Health: Strict Liability, Torts, & Legal Quacks

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Functions

The primary objective of the Department of Health and Family Welfare of the Delhi government and other civic agencies is to provide medical and health care through hospitals and public health centres and to protect citizens against food and drug adulteration.

Findings

- Hospital bed density of 2.2 per thousand people. The WHO standard is 5 per thousand. Occupancy rate of three patients per bed. The doctor:patient ratio was 1:598 as of 2001.
- Average annual expenditure of Rs 211.21 crore which amounts to 7.60% of the state budget
- 29 drug inspectors to inspect over 5,000 drug retailers. Flourishing fake drug market worth more than Rs 4,000 crore.
- 28 inspectors to inspect over 1.50 lac (registered) food establishments. According to the Director, Prevention of Food Adulteration Department (PFA), if one inspector was to visit one shop in a day, the shop would be visited again after 17 years. The number of inspectors has remained the same since 1960.
- In a period of five years (from 1994-1999), the PFA Department collected 4,485 samples out of which 607 (13.5%) were found to be adulterated. The Department initiated prosecution in 557 cases and courts settled 467 cases. The rate of conviction was 44% and the rate of acquittal was 29%. The courts, acting on the reports of Central Food Laboratory, Kolkata, discharged a 27% of the cases. During this five-year period, the average percentage of coverage (number of outlets inspected as a percentage of total number of outlets) was 0.6%.

Reforms

- Increase the number of consumer courts where patients can seek legal remedy for malpractice of hospitals and medical practitioners. Along with manufacturers, hold wholesalers, and retailers liable.
- Currently PFA and Drug Control Department (DCD) treat violations as criminal offenses where the degree of evidence required is 'beyond a reasonable doubt.' These violations should be first tried as civil offense under the tort system, which needs a lower degree of evidence, 'the preponderance of evidence.' The threat of financial liability would be a better deterrent than the current low probability of criminal prosecution. Monetary fines would also provide restitution to the victims who get no compensation under criminal prosecution.
- Increase the supply of doctors by devising a system where college graduates with 2 years of training can treat common diseases. More than 90% of the cases in India are of waterborne diseases and require a small pool of medicines in various combinations. A brief but rigorous training would be sufficient to deal with these diseases. Those operating illegally--quacks--can also be brought into this new training system. Against 26,000 legal practitioners, 40,000 quacks work in Delhi . Simply banning them will not solve the problem of people who cannot afford to pay fees of regular doctors.

- Increase transparency in the process of procurement of drugs and all other equipment by putting up the tenders, all submitted bids, and the finally selected bid with details of the procurement on the website of the Department and hospitals.
- The Delhi Medical Council should maintain a 24-hour helpline where customers' complaints about doctors and hospitals are recorded. These complaints, categorised by the name of the hospital and the doctor, should be immediately put up on its website, with a caveat that it is preliminary information and the investigation is pending.
- A False Claims Act (or *Quit Tam* Act) would allow anyone to bring a lawsuit or provide information on any supplier of goods or services to the government who makes 'false claims' about quality or quantity of the supplies.

The health care facilities in Delhi are provided by a multiplicity of government agencies, and for-profit and non-profit private groups.

Table 1: Agency-wise Distribution of Services

Institutions	Delhi Government	Municipal Corporation of Delhi	New Delhi Municipal Council
Hospitals	25	15	2
Hospital Beds	5,391	3,565	200
Dispensaries	362	294	45
Maternity and Child Welfare Centres	-	109	12
Primary Health Centre	-	5	-

Source: Government of NCT Delhi. 2003. Annual Plan 2003-04. Department of Planning

Department of Health and Family Welfare

In addition to the number of hospitals, following institutions also function under this Department:

