

**Promoting Rational Drug Use:
The Need for a National Rational Drug Use 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 through 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 accountability 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 misinformation 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.

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 level and 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: Access to Essential Drugs

This depends largely on the manufacture of drugs and its availability in the market- the area of pharmaceutical policy. It also depends on the extent of the public health systems and the adequacy of its provisioning with essential drugs. And finally it depends on the penetration of the private sector and the affordability of drugs in the private sector pharmacy shops. As far as the multiplication of pharmacy shops go, this has increased by leaps and bounds and for the private sector, in most parts, 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 duties for drug control, for safety and quality and efficacy. The two main objectives of India's health policy in the pharmaceutical sector have been to ensure the availability of reasonably priced high quality drugs and to promote the growth and development of a vibrant domestic drug industry. However one notes, that , pharmaceutical policy in India is perceived primarily as an part of industrial policy rather than a health policy (Modifications in Drug Policy,

Comment [DSR1]:

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.

1986), coming under the ministry of chemicals and fertilizers. The focus of pharmaceutical policy thus becomes promoting high growth rates and profitability in this area- a focus that potentially could conflict with the health goals of obtaining universal affordable essential drugs and phasing out irrational drugs. 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 on largely on the density of public health facilities and the density of health human resources deployed in them. It also depends on the proportion of public health expenditure that goes to drug expenditure. Though expenditure on drugs not the largest expenditure but it is 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 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 we would almost all states fall well below this modest benchmark. This 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. Tamil Nadu itself is well below the international norms for this. World Health Organisation recommends a skilled health care provider density of 230 per 100,000 population, an average direct out of pocket payment per hospitalization episode which is nil and a per capita public expenditure on drugs as \$1 or approximately Rs 50.

Section – II: The Affordability of Drugs

Health costs are rising steeply and of these costs the component whose costs rise most steeply and almost invisibly is the cost of drugs.

The rising prices of drugs is a drain on the pockets of the entire population. It affects the poor most. It is estimated that 20 million people each year fall below the poverty line because of indebtedness due to 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 expenditure such as nutrition, housing, education etc. In most poor households, health care is the second highest item of expenditure, second only to food.

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 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, and the increasing costs of treating chronic diseases, the rising incidence and costs of heart disease, and of cancers. Senior citizens are especially at risk for rising drug costs. Drug costs for seniors are rising faster than for any other age group.

The rising price of drugs in the private sector, thus acts through affordability to limit access to the drugs for a majority of the population.

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 the patients who seek care within the public health system. This in turn reflects in increased prescription by doctors of drugs not available in the facility's own stored 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 prices under regulation by the Drug Price Control Order. Even then the list of drugs that were brought under the order were relatively few, and the ways of getting around the order were numerous. With subsequent relaxations of this order, 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.

In most other products the market acts to regulate prices- depending on the costs of raw material, the costs incurred in manufacture and the dynamics of supply and demand. This logic of the market place does not quite apply to drugs. Consumers do not make the choice on which drug to consume- doctors make the decision on their behalf. Doctors seldom know the costs of the drugs they prescribe and are little affected by it. They would have no knowledge of the comparative costs of different brands, making a rational choice difficult. Most drug promotion is based on branding of drugs and promotion through doctors. 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. When the public hospital buys on their behalf considerable control on prices is possible. But when the patient is an individual client facing the market, there is no way that he could make a rational choice given the high degree of what is called "information asymmetry." This is the same set of reasons why so much irrational drug use occurs and we shall see this in the next section.

Generic drugs are less expensive than brand name drugs: Generic drugs can increase availability, affordability and efficient use of medicines. Generic drugs are usually produced when a branded drug loses its patent, approximately 20 years after the drug patent application was registered. Price appears to be the real difference between most brand and generic drugs. Generic drugs are held to the same quality standards for safety and performance as the brand names, yet can sell for 30-80% less. On average, most generic drugs are approximately half the price of their brand name counterparts. Presently, many drug companies are merging, with larger companies acquiring smaller generic companies. These changes have affected the price difference between brand and generic products. Since a company may own both the brand and generic names, it prices the generic at a higher price to discourage sales of the generic. Because of this, people may not get the savings benefits of generic drugs. The use of generic drugs also helps the government use of healthcare budget judiciously, 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	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)
Norfloracin (400 mg.)	4.70	-	1.31	4.60	-	-	4.50	(Ranbaxy)
Cetirizine (10 mg.)	2.50	-	0.27	2.31	0.74	2.10	2.55	-
Ciprofloxacin (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 Manufactured by Different Companies

Manufacturer	Name of different Drugs				
	Nimesulide	Omeprazole	Sparfloxacin	Ciprofloxacin	Cetirizine
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 on the market:

The pharmaceutical industry has witnessed tremendous transformation since the 1950s but at the same time irrational, non-essential and hazardous drugs flooded the market.

