Baseline Study of Private Drug Shops in Bangladesh: Findings and Recommendations

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Centre of Excellence for Universal Health Coverage

JPG SCHOOL OF PUBLIC HEALTH
JAMES P. GRANT

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CONTENTS

ACRONYMS AND ABBREVIATIONS

ADDO	Accredited Drug Dispensing Outlet
AHUB	Ayurveda, Homeopathy, and Unani Board
BCDA	Bangladesh Chemist and Druggist Association
BCDS	Bangladesh Chemist and Druggist *Samity* (Association)
BM&DC	Bangladesh Medical and Dental Council
B Pharm	Bachelor of pharmacy
BPS	Bangladesh Pharmaceutical Society
BRAC	previously 'Bangladesh Rural Advancement Committee', now a brand name
BDT	Bangladeshi Taka
CAB	Consumer Association Bangladesh
DAR	drug administration registration number
DGDA	Directorate General of Drug Administration
DOTS	directly observed treatment short-course
DGHS	Directorate General of Health Services
DGFP	Directorate General of Family Planning
DS	drug superintendent
DI	drug inspector
FGD	focus group discussion
GMP	good manufacturing practice
H.S.C.	higher school certificate
HRH	human resources for health
IEC	information education and communication
IP	International nonproprietary name
KII	key informant interviews
LMAF	local medical assistant and family welfare
LMIC	low- and middle-income countries
MSH	Management Sciences for Health
MBBS	Bachelor of Medicine, Bachelor of Surgery
MDR TB	multidrug resistant tuberculosis
M Pharm	master of pharmacy
MRP	maximum retail price
NGO	nongovernment organization
NTP	National Tuberculosis Programme
ORS	oral rehydration salts
OTC	over the counter
PCB	Pharmacy Council Bangladesh
PI	Principal Investigator
PPP	private-public partnership
RMP	rural medical practitioner
SIAPS	Systems for Improved Access to Pharmaceuticals and Services
S.S.C.	secondary school certificate
SPSS	statistical package for the social sciences
TB	tuberculosis
TT	tetanus toxoid
TIN	tax identification number
UZ	upazila
UHC	upazila health complex

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EXECUTIVE SUMMARY

"Private medicine retailers are fast becoming key players in promoting access to medicines in low- and middle-income countries."
—Wafula, Miriti, and Goodman 2012

Introduction

Retail drug shops[1] are the preferred first point of contact for a majority of the population in developing countries including Bangladesh. Currently in Bangladesh, 1,03,451 licensed retail drug shops and approximately an equal number of unlicensed retail drug shops are involved in selling drugs "over-the-counter." Most of the salespeople and dispensers at those retail drug shops do not have training in dispensing drugs or in offering diagnoses and treatment, which they frequently do.

Because those drug shop salespeople have no other channel of information beyond the formal sectors open to them, they fall easy prey to the aggressive marketing strategies of the pharmaceutical companies. Irrational use of drugs such as overprescribing, multidrug prescribing, using unnecessarily expensive drugs, dispensing drugs without a prescription, and overusing antibiotics and injections have been the most common problems found with those retailers for a long time.

Given the importance of the informal sector, including retail drug shops in Bangladesh, improved regulation of this sector offers an important opportunity to improve community health. Experiences in other parts of world have demonstrated that private-sector drug seller initiatives that are based on an accreditation and regulation model are feasible, improve access to medicines, and can be scaled up.

This study aims to fill in the knowledge gaps about those unregulated drug shops in the private sector and about management of them through the informed design of an accredited drug shop model in Bangladesh. The inclusion of the tuberculosis-related assessment in this study is a result of the priority for a TB program that will increase the number of cases that are detected and referred early to a TB treatment and diagnosis center for proper management.

Methods

This paper was a facility-based (drug shop–based), cross-sectional study exploring the status, operation, and regulation of the retail drug shops including dispensing practices and the availability, quality, and affordability of essential drugs, as well as perceptions of different stakeholders regarding the feasibility of an accredited drug shop program in Bangladesh. In addition, the possibility of facilitating a TB directly observed treatment short-course (DOTS) program through accredited retail drug shops in Bangladesh was explored.

[1]Retail drug shops are defined as private retail pharmacies or drugstores that are eligible for mandatory approval and registration from the Directorate General of Drug Administration. This did not include Ayurveda, Homeopathy and Unani Board (AHUB) facilities selling drugs and medicines

Respondents included (a) the salesperson or dispenser or the owner of each of the drug shops who was present at the time of the survey (when the owner was a different person[12% of cases], only the salesperson or dispenser was interviewed; (b) a sample of community people who were in the catchment area of each shop and who visited it in the past one month (for focus group discussions); (c) relevant stakeholders (e.g., Directorate General of Drug Administration [DGDA]) people at the district and central level; (e) and association representatives and experts in the field (in-depth interview).

A variety of methods was used to elicit relevant data. Among the methods were (a) document review (for policy and regulatory environment); (b) quantitative survey (for profiling retail drug shops and for training and experiences of the drug sellers);(c) qualitative exploration (for eliciting perception of the community and other stakeholders), and (d) structured observation in a subset of the sampled retail drug shops (to document the dispensing practices of the salesperson or dispenser). A total of 111 drug shops (90 rural and 21 urban) from the seven divisions were included in the survey.

Key Findings

The findings are presented next thematically.

Drug Shops and Dispensers

Many of the drug shops (45%) studied had been in business 10 years or longer, and almost all (96%) had a trade license (which was issued by local bodies such as a union council in rural areas and by city corporations or municipalities in urban areas). However, approximately 80% reported to have had a drug license (issued by DGDA under the Ministry of Health and Family Welfare [MOHFW]).

The shops were attended mostly by a single dispenser (69%), of whom nearly half (49%) did not receive any training as a pharmacist, although the law (Ordinance 13, rule 2) requires the presence of at least a grade C pharmacist. Among the professional dispensers were 91% grade C (certificate) pharmacists, 7% grade B (diploma) pharmacists, and 2% grade A (graduate) pharmacists in the studied drug shops.

Non-pharmacists had learned the trade by working as an apprentice either of someone who had a MBBS (Bachelor of Medicine and Bachelor of Surgery) degree (10%) or a village doctor (16%), or they inherited the trade as a family business (18%). A substantial proportion (38%) received dispensing training from the representatives of the pharmaceutical companies. Only a small proportion of the surveyed shops maintained sales and stock records.

Clients

A majority (68%) of the clients visiting the drug shops came by self-referral and without a prescription. Dispensing drugs on the basis of a patient's request (83%) or a patient's symptoms of illness (59%) was quite common. Other than selling medicines, the drug shops provided additional services such as pushing injections (60%), basic diagnostic services (63%), burn and wound dressings (63%), and vaccinations (31%), all of which are not sanctioned by the drug license.

Lack of availability of essential drugs (e.g., varying from as low as 22% for benzyl benzoate to a maximum of 43% for Cotrim tablets) was a common phenomenon, and the price range for the same drug varied widely from brand to brand.

Feasibility of Using Drug Shops for Facilitating DOTS for TB

The respondents have a general awareness about TB (90%), how it is transmitted through coughing and sneezing (93%), how a perceived persistent cough can be a common symptom of possible TB (87%), and how sputum examination can be an important diagnostic method for TB (95%). To a lesser extent, they know about DOTS for TB program (50%) and about places where DOTS are provided. Among the respondents, 32% received some training about TB and DOTS, and 79% expressed their willingness to take training about TB and DOTS, provided they received some financial incentive besides the training (49%).

Regulatory Process

Applying for and getting a drug license appeared to be a cumbersome, lengthy, and costly process. Because of a shortage of required personnel, the inspection and checking process of the drug shops appeared to be superficial, few and far between, and that process was not compliant with stipulated laws.

Resentments were echoed uniformly by the drug shop dispensers and owners regarding both the licensing and the inspection process. All tiers of the regulators were of the opinion that the existing system is not adequate. They emphasized that the existing regulatory system needed to be improved in areas such as logistics, available personnel, budget for shop visits and inspections, regular visits for inspection, and reduction of lead time for the licensing process. They also emphasized that the Drug Act needed to be updated to conform to current realities.

Feasibility of Developing an Accredited Model of Drug Shops in Bangladesh

The regulators at the central and district levels were unanimous about the necessity of developing an accredited model of a drug shop in the country to improve the current chaotic situation. According to them, a model drug shop run by registered pharmacists (those who are graduates or have diplomas) will reduce the margin of error and will also promote rational use of drugs.

Regulators said that in the short term, the shops could be run by grade C pharmacists, but they suggested extensive review of the current course for content and form to serve this purpose. According to them, recruited students should have a science background, basic primary health care (PHC) topics should be covered in the curricula, and some job placement or internship work (for gaining practical experiences)needs to be included, in addition to the legal and ethical aspects of dispensing and the rational use of drugs.

They thought that the Accredited Drug Dispensing Outlet (ADDO) model shops should be able to provide basic PHC services (e.g., understanding health education and promotion, dressing wounds and burns, knowing first aid for victims of drowning and snake bites,

measuring body weight and temperature, taking blood pressure, testing urine for sugar, providing DOTS services, etc.) as well as dispensing services. To achieve this goal, the key informants emphasized building an extensive awareness that demands quality services from trained personnel in the drug shops. A number of suggestions were put forward: organizing "Drug Day" or "Drug Week" campaigns and arranging a "Drug Fair'' to generate awareness among the consumers and dispensers.

The consumers' associations or pressure groups such as Consumer Association Bangladesh (CAB) can play a critical role in helping the DGDA in this endeavor. For example, the CAB can give the DGDA information about malpractices in the drug shops such as selling expired, fake, or low-quality substandard drugs; overpricing beyond the printed maximum retail price (MRP); selling sample drugs that were given to physicians; operating drug shops without a valid drug license; and so forth. The CAB can also recommend remedial measures.

Recommendations

Immediate and Short-Term Measures

- Create **a crash program to train** the vast number of **dispensers in unlicensed shops** within a short time, such as a maximum of one year.

- **Make the licensing process user-friendly, efficient, and inexpensive** so that unlicensed drug shop owners are encouraged to become licensed after fulfilling the requirements.

- **Make shop inspections regular, comprehensive, and supervised** (by district DGDA), with the intent to solve **problems, not punish.**

- **Increase the supervisory capacity of the DGDA** with more personnel and improved logistics so that shop inspections can be conducted **countrywide, year round, on a regular and planned schedule**.