1. Directorate of Health Services
2. Directorate of Family Welfare
3. Drug Control Department
4. Department of Prevention of Food Adulteration
5. Directorate of Indian System of Medicine and Homeopathy (ISM & H)
6. Institute of Human Behaviour and Allied Sciences (IHBAS)
7. Centralised Accident Trauma Services (CATS)
8. *Indraprastha Vyabsaik* and *Paryavarniya Swasthya Samiti* (IVPSS)
9. Delhi State Aids Control Society (DSACS)
10. Delhi *Tapedik Unmulan Samiti* (DTUS)

Directorate of Health Services (DHS)

Directorate of Health Services is the nodal agency among the health care providers of Delhi government. It is responsible for establishment of hospitals and dispensaries, implementation of various national and state programs related to medical and public health, health care and prevention of disease, and control and eradication of major diseases. Hospitals with an in-patient capacity of 100 or less beds also come under DHS. Number of health delivery institutions under Health and Family Welfare Department/ Directorate of Health Services are shown in Table 2.

Table 3 gives the information about the physical targets and achievements of the during the Ninth Five Year Plan.

Table 2: Number of Beds and Hospitals

Name of the Institution	*Numbers of Institutions*	*Number of beds*
Hospitals (all types)	67	19,287
Dispensaries	937	-
Primary Health Centers	8	79
Sub Centers attached to PHC	48	-
Maternity Homes	31	321
Poly Clinics	4	-
Private Nursing Homes	493	10,980
Total (all institutions)	1,588	30,667

Source: Government of NCT Delhi. 2003. Annual Plan 2003-04. Department of Planning

Table 3: Targets and Achievements

Name of the scheme	**NFYP Targets**	**NFYP Achievements**
Opening of health centres	100	36
Opening of homeopathic dispensaries	25	13
Opening of ISM & H dispensaries	20	12
Opening of *Unani* dispensaries	20	7

Source: Government of NCT Delhi. 2003. Annual Plan 2003-04: Physical Targets and Achievements Vol. 4. Department of Planning

NFYP: Ninth Five Year Plan

Directorate of Family Welfare

Directorate of Family Welfare was established in October 1966 to coordinate family welfare activities implemented by various agencies.

The Directorate is responsible for providing services like sterilisation, oral pills, condoms and other family planning tools. The immunisation programme targets vaccine-preventable diseases like polio, diphtheria, pertussis, tetanus, tuberculosis and measles. It is also responsible for the enforcement of Medical Termination of Pregnancy Act, 1971 and the Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994. It also conducts 'Health and Family Welfare Training Programme' for sensitising various categories of health personnel on the various programmes of the Delhi government and Government of India. It is also responsible for the implementation of Reproductive and Child Health Programme.

Department of Drug Control

The Drug Control Department of Delhi government enforces the provisions of following statutes, enacted by Government of India:

1. Drugs and Cosmetics Act, 1940
2. Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954
3. Drugs (Prices Control) Order, 1995

Besides, the Drugs Control Department (DCD) also carries out the following activities:

1. Advises a new entrepreneur regarding requirements of premises, location, plant and machinery for setting up a factory for manufacture of drugs/ cosmetics.
2. Allocates narcotic drugs to the licensed drugs manufacturing units

3. Carries out surveys to find out availability of essential drugs in the market and communicates details of shortage, if any, to the National Pharmaceutical Pricing Authority, Ministry of Chemicals and Fertilisers, Government of India, every month, for follow-up action.

Performance

- Extremely poor infrastructure
- Lack of manpower: 29 inspectors to inspect over 5,000 retailers
- No permanent public analyst for a long time
- No permanent high quality laboratory
- In 1997, there were only 198 pharmaceutical distributors in Bhagirath Place, but the numbers swelled to 693 by 2001.
- During the last three years, Delhi Police had registered 14 cases of spurious drug manufacture or sale and arrested 45 persons.
- The Drug Control Department conducts raids only at the instance of interested parties. No action is taken on consumer complaints [2]

Department of Prevention of Food Adulteration

In 1954, the Central Government enacted the Prevention of Food Adulteration (PFA) Act. In 1977, a Prevention of Food Adulteration Department was set up in Delhi for effective implementation of the provisions of PFA Act, 1954 and PFA Rules, 1955. The offence of adulteration, if proved in court attracts a sentence ranging from three months imprisonment and a fine of Rs 500 to life imprisonment and a fine of Rs 5,000 depending upon the degree of adulteration.

