Quality medicines for the poor: experience of the Delhi programme on rational use of drugs

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Prior to 1994, most Delhi hospitals and dispensaries experienced constant shortages of essential medicines. There was erratic prescribing of expensive branded products, frequent complaints about poor drug quality and low patient satisfaction. Delhi took the lead in developing a comprehensive Drug Policy in 1994 and was the only Indian state to have such a comprehensive policy. The policy’s main objective is to improve the availability and accessibility of quality essential drugs for all those in need. 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 universities to implement various components of the policy. 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.

The EDL was developed by a committee consisting of a multidisciplinary group of experts using balanced criteria of efficacy, safety, suitability and cost. The first list contained 250 drugs for hospitals and 100 drugs for dispensaries; the list is revised every 2 years. The pooled procurement system, including the rigorous selection of suppliers with a minimum annual threshold turnover and the introduction of Good Manufacturing Practice inspections, resulted in the supply of good quality drugs and in holding down the procurement costs of many drugs. Bulk purchasing of carefully selected essential drugs was estimated to save nearly 30% of the annual drugs bill for the Government of Delhi, savings which were mobilized for procuring more drugs, which in turn improved availability of drugs (more than 80%) at health facilities. Further, training programmes for prescribers led to a positive change in prescribing behaviour, with more than 80% of prescriptions being from the EDL and patients receiving 70–95% of the drugs prescribed. These changes were achieved by changing managerial systems with minimal additional expenditure. The ‘Delhi Model’ has clearly demonstrated that such a programme can be introduced and implemented and can lead to a better use and availability of medicines.

Key words: quality medicines, rational use of drugs, essential drugs, centralized pooled procurement, standard treatment guidelines, accessibility

Introduction

The programme to ensure global accessibility to quality-assured and affordable medicines, particularly for the poorest, was initiated by the World Health Organization (WHO) about 25 years ago (Hogerzeil 1995). The organization’s policy, based on the concept of essential drugs, tackled the problems of equity of access, efficacy, quality and rational use. Experience from many countries shows different degrees of success in achieving these objectives (Hogerzeil 1995). We know that it is not enough to draft a pharmaceutical reform policy and formulate the changes that are required: we must study how it is to be put into practice and who is likely to be for or against the reforms proposed. Problems of irrational use of drugs and non-availability of drugs in the public sector are often similar in many countries (Laing 1990; Hogerzeil 1995).

Different intervention strategies can be implemented to address the problems. Bangladesh was the first country to put the principles of the essential drugs concept into practice. In 1982, it introduced a strong National Drug Policy (NDP) and promulgated a Drugs (Control) Ordinance to provide the initial legal instruments for its implementation (Chetley and Rohde 1994). The two immediate effects of the NDP were the banning of 1666 products that were useless, ineffective or harmful, and the selection of essential drugs (150 substances) to meet most therapeutic needs in the country, together with a supplementary list of 100 drugs for specialized use. There has been a tremendous change in the nature of the pharmaceutical market in Bangladesh since then, leading to increased production of essential drugs, stable drug pricing and decreasing dependency on imported drugs. In Myanmar,
Essential Drugs Programme, started in 1988, had a tremendous impact on improving the quality of health care at the primary level because of public participation in the health programme – and specifically the programme on rational use of drugs (Myint et al. 1996). The Zimbabwe Essential Drugs Action Programme (ZEDAP) was established in 1986 and excellent training materials, such as Standard Treatment Guidelines (STGs) developed in a participatory way and implemented through an active educational process, led to improved rational use of drugs and stock management, but ZEDAP could not be sustained (Trap et al. 1996).

The success of interventions depends on many factors, including the availability of trained human resources, infrastructure, cultural factors and the socio-economic situation. What is defined as a good solution in one country may not necessarily be as effective in another. However, through international comparisons, countries can benefit from experiences in other countries, even though there is limited information on successful solutions. The objective of this paper is to provide information on the model adopted for improving access to and use of essential medicines in Delhi State, the National Capital State of India.

Central Government of India — essential drugs concept status

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. In spite of advocacy and evidence of the clear benefits of the essential drugs concept (EDC), India was slow to adopt and initiate a comprehensive essential drugs programme. Although much has been achieved over the last two decades, a huge gap remains between the needs for drugs, and their supply and accessibility, especially among poorer populations.

Background on the health sector in India

India’s health care delivery system is divided into four levels of care: rural health centres, district hospitals, tertiary care hospitals and teaching hospitals. Pharmaceutical policy in India is perceived primarily as an industrial policy rather than a health policy (Government of India 1986). Under the Constitution of India both the Central Government and the States have concurrent duties for drug control, for safety and quality and efficacy. Public expenditure on drugs has generally remained low at about US$1 per capita. The public have largely depended on out-of-pocket expenditure, purchasing from chemists and private practitioners. While nearly three-quarters of health care, including drugs, is obtained from private sources, underprivileged populations, often living in remote rural areas, depend largely on public facilities.

Considering the diverse nature of India, its population size and socio-cultural characteristics, and as health care is a state matter, the first attempt to introduce an essential drugs programme was made in Delhi State, the National Capital State of India, in 1994. The objective of this paper is to share the methods and strategies for implementation of the Drug Policy in Delhi State. The following sections give the background to the State health system, the pharmaceutical situation before and after implementation of a drug policy, and finally discuss the factors which, in our experience, could determine the success and sustainability of an essential drugs programme.