- **Develop amicable relationships between DGDA officials and other stakeholders** to effectively implement regulations, and make high-quality essential drugs available at the people's doorsteps.

Long-Term Measures

- **Revise the contents, forms, and duration of the grade C certificate course** to develop a standard curriculum that also includes basic PHC services (first aid and health education, including TB and TB DOTS) for these to work as PHC outposts in remote rural areas.

- **Increase the technical capacity of DGDA** (e.g., establish more drug-testing laboratories) to discourage marketing of counterfeit, expired, and poor-quality drugs; develop a functioning regulatory and supervisory system overseen by the DGDA.

- **Develop the capacity of the dispensers** by training and providing monetary incentives to be providers of TB DOTS.

- **Ensure strict adherence to GMP for all pharmaceuticals** to maintain the standard and quality of drugs.

- **Understand that requirements** to be fulfilled **for developing an ADDO model in Bangladesh** include the following—

    - Ensure the presence of a pharmacist who is well trained in the revised curriculum in the drug shop.
    - Conduct an extensive information, education, and communication campaign to build awareness of the public and pharmacy stakeholders on the irrational use of drugs and their harmful effects (e.g., antimicrobial resistance, MDR TB, etc.).
    - Include health professional associations in developing ownership of the ADDO process.
    - Encourage the critical role of CAB and similar associations to apply leverage and promote the rational use of drugs.

BACKGROUND

The private sector is an important provider of care in Bangladesh, with more than 80% of the population seeking care from non-state providers (Ahmed and Hossain 2007). Retail drug shops are often the first and only source of healthcare outside home for a majority of patients in developing countries such as Bangladesh (Ahmed, Hossain, and Chowdhury 2009; Ahmed et al. 2011). In Bangladesh currently, approximately 1,03,451 licensed retail drug shops (as of September 7, 2015, DGDA website) and an estimated approximately equal number of unlicensed retail drug shops are involved in selling drugs "over-the-counter".

Most of the salespeople or dispensers at those retail drug shops do not have training in dispensing drugs or in diagnosing and treating medical conditions, which are tasks they frequently do. According to law, the persons dispensing drugs at retail drug shops should have at least a short training of 12 weeks (grade C pharmacists) before they can apply for a drug shop (pharmacy) license. This certificate course is conducted by the Bangladesh Pharmaceutical Society (BPS) in cooperation with the Bangladesh Chemist and Druggist Samity (Association) (BCDS). The content, form, and utility of this training remain a matter of grave concern (Bangladesh Health Watch 2010).

Because drugstore salespeople have no other channel of information from the formal sectors open to them, they fall easy prey to the aggressive marketing strategies of the pharmaceutical companies (Bangladesh Health Watch 2008). Overprescribing, prescribing multiple drugs, prescribing drugs that are unnecessary and expensive, dispensing drugs without prescription, and overusing antibiotics and injections are the most common problems found with these retailers (Chuc 2002; Chalker 2003; Chowdhury 2010; Bloom et al. 2015).

Given the importance of the informal sector, including retail drug shops in Bangladesh, improved regulation of this sector offers an important opportunity to improve community health. Experiences in other parts of world have demonstrated that private-sector drug seller initiatives designed on the basis of an accreditation and regulation model are feasible, improve access to medicines, and can be scaled up (Goodman et al. 2007; Drug Seller Initiatives 2014). This study aims to fill-in the knowledge gaps on drug shops and their management and to create an informed design of an accredited drug shop model in Bangladesh.

The two related assessment components—including one for the broader accreditation that is based on the Tanzania model—seek to inform the design of the Bangladesh model that would (a) ensure that the drug-seller platform is linked to primary care service and (b) provide a community-level platform to link major public health programs such as TB with the drug sellers. The TB-related assessment in this study is included because of the priority of the TB program to increase the number of cases that are detected and referred early to a TB treatment and diagnosis center for proper management. This assessment and management will ensure that TB transmission is curtailed and that the probability of drug-resistant TB occurring is reduced.

Research Questions

The essential questions that guided the research of this paper are as follows—

1) Do the pharmacies and drugstores in Bangladesh meet the legal and regulatory standards—such as having valid business licenses and registrations to sell medicines—for operating the business?

2) What are the opportunities for an accreditation program for pharmacies and drugstores to improve access to quality medicines and pharmaceutical services in Bangladesh?

3) What are the availability, affordability, and quality (assessed according to the expiration date, packaging status, and drug storage conditions) of essential medicines circulating in the private retail pharmaceutical market in Bangladesh?

4) What are the perceptions of the community, drug shop owners, and regulators regarding drug shops? What are their perceptions regarding the acceptance of regulations?

5) What is the feasibility of implementing accreditation strategies in Bangladesh as assessed in part through (1) drug seller or owner interest in licensing the shop and (2) key informant perception of accreditation, including perceived benefits and barriers to implementation?

Purpose

This paper's purpose is to provide comprehensive information about retail drug shops and that will inform the successful designing of an accredited model of drug shop for Bangladesh.

Objectives

The objectives of this paper are as follows—

1) To study the characteristics of the retail drug shops in Bangladesh and to assess the legal and regulatory environment in which they are operating

2) To identify barriers and opportunities and to explore perceptions of the community, regulators, and drug sellers toward developing a model of accredited drug shop for Bangladesh

3) To determine the availability, affordability, and quality of selected essential medicines in the retail drug shops in Bangladesh

4) To explore the feasibility of adapting an accreditation program for retail drug shops in Bangladesh

5) To explore the possibility of facilitating TB DOTS program through accredited retail drug shops in Bangladesh

MATERIALS AND METHODS

Study Design

This study is a facility-based (drug shop–based) cross-sectional study exploring the status, operation, and regulation of the retail drug shops. It includes dispensing practices and the availability, quality, and affordability of essential drugs, as well as exploring perceptions of different stakeholders regarding the feasibility of an accredited drug shop program in Bangladesh.

To gather relevant data, we used (a) document review for policy and regulatory environment, (b) quantitative survey for profiles of retail drug shops and for information about thetraining and experience of the drug sellers, and (c) qualitative methods to elicit perceptions of the community members and other stakeholders. Structured observations were done in a subset of the sampled retail drug shops to document the dispensing practices of the salesperson or dispenser (table 1).

Table 1. Study Methods, Objectives Addressed, Sample Size, and Study Population

Methods	Study population
Drug shop survey (Obj. 1, 3, 5) (***n***=111)	• Salesperson or dispensers from sampled retail drug shops
Structured observation of interaction between salesperson or dispensers and clients (Obj. 2) (***n***=345)	• Interactions between salesperson or dispensers and clients visiting sampled retail drug shops
Focus group discussion (Obj. 1, 2, 3) (***n***=16)	• Community members using the sampled retail drug shops
Key informant interview (Obj.2, 4) (For list, see appendix C)	• Regulatory authority at district levels(drug superintendent or inspector) • National-level key stakeholders (from DGDA, BCDS,PCB)

n = observation subset; Obj. = objective; PCB = Pharmacy Council Bangladesh

Study Population

The study population of this paper includes(a) retail drug shops in the neighborhood of the upazila health complex, market, and key business hub and the peri-urban areas of the seven city corporations; (b) salespersons or dispensers in those retail drug shops; (c) samples of community members who purchase from the shops (focus group discussions [FGDs], structured observations); and(d) key informant interviews (KII)with drug superintendents (DSs), drug inspectors (DIs), regulators, and members of professional associations.

Operational Definition of Drug Shop

For this study, retail drug shops are defined as private retail pharmacies or drugstores eligible for mandatory approval and registration from DGDA. This definition does not include Ayurveda, Homeopathy, and Unani Board (AHUB) facilities that are selling drugs and medicines.

Sampling

This facility-based study includes retail drug shops from rural and urban areas in all seven divisions of the country. The rural samples include drug shops in the neighborhood of the upazila health complex (UHC), market, and key business hub. The urban samples were those situated in the center and peri-urban areas of the seven city corporations. Those are detailed next.

Rural Sample

Because of constraints in time and resources, we conveniently limited the number of sampled upazilas to 30 that were selected from the 7 divisions, proportionate to the size of the division (proxied by the number of upazilas in a division). In the divisions, we divided the districts into two groups: districts that have a public or private medical college and hospital or other tertiary facilities, and districts that do not have such facilities, preferably situated farthest away from district sadar. We tried to sample from both groups in equal proportion as much as possible. This sampling procedure was implemented to capture the diversity in a division.

Only one upazila was selected from a district. When selecting upazilas from the districts, this study chose (a) upazilas that were remote from the districts situated centrally in a division and (b) central upazilas from districts situated in the periphery of the same division. Three retail drug shops were selected from each of the sampled upazilas which fulfilled the following criteria—

1) Drug shops in the neighborhood of the UHC, sadar market, and business hub (which were within a 3-kilometer radius of UHCs)

2) Drug shops on the basis of their distance from the UHC (one nearest to the UHC, one farthest from the UHC, and one at a distance in-between) as available

3) Drug shops that have a maximum of customer visits (from spot assessment)

Table 2 shows the sampling distribution of upazilas in the seven divisions.

Table 2. Distribution of Study Upazilas (Subdistricts) Proportionate to the Size of the Divisions

Divisions	Total no. of upazilas in each division	% of total upazilas	Proportionate no. among 30 upazilas	No. of sampled drug shops from each upazila
Barisal	41	8	3	9
Chittagong	100	21	6	18
Dhaka	123	25	8	24
Khulna	59	12	4	12
Rajshahi	67	14	3	9
Rangpur	58	12	4	12
Sylhet	38	8	2	6
Total	486	100	30	90

Source: http://www.bangladesh.gov.bd/site/page/fc63120c-63e9-406f-904a-48e399ca0f79/District%20Portals

This selection was made to get a comprehensive picture of the drug shops that are distributed across different parts of a district including their proximity to a secondary or tertiary facility.