Performance

The Department has 37 inspectors to inspect over 1.50 lac (registered) food establishments. The number of unlicenced establishments is estimated to be three times this number. The department did not have a permanent public analyst for a long time, and no permanent laboratory either. It's also interesting to note that PFA does not know the number of food outlets in Delhi. According to the Director of (PFA), if one inspector was to visit one shop in a day, a shop would be visited once in 17 years. The number of inspectors has remained the same since 1960.

During a period of five years (1994-1999), the Department collected 4,485 samples out of which 607 (13.5%) were found to be adulterated.

The Department initiated prosecution in 557 cases and courts decided 467 cases. The rate of conviction was 44% and the rate of acquittal was 29%. The courts discharged 27% of the 467 cases, acting on the reports of Central Food Laboratory, Kolkata, because either the samples had decomposed due to poor handling and storage by the Department or the laboratory found the samples unadulterated.

During this five-year period, the average percentage of coverage (number of outlets inspected as a percentage of total number of outlets) was 0.6%.

Table 4 gives information on the budget, employment and salary expenditure of the important agencies in the health sector. DHS spends only 18% of the total expenditure on salary which is in stark contrast with DCD and PFA which spend 80% and 69% respectively. This happens because DHS spends a lot of its allocation on schemes that are run by other agencies which do not require manpower from DHS.

Table 4: Budget, Employment and Salary Data

SNo	Name of the Agency	NFYP		TFYP Allocation	Total Expr plan+non plan) 2001-02	Employees 2001-02 (I+II+III+IV)	Expr on Salary 2001-02	Salary as % of Total Expr	Salary per Employee
		Allocation	Actual						
1	DHS *(Medical)*	47720.00	27453.97	85200.00	15256.31	4472 (783+41+2200 +1448)	2772.49	18%	0.62
1.1	*(Public Health)*	445.00	330.83	1000.00					
2	DFW *(Medical)*	510.00	122.25	200.00		151 (22+9+104+16)			
3	DCD	1200.00	834.17	50.00	155.78	81 (7+26+27+21)	125.28	80%	1.55
4	PFA	170.00	142.01	200.00	254.90	152 (11+13+101 +27)	176.07	69%	1.15

Sources: *Government of NCT Delhi. 2003. Annual Plan 2003-04; Vol. 3. Department of Planning*
Government of NCT Delhi. 2003. Demand for Grants 2003-04
Government of NCT Delhi. 2001. Report on Classification of Employees in Delhi Government & Autonomous/Local Bodies
Directorate of Economics and Statistics and Office of Registrar, Births and Deaths
NYFP: Ninth Five Year Plan *TYFP:* Tenth Five Year Plan *Expr:* Expenditure

The Directorate also spends a significant amount on grants-in-aid to NGOs and various other organisations.

The Department of Health and Family Welfare is responsible for the implementation of the following acts:

- Delhi Prohibition of Smoking and Non-Smoker's Health Protection Act, 1996
- Medical Termination of Pregnancy Act, 1971
- Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act, 1994
- Drugs and Cosmetics Act, 1940 and rules made there under
- Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954
- Drugs (Prices Control) Order, 1995
- Prevention of Food Adulteration Act, 1954

Eligibility for Practicing Medicine

The Indian Medical Council Act[3] was passed by the Parliament in 1956. It requires each state to have a medical council with which practitioners of medicine must register to practice medicine in the territory of the state. (In Delhi, this function is performed by the Delhi Medical Council.). Schedule II of the act lists the qualifications required to be able to register. Practitioners of Ayurveda and Unani medicine are governed by the Indian Medicine Central Council Act, 1970[4] and they have to be registered with the Delhi *Bharatiya Chikitsa Parishad*. Homeopathic practitioners are governed by Central Homeopathic Act, 1973[5] and the legal body is the Board of Homeopathic System of Medicine.