Delhi State Public Health System

In 1999, the total population of Delhi was 13 782 976 with an area of 1483 km² (IIPS 2000), a population density of 9294 persons per km², which is the highest in India. Ninety-three percent of the population are urban, and about 35% live in urban slums. The Directorate of Health Services (DHS) is the major government implementing agency covering medical and public health in the State. The total number of hospital beds in Delhi State under the DHS is 4670, of which 330 belong to ayurvedic and homeopathic hospitals (National Capital Territory of Delhi 2002). Bed occupancy rates increased from 75% in 1998–99 to 85% in 2000–01, despite the number of beds increasing by over 50%. The hospital population/bed number ratio is 2.6/1000 for Delhi compared with 0.8/1000 for India in 2000 (National Capital Territory of Delhi 2002).

Pharmaceutical situation in 1994 before the implementation of the Delhi Drug Policy

Prior to 1994 the Government of Delhi State was spending 30–35% of the health budget on drugs and yet the situation was dismal (Chaudhury 1996). In 1994, following the declaration of Delhi as a state, a chaotic situation prevailed, with poor availability of good quality drugs and irrational prescribing leading to huge waste of the limited resources on unnecessary drugs (Essential Drugs Monitor 1994, 1999). Closer examination revealed that a number of problems afflicted State health facilities, including those listed in Box 1.

The Drug Policy for the National Capital Territory of Delhi, approved by the Cabinet, was issued in April 1994. The policy indicated the commitment of the State Government to address the pharmaceutical situation proceeding from the essential drugs concept, giving priority to the government health care system. The policy specified the list of activities to be carried out for its achievement (Essential Drug Monitor 1994, 1999). The Delhi State policy objectives were:

- To make available at all times and at all health facilities safe, effective and good quality essential drugs obtained at competitive prices;
- To promote the rational use of drugs;
- To promote the use of generic names;
- To strengthen health education and research with particular reference to use of medicines.

The policy further outlined steps to be taken for its implementation in Delhi State

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

The India-WHO Essential Drugs Programme is funding the programme and technical activities are implemented by a non-governmental organization (NGO), the Delhi Society for the Promotion of Rational Use of Drugs (DSPRUD). The objective of this paper is to provide information on the impact of the new Drug Policy of Delhi in improving availability and access to essential medicines.

Methods

This paper reports on archives and evaluation undertaken during the implementation of the overall programme. Data were collected as part of routine monitoring activities. Several surveys of drug use were undertaken using WHO standard indicators and methods (WHO 1993). Based on epidemiological data (on drug use, availability, morbidity and mortality patterns) an Essential Drugs List (EDL) was drawn up by a Gazette notified Selection Committee consisting of a multidisciplinary group of experts including administrators, the Drugs Controller, clinicians, pharmacologists and medical superintendents. The WHO Model List, morbidity data and other relevant information from the different levels of care were used as reference material. Delhi State became the first Indian state to prepare an EDL.

The selection involved balancing the cost with consideration of the efficacy, safety and ease of administration of the medicine. A unique feature was that separate lists for inpatients and outpatients were drawn-up to ensure appropriate use. Expensive drugs and drugs to be used under specialist recommendation were denoted separately as ‘Selective Drugs’. Separate lists containing drugs for dispensaries and health centres based on local morbidity patterns were drawn-up from the main list. Doctors were required to prescribe only those drugs on the list. The hospitals in Delhi were instructed to spend 90% of their drug budget on essential drugs only. However, to allow flexibility, hospitals were provided with a discretionary budget of 10% to procure drugs outside the EDL.

Centralized pooled procurement of drugs

A Centralized Procurement Agency (CPA) was set up in the Directorate of Health Services. A high level Special Purchase Committee was constituted to implement the centralized procurement and distribution system. This committee was headed by a non-official member and comprised seven official and three non-official members; the Secretary (Health) was a member. The chairperson of the Essential Drugs Selection Committee is a member of the Special Purchase Committee, to maintain a link and provide coordination between the selection and procurement of medicines. The basic steps and principles of the system are highlighted in Box 2.

The hospitals and other health facilities send their drug requirement to the CPA every 4 months. The CPA places the orders and the manufacturers are required to supply directly to the health facilities within 35 days.

Quality control of drugs

Quality control of drugs was built into the procurement system, including Good Manufacturing Practice inspections.

Box 1. Reasons for the increasing gap in access to drugs in Delhi State

- Many prescribed drugs were unavailable or in short supply, and several unnecessary drugs, irrational combination drugs and traditional medicines of unproven efficacy were procured. As many as 120 of the 300 drugs in one hospital list were unnecessary drugs.
- A consolidated list of essential drugs was not available. Each hospital had its own, often irrational, list. An ABC analysis found that 66 expensive items (21% of all items) consumed 80% of the drug budget, with the 179 lowest-priced items (57%) consuming 5% of the budget.
- The procurement and distribution of drugs was largely ad-hoc. Drugs that could be procured by the tender system were directly purchased from the government retail outlet (Super Bazar) at a very high price.
- There were no regular quality control mechanisms, and frequent complaints about quality occurred. It was estimated that about 15–20% of all drugs were counterfeit and/or substandard.
- Drugs nearing expiry date were supplied, and several drugs reached their expiry date causing wastage of money.
- The doctors were under pressure to prescribe drugs even when these were not needed.
- Medical professionals' prescribing behaviour was unrestrained, often prescribing expensive alternatives. Five to ten percent of prescriptions were found to include the same antibiotic under different brand names.
- Information on drug use provided to patients was grossly inadequate. The average consulting time was 1.5 minutes and average dispensing time was 50 seconds. Only 50% of patients had knowledge of important dosage instructions. Labelling as per WHO requirements was totally absent.
and sample quality testing at reliable laboratories. Box 3 shows the series of steps necessary to ensure quality.

