

Injection practices in India

IPEN Study Group^a

Background: About 16 billion injections are administered each year worldwide, and at least half of them are unsafe. India contributes 25% to 30% of the global injection load. A majority of curative injections are unnecessary. The present study was undertaken to assess the burden of injections and prevalent injection practices in India.

Methods: A nationwide population-based cluster survey (1200 clusters; 24 021 subjects) at household level; along with observations, interview of prescribers (2402), and exit interview of the patients (12 012) at health facility level in the selected clusters was carried out - using probability proportionate to size (PPS) technique. Observations at health facility included generic observation (3592), observation of injection process (17 844), and observation of prescriber-client interaction (24 030).

Results: The frequency of injections was 2.9 (95%CI: 2.8-3.2) per person/year. Of the total injections, 62.9% (95%CI: 60.7-65.0) were unsafe. Injections administered for curative purpose constituted 82.5% and a large majority of these were prescribed for common symptoms like fever/cough/diarrhoea. Use of glass syringes was consistently associated with potential risk of blood-borne viral transmission. Satisfactory disposal of injection waste was observed at 61.3% (95%CI: 58.2-64.3) of the health facilities, and at 50.9% (95%CI: 46.7-55.2) of the immunization clinics. Significant differences were observed in the injection prescription pattern in public and private facilities, and in rural and urban areas.

Conclusions: Three billion injections were estimated to be administered annually in India; of them 1.89 billion were unsafe. Evidence suggests that the micro-level leadership for reducing injection overuse and making injections safer lies with the prescriber.

Key words: Injection, safety, practices, waste, rational use, India.

Introduction

Injections are among the most commonly used medical procedures with an estimated 16 billion administrations each year worldwide. An overwhelming majority (90%-95%) of these injections are administered for curative purposes.¹ Estimates suggest that at least 50% of the world's injections administered each

year are unsafe, particularly in developing countries. Moreover, a majority of the curative injections have been judged to be unnecessary. People residing in developing regions receive 1.5 to 11.3 injections per person/year and up to 75% of them are given with unsterilized, reused equipments – the reuse being highest in South-East Asia Region.^{2,3}

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A safe injection does no harm to the recipient, does not expose the healthcare worker to any risk, and does not result in waste that puts the community at risk.⁴

Faults in injection practices coupled with overuse of injections may expose all of them to several harms including life-threatening blood-borne viral (BBV) infections. Global estimates arrived at by using mathematical models have suggested that unsafe injections account for 32% of new hepatitis B virus (HBV) infections, 40% of new hepatitis C virus (HCV) infections and 5% of new HIV infections. This will pose a burden of 9.2 million disability adjusted life years (DALYs) between 2000 and 2030.⁵ In the developing countries, inadequate supplies and improper waste disposal has led to large-scale reuse of injection equipment without sterilization. In addition, the improperly disposed chlorinated plastic and sharps pose a threat to the environment.

Anecdotal evidence suggests that the overuse of injections is increasing.⁴ In India, studies documenting such changes are not available. However, broad trends can be observed from small studies indicating a rise from 1.2 injections/person/year in 1987 to 2.46 injections/person/year in 2001.⁶⁻⁷ A high proportion of injections given in India might be unsafe, mainly due to reuse of needles/syringes - which are also scavenged for resale, to confound the situation. The popularity of curative injections remains high due to various factors influencing the behaviour of prescribers/injection givers as well as clients. A large proportion of these injections are unnecessary.^{4,8-9} While addressing the need for a countrywide evidence on prevalent injection practices, the present study was undertaken in 2003-2004 to assess: the frequency of injections; proportion of unsafe injections; and injection-related waste disposal in government and private health facilities, and in rural and urban areas of India.