Urban Sample

To make the most efficient use of resources and time, the urban samples were included exclusively from the 7 city corporation areas (out of a a total of 11 city corporations),which were the divisional headquarters. From the central thana (a subdistrict or police district also known as a kotwali) of each city corporation area, three drug shops were selected according to the following criteria, for a total of 21drug shops—

- First drug shop was selected from the central area near to kotwali thana
- Second drug shop was selected 1 kilometer away from the first one
- Third drug shop was selected from the border area of the city (peri-urban)

Table 3. Summary of the FGDs and IDIs Conducted, by Different Divisions

Divisions	No. of sampled drug shops in each UZ	FGDs	KII
Barisal	9	2	Central (Dhaka) 1. DGDA 2. PCB 3. BCDS Divisional sadar 4. DGDA—superintendent of drugs, drug inspectors
Chittagong	18	2	
Dhaka	24	2	
Khulna	12	3	
Rajshahi	9	2	
Rangpur	12	3	
Sylhet	6	2	
Total	90	16	

FGDs = focus group discussions; KII = key informant interviews; UZ = upazila

Respondents

The salesperson/dispenser, or owner of each of the drug shops who was present at the time of the survey, was included as the respondent for this study. If the salesperson/dispenser and the owner of the shop were different individuals, only the former was included in the study. If multiple salespersons/dispensers were present at the time of the visit, one person was selected at random.

In addition, a sample of community members in the catchment area of each shop who had visited it in the past month was identified. FGDs were conducted to elicit the participants' perceptions of services received and expectations from the retail drug shops. We also conducted KII with relevant stakeholders in the divisional sadars (DSs or DIs, if any) and centrally at Dhaka (table 3), including personnel from DGDA. A summary of the FGDs and IDIs conducted by different divisions is shown in the table.

The sites of the districts from where the sample upazillas/urban thanas were selected are shown in Figure 1.

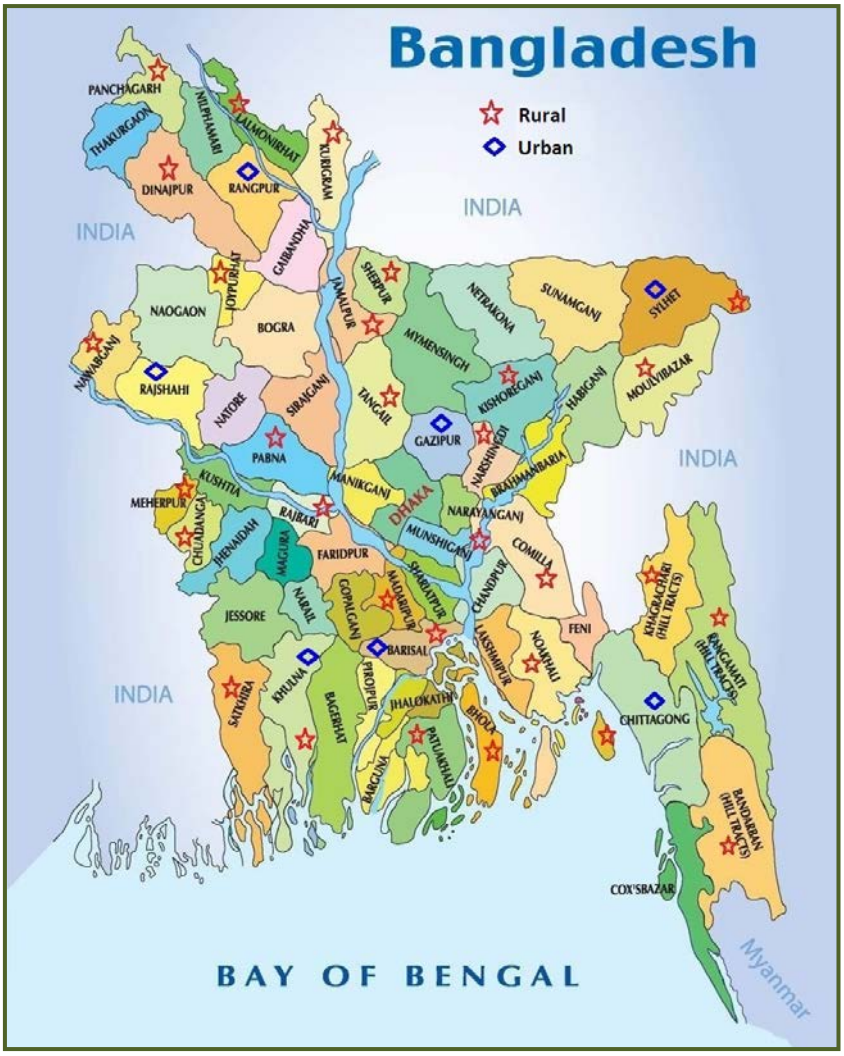

Figure 1. Rural and urban sites from where the sample upazilas and thanas were drawn. *Source*: http://www.ngof.org/nrc/wdb/watsanmap.php

Data Collection

Tools for data collection such as survey questionnaires and FGD and KIIs guidelines were developed (adapting and contextualizing from tools used by SIAPS in similar studies in Tanzania and Uganda) and were used for collecting data from the respective study population and samples. A reference list of key drugs for common illnesses, (based on the latest government-approved list of essential drugs) was prepared to check availability in the retail drug shops, whether prices were clearly mentioned on the package, and whether the expiration date, packaging status, and storage of the drug were in order.

The research assistants recruited for this study had sound backgrounds of science and health survey experience and underwent five days of training. The training consisted of didactic lectures on the content of the instruments followed, mock interviews, and field-testing through repeated practice sessions outside the study areas. End-of-training debriefings and necessary feedback, suggestions, and guidance was provided by the principal investigators (PIs) and co-PIs.

The day-to-day field activities of the teams were overseen by the team leaders and assigned supervisors. The whole survey activity was supervised and managed by the PIs and co-PIs, who made frequent field visits and provided assistance and guidance as and when needed. The field activity and data entry work was completed within 45 working days.

Quality Control, Data Management, and Analysis

To ensure completeness of the survey, the field research team members cross-checked each other's filled-in questionnaires every day before leaving field under the supervision of the team leader. An independent, mobile quality-control team also randomly checked a proportion of the questionnaires completed the previous day in the working areas of each of the study teams. Such checks occurred in random spots in the field and feedback provided to the team on any errors or gaps identified. Instructions for corrections were communicated to all the teams simultaneously to ensure standardization.

Again, the research team in the head office also cross-checked all questionnaires for inconsistencies not conforming to the instructions given at the time of training of the interviewers. If any were found, the questionnaire was discarded, and the survey was redone. This extensive process ensured the quality of data in a time of great political instability and difficulty of movement in the field.

When the field activities were completed, data were entered using the statistical package for the social sciences (SPSS) by a professional data management team. Of the total data, 5% was reentered to control data-entry quality. During the data entry, the PI, co-PIs, and project managers supervised the data management team to ensure the quality and validity of the data, and the codebook developed by the research team was used for this purpose.

When data entry was completed, the files were transferred into the SPSS for cleaning, consistency check, and cross-tabulation. The research team analyzed the final cleaned dataset with SPSS, following an analysis plan prepared beforehand.

Ethical Clearance

The study protocol was approved by the ethical review board of the James P. Grant School of Public Health, BRAC University, Dhaka. Informed consent was obtained from the participants before conducting the interviews. This study involved no invasive procedure and confidentiality of the data and participants was maintained at all stages of the study.

RESULTS

Findings from Quantitative Survey of the Drug Shops

Data are presented to describe the characteristics of the drug shops, the dispensers, availability and prices of the essential drugs, and knowledge on TB and DOTS for TB.

Profile of the Drug Shops

Most of the sampled drug shops were in operation for more than 10 years, especially in the rural areas (table 4). In general, those shops were open seven days a week and more than eight hours a day, and most were attended by a single person (69%). The floor space of the rural drug shops was larger than those in the urban areas (214 sq. ft. and 195 sq. ft., respectively).[2]

Table 4. General characteristics of the drug shops, %

	Rural (*n*=90)	Urban (*n*=21)	All (*N*=111)
Duration of operation (years)			
≤5	32	38	33
5–10	21	24	22
>10	47	38	45
Mean (±sd)	11 (10.3)	11(12.7)	11 (10.7)
No. of days open in a week			
< 7	8	19	10
7	92	81	90
Mean (±sd)	7 (0.6)	7(0.4)	7 (0.5)
No. of hours open in a day			
≤6	—	—	—
6–8	4	9	5
>8	96	91	95
Mean (±sd)	12 (2.6)	11 (1.9)	12 (2.5)
Floor space of the shop (sq. ft.)mean (±sd)	214 (186.2)	195 (136.6)	211 (177.5)
No. of persons working in the shop			
1	70	67	69
>1	30	33	31

sq. ft. = square feet; *N* = all observations; *n* = observation subset; sd = standard deviation

Possession of trade licenses that are issued by local bodies, such as city corporations in urban areas and union councils in rural areas was almost universal for the drug shops; yet only 80% to 90% of the shops had drug licenses issued by the DGDA (table 5). According to the respondents, approximately 80% of the shops were inspected by the DSs or DIs within the past year. The inspectors used a checklist during the inspection (see appendix B). Regarding documents required for applying for a drug license, researchers observed substantial

[2]The floor area is not fixed by DGDA licensing requirements.

awareness in drug shop personnel about trade licenses (79%), national IDs (76%), and pharmacist registration certificates (52%), especially in the urban areas. Interestingly, 13% of the respondents were found to be unaware about such requirements.

A majority of respondents (55%) stated that a drug license cost less than BDT 10,000, whereas approximately 40% perceived the cost to be from BDT 10,000 to BDT 20,000 (table 5). However, the official licensing fee is standard across the country (BDT 2,500 in city areas and BDT 1,500 in rural areas). A majority of respondents also perceived the process of getting a drug license to be lengthy, spanning from a few weeks to a few months. When asked why some of them did not obtain a drug license, the majority of respondents mentioned that the process was too complicated.

Table 5. Legal Status and Issues of the Drug Shops, %

	Rural (*n*=90)	Urban (*n*=21)	All (*N*=111)
Reported possession of trade license	96	100	96
Reported possession of drug license	81	90	83
The shop was reported to be inspected			
Within past one year	84	79	83
Within past two years	16	21	17
Knows about the documents required for drug license (multiple responses)			
Trade license	78	86	79
Bank solvency certificate	19	38	22
National ID photocopy	73	86	76
Pharmacist registration certificate	50	62	52
Proof of deposit of license fee	43	38	42
Passport-size photo	39	29	37
Education certificate	12	9	12
Physical status of the shop	11	5	10
Don't know	13	9	13
Perceived amount of license fee (BDT)			
<10,000	54	57	55
10,000–20,000	41	38	40
20,000–30,000	3	9	4
>30,000	1	—	1
Perceived challenges (multiple responses)			
Lengthy process	58	76	61
Lack of information	11	14	12
Licensing fee too high	51	38	49
Problem related to documents	16	14	15
No problem perceived	7	—	5
Reasons for not obtaining drug shop license (multiple responses)			
Have drug shop license	81	90	83
No idea on how to apply for license	4	5	4
Complication of licensing procedure	10	10	10

	Rural (*n*=90)	Urban (*n*=21)	All (*N*=111)
Do not feel licensing as necessary	2	5	3
Need a lot of money	7	—	5
Shop relocation	1	—	1

— = not applicable

The majority of the clients (65%) came to purchase drugs without a prescription. Self-referral (68%) was dominant especially in the urban areas; this method was followed by public health facilities (31%), more so in the rural areas (table 6). Other than selling medicines, the drug shops also provided additional clinical services such as giving injection (60%), diagnostic services (63%), burn and wound dressing (63%), and vaccinations (31%), which are services that are not allowed under the drug license. Those services were administered in the urban shops more frequently than in the rural shops (table 6). In most cases (91%), the nearest health facility was 30 minutes away on foot. Patients were usually referred to the nearest government hospital (92%) and nearest private hospital or clinic (44%).