**Promotion of rational use of drugs**
Several training courses (two international and three national) were organized jointly with other government organizations to strengthen the technical knowledge and capacity of a large number of national experts in government, academia and NGOs in various areas, namely drug policies, standard treatment guidelines, an essential drugs list, drug formularies, quality assurance, access to essential drugs and rational drug use. In addition, 25 state-level training courses were conducted in six states of India. These courses focused on how to identify and solve problems related to prescribing, dispensing and consumption of drugs. In order to have state-of-the-art training skills, 14 people attended international training courses organized by WHO. These trainers in turn conducted national and regional training programmes. Aside from the training programmes, these concepts were introduced in medical students’ undergraduate curriculum.

**Preparation of an Essential Drugs Formulary**
In order to provide unbiased information on drugs in the EDL, a sub-committee to the EDL Committee was set up to prepare the Formulary. The British National Formulary was used as a model reference book. A participatory approach was adopted in the write-up, involving experts from outside the Committee. The Essential Drugs Formulary was published in 1997, and provided the following information for each drug: category of drug, indication, cautions, contraindications, side effects, interactions, dosage forms and dosage. An index provided a reference of brand versus generic names.

**Development of standard treatment guidelines**
The Delhi Standard Treatment Guidelines (STGs) for primary health care were developed in 1998 and included the 12 most common diseases in adults and five diseases in children. The STGs were introduced to prescribers working at dispensaries who were also given a number of training sessions. Based on the experience gained from the selective guidelines for

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**Box 3. Quality assurance systems**

- Pre-qualification of tenders by application of rigid parameters of selection.
- Purchasing drugs directly from manufacturers having a minimum annual turnover of Rs. 120 million (US$ 2.66 million).
- Inspection of manufacturing facilities by experts: a panel of 12–15 experienced and highly qualified experts, working in teams of two, to carry out Good Manufacturing Practices inspections as per WHO standards.
- Drawing samples from each consignment and getting these tested at testing laboratories approved by the State Drug Controller.
- Taking action against the manufacturer if a drug sample is found to be below standard quality on testing.
- Random sampling by the State Drugs Controller from drugs on the market.
- In addition, if any doctor has any doubt about the quality of a drug, they can send the sample to the hospital superintendent for quality testing in any recognized testing laboratory.
primary health care, comprehensive STGs, covering 285 priority diseases for hospitals from 11 clinical specialties, were published in 2002 following a lengthy process of consultation with a wide range of physicians. These diseases were identified based on data on morbidity, mortality and national programmes. A total of 71 contributors, representing all levels of health care, were involved in the process. Contributors were sensitized to the essential drugs concept and the role of basic tools, and were provided with guidelines to streamline their contribution. Consensus was reached on inclusion of priority diseases, format and layout. Fifteen external reviewers from premier institutes in Delhi and elsewhere reviewed the STGs.

Unbiased drug information (to doctors and patients)
Promotion of rational prescribing among doctors was complemented by a simultaneous set of activities to inform and educate the public about the salient factors concerning drugs and their optimal use. To start with, information and education were provided using publications, brochures, newsletters, lectures and seminars as well as face-to-face interactions. Over time, both print, electronic media and folk media were employed to carry these messages to the widest possible audience (Essential Drugs Monitor 2001).

Monitoring and evaluation
Monitoring and evaluation of programme management and implementation were integrated and programme impact evaluation was undertaken on a continuous basis. Since 1994, five comprehensive surveys using WHO core indicators were carried out; the first and the fifth surveys were conducted by outside agencies, AF Ferguson and Company and ORG MARG, respectively (Gupta and Sharma 1999; ORG MARG 2002).

Research
Research, particularly that intended to highlight lessons from the operational experiences of the Programme, was all along an important component of policy and its implementation in the State of Delhi. Several research projects were initiated.

Results
Multiple different areas have generated data, which are reported below and include the Essential Drugs List, procurement and prices of drugs, training on promotion of rational use of drugs, tools for training (such as STGs and a formulary), and research and monitoring of the Programme.

Essential Drugs List
The first EDL was drawn up in 1994, based on WHO guidelines. This is a dynamic list and is being revised every 2 years. The last list, prepared in 2003, included 328 drugs for large hospitals and 100 drugs for dispensaries and sub-centres. This was a pioneering activity, dynamic and consensual in nature. It not only led to a reduction in overall expenditure on the procurement of quality drugs, but also to direct benefits for the public by ensuring improved availability of drugs at all facilities. Figure 1 shows that overall, 80% of the essential drugs prescribed were actually dispensed to patients free of charge at various levels of health care, including two teaching institutions, six secondary-level 100-bedded hospitals and six primary-level health facilities (dispensaries). Figure 1. Results of the independent survey by ORG MARG to assess the extent of drugs dispensed free of charge at various levels of public facilities including two teaching hospitals, six 100-bed hospitals and six primary-level health facilities (dispensaries)

Centralized pooled procurement of drugs
After the selection of drugs for procurement, the next crucial issue was the procurement process. The Special Purchase Committee has been adopting a problem-solving approach learning from experience, and decisions have been by consensus. The system has provided transparency and objectivity in the selection of suppliers at all stages, minimized the number of qualified tenders and permitted a dialogue and links between those responsible for drug selection and the end-users. The pre-qualification of tenders ensured a proper basis for assessment of the capability of the manufacturer, based on information on the manufacturing plant environment, marketing equipment, Good Manufacturing Practices followed and technical knowledge.