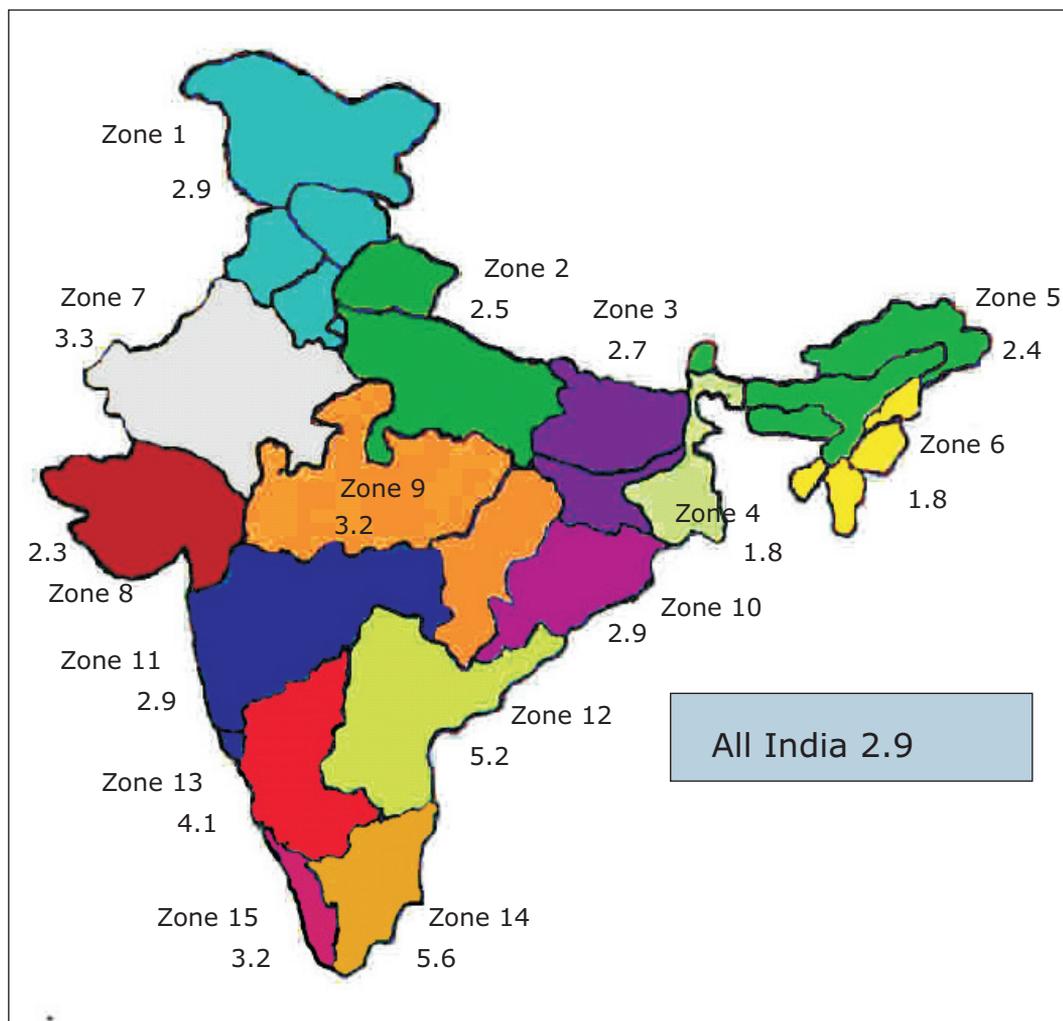
Methods

Study design

A nationwide population-based cluster survey (1200 clusters; 24 021 subjects) at the household level along with observations, interview of prescribers (2402), and exit interview of the patients (12 012) at health facility level in the selected clusters was carried out, using probability proportionate to size (PPS) technique. Observations at health facility included generic observations (3592), observation of injection administrations (17 844), and observation of prescriber-client interactions (24 030). The whole country was demarcated into 15 zones on the basis of socio-cultural and geographic factors. The sampling universe was a zone and each zone comprised of either a single state or a group of two to five small states (Figure 1). The clusters were drawn separately for urban and rural areas. The details of the sample size and plan are given in Table 1.

