Under the Constitution of India both the Centre and the States have concurrent duties for Drug control, for safety and quality and efficacy.

Under the Drugs and Cosmetics Act the regulation of manufacture, sale and distribution of drugs is primarily the concern of the state authorities, while the central authorities are responsible for approval of new drugs, clinical trials in the country, laying down standards for drugs, control over imported drugs, coordination of the state drug control authorities and providing expert advice with the view to bringing about uniformity in enforcement of the Drugs and Cosmetics Act. The central Drugs Standard Control Organization is located in Delhi and functions under the DGHS. Its senior officers are the Drugs Controller-General of India (DCGI) and the deputy drug controllers and technical officers. It has four zonal offices.

In practice, while imported drugs and new drugs are regulated and approved by the Centre , a large majority of drugs are licensed for manufacture, sale and distribution by state agencies, which do not uniformly interpret and implement the law.

Regulatory measures to support rational use:

- Registration of medicines to ensure that only safe efficacious medicines of good quality are available in the market and that unsafe non-efficacious medicine are banned; India should enforce a legislation against the Fixed drug combinations and other clearly irrational, or inessential drugs.
- Limiting prescription of medicines by level of service provider, based on the skills that particular provider is trained for. This includes limiting certain medicines to being available only with a prescription and not available over-the-counter. It would allow new categories of health workers to prescribe drugs they are trained to use.
- Setting educational standards for health professionals and certification standards for health workers and developing and enforcing codes of conduct; this requires the cooperation of professional societies and universities;
- Certification of health professionals doctors, nurses, paramedics to ensure that all practitioners have the necessary competence with regard to diagnosis, prescribing and dispensing;
- Licensing of medicine outlets retail shops, wholesalers to ensure that all supply outlets maintain the necessary stocking and dispensing standards;
- Monitoring and regulating medicine promotion to ensure that it is ethical and unbiased. All promotional claims should be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good

taste. WHOs ethical guidelines (1988) may be used as a basis for developing control measures.

- Need for regulation of multiple aspects of the generic pharmaceutical market, for example by assurance of drug safety, efficacy and quality, reduction of barriers to generic use and providing incentive for use of generics.
- There is an urgent need to enforce the Essential Drugs List in public as well as private medical practice. The Government must take the lead by purchasing generic drugs for hospitals and peripheral health outlets. Private medical setup will either follow or can be made to fall in line through legislation and legal enforcement.
- Financial incentives may strongly promote rational or irrational use. Prescribers who earn money from the sale of medicines (e.g. dispensing doctors), prescribe more medicines, and more expensive medicines, than prescribers who do not. Therefore the health system should be organized so that prescribers do not dispense or sell medicines. Other similar conflict of interest situations like kick-backs on investigations, should also be legally banned and the ban should be monitored.
- Patients prefer medicines that are free or reimbursed. If only essential medicines are provided free by government or reimbursed through insurance, patients will pressure prescribers to prescribe only essential medicines. If medicines are only reimbursed when the prescription conforms to clinical guidelines, there may be an even stronger pressure on prescribers to prescribe rationally.

There is an urgent need to enforce the Essential Drugs List in public as well as private medical practice. The Government must take the lead by purchasing generic drugs for hospitals and peripheral health outlets.

Sufficient government expenditure to ensure availability of medicines and staff

Public expenditure on drugs has generally remained low in India. Of the total value of health sector in India 18 to 22 %, by different estimates, is public financed and per capita expenditure is much less than the recommended US $ 1 per capita on drugs. Further the insurance coverage is minimal. In any case, even the overall public expenditure on health is about 1.2% of the GDP which is well below the average of 2.8$ for low and middle income countries and the global average of 5.5% of the GDP (ICRIER 2001). The public has largely depended on out-of-pocket expenditure, as nearly three quarters of health care, including pharmaceuticals, is obtained from private sources.

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According to the NSSO Consumption expenditure survey, out-of-pocket drug spending is high in lesser developed states such as Orissa (90.56%), Bihar (88.26%), Rajasthan (87.67%), Jammu Kashmir (87.09%) and Himachal Pradesh

(87.14%). In rural areas the share of drugs in total outpatient treatment is 83%, and in urban area it is 77%, whereas share of drugs in inpatient treatment is 56% in the rural and 47% in urban areas.

What is needed is a strengthening of the public health facilities such that they achieve the Indian Public Health Standards in terms of their density, as also the density of public health workforce and in terms of service guarantees for each facility level. This along with increasing the public expenditure on the health sector to 3% of the GDP, and on drugs to at least 1% of the GDP, along with the implementation of a rational drug policy, would be mandatory to achieve the goals of universal access to essential drugs.