The centralized pooled procurement system not only ensured good quality supply on a regular basis and held down the procurement costs of many drugs, but also led to a reduction in the procurement costs of some drugs over the 5 years from 1996 to 2000 (Table 1), despite a general rise in retail sector drug prices (unpublished data). Thus, bulk purchasing of carefully selected essential drugs was estimated to have led to a saving of nearly 30% in the annual drugs bill for the Government of Delhi, savings which were mobilized for procuring more drugs. These savings in return improved drug availability and accessibility at health facilities (Figures 1 and 2) (ORG MARG 2002; Chaudhury 2004). This has been achieved by changing managerial systems, with no additional expenditure. Another outstanding feature of the pooled procurement system of Delhi State was the substantially
reduced procurement cost of drugs compared with drugs purchased by other Central Government agencies (Table 2). The other Government agencies procured drugs at prices ranging from 12.7% to 728% (average 118% to 248%) more than the procurement costs under the Delhi State System (unpublished data).

Rigorous selection of the suppliers by pre-qualification criteria and a quality assurance system led to a documented quality failure rate of less than 1%, with an expenditure of only 0.52% of the annual drugs budget. Results prior to the introduction of the procurement system are not available but estimates and results from other states indicate that as many as 20% of samples could fail. In addition, Good Manufacturing Practice inspections were carried out for selected manufacturers who had qualified according to the pre-qualification criteria. The rejection rate of these inspections was 25% (out of 27 firms inspected, 7 were rejected).

The centralized pooled procurement system has been well accepted, with little public criticism. So far no charges of discrimination or corruption have arisen against the Special Purchase Committee. Such accusations normally plague many drug purchasing schemes and have occurred in the different states of India and the Central Government.

Increased drug availability and accessibility have been ensured since the start of the Programme (Tables 3–5, Figure 1). The average number of stock-out days for key drugs decreased from 110 to 24 in the 500-bedded non-teaching tertiary care hospital and from 43 to 31 in other tertiary care hospitals (Bhoi et al. 2004). Figure 2 depicts the availability of key drugs before and after implementation of pooled procurement at one of the tertiary-care specialty hospitals. Independent studies have shown that two of the largest Central Government hospitals in Delhi where there is no Essential Drugs Programme provide only about 20% of the drugs prescribed to patients (Biswas et al. 2000).

Training
A total of nearly 2000 health professionals have been trained on various aspects of essential drugs and the rational use of medicines to date. The principle behind the training has been

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**Table 1. Cost of procurement (Rupees) of some of the essential drugs purchased under the pooled procurement scheme for the Delhi State public health facilities from 1996 to 2000**

<table>
<thead>
<tr>
<th>Sample no.</th>
<th>Drug</th>
<th>Cost of drugs (Rupees), by year</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High unit-cost drugs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Inj Streptokinase 15 Lac vial</td>
<td>1770.00</td>
</tr>
<tr>
<td>2</td>
<td>Inj Cefazidime 1 g vial</td>
<td>187.72</td>
</tr>
<tr>
<td>3</td>
<td>Polymer degraded gelatin bottle</td>
<td>109.00</td>
</tr>
<tr>
<td>4</td>
<td>Sol Amino acid 200 ml bottle</td>
<td>105.00</td>
</tr>
<tr>
<td>5</td>
<td>Inj Hydrocortisone 1 vial</td>
<td>12.94</td>
</tr>
<tr>
<td>6</td>
<td>Inj Heparin 5000 IU/ml amp</td>
<td>36.89</td>
</tr>
<tr>
<td>7</td>
<td>Inj Thiopentone sodium 1 g vial</td>
<td>23.44</td>
</tr>
<tr>
<td><strong>High-volume drugs</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Inj Pentazocine 30 mg amp</td>
<td>4.09</td>
</tr>
<tr>
<td>2</td>
<td>Cap Rifampicin 450 mg</td>
<td>2.92</td>
</tr>
<tr>
<td>3</td>
<td>Cap Omeprazole 20 mg</td>
<td>1.15</td>
</tr>
<tr>
<td>4</td>
<td>Inj Dicyclomine 1 amp</td>
<td>4.36</td>
</tr>
<tr>
<td>5</td>
<td>Inj Diclofenac sodium 1 amp</td>
<td>1.07</td>
</tr>
<tr>
<td>6</td>
<td>Inj Crystalline penicillin 4 Lac unit vial</td>
<td>3.30</td>
</tr>
<tr>
<td>7</td>
<td>Inj Ampicillin 500 mg vial</td>
<td>3.20</td>
</tr>
<tr>
<td>8</td>
<td>Inj Etofylline 1 amp</td>
<td>1.20</td>
</tr>
<tr>
<td>9</td>
<td>Tab Phenobarbitone 60 mg</td>
<td>0.11</td>
</tr>
<tr>
<td>10</td>
<td>Inj Dextrose 5 1 bottle</td>
<td>5.50</td>
</tr>
<tr>
<td>11</td>
<td>Inj Normal saline 1 bottle</td>
<td>5.25</td>
</tr>
</tbody>
</table>

**Notes:** Exchange rate: US$1 = Rs. 43 (as of 2004).
Cost given above is per unit.
n.a. = not applicable, as the drug was excluded from the Essential Drugs List.
training of trainers, who would then be able to repeat the training at state level and in this way it can be cascaded out.

**Standard treatment guidelines**

The STGs are evidence-based, and summarize the data needed to treat patients presenting with common and priority diseases at all health facilities in the State. The STGs include a brief introduction to the disease; important signs, symptoms and diagnostic issues; treatment (non-pharmacological and pharmacological); patient education; and references. The distinctive feature of these guidelines is a patient education section which provides information on various aspects of treatment to empower the patient; topics include precautions to be taken while on treatment, follow-up duration and interval, advice on prevention, and some do’s and don’ts. All the public and private sector doctors in Delhi were given a personal copy of the STGs free of charge and so far about 20,000 copies have been distributed. These guidelines were developed using a participatory approach, which helped to create ownership, and prescribers have largely accepted the guidelines. Overall, the adherence of prescriptions to the STGs before their dissemination was 31.7%, and this improved to 46.8% after dissemination in tertiary care hospitals (Sharma et al. 2004). Most doctors welcomed the STGs and reported that they follow the guidelines, particularly junior doctors. Consultants reported using the guidelines for conditions other than their own specialty. Some of the doctors found the guidelines useful for conditions outside their own specialties.