The survey commenced at a randomly selected household. Household members were listed and one individual was randomly selected and interviewed. Consecutive households were covered until 20 clients were interviewed. One government and one private health facility located in or nearest to the cluster were selected. If more than one private health facility existed in the cluster, the one which was reported to administer more injections was selected. For the immunization clinic, a nearby out-reach area/sub-centre/dispensary where routine immunization was done was selected. Exit interviews were conducted to neutralize Hawthorn effect during direct observations. Five consecutive patients coming out of both the public and private health facilities were interviewed among those who agreed to participate.

Figure 1: Number of injections per person/year according to study zones



Study tools

The draft instruments were developed by a multidisciplinary central coordinating team, with inputs from programme managers in the Ministry of Health and Family Welfare, Government of India. The instruments, consisting of a mix of structured close-ended and semi-structured open-ended questions, were validated and piloted at eight sites across the country, and were finalized during the national protocol finalization workshop.

The factors that make an injection safe were studied in detail by senior investigators through direct observation of the injection administration. These were grouped under factors associated with injection equipment and its sterilization; and those associated with the technique of administering an injection. A checklist for safe/unsafe injections was developed for this assessment. This checklist was based on various criteria suggested by the World Health Organization (WHO).¹⁰ An injection was classified as unsafe if: it had

Table 1: Sample plan of the study for interviews and observations

	Zonal sample			No. of zones	Total sample size	
	No. of Clusters	Sample per cluster	Sample per zone		Proposed	Covered
Community Level						
Community survey	80 (Rural-40, Urban-40)	20	1600	15	24000	24021
Health Facility Level						
Generic observation	80 (Rural-40, Urban-40)	3 (Government-1, Private-1, Immunization clinic-1)	240	15	3600	3592
Observation of injection process	80 (Rural-40, Urban-40)	15 (Government-5, Private-5, Immunization clinic-5)	1200	15	18000	17844
Observation of client-prescriber interaction	80 (Rural-40, Urban-40)	30 (Government-10, Private-10)	1600	15	24000	24030
Exit interview of patients	80 (Rural-40, Urban-40)	10 (Government-5, Private-5)	800	15	12000	12012
Prescriber's interview	80 (Rural-40, Urban-40)	2 (Government-1, Private-1)	160	15	2400	2402

potential to transmit blood-borne viruses (being given using inadequately sterilized syringe/ needle and or syringe/ needle were reused for another patient) and/or it was administered using faulty technique (and could cause local infection and or reaction).

Quality assurance

A uniform understanding of the study protocol, methods and instruments among the senior investigators and research associates was assured through a national protocol finalization workshop followed by 15 zonal workshops. Members of the Central Coordinating Team made quality assurance visits to 150 clusters (12.5%) covering all 15 zones. All Intelligent Character Recognition (ICR) sheets were screened for completeness and appropriate

coding of responses. Range checks and logical runs were incorporated in the data management software to minimize errors.

Data analysis

Intelligent Character Recognition sheets were filled by the senior investigators, for each unit of community-based survey and facility-based observations and interviews, on a daily basis during data collection phase. The data were scanned and directly transferred to the computers from the ICR sheets using ABBYY Form Processing Solutions (Form Reader 4.0). Recognized data were first transferred to Excel spreadsheets for data cleaning. The survey feature of 'STATA release 7.0' was used for analysis of the whole data set. Magnitude of injections, proportion of unsafe injections,

awareness and perceptions regarding injection practices and inappropriate disposal of sharps waste were calculated for the individual zones and thereafter for the whole country by imputing weights for the population. The zone-wise estimates of urban and rural population were used according to the 2001 census. For health facility-based data, all-India estimates were derived by applying weightage for proportion of injections given at different health facilities (as determined during community survey).

Ethical issues

A prior written consent was obtained from all study participants. The consent forms were prepared in local languages and one copy was given to the interviewees for their records. For those unable to read, a person not connected with the study read out the consent form and assured that the contents were made explicitly clear.