Table 6. Patient Flow and Services at the Drug Shops, %

	Rural (*n*=90)	Urban (*n*=21)	All (*N*=111)
Major source of clients (multiple responses)			
Public health facilities/clinics/hospitals	34	19	31
Private health facilities/clinics/hospitals	10	19	12
Private practice (chambers)	7	5	6
Self-referral	67	76	68
No. of clients visiting daily			
With prescription	31	36	35
Without prescription	69	64	65
Other services available			
Pushing(giving) injections	59	67	60
Diagnostic services (blood sugar, blood pressure)	62	67	63
Vaccination services (TT, rabies vaccine)	30	38	31
Burn and wound treatment/dressing	66	52	63
Distance from nearest health facility			
Less than 30 minutes on foot	90	95	91
31 minutes to 1 hour on foot	8	5	7
More than 1 hour on foot	2	—	2
Referral options (multiple responses)			
Nearest government hospital	93	86	92
Nearest private hospital/clinic	39	67	44
NGO-run hospital	7	14	8
Doctor available at the shop	4	5	4
Nearest village doctor	1	—	1
Nearest private MBBS doctor	4	—	4
Nearest upazila health complex	4	—	4

MBBS = bachelor of medicine, bachelor of surgery; NGO= nongovernmental organization; TT = tetanus toxoid

The drug shops procured medicines directly through the pharmaceutical company representatives, or medical detailers, (93%) followed by the wholesalers (48%) (table7). Most orders were placed directly with the sales person (92%). In general, orders were placed weekly (52%), especially in the rural areas, and some were placed daily (36%), especially in the urban areas.

Table 7. Drug procurement system in the drug shops, %

	Rural (*n*=90)	Urban (*n*=21)	All (*N*=111)
Main drug suppliers (multiple responses)			
Wholesalers	48	48	48
Pharmaceutical company representatives	92	95	93
Pharmaceutical company suppliers	38	38	38
Collect from district-level drug shop	11	—	9
Mode of order placement (multiple responses)			
In person	50	48	49
By telephone	36	33	35
Through contact with sales person	93	86	92
Frequency of placing an order(multiple responses)			
Daily	31	57	36
Weekly	57	33	52
Monthly	13	9	13
When needed	8	4	7
Waiting time toreceive asupply			
< 7 days	100	100	100

Interestingly, sales and stock records were maintained only in a small proportion of the drug shops—10% and 9%, respectively (table 8).Refrigerators that were mostly functional were available in about one-third of the shops. The expired drugs were either dumped (60%) or returned to the supplier (80%).

Table 8. Record-Keeping Storage Process in the Drug Shops, %

	Rural (*n*=90)	Urban (*n*=21)	All (*N*=111)
Keeps a record of drugs sold	8	19	10
Keeps a record of drugs stocked	8	14	9
Refrigerator available	31	33	31
Mode of dealing with expired drugs (multiple responses)			
Burn	2	—	2
Bury	9	—	7
Dump	60	62	60
Return to supplier	82	71	80
Throw in the canal	2	9	4

Profile of Respondents (Dispensers), including their Training Scenario

Only 51% of the shops were staffed by a pharmacist.Of those pharmacists, 91% were mostly certificate holders of the three-month course in pharmacy (table 9). In 12% of the shops, the owner and the dispenser were different persons (not shown). Inthe rural areas, about 4% of the respondents had 10 years or lessof schooling. One-third of the respondents either passed the higher secondary certificate (H.S.C.) (12 completed years of schooling) or were graduates. Of them, 32 respondents were involved in other income-earning activities.

Table 9. Characteristics of Dispensers/Respondents in Drug Shops, %

	Rural (*n*=90)	Urban (*n*=21)	All (*N*=111)
Ownership status			
Pharmacist, dispenser, owner is same person	76	81	76
Owner only	13	5	12
Dispenser only	11	14	12
Status of the respondents/dispensers			
Pharmacist dispenser	49	62	51
Non-pharmacist dispenser	51	38	49
If pharmacist,			
Category			
Category A pharmacist (M Pharm, B Pharm)	2	—	2
Category B pharmacist (diploma)	7	8	7
Category C pharmacist (certificate course)	91	92	91
Education			
≤10 yrs. of schooling	4	—	4
S.S.C.passed	27	38	29
H.S.C.passed	32	38	33
Graduate	37	24	34
Involvement in any other occupation			
Farming	48	20	43
Self-employment	15	40	19
Others*	37	40	38

B Pharm = bachelor of pharmacy; M Pharm = master of pharmacy; S.S.C. = secondary school certificate

* nursery, fishery, business, or student

Around 30% of the respondents received any training related to dispensing (table 10).In the case of respondents from rural shops, this training was exclusively from the pharmaceutical companies. In the urban areas, government and private organizations played a major role in providing the training. Interestingly, respondents used a variety of informal sources and agents in learning the trade, for example, family members, an apprenticeship with an MBBS doctor or a certified pharmacist, and so forth.

A majority of the non-pharmacist respondents expressed their willingness to receive formal training in dispensing and other relevant topics (e.g., PHC and first aid).They perceived that the training would make them aware of the rules and regulations of dispensing medicines to

the clients (84%), would improve their efficiency in dispensing medicines (66%), would improve their relationship with clients (21%), and would be good for business (21%).

Table 10. Training Profile of Respondents who are Non-Pharmacist Dispensers in Drug Shops, %

	Rural (*n*=46)	Urban (*n*=8)	All (*N* =54)
Received any dispensing training	30	25	30
Training provided by			
Government organization	36	—	31
Private organization	29	—	25
NGOs	7	—	6
Pharmaceutical companies	28	100	38
Informal learning while working with and trained by (those receiving no training)			
Fellow drug seller in other store(s)	44	33	42
MBBS doctor in the drug shop or pharmacy*	9	17	10
Pharmacist	3	—	3
Village doctor	16	17	16
Relatives	22	—	18
LMAF course	3	—	3
Pharmaceutical company	3	33	8
Willing to receive formal training	87	100	89
Perceived necessity for having training (multiple responses)			
Security of shop	16	33	18
Efficient dispensing	69	50	66
Knowledge of rules and regulations	81	100	84
Good reputation with government	6	—	5
Good relationship with clients	16	50	21
Good for business	19	33	21

LMAF = local medical assistant and family planning welfare
*Doctors may practice in any pharmacy or drug shop if they have licenses from the Bangladesh Medical and Dental Council.

Availability, Affordability, and Quality of Selected Essential Drugs

Most of the selected essential drugs were not available universally, availability varying anything from 22% for benzyl benzoate solution in the rural areas to 43% for co-trimoxazole tabs in the urban areas (table 11).Labels indicating maximum retail price and expiration date were found to be universal (data not shown).

Table 11. Drug Shops with Selected Essential Drugs Available, %

	Rural (*n*=90)	Urban (*n*=21)
ORS (oral rehydration salts) (1 pack)	100	100
Tablet co-trimoxazole (1 tablet)	64	43
Syrup co-trimoxazole (60 ml)	64	62
Syrup amoxicillin (100 ml)	91	95
Tabletciprofloxacin(1 tablet) (500 mg)	100	100
Syrup ciprofloxacin (60 ml)	92	100
Syrup aluminum hydroxide + magnesium hydroxide	84	90
Tablet ranitidine (1 tablet)	100	100
Tablet paracetamol (1 tablet) (500 mg)	100	100
Tablet aspirin (1 tablet) (300 mg)	61	71
Tablet iron folic acid (1 tablet)	77	71
Tablet ascorbic acid(1 tablet)	81	90
Tablet mebendazole (1 tablet)	81	90
Tablet atenolol (1 tablet) (50 mg)	91	95
Benzyl benzoate lotion 25% (ph)	22	48
Chloramphenicol eye drop 10 ml (1 bottle)	91	90
Xylometazoline nasal drop 15 ml (1 bottle)	71	90
Miconazole ointment 10g (1 tube)	69	62
Tablet metronidazole (1 tablet) (400mg)	98	100

Table 12 presents the two most commonly sold brands of selected essential drugs in the rural and urban areas on the basis of responses from the dispensers. The lowest and highest price of a unit of selected essential drugs and the percentage difference is shown in table 13. As can be seen, a wide variation in prices exists, depending on the brand, and may range from as low as 10% for a bottle of co-trimoxazole syrup (60 ml) in the rural shops and 7% for a bottle of amoxicillin syrup (100 ml) in the urban areas to as high as 100% for a tablet of atenolol (50 mg) in the rural shops and 100% for a tablet of co-trimoxazole or aspirin (300 mg).