Just consider this. All the useful therapeutic value that any medicine can provide for any type of illness is provided by as little as about 300 pharmaceutical formulations. This is the essential drug list. If we include a number of drugs who are safe and efficacious but who duplicate the effects provided by one of these 300 chemicals- we still would have a list as limited as 750 to 1000 drugs. Yet it is estimated that there are 70,000 formulations available in market. This is a source of tremendous confusion. Patients would have little knowledge of what drug has been prescribed to them and even doctors would not be able to interpret the prescription of another

doctor. It is estimated that as many as 90% of the drugs sold and consumed may belong to one or other category or inessential or 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. We note 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 etc are examples of this category. It is worth noting 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 or more hazardous 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, which are still available on the market. 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 there illegally- a reflection on the poor state of drug control.

Types of Irrational Prescription

The problem of irrational drugs is not merely a problem of drug manufacturers and drug control. Since almost all drugs consumed are being prescribed, one has to explain why doctors prescribe such drugs. The problem of irrational or inappropriate prescription is both caused by the situation in the market – but also in itself is a contributor to the chaos of the pharmaceutical market. Also the problem of irrational or inappropriate prescription is much larger than the availability of irrational drugs.

Various prescription audit and monitoring and evaluation studies done in India show a wide variety of irrational use. Common types of irrational medicine use are :

- The use of too many medicines prescribed per patient (poly-pharmacy); Often there are 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.

Comment [DSR2]: A list of banned and bannable drugs was published by VHA 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.

- 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 on a fixed low periodicity, lifelong.
- Inappropriate self-medication, often of prescription-only medicines.
- 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.

Impact of irrational use of medicines: Massive detrimental effects

- 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.
 - Iatrogenic diseases- diseases caused by the choice of hazardous drugs or 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.
 - Inappropriate use and over-use of medicines leading to high out-of-pocket payments by patients and result in significant patient harm in terms of poor patient outcomes and adverse drug reactions and needless and avoidable impoverishment of the patient.
 - 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.
 - 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.
- g) Increasing antimicrobial resistance: Inappropriate use of antimicrobials is leading to increased antimicrobial resistance Antimicrobial resistance (AMR) is one of the worlds 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 (Fig. 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 20-50% of antibiotic use is questionable. Currently use of the fluoroquinolone group is much higher than other antibiotic classes.

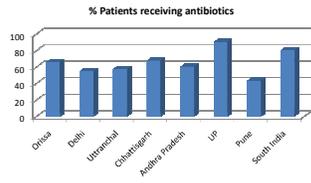
Comment [DSR3]: Definition of rational use of medicines Patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community. (WHO, 1985).

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

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



Completion of published and unpublished data. Graph. 8. Irrational Use of Antibiotics. Indian Journal for the Practising Doctor. Vol. 5, No. 1 (2008-01 - 2008-06)

Impact of inappropriate use of drugs

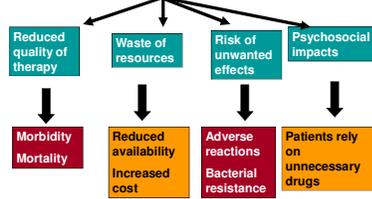
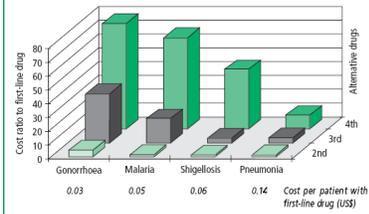


Figure 2 Cost ratio of alternative drugs to first-line antimicrobials for common acute infections



Section: IV: Working towards Rational Use of Medicines

The History of Promoting Rational Drug Use:

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 enquiry 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.

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 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 countries work both to increase drug financing within overall health financing and that they 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 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 set an national and international benchmark in the rational use of drugs in the public sector- especially as regards procuring and 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 states.

We study below as obtains today the 12 core interventions that would constitute a rational drug use policy.

Twelve core interventions to promote more rational use of medicines

1. Essential medicines list and drug formulary based on this.
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, Audit,
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.

I. 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.

Comment [DSR4]: 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](#).

The 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.

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 is in a way a condition for the success of any health reform. 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 Delhi, Tamil nadu, Orissa, Chhattisgarh. All of 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 on 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 exists for most leading infectious diseases as well as leading non-communicable diseases such as diabetes, ischemic heart disease and cancer.