Results

Based on the data obtained from the survey, we estimate that in the over one billion population of India, three billion injections were administered annually. Of these, 2.49 billion injections were given for curative purposes and 1.89 billion injections were unsafe. The private sector was contributing 2.1 billion injections to the total injections and 1.26 billion to the unsafe injections.

Frequency of injections

In the three months recall, 27.1% (95%CI: 25.9-28.3) of the subjects in the community survey reported to have received injection(s). The number of injections received per person-year was estimated to be 2.9 (95% CI: 2.8-3.2) (Figure 1). The frequency of injections was almost twice among infants (5.6; 95%CI: 5.0-6.2) as compared to older

subjects (2.8; 95%CI: 2.6-3). Of all the injections, 17.5% (95%CI: 16.0-18.9) were for vaccination. Among infants, injections for vaccination were 63.2% (95%CI: 56.8-69.6) compared to 12.2% (95% CI: 10.9-13.4) among older subjects. More than three fourths (77.0%; 95%CI: 75.1-79.0) of curative injections were prescribed in the private facilities. Among preventive injections, two third injections (66%; 95%CI: 62.5-69.6) were given in the government sector.

Prescription pattern

On direct observation, 44.1% (95%CI: 42.9-45.6) of all outpatient clients were prescribed injections. A larger proportion of clients in the private health facilities received injections 45.9% (95% CI: 44.2-47.7) as compared to those attending government health facilities 38.5% (95%CI: 36.7-40.3). Non-formal prescribers were giving 12% to 15% more injections as compared to allopathic doctors. A similar trend was seen with exit interviews where nearly half of the respondents (48.1%; 95%CI: 46.3-49.9) had received injections, with a higher proportion in private facilities (50.6%; 95%CI: 48.5-52.7) as compared to government facilities (40.7%; 95%CI: 38.6-42.9).

Exit interviews revealed that the highest proportion of injection prescriptions were seen at the clinics of non-formal prescribers (57.5%), followed by Indigenous Systems of Medicine (ISM) (52.6%) and allopathic clinics (42.6%). This trend of prescribing injections, as assessed through direct observation of the client-prescriber interaction, was similar to that obtained from exit interviews (52.3%, 48.2% and 40.5% respectively). Exit interviews (51.1%; 95%CI: 48.9-53.3) as well as community survey (51.7%; 95%CI: 49.8-53.7) indicated that over half of the curative injections were prescribed for

symptoms of fever/cough/diarrhoea. A vast majority of prescribers (88.6%; 95%CI: 86.8-90.5) was of the opinion that injections gave psychological relief to the patients as they insisted on injections. Notwithstanding these perceptions, direct observations revealed that most of the times (70.6%), doctors took a decision about the prescription and the clients accepted it. Enquiries with clients underscored this, where a large proportion of clients 44.1% (95% CI: 42.7-45.6) accepted the doctor's decision to administer injections even when these were perceived to be unnecessary. When clients who were insisting on an injection were questioned about why they prefer to receive injections, 73.8% (95%CI: 72.5-75.1) cited certain benefits of the injections over oral medicines (e.g. quick relief, more effective method of illness treatment).

Unsafe injections

Of all the injections administered in India, one third (31.6%) carried a potential risk of transmitting BBV. Unsafe injection due to faulty technique was observed in 53.1% of the observed administrations. Together, these two factors made nearly two third (62.9%) of the injections unsafe (Table 2). The proportion of unsafe injections was highest at the immunization clinics (74.0%) followed by government (68.7%) and private (59.9%) health facilities (Table 3).