Table 12. Two Most Common Brand Names of Essential Drugs Sold in the Sampled Drug Shops, as Reported by Respondents

	Rural (*n*=90)		Urban (n=21)	
	Brand name 1	**Brand name 2**	**Brand name 1**	**Brand name 2**
ORS (oral rehydration salts) (1 pack)	Orsaline-N (77)	NEO-Saline (26)	Orsaline-N (76)	NEO-Saline (29)
Tablet co-trimoxazole(1 tablet)	Cotrim (48)	Megatrim (29)	Cotrim(67)	Politrim (12)
Syrup co-trimoxazole(60 ml)	Cotrim (74)	Megatrim(30)	Cotrim (92)	Megatrim (33)
Syrup amoxicillin (100 ml)	Moxacil (40)	Tycil (8)	Moxacil(40)	Tycil (17)
Tablet ciprofloxacine(1 tablet) 500 mg)	Ciprocin (69)	Neofloxcin(30)	Ciprocin(86)	Neofloxcin(43)
Syrup ciprofloxacine(60 ml)	Ciprocin(55)	Neofloxcin(28)	Ciprocin(86)	Neofloxcin(53)
Syrup aluminum hydroxide + magnesium hydroxide	Antacid Plus(44)	Oxicon(33)	Antacid(47)	Oxicon(25)

	Rural (*n*=90)		Urban (n=21)	
	Brand name 1	**Brand name 2**	**Brand name 1**	**Brand name 2**
Tablet ranitidine (1 tablet)	Neotak (47)	Neoceptin(22)	Neotak(76)	Neoceptin(35)
Tablet paracetamol(1 tablet) (500 mg)	Napa (59)	ACE (37)	Napa(76)	ACE(45)
Tablet aspirin (1 tablet)(300 mg)	Ecospirin (67)	Carva (26)	Ecospirin(53)	Carva(37)
Tablet iron folic acid (1 tablet)	Folison(17)	Folic(10)	Folison(27)	Prenat-CL(8)
Tablet ascorbic acid(1 tablet)	Cevit (84)	Vasco (36)	Cevit (95)	Vasco (61)
Tablet mebendazole(1 tablet)	Solas(49)	Almax(16)	Solas(58)	Almax(20)
Tablet atenolol (1 tablet) (50 mg)	Tenaloc(73)	Tenoren (49)	Tenaloc(60)	Tenoren(29)
Benzyl benzoate lotion 25% (ph)	Ascabiol(30)	Scabisol(10)	Ascabiol(30)	Chermethin(33)
Chloramphenicol eye drop 10 ml (1 bottle)	Chalorphen(27)	Ofsophenical(11)	Chalorphen(37)	Ofsophenical (19)
Xylometazoline nasal drop 15 ml (1 bottle)	Antazol (47)	Afrin (4)	Antazol (58)	Afrin (16)
Miconazole ointment 10g(1 tube)	Micoral(19)	Xelora (17)	Micoral(15)	Fingdal(12)
Tablet metronidazole (1 tablet) (400 mg)	Amodix(36)	Flagyl (21)	Amodix(43)	Filamet(29)

Note: This list has been identified on the basis of the highest proportion of responses

Table 13. Percentage Differences between the Lowest and Highest Price of a Unit of Selected Essential Drug in Rural and Urban Areas

	Rural (*n*=90)			Urban (*n*=21)		
In BDT	**Lowest (mean)**	**Highest (mean)**	**% diff.**	**Lowest (mean)**	**Highest (mean)**	**% diff.**
ORS (1 pack)	4	6	50	5	6	20
Tablet co-trimoxazole(1 tablet)	2	2	NA	1	2	100
Syrup co-trimoxazole(60 ml)	21	23	10	21	21	NA
Syrup amoxicillin (100 ml)	44	49	11	44	47	7
Tablet ciprofloxacine(1 tablet) (500 mg)	12	15	25	11	15	36
Syrup ciprofloxacine (60 ml)	86	97	13	85	96	13
Syrup aluminum hydroxide + magnesium hydroxide	58	75	29	61	75	23
Tablet ranitidine (1 tablet)	2	3	50	2	3	50
Tablet paracetamol (1 tablet)	1	1	NA	1	1	NA
Tablet aspirin(1 tablet)	2	2	NA	1	2	100
Tablet iron folic acid (1 tablet)	3	5	67	2	2	NA
Tablet ascorbic acid (1 tablet)	1	1	NA	1	1	NA
Tablet mebendazole (1 tablet)	3	3	NA	2	3	50
Tablet atenolol (1 tablet) (50 mg)	1	2	100	1	1	NA

In BDT	Rural (*n*=90)			Urban (*n*=21)		
	Lowest (mean)	Highest (mean)	% diff.	Lowest (mean)	Highest (mean)	% diff.
Benzyl benzoate lotion 25% (ph)	39	45	15	36	42	17
Chloramphenicol eye drop 10 ml (1 bottle)	30	34	13	28	34	21
Xylometazoline nasal drop 15 ml (1 bottle)	13	17	31	21	27	29
Miconazole ointment 10g (1 tube)	44	51	16	46	49	7
Tablet metronidazole(1 tablet) (400mg)	1	1	NA	1	1	NA

BDT = Bangladeshi taka; NA = not available; ORS = oral rehydration salts

Knowledge of TB and DOTS

Approximately 90% of the respondents stated that they were aware of the disease tuberculosis (table 14). A majority (93%) knew that TB's mode of transmission was through air; however, some respondents said that smoking (59%), sharing needles and syringes (25%), and using narcotics (20%) could transmit TB. A persistent cough lasting more than two weeks (87%) was identified as the most common symptom of TB by the respondents. Other symptoms mentioned included coughing blood (62%), fever for more than two weeks (50%), and weight loss (56%). A chest x-ray (50%) and sputum examination (95%) were frequently mentioned for diagnosing TB infections.

Table 14.Respondents' Knowledge of Tuberculosis Infection (Multiple Responses), %

	Rural (*n*=90)	Urban (*n*=21)	All (*N*=111)
Aware of the disease TB	88	100	90
Mode of TB spread			
Through handshakes	7	5	6
Through the air when a person with TBcoughs or sneezes	91	100	93
Through sharing dishes	23	19	22
Through touching items in public places (doorknobs, handles in transportation, etc.)	10	10	10
Through sexual intercourse	7	5	6
Sharing needles and syringes	24	29	25
Smoking cigarette	62	43	59
Using narcotics	20	19	20
Through air	7	—	5
Don't know	2	—	2
Symptoms of TB infection			
Persistent cough (two weeks or more)	88	86	87
Coughing blood	64	52	62
Fever for more than two weeks	51	48	50
Loss of weight	51	76	56
Excessive night sweat	7	9	7

	Rural (*n*=90)	Urban (*n*=21)	All (*N*=111)
Chest pains	28	29	28
Shortness of breath	37	24	34
Fatigue, body malaise	12	9	12
TB diagnosis			
Chest x-ray	48	62	50
Sputum exam	97	90	95
Physical examination	8	5	7
Skin test	2	19	5
Others	16	29	20

Only 50% of the respondents had heard about TB DOTS whereas only 39% heard about multidrug resistant (MDR) TB and 48% about the National Tuberculosis Program (NTP) (table 15). Of the respondents, 4% didn't know about the place from where TB treatment could be accessed. In the urban areas, 14% of the respondents stated that TB care was available from NGO clinics, and 29% said care was available from the Bangladesh Rural Advancement Committee (BRAC).In the rural areas, 21% of respondents mentioned upazila health complexes, whereas BRAC was mentioned by 12% of respondents. Besides death (62%), respondents were also aware of the consequences of incomplete treatment such as worsening of the condition (36%) and recurrence of the disease (20%), but they were only marginally aware about its spread (6%) (table15).

Table 15. Respondents' Knowledge of TB and DOTS for TB, %

	Rural (*n*=90)	Urban (*n*=21)	All (*N*=111)
Heard about TB DOTS	50	48	50
Place where TB DOTS service was available			
Do not know the place(s)	50	52	50
BRAC	12	29	15
Government hospital	8	19	10
Upazila health complex	21	—	17
NGO clinic	2	14	5
TB hospital	1	—	1
Patient's home	3	—	3
Don't know	4	—	4
Consequence of incomplete TB DOTS			
Patient dies	62	62	62
Disease gets worse	32	52	36
Disease comes back	21	14	20
Disease spread to others	7	5	6
TB becomes resistant	3	5	4
Don't know	6	—	5

The respondents stated that in a month, on an average, they encountered two diagnosed TB patients and referred two to three patients for diagnosis (table 16). Approximately 89% of

them came to buy TB drugs with a prescription; zero patients in the urban areas came to buy TB drugs without a prescription. This percentage of patients coming without a prescription was 17% for shops in rural areas.

Among the respondents, 32% received some training on TB, mostly from the NGOs including BRAC (table 17). This training included a general overview on TB and MDR TB.

Table 16. TB Patient Flow at the Drug Shops (Monthly)

	Rural (*n*=25)		Urban (*n*=8)		All (*N*=33)	
	Mean (± sd)	Median	Mean (± sd)	Median	Mean (± sd)	Median
Identified TB patients	2 (1.1)	2	2 (0.7)	2	2 (1)	2
	Rural (*n*=59)		**Urban (*n*=10)**		**All (*N*=69)**	
Patients referred for TB diagnosis	3 (2.4)	2	3 (1.2)	2	3 (2.3)	2
	Rural (*n*=9)		**Urban (*n*=6)**		**All (*N*=15)**	
Patients came with prescription, %	83		100		89	
Patients came without prescription, %	17		—		11	

Table 17. Formal and Informal TB-Related Training Received by Respondents in Drug Shops, %

	Rural (*n*=90)	Urban (*n*=21)	All (*N* =111)
Received TB-related training in past two years	31	38	32
Providers of training (multiple responses) (*n*=36)			
NGO	68	75	69
Government and private hospital	21	12	19
Specialized chest hospital	—	12	3
BRAC	18	25	19
Upazila health complex	7	—	6
Topics of the training(multiple responses)			
General overview on TB	100	100	100
Drug-resistant TB	54	62	56
DOTS	68	88	72

Of the total shops, 13% sold TB drugs, three times more in urban shops (29%) compared to those in the rural areas (10%) (table18). In exploring the willingness to submit incoming TB prescriptions (patients) to the NTP, the survey found that only 22% complied in the rural areas. Among the respondents, 79% expressed their willingness to work as a DOTS provider if they could get expected financial and training support (49%).

Table 18. Willingness of Respondents in Drug Shops to Work as TB DOTS Provider, %

	Rural (*n*=90)	Urban (*n*=21)	All (*N*=111)
TB drugs sold	10	29	13
Willingness to work as TB DOTS provider	81	71	79
Expected supports (*n*=88)			
Financial	11	27	14
Training	36	20	33
Both (financial and training)	48	53	49
Others	5	—	4

Findings from the FGDs with Population of the Catchment Areas of the Selected Drug Shops

In the FGDs, we explored issues such as (a) the history of the drug shops, including their establishment; (b) clients' perceptions of and experiences with the shops; (c) the availability of drugs; and so forth. Those points are described next and in sequence.

The Shop, the People, and the Transaction

The selected shops for the FGDs (*n*=16) dates from the past 3 to 30 years. Some participants in the FGDs mentioned that they have been seeing the particular retail drug shops since their childhood. However, some respondents were not sure of the timeline, and an element of guess was involved. Table 19 shows the approximate age of the shops as reported by the respondents.