Budget Information

Table 5 gives a statement of plan expenditure on health sector as a percentage of total plan expenditure by the Delhi government.

Infrastructure and Personnel

Availability of Beds

Total bed strength in the area of NCT Delhi is 30,667 which includes Government hospitals as well as 10,980 beds of private hospitals. The bed:patient ratio in Delhi is 2.2 beds per 1,000 persons. In rural areas, this ratio is only 0.38 per 1,000. However, the norm established by the World Health Organisation is 5 beds per 1,000 persons. There are a total of 5,327 beds available in hospitals under the Delhi government. Against a plan target to 2,200 beds fixed for Ninth Five Year Plan, the achievement was about 1,850 beds. The target of additional beds during the Tenth Five Year Plan is pegged at 2,500 beds. The comparative workload and employment data for various hospitals is shown in Table 6.

Table 6:Information on Staff Position and Work Load

Name of the hospital	No of Employees 2001	No of Beds	No of OPD for 2000	No of PD For 2000	No of Employees per bed	No of per Employee	No of IPD per Employee	No of OPD+IPD by No of Employee
Aruna Asaf Ali	275	100	244957	149	2.75	890.75	4.17	894.93
Deen Dayal Upadhyay	1158	500	634403	49875	2.32	547.84	43.06	590.91
Guru Nanak Eye Centre	313	184	196258	10021	1.70	627.02	32.01	659.03
Lok Nayak	1549	2811	1143538	69350	1.81	406.80	24.67	431.48
G.B.Pant	1930	601	310938	14221	3.21	161.10	7.37	168.48
Guru Tej Bahadur	1967	950	933103	55534	2.07	474.37	28.23	502.61
Sanjay Gandhi Memmorial	428	100	474049	9082	4.28	1107.59	21.21	1128.81
Guru Gobind Singh	246	100	306122	0	2.46	1244.39	--	1244.39

Source: Government of NCT Delhi. 2001. Report on Classification of Employees in Delhi Government, Autonomous/ Local Bodies.

Directorate of Economics and Statistics and Office of Registrar, Births and Deaths

Government of NCT Delhi. 2003 Budget Information; Department of Health and Family Welfare

Availability of Drugs in Hospitals

Drug procurement is done through the Central Drug Procurement Agency, which is a centralised agency under the Directorate of Health Services. An essential list of medicines/ formulations (about 320 in number) is maintained by the Agency and 90% procurement of drugs is done through the Agency for all the hospitals/ dispensaries under the Delhi government. The hospitals are at liberty to procure 10% of the medicine for emergency purposes. Enough provisions are maintained for availability of free medicines in the hospitals/ dispensaries.

Significant Problems and Drawbacks

Hospitals

1. Inefficient and Wasteful Procurement:

'Large number of machines and equipment have been lying in the stores for years together without being issued to respective indenting Departments. This, on one hand has resulted in no value for money from the equipment, on the other, denied the patients the facility for use of these equipment.'[6]

2. Wastage and Mismanagement of Resources like Water, Electricity: No incentive to minimise costs. 'Failure of three Delhi hospitals to take timely and effective remedial measures to ensure adherence to the stipulations of Delhi Vidyut Board resulted in avoidable and recurring additional liabilities on account of energy charges aggregating to Rs 977.50 lac.'[7] 'Director, Govind Ballabh Pant Hospital failed to maintain power factor by installing shunt capacitors and provided extension of electric supply to Guru Nanak Eye Centre in violation of conditions for supply of electricity resulting in avoidable expenditure of Rs 3.07 crore.'[8] Lack of managerial controls led to payment of Rs 2.20 crore in GTB Hospital.[9]

3. Lack of Trained Personnel:

'On account of problems in procurement of essential accessories and failure to position trained personnel, investments of Rs 51.35 lac on vital medical equipment proved to be largely unfruitful and detrimental to the interests of the patients.'[10]

4. Poor Quality of Services:

The management of the equipment required for patient care in the super specialty GB Pant hospital has been unsatisfactory over many years, affecting the quality of service to the patients.