The type of injection equipment (glass or plastic syringe) had a profound effect on the safety of injections, be it potential risk of BBV transmission; faulty injection technique or the overall unsafe injections (Table 2). Regression analysis showed that there was a linear but

Table 2: Characteristics of unsafe injections in India (data in percent)

Characteristics	Overall unsafe injections	Unsafe injections with plastic syringe	Unsafe injections with glass syringe
Injections carrying risk of blood borne virus transmission	31.6 (29.4-33.7)	18.2 (16.3-20.1)	70.7 (67.2-74.3)
Faulty technique	53.1 (50.8-55.4)	46.2 (43.5-48.9)	73 (69.9-76.1)
Overall	62.9 (60.7-65.0)	53.3 (50.6-55.9)	90.8 (88.8-92.8)

Figures in parentheses show 95% confidence interval.

Table 3: Unsafe injections according to type of health facility and syringe use in India (data in percent)

Type of health facility	Overall unsafe injections	Injections with plastic syringe	Injections carrying risk of blood-borne virus transmission		
			Overall	With plastic syringe	With glass Syringe
Government health facilities	68.7 (66.1-71.3)	62.7 (59.8-65.5)	35.4 (32.7-38.1)	18.5 (15.7-21.3)	63.7 (59.1-68.3)
Private health facilities	59.9 (56.9-62.8)	80.7 (78.2-83.2)	30.1 (27.3-32.9)	18.1 (15.8-20.5)	80.1 (74.7-85.5)
Immunization clinics	74.0 (71.4-76.6)	52.3 (49.1-55.5)	33.5 (30.5-36.5)	18.0 (14.9-21.1)	50.5 (45.8-55.2)
All India	62.9 (60.7-65.1)	74.6 (72.6-76.6)	31.6 (29.4-33.7)	18.2 (16.3-20.1)	70.7 (67.2-74.3)

Figures in parentheses show 95% confidence interval.

inverse relationship between the quantum of plastic syringe use in a zone and overall prevalence of unsafe injection as well as potential risk of BBV transmission irrespective of the type of health facility.

In multivariate logistic analysis, use of glass syringes consistently emerged as the most important factor behind unsafe injections (OR 8.4); for risk of BBV transmission (OR 12.2); and for unsafe injection due to faulty techniques (OR 3.0). The likelihood of unsafe injection was marginally lower in urban areas as compared to rural areas. The risk of unsafe injection when administered at non-allopathic health facilities (ISM and non-formal prescribers) was over one and a half times as compared to that with allopathic prescribers (Table 4).

Written guidelines for sterilization were available at only 10.1% (95% CI: 8.8-11.4) of all health facilities across the country. More than half of the prescribers (55.6%; 95%CI: 51.7-59.5) reported an incorrect

sterilization process. Sterilization equipment was available at 84.2% (95%CI: 81.4-87.1) of the government health facilities, 76.9% (95%CI: 73.9-80.0) of the immunization clinics and 57.7% (95%CI: 54.1-61.3) of private health facilities. Over three fourths (75.9%; 95%CI: 72.7-79.0) of the available sterilization equipment were functional.

The guidelines for waste disposal were available at only 14.2% (95%CI: 12.6-15.7) of the health facilities. Satisfactory facility-level disposal of injection waste was observed at 61.3% (95%CI: 58.2-64.3) of the health facilities; immunization clinics being the worst performers at 50.9%. Satisfactory terminal disposal was observed in less than half of the health facilities (44.8%; 95%CI: 41.9-47.7); 41.55% in private health facilities. A marked difference existed between the observed status and prescribers' perception about waste disposal at the health facility as well as at the terminal levels (Table 5). Direct observation at health facilities documented that the selling of

Table 4: Risk of unsafe injections in India (multivariate logistic regression analysis)