Table 19. Age of the Studied Drug Shops

Shop age, years	No. of shops
3–4	2
5–7	1
7–8	2
10–12	3
12–15	2
15–25	2
25–30	2
More than 30	2
Total	16 shops

How Well Known Are the Drug Sellers and Owners?

Respondents from all the areas knew their drug shop owners and dispensers very well and were satisfied with the behavior of those people. Some respondents also mentioned that their dispenser was amiable and trustworthy and had a very good relation with them. Others mentioned that every time they visit the drug shops, the owner welcomes them and provides service properly.

The respondents knew that the drug sellers received various training about drug dispensing in sadar hospitals and different pharmaceutical companies. Some respondents said that they did not think training was necessary because the dispensers had many years of experience. One even said that the dispenser already had extensive knowledge:

> *"He doesn't need training; he already has achieved vast knowledge on drug dispensing from his 30 years work experience."*
> (FGD_DHA_MAD_SHI_1; 113-115)

Some respondents knew about their dispenser's educational qualifications, such as if the dispenser had passed the H.S.C. (some were graduates), whereas other respondents had no idea about the education. In general, respondents thought that although dispensers may not have the requisite education, they had learned the trade of dispensing from various sources, including apprenticeships and inheritance of the family's business. Respondents also mentioned that some dispensers had qualifications such as local medical assistance and family welfare (LMAF) and rural medical practitioner (RMP),as well as various government- and NGO-sponsored training about drug dispensing and primary health care treatment.

Perceived Importance of Knowing the Drug Seller

Most respondents expressed concern about and emphasized the educational qualification of the drug dispensers; respondents thought that if the drug sellers were not properly qualified, the treatment provided would be improper and would be harmful for the patient's health. The respondents emphasized that because they visited the drug shops nearest them for any illness, knowing the drug seller's qualifications were very important. However, respondents said they had not thought about this importance earlier. Also, in most instances, respondents were not bothered much because they thought that the dispensers and drug sellers had sufficient experience. A respondent shared his experience on the importance of knowing dispensers' qualifications in the following words:

> *"Of course I think! Because when I visit the drug shop, if the drug seller does not know about drug dispensing, he cannot provide me proper medicine that I need.…Once I went to a drug shop to get some necessary medicine but the dispenser provided me sleeping pill instead of my required drug."*
> (FGD_KHU_CHU_ALA_8; 183-187)

Another respondent equated qualifications with proper service:

> *"It is important to know because if the drug seller has educational and professional qualification, then he will be able to provide us a proper service, and we do not have to suffer for that."*
> (FGD_RAN_PAN_SAD_14; 107-108)

Availability of Drugs

Availability of drugs varied according to location. For example, respondents from Barishal, Bhola, Dhaka, Noakhali, and Patuakhali were satisfied, whereas those from the Khagrachari, Rangpur, and Sylhet areas had difficulties getting all drugs from the shop. Again, respondents from Khulna division said that, in most of the cases, when they visited a shop they did not get all required drugs from that shop. One of them mentioned this lack of supply:

"If there are five drugs written in the prescription, then one or two drugs will not be found in this shop."
(FGD_KHU_KHU_MET_09; 12-14)

Also, according to the respondents, all drugs that are prescribed from government hospitals are not always available. However, some were of the opinion that "unavailable" drugs become available if a higher-ranking hospital employee were to order the pharmacy to deliver those drugs.

When a drug is not available from the relevant shop, respondents say they visit other nearby shops to procure it, and sometimes the drug sellers assist them. When drugs are not available locally, the drug sellers procure the drugs from nearby towns or cities or from another sadar or thana. Respondents in the Barishal area mentioned that it was mainly the seller's responsibility to collect the necessary medicines from metropolitan areas.

Is a Prescription a Must?

Having a prescription is not necessary to buy drugs for common health problems such as a cold, a fever, a headache, or a gastric problem, but some dispensers do not sell certain drugs (e.g., sleeping pills) without a prescription, especially to strangers. According to respondents, if a person who needs a drug explains the health problem to the drug seller, then on the basis of the symptoms only, the seller would provide the ill person with medication. One respondent said that for common illnesses, he did not think it necessary to obtain prescribed medicine. Also, respondents who had been taking the same medicine for a long time didn't think it necessary to carry the prescription when buying that medicine. One respondent mentioned that drugs for common illnesses could be had without a prescription:

"Without prescription, we can get medicine from this shop in case of normal disease such as gastric, fever, and so on."
(FGD_BAR_PAT_SAD_6; 63-68)

If a prescribed drug is not available, the drug sellers often substitute another brand, sometimes without informing the client. The clients have no say in this because they are ignorant about the quality of a particular brand, the respondents said. In some cases, respondents pointed out, the dispenser does not sell antibiotics and sleeping pills without a prescription. Two respondents mentioned that because the dispenser was known to them, they did not have a problem getting medicine without prescription. They also noted that sometimes they visited the shops with old receipts or they used empty packets of medicine to buy the same drug.

How to Take Medicine, What is the Duration of Dose, and What Are the Side Effects?

Most respondents said that the drug sellers apprised them of the quantity, frequency, time, and duration of intake, of whether to take the medicines before or after a meal, of how to prepare syrup for kids, and so forth. They mentioned that the dispensers write the instructions for them, but sometimes the dispensers also gave verbal instructions. In case the customer cannot read, the drug seller marks the medicine packet to indicate how many times and when the patient should take the medicine in a day. For prescriptions, sometimes the dispensers do not think it necessary to explain instructions. A majority of the respondents agreed that drug

dispensers explained the total duration of a dose of drugs that they sold. One respondent said the drug seller offers counsel:

> *"Sometimes the drug seller counsels us about the total doses that if you do not complete your dose … you will not get effective result."*
> (FGD_KHU_KHU_DUM_7; 36-38)

Most of the respondents stated that drug sellers usually do not explain the side effects of the drugs, unless asked. In Khulna and Rajshahi, all respondents pointed out that dispensers inform them about side effects and give advice accordingly, for example, the consequences of taking gastric medicine while taking a pain killer. In Rangpur, the dispensers usually explain the side effects if the medicines are for children. One respondent added that the dispenser could go one step further:

> *"If the patient's condition became worse than his previous condition, then the drug seller usually changes the medicine."*
> (FGD_RAN_DIN_PAR_15; 132-133)

Paying for Medicines

Usually drug sellers do not provide receipts for payment, and the clients also were not interested to receive such after buying drugs. In most cases, the drug seller was known to the clients (as either a neighbor or someone who lived in the same village), so the respondents also did not think having a receipt was necessary. According to one respondent, the seller and the client have a relationship of trust:

> *"The drug seller does not provide any money receipt and, as a consumer, I do not feel like to collect the money receipt because we both know each other and we are neighbors."*
> (FGD_CTG_KHA_MAN_4; 495-498)

If the client needed a receipt, the drug dispensers provided a white paper with the rubber stamp of the shop. One respondent mentioned that he usually checks the price, but collecting the payment receipt was not a common practice. Some respondents were able to buy medicine without any payment because the drug shop owner knew them. Other respondents mentioned that, in case of an emergency or a financial problem, they were able to get the medicine without making any payment. However, in Rajshahi, the respondents stated that they were not able to get the medicine without making full payment.

Disposing of Expired Drugs

The FGD participants said that because they were mostly illiterate or semiliterate, they hardly checked the expiration dates of the medicines they purchased. Instead, they trusted their drug sellers. One expressed doubts about understanding expiration dates:

"I am not an educated person, and I will not understand this kind of issue."
(FGD_RAN_RAN_MET_16; 216)

In contrast, another always checks expiration dates:

"Of course I check! When we go to the market to buy goods, we always do check the market, so when we visit the drugs shop, why we should not check the expiry date of medicine? I always check the manufacturing date and expiry date of medicine."
(FGD_KHU_CHU_ALA_8; 253-257)

A third respondent said he did not have enough time to check expiration dates when he visited the shop. Some respondents mentioned that the dispenser checked the expiration dates for them. One of the respondents shared his experience in this way:

"One day Ratan (owner/drug seller) took back the packet of drugs just after handing it over to me. He rechecked expiry date of all the drugs and told me: 'I gave you a date expiry drug by mistake; that is why I am rechecking it.' He checks the expiry date before selling it to the consumers."
(FGD_RAJ_JOY_PAN_11; 48-54)

Other Services Offered from Drug Shops

Most of the respondents said that drug shops offered first aid for burns and cut wounds that included stitching and dressing. Also services such as measuring blood pressure, giving injections, and administering intravenous saline are provided at the shops. PHC treatment for fevers, backaches, coughs and colds, gastric upsets, headaches, and so for this also available from the shops. In most cases, the shop owner or the dispenser provides those services. For situations that the dispenser could not address, respondents said the dispenser usually refers the patient to a doctor or hospital. When asked, the dispensers sometimes give clients health-related information and suggestions while performing the usual tasks.

What Factors Satisfy Clients?

Factors related to the satisfaction of services received from the drug shops included (1) the familiarity of the drug seller as a member of the community, (2) a short response time, (3) good behavior, (4) good services and late-hour services, (5) the availability of quality drugs, and (6) the option to pay in installments. In addition, proximity of the shops also mattered as did availability of services at odd hours.