Action Points for Promotion of Rational Drug Use

As expenditures on drugs continue to rise and the hazards of unnecessary medication are increasingly recognised, the rational use of medicines movement will continue to grow. Consumers, health practitioners and governments need to ensure optimal therapeutic care. Following action points are recommended:

At the Policy level

- Policy on rational use of drugs
- Policy for provision of free medicines to all patients in all facilities
- Efficient procurement policies; setting up of centralized procurement with efficient distribution system
- Enforce regulation
- Regular monitoring and evaluation of the programme
- Capacity development
- Development of IEC material for patient education

At the State level

- State Essential Medicines List
- Essential Drug Formulary
- Standard Clinical guidelines
- Procurement restricted to medicines on the EML and generics
- Drug Management Information System
- Support to district functionaries - training programmes for doctors, pharmacists, nurses etc.

At the District level

- Active promotion of RDU in all health facilities
- Training programmes
- Prescription audit on annual basis
- Drugs and Therapeutics Committee
- Continuing Medical Education (CME) programmes

At the Health Facility level

- Setting up of Drugs Therapeutic Committees
- Orientation of Rogi Kalyan Samitis
- Inter-personal communication with patients

At the Patient, Community and Public level

- Advocacy materials
- Inter-personal communication with patients
- Social marketing of Rational Use of Drugs through a mass media campaign

Appendix-1

Average medical expenditure (Rs.) for treatment under different heads of treatment during stay at Public Hospitals as inpatient during last 365 days per hospitalisation case receiving treatment - 60th round - Rural

States	Doctor's fee	Diag. test	Other services, bed	Medicine	Blood etc.	Food	Total
Andhra Pradesh	76	72	23	702	30	104	1007
Arunachal Pradesh	0	158	68	805	36	228	1295
Assam	233	280	119	1363	256	142	2393
Bihar	86	871	71	1578	130	342	3078
Chattisgarh	237	43	0	338	0	9	627
Goa	0	19	0	938	0	111	1068
Gujarat	11	179	12	1113	182	186	1683
Haryana	114	327	136	3268	14	123	3982
Himachal Pradesh	8	277	37	2166	95	97	2680
Jammu & Kashmir	36	263	40	1579	61	144	2123
Jharkhand	60	110	60	974	2	214	1420
Karnataka	116	110	20	566	6	91	909
Kerala	36	182	41	497	15	111	882
Madhya Pradesh	34	54	22	933	25	125	1193
Maharashtra	38	23	30	457	73	146	767
Manipur	137	402	6	1756	18	301	2620
Meghalaya	0	19	0	102	0	143	264
Mizoram	0	30	509	26	35		600
Nagaland	10	173	0	2832	0	13	3028
Orissa	107	151	47	1496	40	220	2061
Punjab	176	37	223	1624	45	344	2449
Rajasthan	77	697	59	3187	109	253	4382
Sikkim	2	293	2	1547	76	262	2182
Tamil Nadu	15	20	27	102	1	90	255
Tripura	17	135	61	927	32	148	1320
Uttarakhand	637	282	303	1821	25	499	3567
Uttar Pradesh	411	439	341	1730	117	166	3204
West Bengal	21	180	131	1098	91	87	1608
ALL INDIA	61	175	64	976	55	137	1468

Source: NSSO 60th round (2004)

Appendix-2

CASE STUDY: Delhi Drug Policy

First attempt to introduce an essential drugs programme was made in Delhi State, in 1994. Prior to 1994, the Government of Delhi State was spending 30-35% of the health budget on drugs and yet the situation was dismal with poor availability of good quality drugs and irrational prescribing, leading to huge waste of limited resources on unnecessary drugs. Delhi State Drug Policy seeks to promote equity, improve access to quality drugs at affordable prices and efficiency of the system, and promote rational use of drugs (Roy Chaudhury, 2005).The policy outlined the steps to be taken to implement it Delhi State, which are as follows

1. Selection of an Essential Medicines List
2. Establishment of a pooled procurement system
3. Preparation of a formulary
4. Introduction of a quality assurance system
5. Training in rational prescribing
6. Provision of drug information (to doctors and for patient guidance)
7. Development of standard treatment guidelines
8. Research

9. Monitoring and evaluation
10. Monitoring and regulating of contents of drug advertising and promotion.

The Delhi Society for the Promotion of Rational Use of Drugs (DSPRUD), a non-governmental organization, worked in close collaboration with the Delhi Government and with the participation of universities to implement various policy components. The first Essential Drugs List (EDL) was developed, a centralized pooled procurement system was set up and activities promoting rational use of drugs were initiated. In 1997, the Delhi Programme was designated the INDIA-WHO Essential Drugs Programme by the World Health Organization, Geneva.

As in most health systems, the potential for improving the supply process is tremendous, reflecting in part the magnitude of current inefficiencies and waste. The Delhi model demonstrated the improved availability and accessibility to essential medicines through following interventions and through good governance in the government health care system.