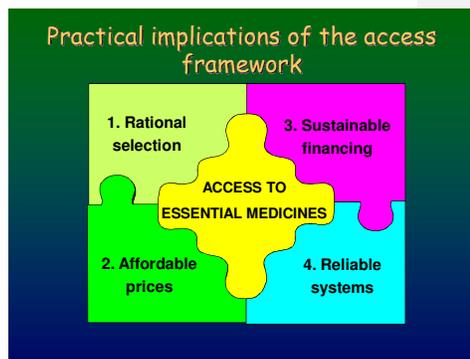
.....**cost-effectiveness of health expenditure** – medicines represents the largest household expenditure, and public pharmaceutical expenditure is second only to spending on staff costs. By focusing on drug expenditure on essential drugs, the cost-effectiveness of government and out-of-pocket drugs expenditure can be enhanced and health impact heightened.

.....**health system effectiveness** – 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 is increased, and provision of resources 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 and that the clinical guidelines and the list be divided into levels of care, and that both are regularly reviewed and updated. Many Indian States have developed their own List. Delhi State developed its first list in 1994 and is being revised every two years and 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 and 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 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 one could note:

- Not only should we engage support from medical opinion leaders, senior clinicians, training institutions, professional organizations, , but we also need to consider persons trained and sensitized to this concept who could explain specific choices or exclusions and who are familiar with the discipline of evidence based decision making. The trend to go on the authority of the senior most needs to be avoided- without losing the support of the seniors! 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.
- Needs to be supported by an enabling government orders for strict implementation in the public sector with provision of dealing with violations. Particularly to use of generic names, and for

purchases only from within the list at every level- with powers for exemption being only at the highest level. All Doctors are required to prescribe only those drugs on the list.

- 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.
- Make clear the specific legal or administrative authority of the essential medicines list for updating including feedbacks, for training, or 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. The hospitals to be instructed to spend 90% of their drug budget on essential drugs only. However, to allow flexibility, tertiary care and super-specialty hospitals to 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.
- Regularly update the list so that it reflects therapeutic advances, changes in cost, resistance patterns, past experiences and public health relevance. A review of the clinical guidelines and the list should be carried out at least every second year, and their use and the impact should be monitored. However, frequent and extensive changes are undesirable.

Reasons for Failure of Essential Drugs Policy

- Lack of credibility and resistance from medical professionals: Reassure doctors that this it does not restrict professional freedoms- but there is a professional consensus on good treatment where the costs of drugs are taken into account. Involve professional stalwarts in this process.
- Opportunity for pressure groups (pharmaceutical industry) to defeat the endeavor.
- Selection is perceived as unrealistic e.g. when sophisticated drugs or 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.

- **//. Clinical Guidelines or Standard Treatment Guidelines (STGs)**

Together with Essential Medicines List and Drug Formularies, Standard Treatment Guidelines are the most powerful tools for promotion of Rational Use of Medicines. Clinical guidelines (standard treatment guidelines, prescribing policies) consist of systematically developed statements to help prescribers make decisions about appropriate treatments for specific clinical conditions. Essential drugs lists, formularies, and standard treatment guidelines are interdependent and should be developed in 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 a good opportunity to integrate the technical advice of different disease programmes into an overall training programme.

Key factors for successful implementation of Standard Treatment 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 provided they are:

- Developed in a participatory way involving end-users
- Easy to read
- Introduced with an official launch, training and wide dissemination
- Reinforced by prescription audit and feedback.
- Evidence-based treatment recommendations and regular updating help to ensure credibility and acceptance of the guidelines by practitioners.
- Sufficient resources are needed to reimburse all those who contribute to the guidelines, and to cover the costs of printing, dissemination and training.

Implementation issues

Development Process is more important than the end product. The most common failure in the implementation of STGs is a lack of 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 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. 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 DSPRUD first developed in 2002 under India-WHO Essential Drugs Programme which is in its 3rd edition giving treatment approach for more than 320 priority diseases from primary to tertiary care;
- ii). STGs developed by Armed Forces Medical College, WR India (2007) for 35 common conditions, selected on the basis of prevalent morbidity and across four levels of care. A special feature is estimation of the costs incurred for providing services as per the STGs. Costs have also been computed for human resources, equipment, tests, medicines and system cost. An abridged version of the diagnostic and treatment modalities of individual National Disease Control Programmes has been attempted.
- iii). STGs developed by Chhattisgarh for both medical officers and health workers lists an overview of approach to diagnosis fro primary and secondary level health facilities. The special feature of Guidelines for health workers is that it is written in hindi. This has been further developed upon, especially in the pediatrics areas, to produce the STGs for Maharashtra.