Knowledge of Legal Status of Drug Shops

Most respondents knew that the drug shops they visited had a valid license because selling drugs without a license is a punishable crime. Some were not so sure:

"I do not know the importance to have license for a drug shop, but I know that this drug shop has a valid license."
(FGD_CTG_NOA_SON_3; 250-251)

> *"I do not know about licensing; is it important or not, but I think it is a good practice to have a license because if they have a valid license they will not be able to dispense harmful medicine."*
> (FGD_BAR_BHO_CHA_5; 411-414)

One respondent stated that he did not think it necessary to know about licensing when visiting drug shops. In Barisal, most respondents did not know whether the shop was licensed, although they emphasized that a licensed shop was not allowed to sell substandard drugs. In Khulna, most respondents were not sure if the shop was licensed; only one thought it important to have a license. In the Khulna metropolitan area, respondents stated that the drug shop had a license and displayed it. In Rajshahi and Rangpur, the majority of the respondents knew licenses were mandatory, but they were not sure if their shop had a license. In Sylhet, the majority of respondents had no idea about the licensing status of their drug shops. One of the respondents noted that a drug seller closed his shop at a questionable time:

> *"Once I observed that the drug seller shut down his shop, while the government authority came to inspect the drug shops of this area."*
> (FGD_RAN_DIN_PAR_15; 257-259)

Recommendations Made by the Respondents

The respondents made several recommendations to improve the quality of service at the drug shops—

- Creating community awareness of primary healthcare regularly offered through drug shops
- Adding more drug shops to increase accessibility and availability
- Training all the dispensers in the area
- Assisting with family planning services and providing mandatory presence of doctors, including specialists
- Providing necessary equipment for diagnostic tests; improving primary healthcare facilities
- Improving infrastructure of the shop's storage facilities, including the vaccination facilities
- Strengthening the government monitoring system
- Providing referral facilities for emergency cases, including providing ambulances
- Extending drug shop services to include secondary healthcare services
- Reducing drug prices and improving drug quality
- Obtaining financial support from the government and NGOs to improve the quality of the drug shop service including diagnostic and primary healthcare services

Findings from Structured Observations of Client-Dispenser Interaction in Selected Drug Shops

The structured observations of the patient, the caregiver, and the dispenser were carried out simultaneously when the survey was in progress. This task was accomplished by a team of two interviewers: one proceeded with the survey while the other took notes about interactions occurring during the survey. To reduce the Hawthorne effect, interviewers spent time building rapport before the actual data collection took place. Note that the observation was not specific to any particular illness but to any such interaction that occurred during the period of survey.

When clients came to buy medicine with or without prescriptions but asked for a specific medicine, most of the conversation between clients and dispensers during the transaction was about price. For those who sought advice for treatment, the dispenser asked questions about the illness. In about one-third of such client-dispenser interactions in urban areas, the dispenser asked about the nature of the illness (36%), the symptoms of the illness (27%), the duration of the illness (26%), and more. For example, when the client complained of pain, the drug seller asked about the exact location, nature, and duration of the pain, including the client's history of taking medicine. Or when the client complained about loose motion or diarrhea, the drug seller asked about frequency and consistency of the stool, whether blood and mucus was seen along with the stool, and so forth.

Sometimes, according to complaints, the drug seller made a superficial, nonspecific physical examination such as taking the client's pulse, checking for anemia, pressing the abdomen, taking temperature, checking blood pressure, and so forth. For a client with a complaint of a cough and cold, the drug seller would examine the chest with a stethoscope.

At times, the drug seller asked about the client's history of past illnesses; for example, in the case of hypertension or diabetes, the drug seller asked if the client had had any medication up until then and if the client had visited any other health care provider. Sometimes, the drug seller was found to prescribe, for example, drinking cold water for fever. Yet none of the dispensers asked about the client's family history of the disease.

The drug sellers mostly dispensed medicines per prescription. When a particular medicine was not available, the seller tried to procure it from neighboring dispensary or substituted another brand of the same medication. Those without prescriptions either asked for the medicine by name (sometimes also mentioning brand) or brought an empty package or container of the medicine. Pain killers, antacids, medicines for loose motion or fevers, cough syrups, and antibiotics are commonly mentioned drugs that clients bought from the drug shops without prescriptions.

For prescription drugs, the drug sellers advised clients to follow the prescription. They also advised about the timing of taking the drugs, for example, before or after food. Sometimes, the sellers would write instructions on the package or a blank paper. In a few cases, the dispenser emphasized completing the full course and following up after completing the course. In most cases, side effects were not mentioned. In only one case, the dispenser asked if the client had any previous history of problems after taking a particular drug (Alatrol).

Drug sellers also gave advice about (1) how to take common preventive measures so that the illnesses would not get worse, (2) how to watch for danger signs, and (3) when to consult a qualified physician or visit the nearest heath facility.

Findings from Key Informant Interviews with Relevant Stakeholders

We interviewed people from the regulatory authorities, the association of drug shop owners, and the pharmacy council that conducts the three-month certificate training program for dispensers. Findings are described subsequently according to themes.

Perspectives of the Regulators (DGDA Staff to Field Officers at District and Upazila Levels)

Regulatory Processes

According to the respondents, before opening and operating a retail drug shop in Bangladesh, the shop owner must obtain a license. Without a license, the storage, display, and sale of drugs are punishable crimes. The DGDA is the only licensing authority in the country. Once the district superintendent's office recommends the proposed shop after inspection, the DGDA's director general gives the approval. Every month, from 200 to 300 such licenses are approved. So far, the DGDA has licensed 1,15,439 drug shops. Interestingly, many people do not know that a license is required before opening a drug shop; they usually apply after opening a shop.

Other DGDA activities include training DSs and drug officers to do (a) quality assurance checks; (b) company audits;(c) compliance checks for good manufacturing practices (GMP) guidelines; and (d)routine checks to assess the shop's physical condition, its storage facility, its medicine expiration dates, the presence of a pharmacist, its dispensing process, and so forth.

According to the guidelines for operation of a drug shop, the license holder for a drug shop must have passed the secondary school certificate (S.S.C.) examination. If the license holder wants to dispense drugs, he or she must have a professional certificate (grade A to grade C). Alternatively, he or she must employ a registered pharmacist at the shop. A list of necessary documents for opening a drug shop is given in appendix A.

The DGDA office handles licensing, whereas its district-level offices (n=46) conduct field-level inspection and control of drug shops with a team of DSs and DIs. An inspection checklist for drug shops is found in appendix B.

Besides visiting drug shops to inspect for compliance, district-level office responsibilities include issuing new drug shop licenses (after clearance from central authority), renewing licenses, arranging for mobile courts, and taking action against drug shops not following the drug rules. District-level teams also visit pharmaceutical factories, collect samples from drug shops, and send those samples to labs for quality checks. A district drug licensing committee comprising the DS, field officer, civil surgeon, education officer, and upazila health and family planning officer helps in the process. Currently, only three drug inspectors are based in Barisal, Gazipur, and Sylhet. Thus, most of the field work is done by the superintendents.

Licensing Process

For someone to open a retail drug outlet, the first step is to apply to the district DSandto complete the required documents. After receiving the application, the DS inspects the shop and cross-checks the information provided in the documents. The DS then submits a report to the district drug licensing committee. When a number of such reports accumulate (one reason for delays in licensing), the district committee meets. After approving the application, the district committee sends the application to the DGDA office. The DGDA checks the documents, prepares a list of eligible drug shops, and returns the eligible list to the district DS's office. On the basis of this approved list, drug shop licenses are then issued by the district superintendent's office. The overall process may take from a few weeks to two or three months, according to the district superintendent's office. The license is valid for two years, after which it needs to be renewed.

How to Improve the Scenario: Problems and Prospects

The regulators at the central level said that the population explosion, unemployment, rapid urbanization, a high demand for drugs, and so forth are the root causes of unlicensed shops. According to the regulators, the monitoring process for drug shops should be strengthened; however, not enough regulators are now on staff. The regulators also advocated for a greater role of the MOHFW for improving this situation. One respondent made an observation:

> *"Life is a result of multidisciplinary action."*
> (KII_CEN_DGDA_1; 18)

As such, continuous work is needed. The respondents also emphasized the need for the public to closely watch for counterfeit and expired drugs, indiscriminate use of antibiotics, and polypharmacy. According to them, some medicines should be transferred from over the counter (OTC) to 'prescription only' to prevent misuse; a list of OTC drugs should be developed and implemented strictly. Only grade A and B pharmacists should be allowed to sell the 'prescription only' medicines because grade C pharmacists sometimes make mistakes resulting from lack of training. They stated benefits of 'prescription-only' drugs to be as follows—

- Require exact diagnosis by the doctor
- Reduce misuse of client's money
- Stop dispenser from fraudulently selling medicines
- Stop misuse or abuse of drugs by clients
- Raise awareness of indiscriminate use of antibiotics
- Increase people's trust in medicine
- Decrease irregular use of drugs
- Improve drug standards

However, respondents said that the DGDA was not authorized to control prescription practices, which is under the jurisdiction of the Directorate General of Health Services (DGHS).

All tiers of the regulators are of the opinion that the existing system is not adequate. They emphasized that the existing regulatory system needed to be improved in areas such as logistics, number of personnel, transport and communication systems for inspecting drug

shops, a fixed schedule for inspection, and so forth. Some respondents mentioned the difficulty of traveling in "Char" areas.[3]If sellers know about an upcoming inspection, they will close the shop in advance. Sometimes other shop owners close their shops and leave when they find that shops are being inspected. Or they remove unregistered medicines when they find that an inspection is occurring.

DSs and DIs can inspect the drug shops any time; but they are not given sufficient personnel. It is difficult for them to inspect all the drug shops in a working area that usually includes many districts. One respondent pointed out several problems:

> *"If I go for any inspection, I need to go along with magistrate and police. If I go without them, people ask why I am alone. Even if we caught any crime, we can't fine. We have the authority to file a case; we need to present evidence in the court. If no evidence is available, then the case is dismissed. Sometimes it happens that I found the crime and identify a person to give evidence, the person doesn't appear to the court as he lives in the same area as the criminal."*
> (KII_KHU_CHU_CHU_13; 54-67)

Another respondent describes his limitations:

> *"These things I am unable to do from my district; it would be better if actions are taken from higher level."*
> (KII_KHU_CHU_CHU_13; 98-100)

One respondent mentioned another difficulty:

> *"We advise them for licensing while inspecting; if we only fine them, then they will become our enemy."*
> (KII_KHU_CHU_CHU_13; 68-70)

Some respondents mentioned that sometimes—because of interference in the workings of the local committee by influential peoples—they could not take proper action for social reasons. Even after finding fake, unregistered medicine, they cannot fine or seize the shop. Sometimes because of political pressure, licenses are issued. One respondent described his experience of taking action against a *pallichikitshak*(village doctor) running an unlicensed drug shop The mayor called him the next day requesting for the release of the *pallichikitshak* and asking for special consideration.

> *"They are poor people, they live on this, and besides he is closer to me. I am sending him to you; consider his case."*
> (KII_KHU_CHU_CHU_13; 28-30)

One respondent summarized the scenario thus:

[3]A Char comprises temporary river islands formed from sedimentation that are solely connected by rivers, canals, and so forth and are hard to reach with services such as health care.

"We don't have our own office, no transport facilities, no protocol. There are around 3,000 shops in my area. Civil surgeon visits the clinic; he has car facilities; my work area is more, but I don't have that facility"
(KII_BAR_PAT_PAT_9; 79-84)

Limitations and Recommendations

Authorities in the existing regulatory and monitoring system are still following the 1940 and 1982 Drug Act, which they think need to be updated. Even then, the existing laws are not being followed properly. Most respondents were not satisfied with the existing laws because they could not take any immediate direct action. To improve the situation, they suggested some measures.