### Table 2. Comparative procurement cost per unit (Rupees) of selected drugs purchased through Delhi State pooled procurement system (1999–2000) and other government agencies viz open tender by hospitals, government retail outlet (Super Bazar) and government medical supplies depot

<table>
<thead>
<tr>
<th>Sample no.</th>
<th>Drug</th>
<th>Pooled quality procurement by Delhi State</th>
<th>Open tender (Super Bazar)</th>
<th>Govt retail outlet (Super Bazar)</th>
<th>Govt medical supplies depot (MSO)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Syrup Amoxycillin (125 mg)</td>
<td>7.50</td>
<td>14.65 (95)</td>
<td>23.10 (208)</td>
<td>11.45 (53)</td>
</tr>
<tr>
<td>2</td>
<td>Inj Cloxacillin (500 mg)</td>
<td>4.79</td>
<td>8.19 (71)</td>
<td>19.22 (301)</td>
<td>13.50 (181)</td>
</tr>
<tr>
<td>3</td>
<td>Tab Erythromycin, 250 mg</td>
<td>0.15</td>
<td>0.32 (110)</td>
<td>0.37 (144)</td>
<td>0.57 (275)</td>
</tr>
<tr>
<td>4</td>
<td>Syrup Erythromycin (125 mg)</td>
<td>9.80</td>
<td>12.95 (32)</td>
<td>26.10 (166)</td>
<td>20.80 (112)</td>
</tr>
<tr>
<td>5</td>
<td>Inj Amikacin</td>
<td>23.61</td>
<td>47.88 (103)</td>
<td>68.00 (188)</td>
<td>92.85 (293)</td>
</tr>
<tr>
<td>6</td>
<td>Tab Ciprofloxacin 500 mg</td>
<td>0.14</td>
<td>0.18 (36)</td>
<td>0.42 (213)</td>
<td>0.29 (112)</td>
</tr>
<tr>
<td>7</td>
<td>Tab Norfloxacin 500 mg</td>
<td>0.12</td>
<td>0.21 (79)</td>
<td>0.37 (207)</td>
<td>0.40 (235)</td>
</tr>
<tr>
<td>8</td>
<td>Tab Atenolol 50 mg</td>
<td>0.02</td>
<td>0.04 (147)</td>
<td>0.05 (194)</td>
<td>0.05 (224)</td>
</tr>
<tr>
<td>9</td>
<td>Inj Ranitidine (150 mg)</td>
<td>1.63</td>
<td>1.87 (15)</td>
<td>3.80 (135)</td>
<td>4.25 (161)</td>
</tr>
<tr>
<td>10</td>
<td>Inj Diazepam</td>
<td>0.93</td>
<td>5.53 (495)</td>
<td>7.70 (728)</td>
<td>5.20 (459)</td>
</tr>
</tbody>
</table>

**Notes:** Exchange rate: US$1 = Rs. 43 (as of 2004). Cost given above is per unit. Figures in parentheses denote percentage increase in procurement costs of various government procurement agencies compared with Delhi State centralized pooled drug-procurement system.

### Table 3. Monitoring and evaluation: results of comprehensive surveys using WHO core drug-use indicators (prescriber-specific and patient care) in the primary level health facilities (dispensaries) under the Directorate of Health Services, 1998–2002

<table>
<thead>
<tr>
<th>Hospital outpatient</th>
<th>1997</th>
<th>1998</th>
<th>2000</th>
<th>2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of facilities included</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>6</td>
</tr>
</tbody>
</table>

**Prescribing indicators**

- Average no. of drugs/encounter: 2.0, 2.5, 2.4, 2.3
- Drugs prescribed by generic name (%): 11, 57, 87, 49
- Prescriptions with antibiotics (%): 18, 40, 49, 51
- Drugs prescribed from EDL (%) : 85, 83, 99, 94

**Patient care indicators**

- Percentage of drugs dispensed of the drugs prescribed: 16.5, 66, 97, 84
- Percentage of patients having correct knowledge (daily dose + duration) n.a. 31 55 31

**Table 4. Monitoring and evaluation: results of comprehensive surveys using WHO core drug-use indicators (prescriber-specific and patient care) in the primary level health facilities (dispensaries) under the Directorate of Health Services, 1998–2002**

<table>
<thead>
<tr>
<th>PHC outpatient</th>
<th>1998</th>
<th>2000</th>
<th>2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of health facilities included</td>
<td>32</td>
<td>2</td>
<td>6</td>
</tr>
</tbody>
</table>

**Prescribing indicators**

- Average no. of drugs/encounter: 2.4, 2.4, 2.6
- Drugs prescribed by generic name (%): 77, 96, 56
- Prescriptions with antibiotics (%): 77, 96, 56
- Drugs prescribed from EDL (%) : 94, 100, 97

**Patient care indicators**

- Labelling: 0, 0, 0
- Percentage of drugs actually dispensed to the patients: 87, 100, 95
- Percentage of patients having correct knowledge (daily dose + duration): 61, 58, 48

**Table 5. Results of monitoring for various drug use indicators at one of the teaching tertiary-care hospitals in Delhi after implementation of the Drug Policy and the Essential Drugs Programme**