The next crucial point in its implementation is 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 programme. Further it has been observed that dissemination of guidelines alone does not change practitioners' behaviour, a multi-faceted approach, including educating patients, endorsement of the guidelines by clinical groups, book reviews in journals and educational inputs at medical colleges, (especially focusing on interns) to be arranged to increase acceptance and adherence to 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 in 1998 included the 12 most common diseases in adults and 5 diseases in children. **Strengths:** 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. **One publication for all levels served as a complete reference for all recommended treatments.** **Key features:** simplicity and credibility developed by respected clinicians with technical assistance from WHO; provides 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. **Distinctive features:** patient education section which provided information on various aspects of treatment to empower the patient, precautions to be taken 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. Each doctor in Delhi was provided a personal copy of the manual.

Wide Acceptance: These guidelines have now been extensively reviewed and has wide acceptance 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 STG before dissemination was 31.7% and improved to 46.8% after dissemination in tertiary care hospitals. Most doctors welcomed the STGs and reported to that they follow the guidelines, particularly junior doctors. The consultants use these guidelines for conditions other than their own specialty. **Process** Guidelines developed using a participatory approach helped to create ownership, and acceptance by the prescribers. **Regular update** third edition brought out in 2009.

III. 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 the safe and effective use of medicines in the hospitals. 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. Since appropriate medication use in a hospital is a multidisciplinary responsibility that includes physicians, nurses, pharmacists, administrators,

support personnel, and patients. Therefore,, DTC members should be representative of all the major specialties and the administration. 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.

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.

One problem in India with DTCs is that where these committees exist they are non-functional due to s data deficiency, fragmented implementation and lack of operational clarity. Along with managerial interventions such as making the list of essential drugs and efficient procurement and logistics, , Drugs and Therapeutic Committee (DTCs) can help in curtailing inappropriate drug use, reducing drug expenditures and served to increased availability and accessibility to essential medicines thus optimizing the value of limited government funds.

Their existence should be indicated by their annual work reports on each of the 8 areas identified plus prescription audit report and drug use evaluation report.

IV. 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, involves professional societies, universities and the ministry of health, and is face-to-face. 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 key to making progress with the prescriber population, therefore, such programmes to be organized by the government on regular basis for all health professionals

Pharmacists: Training 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.

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 would stimulate 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 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).

V. 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.

VI. Supervision, Monitoring, Drug Use Evaluation and feedback

Supervision is essential to ensure good quality of care. Supervision that is supportive, educational and face-to-face, will be more effective and better accepted by prescribers than simple inspection and punishment. Effective forms of supervision include prescription audit and feedback, peer review and group processes. 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.

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. 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 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 (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 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:

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.

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

From pharmacy inventory we could get facility indicators:

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)

Indicates whether specific diseases are being treated with the correct medicine or whether specific medicines are being given for the correct indications.

Also could assess which drugs are being used the most and whether this conforms to general pattern of illness.

VII. 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 (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.

A government provided Essential Drugs Formulary or providers working in the public health system, provides independent information on all medicines in the List of Essential Medicines. STGs give an overview of treatment approach in the most commonly encountered diseases. However, 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 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. Also simplified the information, but kept to the design of this as a small pocket book that could easily fit into the doctor's coat or even trouser pocket- for easy of

carrying it and using it. In the field this book was used quite intensively.

VIII. Public education about medicines

Without sufficient knowledge about the risks and benefits of using medicines and when and how to use them, people will often 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 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 advertising, 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. Posters, leaflets, slogans, films have been developed by various agencies and 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.

IX. 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 demonstrate that pooled procurement aimed at quality drugs and a transparent tender system with well defined pre-qualification criteria results not only in substantial reduction in procurement costs (thereby savings) due to economies of scale, but also in a better image, 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, increases accuracy, automates repetitive tasks; updates and accesses 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 decentralizes demand estimation but without losing the economies of scale of pooled procurement.
- The most impressive achievement of TNMSC however is the logistics. Every district has always a minimum of three months stock. Each facility also 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.

• **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 laid down by the corporation for manufacturers. 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 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 also resulted in savings in the outlay on drugs to the extent of 36% of the allocation. In addition, it 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 the 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 120 on drugs- as against the all India average of almost Rs 1100 and a figure as high as Rs 3000 to 4000 in other states.
- Every study that has been done shows an uninterrupted availability of all drugs in the Tamil Nadu public health sector.