Model	Independent variables	Overall		Blood-borne virus transmission		Faulty technique	
		OR (95% CI)	p	OR (95% CI)	p	OR (95% CI)	p
Model 1	Glass syringe	8.4 (6.4-10.9)	<0.001	12.2 (9.7-15.5)	<0.001	3.0 (2.5-3.6)	<0.001
	Urban area	0.7 (0.6-0.8)	<0.001	0.9 (0.7-1.1)	0.2	0.7 (0.6-0.8)	<0.001
	Private health facility	0.9 (0.8-1.1)	0.2	1.3 (1.1-1.6)	<0.001	0.9 (0.8-1.1)	0.4
	Immunization clinic	1.1 (0.9-1.3)	0.1	0.6 (0.5-0.8)	<0.001	1.3 (1.3-1.5)	<0.001
Model 2	Glass syringe	8.6 (6.4-11.4)	<0.001	12.5 (9.8-15.8)	<0.001	3.0 (2.4-3.7)	<0.001
	Urban area	0.8 (0.6-0.9)	<0.001	1.0 (0.8-1.3)	0.9	0.7 (0.6-0.9)	<0.001
	ISM practitioner	1.5 (1.1-1.9)	<0.001	1.7 (1.2-2.3)	<0.001	1.3 (0.99-1.7)	0.05
	Informally trained practitioner	1.6 (1.1-2.3)	0.01	1.9 (1.4-2.7)	<0.001	1.4 (0.98-1.9)	0.07

ISM – Indian system of medicine

Table 5: Satisfactory injection-related waste disposal in India: direct observation versus prescriber's perception (data in percent)

Level of waste disposal	Government health facility		Private health facility		Immunization clinic
	Direct observation	Prescriber's perception	Direct observation	Prescriber's perception	Direct observation
Health facility-level disposal	60.5 (56.7-64.2)	90.1 (87.8-92.5)	62.3 (58.6-65.9)	86.4 (83.9-88.9)	50.9 (46.7-55.2)
Terminal disposal	53.5 (49.8-57.2)	69.6 (66.1-73.0)	41.5 (37.9-45.2)	57.9 (54.2-61.6)	49.1 (45.3-52.9)

Figures in parentheses show 95% confidence interval.

used plastic syringes/needles to retail scrap dealers was more in private health facilities (15.2%; 95%CI: 12.3-17.9) as compared to that from government health facilities (3.2%; 95%CI: 1.9-4.5).

Rural-urban differentials

Client-prescriber interactions demonstrated that the proportion of prescriptions with injection was higher in rural areas (46.6%; 95%CI: 44.8-48.4) as compared to urban areas (37.6%; 95%CI: 35.1-39.9). This difference was maintained when data was stratified according to the type of health facilities and type of health providers. The proportion of injections carrying risk of spread of BBV transmission was also higher in villages (33.4%; 95%CI: 30.4-36.5) as compared to urban areas (26.6%; 95%CI: 23.2-30.1). Availability and functional status of sterilization equipment was similar in the two areas. Disposal of injection-related waste at health facility level was better in urban areas (69.6%; 95%CI: 66.0-73.1) as compared to their rural counterparts (57.9%; 95%CI: 53.8-62.0). Similarly, terminal disposal was better in urban health facilities (51.2%; 95%CI: 46.9-55.5) as compared to health facilities in rural areas (42.2%; 95%CI: 38.5-45.9).

Discussion

An overwhelming majority of injections in our study were given for therapeutic reasons. However, their proportionate share seems to be a little lower in India (82.7%) as compared to the global data (95%).⁴ The overall frequency of injections in our nationwide data was 2.9 injections per person/year. This is almost double of the average estimate for developing countries (1.5),² though half of what has been observed in Cambodia (5.9).¹¹ Estimates of injections per person/year in developing countries vary from 1.5 to 11.3.^{2,3} If we apply our data to total population, around 3 billion injections are administered annually in India; of which nearly 2.5 billion are curative injections, and roughly 2 billion injections are unsafe. Barring vaccines, the major share is borne by the private sector. Another indicator of the injection frequency in our data was that every second exit interviewee in the study had received injections. A similar trend has been reported from Cambodia where 47% of the total prescriptions included a therapeutic injection or infusion.¹¹