<table>
<thead>
<tr>
<th>Indicators</th>
<th>1995</th>
<th>2000</th>
<th>2002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average no. of drugs prescribed per encounter</td>
<td>2.75</td>
<td>1.64</td>
<td>2.41</td>
</tr>
<tr>
<td>Percentage of drugs prescribed actually dispensed</td>
<td>73</td>
<td>95</td>
<td>91</td>
</tr>
<tr>
<td>Percentage of drugs prescribed by generic name</td>
<td>35</td>
<td>79</td>
<td>43</td>
</tr>
<tr>
<td>Percentage of prescriptions with antibiotics</td>
<td>66</td>
<td>46</td>
<td>44</td>
</tr>
<tr>
<td>Percentage of drugs prescribed from the EDL</td>
<td>77</td>
<td>98</td>
<td>92</td>
</tr>
<tr>
<td>Research project</td>
<td>Intervention</td>
<td>No. of facilities</td>
<td>N per facility</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
<td>-------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>Impact of educational interventions on prescribers (Sharma et al. 2001)</td>
<td>1 day workshop with interactive discussions</td>
<td>39 PHC</td>
<td>30 cases 1170 ARI and 1170 diarrhoea</td>
</tr>
<tr>
<td>Educational intervention – Guide to good prescribing (Bapna and Sharma 1999)</td>
<td>1 day workshop with interactive discussions</td>
<td>20 private practitioners</td>
<td>10 prescriptions each</td>
</tr>
<tr>
<td>Impact of educational interventions on patients (Gupta et al. 2004)</td>
<td>Patient counselling and patient information leaflets</td>
<td>2 hospitals</td>
<td>100 patients each group; exit interviews</td>
</tr>
<tr>
<td>Impact of educational interventions on patients’ knowledge about correct daily dose (Sharma et al. 2001)</td>
<td>Patient information leaflets (PILs) and labelling</td>
<td>1 hospital</td>
<td>100 patient exit interviews</td>
</tr>
<tr>
<td>Impact on cost of treatment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Impact of irrational prescribing on cost of therapy (Gulati et al. 2000)</td>
<td>Introduction of standard treatment guidelines (STGs) in workshop</td>
<td>25 PHC/Polyclinics</td>
<td>30 prescriptions on ARI and diarrhoea</td>
</tr>
<tr>
<td>Impact of irrational prescribing on cost of therapy (Kotwani et al. 2002)</td>
<td>2 educational interventions; face to face</td>
<td>2 teaching hospitals</td>
<td>100 prescriptions on hypertension and asthma</td>
</tr>
</tbody>
</table>
difficult to adopt. External factors such as a lack of organizational support, practice environmental factors (heavy patient load, complexities in clinical presentation), and professional characteristics (seniority and specialist practice) were frequently offered as reasons for non-compliance (Sharma et al. 2004).

Programme monitoring
Prescribing practices have been monitored from time to time to ascertain progress. The results of these surveys are shown in Tables 3 to 5. Table 5 shows the results of drug use indicators in one of the teaching tertiary-care hospitals in the years after implementation of the Drug Policy and the Essential Drugs Programme. The acceptability of the EDL was good, as more than 90% of the drugs prescribed at the various levels of health care were from the EDL (ORG MARG 2002). The average number of drugs prescribed across different levels remained within the optimum range, but patients’ knowledge about drugs was generally low (50%). The rate of prescribing by generic name was low initially (in 1995) but improved in 2000 because of training programmes on promotion of rational drug use. However, it then dropped again in 2002, particularly at tertiary care hospitals.

Research
Several studies have been undertaken to identify and test intervention strategies to improve drug use or to analyze the situation related to prescribing behaviour or practices (Bapna and Sharma 1999; Gupta and Sharma 1999; Gulati et al. 2000; Sharma et al. 2001; Kotwani et al. 2002). Table 6 lists the research studies undertaken. Two effective intervention models (Patient Information Leaflets (PILs) and labelling) for improving patient knowledge about the correct use of drugs prescribed to them have been demonstrated (Sharma et al. 2001; Gupta et al. forthcoming). Table 7 shows the results of one intervention, i.e. packaging and labelling of medicines at the pharmacy before dispensing. Improving the labelling process increased dispensing time but also increased patient knowledge and thus increased the likelihood of compliance at home (Sharma et al. 2001).

Public information and education activities
An effective programme of public information and patient guidance and education, supported by the advocacy effort, reinforced the work in Delhi and provided the momentum for rapid extension to other states. Regular television, radio programmes and panel discussions among different groups of the public were broadcast over the national channels. The Drug Policy of Delhi has been well accepted and duplicated by several other Indian state governments of different political parties.

The Essential Drugs Programme has been recognized by the following: the Working Group on Health Systems Research and Biomedical Research and Development For the Tenth Five-Year Plan (Government of India 2001); the National Health Policy, 2001; the Indian Council for Research on International Economic Relations (Misra et al. 2001); the Working Group on Strategies to Address Unmet Needs for Contraception (National Commission on Population 2002); the Indian Council for Medical Research, Committee of Health Systems Research.

Discussion
Since 1994 in hospitals run by the Government of Delhi, the Essential Drugs Programme has provided good quality medicines to patients. Establishing and using a limited list of carefully selected essential drugs was the cornerstone to improving drug supply management. It is clear that the WHO-India Programme on Essential Drugs adopted by Delhi State has resulted in improved access to drugs for poor people at all the state health facilities; ensured procurement of only safe, effective and quality-assured drugs; successfully kept down the cost of drug procurement by holding the cost-price line for most drugs; and in the case of certain items, substantially lowered the cost compared with previous years, resulting in a marked reduction in the cost of therapy for a number of diseases. The Programme has been continuously monitored since it was initiated. Its early success was maintained through 2000, 2001 and 2002. Attendance at outpatient departments in public health facilities increased from 6.5 million in 1998/1999 to 12.5 million in 2000/2001, indicating increased use of services – although some of this could be explained by the increase in Delhi’s population from 9.5 million in 1991 to 17.8 million in 2001.