X. Appropriate and enforced regulation

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 and laying down standards for drugs, control over imported drugs and coordination of the state drug control authorities and providing expert advice with the view of bringing about the uniformity in the 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 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 medicines 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 the 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. WHO's 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 the use of generics.
- There is an urgent need to enforce the Essential Drug 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 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.

XI. Sufficient government expenditure to ensure availability of medicines and staff

Public expenditure on drugs has generally remained low, Of the total value of health sector in India 18 to 22 % by different estimates is public financed and insurance coverage is minimal. Public expenditure on drugs in India has generally remained low – much less than the recommended US \$ 1 per capita. Overall public expenditure on health is at 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.

According to 60th Consumption expenditure survey (NSSO) 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 the drugs in total outpatient treatment is 83% and 77% in urban area 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 it achieves the Indian public health standards in terms of density of facilities, density of public health workforce and in terms of service guarantees for each facility level. This along with increase 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

At the policy level

- Policy on rational use of drugs
- 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 facility
- Training programmes

- Prescription audit – annual basis
- Drugs and Therapeutics Committee
- CME programmes

At the Health Facility level

- Setting up of Drug and Therapeutic Committees
- Orientation of Rogi Kalyan Samitis
- Interpersonal communication with patients

At the Patient, Community and Public level

- Advocacy materials
- Interpersonal communication with patients
- Social marketing of RUD through a mass media campaign

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 steps to be taken to implement the policy in 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 experience 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

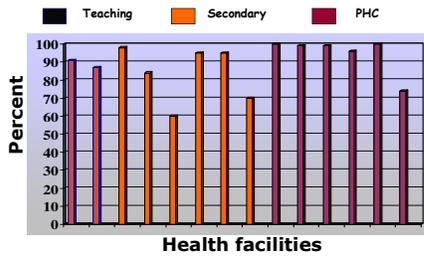
Outcome of the Drug policy

- 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.

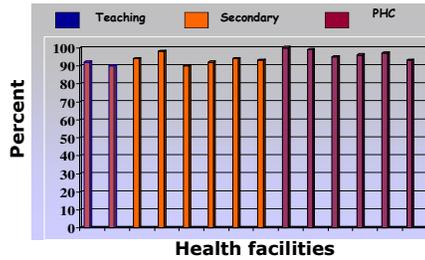
Results of comprehensive surveys using WHO core drug use indicators (prescriber-specific indicators and patient care indicators) in the 100 bed public hospitals from 1997 to 2002.

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

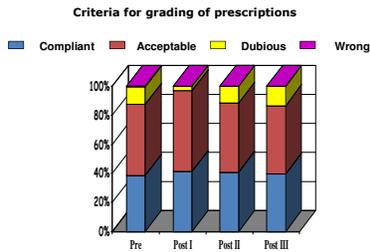
**Impact on availability:
Drugs actually dispensed (2002)**



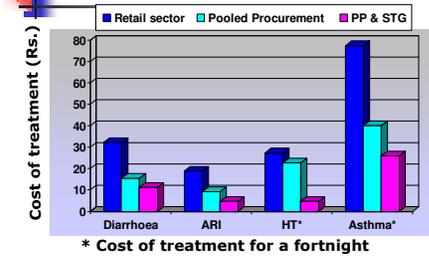
Impact on rational prescribing: Medicines prescribed from EML (2002)



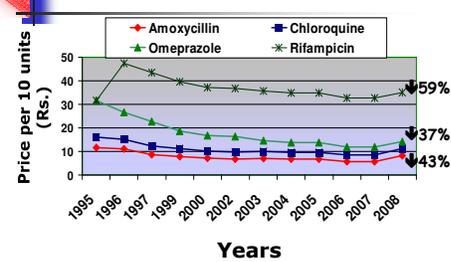
Extent of adherence to STGs in tertiary care hospitals



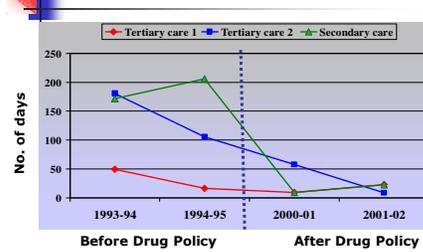
Comparative cost of treatment on pooled procurement followed by STGs



Holding the price line by pooled procurement (Rs.)



Average stock out days before and after Drug Policy



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 bureauocracy, committed technocrats' support and initiatives, financial commitment and clear transparent procedures.
4. Flexibility of operation and innovative moves i.e., the establishment of the 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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