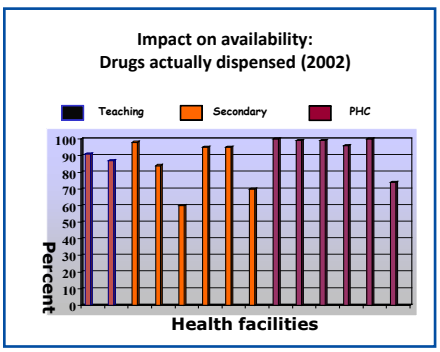
1. Development of an EML was the starting point and is dynamic; regular revisions to keep pace with the therapeutic advances and experiences led to acceptance by the doctors
2. Setting up of a centralized pooled procurement system
3. Basic steps and principles of the pooled procurement system
4. Setting up a centralized Special Purchase Committee
5. Procurement directly from manufacturers by generic name based on competitive bidding through tenders.
6. Pre-qualification of tenders by applying rigid parameters of selection for financial viability and technical competence such as minimum threshold level of turnover, Good Manufacturing Practices (GMP), experience in years of manufacturing the product etc.
7. Objectivity and transparency in the tender process
8. Built-in quality assurance
9. No preferential buying from State-run units
10. Regular training programmes for the doctors, pharmacists and nurses. These training programmes led to a positive change in prescribing behaviour, with more than 80% of prescriptions being from the essential drugs list and patients receiving 70-95% of the drugs prescribed.
11. Development of Standard treatment Guidelines
12. Regular monitoring and evaluation of the programme

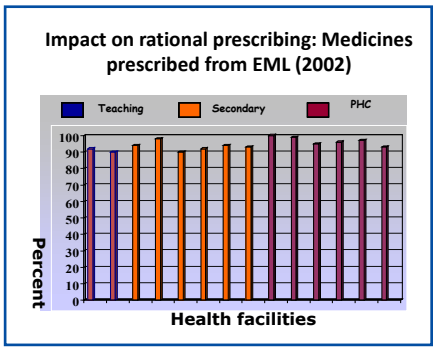
Outcome of the Drug Policy in Delhi

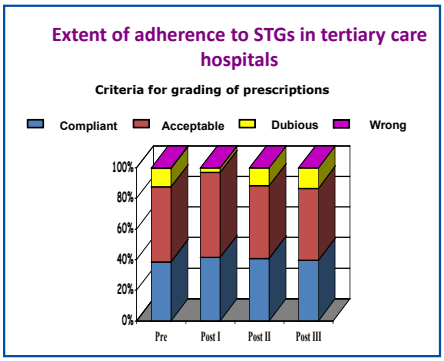
- Improved supply of quality medicines
- Holding down the procurement costs of many of these drugs.
- Savings in annual drug budget (nearly 30%) due to bulk purchasing of carefully selected essential drugs were mobilized for procuring more medicines, which in turn improved their availability (more than 80%) at health facilities.
- Positive change in prescribing by regular training programmes for prescribers led to a positive change in prescribing behaviour, with more than 80% of prescriptions being from the essential drugs list and patients receiving 70-95% of the drugs prescribed.
- Managerial systems change with minimal additional expenditure except for the cost of inspection of pharmaceutical producers for Good Manufacturing Practices.

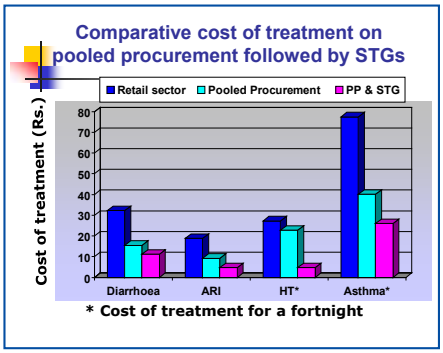
Results of comprehensive surveys using WHO core drug use indicators (prescriber-specific indicators and patient care indicators) in the 100 bed public hospitals from 1997 to 2002.

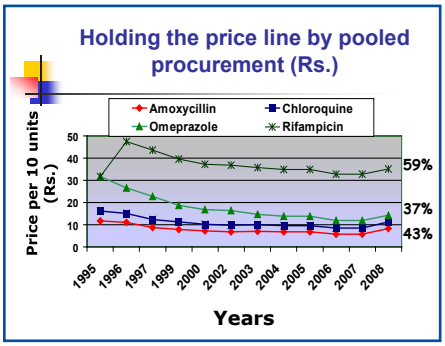
Hospital-out patient	**1997**	**1998**	**2000**	**2002**
Number of facilities included	2	3	3	6
Prescribing indicators				
Average no. of drugs /encounter	2.0	2.5	2.4	2.3
Percent drugs prescribed by generic	11	57	87	49
Percent encounters with antibiotics	18	40	49	51
Percent drugs prescribed from EDL	85	83	99	94
Patient care indicators				
Percent drugs dispensed of the drugs prescribed	16.5	66	97	84
Percent patient having correct knowledge (Daily dose + duration)	NA	31	55	31