Reviews of the Programme have been carried out regularly. The latest in-depth external review occurred in 2002 and was undertaken by WHO, Geneva, after 5 years of implementation of the INDIA-WHO Essential Drugs Programme. The evaluation (Euro Health Consultants 2002) went into great detail and concluded:

The impact in Delhi State hospitals and clinics is self-evident to anyone who visits these places. The basic elements of the EDP have been developed and are implemented or being implemented. The administrators are convinced about the merits of the system and the need to protect it; the doctors in the hospitals are happy about the availability of drugs and are mainly prescribing essential

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Table 7. Patient care indicators at a tertiary-care specialty hospital before and after intervention, i.e. proper packaging of the drugs dispensed and labelling with intended patient’s name, drugs name, dose, frequency and duration, in local language

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Pre-intervention</th>
<th>Post-intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average consulting time (min)</td>
<td>47.98</td>
<td>45.00</td>
</tr>
<tr>
<td>Average dispensing time (sec)</td>
<td>25.40</td>
<td>114.40</td>
</tr>
<tr>
<td>Average no. of drugs</td>
<td>2.20</td>
<td>2.50</td>
</tr>
<tr>
<td>prescribed per prescription</td>
<td>71.64</td>
<td>77.92</td>
</tr>
<tr>
<td>Percentage of drugs actually</td>
<td></td>
<td></td>
</tr>
<tr>
<td>dispensed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percentage of drugs properly</td>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>labelled</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percentage of patients having</td>
<td>57.70</td>
<td>96.60</td>
</tr>
<tr>
<td>correct knowledge of drugs</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
and in its own circumstances to find solutions and answers to problems and priorities in health, and is trying in its own ways now spread to 14 other states in India. Each state has its own...

**Box 4. Factors that determined the success and sustainability of the Essential Drugs Programme in Delhi**

- **Identification of a highly motivated core group.** The difference between success and failure has been the availability of a few dedicated persons and powerful people who interface between the political leadership, the bureaucracy and a number of highly motivated health professionals and experts. Funding and employment of staff to undertake this challenging task was unnecessary as all (the many) inputs were undertaken on a voluntary basis without remuneration.

- **Flexibility of operation and innovative moves, i.e. the establishment of the Special Purchase Committee, headed by a non-official member.** The Government of Delhi showed remarkable flexibility in practical terms by giving all authority regarding purchase to a non-official from the start of the Programme. However, to give the committee statutory authority, senior officers of the departments of law and finance were members. This innovative leadership is unique, and is largely responsible for the successful procurement programme.

- **Committed and motivated government staff.** The change in the system incurred little cost to the Programme because the government functionaries who were already carrying out procurement implemented this new Programme. Procurement procedures were clearly specified and closely followed. The change in mind-set and technical training of the staff in good procurement practices were important factors in the Programme’s success.

- **Repeated dialogue with the stakeholders.** Objectivity in assessment and transparency in the administrative procedures were maintained. Unsuccessful bidders were informed of the reasons for disqualification.

- **Building technical capacity.** As a result of the ongoing training programmes, a large number of experts are now available in all sectors related to procurement, distribution, quality assurance and rational use of drugs. Further, technical expertise in monitoring and research of the Programme on Rational Use of Drugs could also be applied to any other programme.

- **A “bottom up” approach.** This approach has been applied by participatory methods in planning and implementation, particularly with prescribers.

When the Programme was announced there was widespread scepticism over whether it would work, and resentment from doctors that their freedom to prescribe any drug would be curtailed. A change in the attitude of physicians and prescribers to therapeutic and economic rationalization was crucial and was brought about by training programmes on promotion of rational use of drugs and repeated dialogue with doctors at every hospital. The political will in developing the policy, the role of enlightened bureaucrats in providing the managerial framework, along with the support of the committed experts in the field of rational use of drugs, were responsible for the success. Further, the willingness of WHO, Geneva, to take risks and work closely with an NGO for effective and efficient implementation of innovative approaches was crucial for the EDP to take off in Delhi State. Box 4 illustrates the factors that determined the success and sustainability of the Essential Drugs Programme.

However, some components of the Essential Drugs Programme could not be sustained, and the success of others was limited by a number of factors, as detailed in Box 5.

A unique feature of the Programme is its opportunity-based approach. The WHO-India Essential Drugs Programme has now spread to 14 other states in India. Each state has its own problems and priorities in health, and is trying in its own ways and in its own circumstances to find solutions and answers to the question of how to provide medicines to all – either free or at affordable prices. In some states, it is possible to establish a comprehensive programme in line with Delhi State, while others have managed implementation of a few basic components such as an EDL and STGs only. The approach adopted by many states – implementation of a programme in any of the areas considered to be a priority of the state – has worked well, and therefore it is not necessary to wait for a state drug policy to be developed. In one state, implementation of the State Drug Policy was delayed for 2 years, even though there was agreement on most aspects of it, because the new Drug Policy envisaged setting up an independent corporation for procurement. This delay could have been avoided if other components of the policy, such as the EDL, STGs and rational use of drugs, could have been initiated while the more controversial aspects were debated.

In several Indian states the ‘Delhi Model’ is being emulated in a similar way, through the formation of societies which work in close collaboration with the government. The many advantages of having a society working closely with the government include freedom from bureaucratic regulation and speed of implementation.

The success of the Delhi Model so far has been due largely to its comprehensive nature and multi-faceted approach. In several programmes in other countries, one or more of these components has been missing, making it difficult to sustain a successful programme. Under the Myanmar Essential Drugs Programme (MEDP), health workers were trained to estimate the requirements of drug needs using morbidity-based methodology that not only facilitated procurement of adequate amounts of drugs, but also prevented the earlier experiences of acute shortages of essential items with unnecessary accumulation of non-essential drugs. Community participation in...
health care was a special feature of the EDP in Myanmar. Although the MEDP has implemented several successful components, it does not have a good quality assurance programme and has limited training of doctors in rational prescribing (Myint et al. 1996).