Of the total quantum of injections, around two third were found to be unsafe, which is on a higher side from the developing world estimate of nearly 50% injections being unsafe.² Reuse

of syringes, with or without sterilization is a serious problem across countries in the developing regions, being highest in South-East Asia. Injections administered with unsterilized, reused equipment constitute 1.2% to 75.0%.^{3,5} Smaller studies from India have also reported widely prevalent reuse of syringes.^{12,13} The worrisome part was that this was highest at immunization clinics where 74.0% of the injections were either carrying a potential risk of BBV transmission or were administered with faulty technique. There was a wide gap between observed status and prescribers' perception on waste disposal. The situation of terminal disposal of injection waste was worse. Rural-urban differences on injection safety may be explained by the higher use of glass syringes in rural areas, variations in the profile of prescribers, and training of the injection givers. Although basic issues related to the burden of injection, safety and waste disposal broadly remain the same for rural and urban areas, management of injection-related waste in remote villages and outreach clinics is going to pose a significant challenge logistically.

The main area of limitation in this study was that of the observations at health facility level. Hawthorn effect was likely to influence the injection prescribing and injection administering practices, resulting into underestimation of unsafe and irrational injections. The quantum of this error could not be estimated, although direction was possible to assess. To neutralize this, exit interviews of a separate group of clients coming out of the same health facilities were also conducted.

An appropriate and systematic global response to the threat of unsafe injections has been slow to emerge.¹⁴ The goal is not only to make the injection practices safe but also to reduce the overall quantum of injections administered to people by modifying the

prescription practices – both in public and private sectors. We also need to include a large constituency of non-formal prescribers in our scope since they contribute a sizeable proportion of injection prescriptions.¹⁵ Starting from the formulation of a National Safe Injection Policy, these efforts would include behaviour change among health workers and clients; provision of uninterrupted supply of safe injection equipment; and establishment and maintenance of injection-related waste disposal mechanisms. India has recently seen substantive progress in some of these areas.¹⁶ Professional bodies have formulated their policies and plan of action, and a large nationwide grid of Model Injection Centres was established by the INCLIN Programme Evaluation Network, as a follow up to this study.¹⁷⁻¹⁹

One of the most positive translational developments prompted by this study has been the minimization of glass syringe usage. With extra effort and patience required to properly sterilize the glass syringes, particularly in crowded out-patient settings, most of the injections administered through glass syringes were unsafe. The government's response to this evidence has been quick. As a policy, the Auto-Disable (AD) syringes are now being used universally in the national immunization programme and their uninterrupted supply is assured. In addition, it has also been made mandatory for all states to use AD syringes in all government hospitals and health centres. However, much needs to be done in several domains of injection safety - specifically in: (a) inducing and sustaining a culture of rational use of injections among prescribers through advocacy, communication and training; and (b) terminal disposal of injection-related waste. In this regard, the disposal of plastic waste is a big challenge in rural areas because of the economic viability of the rather unclear

system of collection and terminal disposal of such waste in primary care settings.

Community survey as well as exit interviews indicated that over half of the curative injections were prescribed for common symptoms, e.g. fever, cough, or diarrhoea. This enforces the assertions made in reports from India and Bangladesh that most injections in healthcare settings are unnecessary.^{20,21} In the present study, a huge majority of prescribers was of the opinion that clients insist for injections since it gave them psychological relief. However, the evidence generated through direct observation was contrary to these perceptions. In most instances, doctors took a decision about the prescription and the clients accepted it. Enquiries with clients revealed that a large proportion of clients accept the doctor's decision to administer injections even when these were perceived to be unnecessary.

The biggest irony is that a widely practiced health care intervention which has benefited the people so extensively in the last century is also turning into a health hazard and a threat to community health. Excessive recourse of prescribers to injections, when equally effective oral formulations are available or the medication is not required at all, is constantly aggravating this threat. It is not a question of onus, but the evidence suggests that the micro-level leadership for creating a professional as well as social milieu favourable to rational use of injections lies with the prescribers, particularly in the private sector which has an overwhelming influence over the huge domain of non-formal prescribers.

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