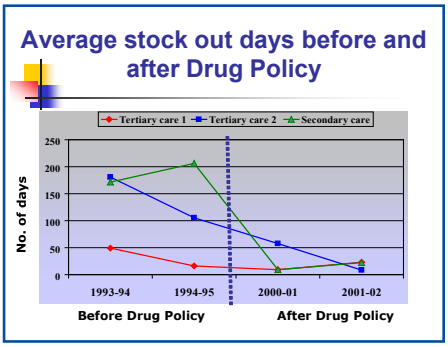












Impact on quality in public facilities: Quality tests (Delhi)

	2000	2001	2002	2003
Total no. of batches tested	1187	2285	2084	2198
Batches not of standard quality	13 (1.09%)	7 (0.30%)	24 (1.15%)	08 (0.36%)
Expenditure of the annual drug budget	0.28%	0.37%	0.34%	0.32%

Factors which determined the success and sustainability of the Essential Drugs Programme in Delhi.

1. Comprehensive programme multifaceted approach.
2. Essential Medicines List was the corner stone complemented by pooled procurement system with inbuilt pre-qualification criteria for quality assurance.
3. Synergy of political will, enlightened bureaucracy, committed technocrats' support and initiatives, financial commitment and clear transparent procedures.
4. Flexibility of operation and innovative moves i.e., establishment of Special Purchase Committee, headed by a non-official member.
5. Committed, motivated, trained government staff.
6. Repeated dialogue with the stakeholders to maintain objectivity in assessment and transparency in the administrative procedures.
7. Building technical capacity with ongoing training programmes, in all sectors related to procurement, distribution, quality assurance and rational use of drugs.
8. A bottom up approach. This approach has been applied by participatory methods in planning and implementation, particularly with prescribers.

The Drug Policy of Delhi has been well accepted and replicated by several other Indian state governments.

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NATIONAL RURAL HEALTH MISSION
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World Health Organization
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Barriers to Rational Use of Medicines

* Demands by Patients
* Inadequate/mis-information of doctors; lack of orientation to issues
* Medical providers-Pharmaceutical nexus
* Inappropriate use of medicines in the community due to financial constraints /lack of access or through self-medication/free availability over-the counter

Overcoming the Barriers Requires

* Provision of generic medicines to the public facilities
* Full supply of free medicines to all patients in all public facilities
* Ensuring prescription of generic medicines in public facilities
* Public information and education

Tools to Ensure Rational Prescribing Practices

1. Essential Drug List
2. Drug Formulary
3. Standard Treatment Guidelines
4. Prescription Audits

The Essential Drug List (EDL) is one that satisfies the priority health care needs of the population with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness. The WHO has created a Model EDL. The DGHS, MOHFW, GOI has a National EDL, last updated 2003. Some States have developed their own EDLs.

The Indian Public Health Standards (IPHS) list medicines for District Hospitals, CHCs, PHCs and Sub-centres.

A Drug Formulary should accompany the EDL. It lists each drug, its indications, doses and formulations, and its side effects, contraindications and interactions with other drugs.

Standard treatment guidelines are necessary for therapeutically effective and economically efficient use of drugs and diagnostics, to decide about drug & equipment supplies, and to assist with adherence to the prescribed treatment.

Standard treatment guidelines (STGs) list the preferred drug and nondrug treatments (including reassurance) for common health problems experienced by people in a specific health system. For each drug it should include the name, dosage form, strength, average dose (pediatric and adult), number of doses per day, and number of days of treatment.

Prescription Audits help monitor the use of STGs and also to show if they require modification or revision according to local needs.

Action Points

1. Drug & Equipment Procurement and Distribution System to be developed/ strengthened on principles of:
   * Local/Facility Need – dependant on disease profile & service utilisation pattern
   * Systems for no stock out
   * Cost and quality considerations
   * Transparency and objectivity in procurement and distribution
2. Drug and Therapeutics Committee to develop & regularly revise the hospital formulary
3. Develop and adopt Standard Treatment Guidelines for important disease conditions
4. Monitor implementation of rational use of medicines through regular Prescription Audits
5. Public Information and Education Campaign about rational use of medicines

Some Resources for Technical Support

Tamil Nadu Medical Services Corporation (TNMSC)
All India Drug Action Network (AIDAN)
National Coordination Committee on Drug Policy (NCCDP)
Delhi Society for Promotion of Rational Use of Drugs (DSPRUD)
Voluntary Health Association of India (VHAI)
Delhi Science Forum (DSF)
Low Cost Standard Therapeutics (LOCOST)
Health Action International (HAI)

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Government of India
New Delhi

World Health Organization
Country Office for India