The Zimbabwe Essential Drugs Action Programme (ZEDAP) was comprehensive in nature and addressed all the problems and issues related to selection, quantification, procurement, management systems, prescribing, utilization and quality assurance. Excellent tools for training, such as STGs developed in a participatory way and implemented through an active educational process, led to improved rational use of drugs (Laing and Ruredzo 1989). However, EDAP surveys showed that this very encouraging trend could not be sustained beyond 1991/92 because of a cumulative shortfall in foreign exchange allocation, which led to a drug supply crisis. Training activities could not be sustained and also quality control and the distribution system were poor; as a result, overall outcome and impact were not sustained (Trap et al. 1996).

The cost of providing better information to prescribers – dissemination of the therapeutic formulary, therapeutic guidelines, essential drugs list, newsletters etc. – can be considerable and there are problems with the sustainability of such activities. When these occur in isolation, their efficacy appears very low. However, when combined with several approaches, such as training in problem-solving, they have been documented to be more successful, especially in developing countries (WHO 1996).

The economic crisis in Thailand provided an impetus for more rational use of drugs in 1989 (Kornkasem et al. 1996). Several components were strictly implemented, including pruning the List of Essential Drugs, restricting prescribing to these limited medicines and reimbursing only those entitled to this benefit. Thailand has also introduced an innovative system known as the 30 Baht Scheme as a measure towards an insurance system for obtaining medicines. People pay 30 Baht to become part of this programme and they receive the medicines they need from hospitals when they are ill. The government then reimburses the hospital for the expense incurred by the hospital within the rules of the system. This policy was strictly implemented in all government health care facilities and resulted in a massive reduction in expenditure on medicines in the country. It also helped in strengthening other relevant activities, such as drug procurement, information on a limited number of drugs as well as drug production and importation. However, this system certainly needs careful study by other countries in the region. In 1992, it was reported that only between 50 and 60% of the drugs budget was used on essential drugs. The reason for this breach was that the EDL was outdated and there was no strict monitoring or control system on drug procurement (Kornkasem et al. 1996).

The essential drugs programme in Bangladesh was introduced by decree and, with a change of government in 1990, support for the programme decreased; the medical association and the industry saw the chance to revise the National Drug Policy (Chetley and Rohde 1994). However, in the case of the Delhi Programme, the aims and objectives of the Programme continued even when there was change in government, largely due to transparency in the system, a participatory approach and visible benefits in terms of availability and accessibility to quality medicines. Moreover, it is important to inform people who are outside the health sector through advocacy efforts, because such programmes can be amended or misinterpreted by people who are not aware of the health implications.

In the Philippines, before the Generic Act of 1988 came into force, all drug products were labelled with brand names. The law mandates the use of generic names in all private and government medicine transactions, i.e. labelling of drug products, advertising, prescribing and dispensing. Several strategies were actively enforced, such as education and

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**Box 5. Programme components which could not be sustained and factors which limited success**

- Independent Good Manufacturing Practice inspections could not be sustained for all selected vendors because of a lack of funds.
- Although availability of drugs at facilities has increased and is more than 80% in most health facilities, occasional stockouts of shorter duration have been noticed because of a lack of quantification of drug needs on a scientific basis or because of some problems at the management level within the health facility.
- Lack of control over budget spent outside the EDL in terms of the nature of the drugs and the amount spent on non-essential drugs. On some occasions, particularly at the tertiary care hospitals, the budgetary limit of 10% for procurement of drugs outside the EDL was exceeded. This could be partly due to delayed allocation of the annual budget.
- Although several training programmes were organized, these were not sufficient to sensitize all doctors – largely because Delhi, as the capital, has many doctors (especially junior residents) migrating there from other states every year. To combat this, induction training programmes are being organized at the beginning of the internship period. The concepts of essential drugs and rational use of drugs have been incorporated in the undergraduate curriculum but they are not yet linked to the examination system.
- Misuse of essential drugs – antibiotic use is still high and prescribing by generic name is low in some health facilities.
- Although a successful model for improving patients’ knowledge has been demonstrated, this has not been incorporated in all hospitals. The number of patients with adequate knowledge about drugs is still very low.
regulation, which proved to be effective. However, there was some regression in 1992 (Carandang 1999). In 1995, compliance was 80% in government hospitals and 42% in private hospitals. There was still opposition from groups whose interests were threatened by the implementation. Prescribers were noted to be more resistant to compliance with the law because they were not involved in the formulation of the Drug Policy (Carandang 1999). The importance of involving doctors in planning and implementation cannot be over-emphasized; a large part of the success of the Delhi Model can be attributed to involving doctors in the Programme. If a programme is implemented only from the top, there will be no sustainability, as shown by the experience in both the Philippines and Bangladesh, which demonstrate that without the involvement of all stakeholders, such programmes do not last.

Conclusions

The availability of and access to essential drugs are crucial for the optimal functioning of health services and are conditions for the success of any programme. There are possibilities for significant savings in most areas of drug supply management and use. Rationalization measures can help to lower costs, which in turn result in prices that are affordable for a larger proportion of the population. The biggest gains from the Delhi Model appear to have come from the wise selection of drugs and adoption of a better procurement system. The Essential Drugs Programme is relevant to other health programmes as well, and results not only in better use of resources but also in better practice of medicine. It addresses several other issues such as good therapeutics and reduced side-effects of medicines, and saves money for individuals, hospitals, health care providers and the country.

References


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