5. Unutilisation and Underutilisation of Allocated Funds:

'Budget allocations of Rs 9.94 crore for the purchase of machines and equipment remained unutilised during 1994-99'[12]

6. Multiplicity of Agencies:

'The single most important problem plaguing the health sector in Delhi today is the multiplicity of agencies. Not just that, it makes impossible any sort of planning with foresight or coordinated allocation, it also hinders initiatives since it is easy to play the blame game.'[13]

7. Outdated Management Practices:

The practice of a senior doctor without any management background being made the administrator of super specialty hospitals adds to the problems of the patients who come from all parts of the city and the country in search of medications.[14]

Prevention of Food Adulteration

'Not only is the infrastructure in the Department inadequate, even the existing infrastructure has been performing very poorly. Against the target of 12 food samples to be lifted per inspector, each one of the 37 inspectors lifted on an average just two samples per month.'[15]

There are a meagre 37 inspectors to inspect over 1.50 lac (registered) food establishments and no regular public analyst has been employed for five years and a permanent laboratory was built only recently. The coverage of food establishments for inspection has been abysmally low.

Drug Control Department

The Drug Control Department of the city is not equipped to bust drug rackets. There are only 29 drug inspectors to keep an eye on more than 5,000 drug retailers. 'Given the enormous problem of fake drugs, our infrastructure and number of employees is too little to manage it.'[16]

'Consumer rights activists allege a nexus between the Drugs Control Department and the fake drug manufacturers, which cannot be dismissed lightly.'[17]

'Citing a recent incident, Ms Kiran Chaudhary (MLA) said 54 samples were lifted during a surprise raid from Bhagirath Place and only four were found to be genuine.'[18] Non-availability and high prices of essential and life-saving drugs contributed to the growth of the spurious drugs industry.'[19] 'Lax laws, slow litigation, light punishment and easy bails are no deterrent for makers of fake drugs that do not cure but can kill.'[20]

Reforms

- Increase the number of consumer courts where patients can seek legal remedy for malpractice of hospitals and medical practitioners. Along with drug manufacturers, held wholesalers and retailers liable.
- Currently PFA and DCD treat violations as criminal offenses where the degree of evidence required is 'beyond reasonable doubt.' These violations should be first tried as civil offenses under the tort system, which needs a lower degree of evidence, 'the preponderance of evidence.' Financial liability would be a better deterrent than the current low probability of criminal prosecution. Monetary fines would also provide restitution to the victims who get no compensation under criminal prosecution.
- The Bureau of Indian Standards now allows NGOs and other laboratories to perform tests of products to check their compliance with the standards. Institute a Citizen Inspector Reward System where information and samples given by a citizen earn rewards when conviction is secured. About 15-25 % of the penalty collected can be given to the citizen depending on the quality of information.
- Given the costs of a state-of-the-art laboratory, PFA and DCD should contract out the testing of samples to NGOs or recognised laboratories. The government contracts would provide necessary revenues to develop high quality laboratories in the city.
- Increase the supply of doctors by devising a system where college graduates with 2 years of training, who may be called People's Medical Practitioner, can treat common diseases. More than 90% of the cases in India are of waterborne diseases and require a small pool of medicines in various combinations. A brief but rigorous training would be sufficient to deal with these diseases. Those operating illegally-quacks-can also be brought into this new training system. Simply banning them will not the solve the problem.
- The Delhi Medical Council should maintain a 24-hour helpline where customers' complaints about doctors and hospitals are recorded. These complaints, categorised by the name of the hospital and the doctor, should be immediately put up on its website, with a caveat that it is preliminary information and the investigation is pending. If the Council promptly prosecutes and delicenses the guilty, then its campaign against quacks would be more credible. DMC could require its members to undergo continuing education programs and renew their license every three years.
- The drug inspectors, irrespective of their increased numbers, would never be sufficient to eradicate the menace of spurious drugs. No individual drug company is keen about supporting the investigation and prosecution work since any news about its drugs being copied reduces the confidence of its consumers and thereby its market. The companies can be encouraged to form their own joint investigation and prosecution teams if the government allows them to prosecute violators without having to reveal the names of the counterfeit drugs. Under the tort system, the companies will collect monetary penalties in successful cases to cover their expenses. In

addition, they can agree to pay for the teams in proportion to the counterfeit drugs captured by them. A company whose drugs are copied in large quantities will pay a higher proportion of the expenses of the teams.

- A False Claims Act would allow anyone to bring a lawsuit or provide information on any supplier of goods or services to the government who makes 'false claims' about quality, quantity, or the price of the supplies. The private suppliers will hesitate to cheat the government since anyone, including their own employees, can furnish evidence to convict them and collect large monetary rewards in exchange. The False Claims Act coupled with a 'Whistleblower Protection Law' for private as well as government employees will mitigate corruption and fraud in government procurement and contracts.
- Increase transparency in the process of procurement of drugs and all other equipment by putting up the tender, all submitted bids, and the selected bid with details of the procurement on the website of the Department and hospitals.
- Contract out non-specialised services in hospitals—cleaning, security, management of canteens and 24-hour pharmacies for better and cost effective services.
- Appoint people with hospital management training as heads of hospitals rather than senior doctors.
- Increase the quantity and quality of primary health centers so as to avoid crowding at super-speciality hospitals.
- Transfer PFA and DCD to the new proposed Consumer Protection Department, which would also include Department of Weights and Measures, and the Department of Food and Civil Supplies without the Public Distribution System (PDS).

Notes

[1] Dr Anil Bansal, President, Delhi Medical Association, Personal Communication

[2] Dr JS Jogi, Consumer Federation of India; The Week July 20; 2003

[3] The full text of the act can be accessed at http://www.healthepic.com/doctors/medico/imc.htm

[4] The full text of this act can be accessed at http://vigyan.org.in/Policy.html

[5] The full text of the act can be accessed at http://www.vigyan.org.in/homeo.html

[6] *CAG Report* investigating the irregularities in the purchase of equipment in G B Pant Hospital

[7] *CAG Report* 2002. Para 3.6, p 62

[8] *CAG Report* 2001. Para 3.10, p 109

[9] *CAG Report* 2000. p 131

[10] *CAG Report* 2002. Para 3.4, p 59

[11] *CAG Report* 1999. Para 3.1.6, p 42

[12] *CAG Report* 1999. Para 3.1.3, p 44

[13] Mr Abdul Mannan, Deputy Secretary, Department of Health and Family Welfare. Personal Communication

[14] Mrs Radhika Sreevastava, Actionaid. Personal Communication.

[15] *CAG Report* 1999. Para 3.2.5(c), p 63

[16] RU Bhaskar, All India Drug Control Officers' Confederation head

[17] *The Week*, 20 July 2003

[18] *Hindu*, Friday, 29 March 2002

[19] Dr Meera Shiva, Voluntary Health Association of India, *The Week*, 20 July 2003

[20] *Times of India*, New Delhi, 14 July 2002

References

http://www.delhihealth.com/index.html

http://www.healthlibrary.com/news/index.htm

http://www.timesofindia.com

http://www.healthepic.com/doctors/medico/imc.htm

http://www.vigyan.org.in/Policy.htm

http://www.vigyan.org.in/homeo.htm

Regarding the citizen's powers to act as an inspector, see
http://www.delhigovt.nic.in/newdelhi/dept/health/dpfe.pdf