Regulatory—

- Create a practical relevant law that is based on an international standard drug act.
- Provide options for immediate action. Mobile court is too time-consuming.
- Increase DI power to take immediate action for issuing fines.
- Increase fine amounts, and make punishment stricter.
- Make the primary licensing selection authority the district drug officer.Cancel the district drug licensing committee's authority.
- Clarify in the drug acts how many times the district authority should visit over the course of a month or a year.
- Appoint a lawyer to look after legal issues.

Capacity Building—

- Create specific regulations and guidelines for food supplements, vitamins and minerals, baby foods, vaccines, and so forth.
- Enact a law on "no objection medicines" to OTC medicines); give training on the Drug Act.

Resource Mobilization—

- Increase the number of personnel employed in the DGDA; current numbers limit regulatory activities.
- Provide vehicles for traveling to the drug shop sites/adequate transport allowance to regularly visit drug shops under jurisdiction for DSs and DIs.
- Increase the amount of travel allowance for DSs and DIs.

Perspectives of the Bangladesh Chemist and Druggist Samity (Association)

BCDA is a registered association of the drug shop owners and is approved by the Social Welfare Ministry. Its network extends from the central to the subdistrict level in the rural areas. This powerful association regulates the local associations and establishes accredited model drug shops. Support from this association is necessary.

According to the respondents, of the300,000 to 400,000 drug shops in Bangladesh, only 120,000 have drug licenses. The respondents said that drug shop owners must have the trade license and TIN (tax identification number) certificate to have a drug license. Shop owners with drug licenses pay BDT 1,800 annually to renew the license, and they pay income tax and renewal fees for the trade license. However, shop owners without drug licenses do not have to pay renewal fees. Although the presence of at least a grade C pharmacist is required by law (ordinance 13, rule 2), the regulatory authority does not give this requirement proper attention during drug shop inspection, respondents said.

The numbers of unlicensed shops are large, and the BCDA thinks this is because of inadequate use of the regulatory authority's legal power of inspection and monitoring. They complained that rules and regulations are frequently not enforced, which results from corruption at the grassroots level. The BCDA does not have a monitoring role; the association informs the relevant authorities about irregularities that come to their notice. The BCDA has distributed about 200,000 informational leaflets to build awareness among the consumers.

To address the severe shortage of trained pharmacists, the BCDA, with help from the PCB and the BPS, conducts a three-month training course to award grade C certificate for dispensers working in the drug shops. The association charges a minimum fee for this course. Currently, two courses a year are being run with 100 students in each course. To qualify to enroll, students must have completed a minimum of 10 years of schooling and be age 18 or older. Classes are on weekends from 9 a.m. to 5 p.m. The syllabus and the training materials are provided by the pharmacy council.

Regarding prescription-only drugs to be sold by Grade A and B pharmacists, the BCDA said that the government has to close all but the 100,000 licensed drug shops if this policy is to be implemented. This will create a chaotic scenario in the drug market because in most of the rural and remote areas, drug shops are the first contact with any treatment facilities for many people. Alternatively, the BCDS advised that the DGDA should improve its capacity to be able to train more drug sellers within a reasonable period of time and to more stringently implement the Drug Act at the grassroots to prevent irrational use of drugs.

Perspectives of the Pharmacy Council of Bangladesh

According to the PCB, there are 62,473 grade C pharmacists (certificate in pharmacy holders), 10,239 grade B pharmacists (diploma pharmacists), and 2,936 (up until 2009; registration stopped due to legal issues) grade A pharmacists (graduate pharmacists) in the country. The certified pharmacists work in the drug shops and community pharmacies whereas the diploma holders work in government and private hospitals. Graduate pharmacists are employed by the pharmaceutical companies.

The certificate course is conducted by the PCB with help from the BCDS and the BPS. The PCB prepares the curriculum, organizes the classes, and conducts the examination. The PCB said that its intention in conducting the certificate course was to include all drug sellers in the

licensing system. Although pharmacies are run by graduate pharmacists in developed countries, in Bangladesh, this structure is not possible. Because of a mismatch in number of drug shops and number of pharmacists, the PCB is taking this short cut to include drug sellers in some kind of licensing system. However, questions arise about the contents and form of the certificate training, including the length of the course. The PCB said that the certificate course syllabus was being revised and would address those issues.

Possibility of Developing an ADDO Model of Drug Shops in Bangladesh

The regulators at the central and district levels were unanimous about the need to develop an accredited model of a drug shop, which may improve the current chaotic situation in Bangladesh. According to the regulators, a model drug shop run by registered pharmacists will reduce the margin of error and promote rational use of drugs. They argue that this accredited model is all the more necessary because Bangladesh has a large population of illiterate or semiliterate people who can't distinguish the good from the bad. Because a drug shop is the first contact with any kind of health care service for a majority of people, especially those in the rural and remote areas, this accreditation is a must for maintaining standards and high quality:

> *"Pharmacists will advise the patients on disease and medicine. Pharmacists should give medicine to patients as per doctor's prescription. If any doctor writes a wrong medicine, the pharmacist should consult with the doctor before giving the medicine to the patient. Pharmacists will counsel the patient how to take medicine and will explain this properly. A pharmacist will check the expiry dates of the medicines in the shop … he will ensure whether the shop is well-organized, and the records are well-maintained."*
> (KII_BAR_MET_MET_10; 77-82)

But the regulators also understood that this model would not be possible in a day, and steps should be taken gradually. In the initial stage, model shops should be run by a grade C pharmacist (certificate holder) at least. As a first step, the regulators suggested, a shop in each upazila could be identified and developed through a public-private partnership (PPP) as a model to be followed. They suggested an extensive program for building awareness about the legal aspects of operating a drug shop as well as about rational use of drugs.

For a proper shop, they recommended offering loans for appropriate physical structures (*pucca*—or solid and permanent—buildings, proper refrigeration, and so forth) and issuing drug licenses to solvent people so that they could invest in establishing a model shop.

The respondents emphasized that to address the gap in the number of trained pharmacists, the courses offered by the pharmacy council should be regular and more frequent, and the curriculum should be revised according to the needs of dispensers and should include basics about PHC services. Almost all respondents thought that, to some extent, the model drug shop should provide PHC services. The regulators said the current grade C pharmacist training course needed to be revisited and revised so that it fulfilled such needs.

Revisiting and Revising the Certificate Course Training (for Grade C Pharmacist) for ADDO

The regulators were unanimous about the shortcomings in the current contents and forms of the grade C course training conducted by the PCB with help from the BCDA. The contents

need to be substantially revised to fulfill current needs, and the training should be extended from the three months it is now to one year—with adjustments to the course fee. Regulators said that the curriculum should be in line with that of community pharmacies in developed countries. Topics covered should include (1) legal requirements to open a shop, (2) legal aspects of operating a drug shop, (3) generic and brand drugs, (4) side effects of drugs, and (5) rational use of drugs.

Also, pedagogic methods should be modernized with audiovisual and other technology tools to make topics lively and understandable for the students. For this program, the students with science backgrounds should be recruited. The DSs and the DIs can teach practical information about running a drug shop legally and ethically. Also, the current training that is restricted to PCB members should be waived so that more and more people can be trained. Of course, the capacity of the council has to be enlarged by partnering with other organizations and the public sector. In that way, large numbers of prospective dispensers can be trained in a short time on the basis of a consensus and using updated curriculum.

Role of Consumer Association in Rational Use of Drugs

According to the regulators, the CAB is not as active in the field of drugs as it is in food. The regulators were not knowledgeable about other civil society initiatives in the food and drug sector. However, they acknowledged the role of consumers in improving the service quality in drug shops and thought that such pressure groups could help the DGDA regulate this sector and weed out corruption and malpractice. For example, the CAB can give the DGDA information about malpractice in drug shops, such as (1) selling expired, fake, or low-quality substandard drugs; (2) overpricing medicines beyond the printed MRPs; (3) selling physician sample drugs; and (4) operating drug shops without a valid drug license. One regulator pointed to an important role that the CAB could play:

> "*They can play a role in improving quality of drug shops. They can work as watchdogs. The dispenser needs to ensure patients' right that will help to maintain consumers' rights as well."*
> (KII_BAR_PAT_PAT_9; 214-215)

The regulators also emphasized the need for awareness on the consumers' side. For example, consumers can check expiration dates, MRPs printed on the package, proper storage, and proper dispensing per prescription. Consumers can also ask about side effects and about interactions with other drugs they may be taking. They should collect their drug receipts, and by doing so, they will make dispensers be cautious and improve their skills and services.

CAB can play a critical role in improving consumers' levels of awareness of the safe use and legal dispensing of drugs by organizing a "Drug Day" or a "Drug Week" campaign. The DGDA and various pharmaceutical companies can arrange a "Drug Fair'' to generate awareness among the consumers and dispensers of such safe practices. DGDA can (a) use electronic media; (b) update websites; and (c) create posters, billboards, and spot advertisements to organize the campaigns with CAB and other organizations. The DGDA, CAB, and pharmaceutical sector should work together in this effort.

DISCUSSION AND CONCLUSIONS

This study was conducted to explore the feasibility of developing ADDOs in Bangladesh in an environment of an unregulated drug market that is characterized by the presence of a large number of unlicensed drug shops. To inform the development of model accredited drug shops, a comprehensive drug shop survey collected relevant data through structured observations of dispenser-client interactions, focus groups, and in-depth interviews with different groups of stakeholders.

Findings reveal important scenarios regarding (a) the status and operation of the drug shops, (b) licensing and regulatory processes, (c) content and form of dispenser training, (d) community and stakeholder perceptions and expectations ofan ideal drug shop, and (e) the problems and prospects of developing an ADDO model for Bangladesh. Those findings are discussed next.

Nature and Operation of Drug Shops

The drug shops were found to be well placed in the community—some for more than 10 years—and to cater to the immediate health care needs of the people (dispensing first aid, pushing injection, dressing wounds, etc.) in addition to selling medicine. Although the majority of dispensers were not certified, the community trusts them to treat common illnesses and to give advice about when to contact a nearby professional health care provider. Thus, most community members were not concerned about the educational and technical credentials for the dispenser and provider of primary health care. They considered the drug dispenser as a "friend in deed".

This view is very common in low- and middle-income countries (LMICs), especially in the remote and hard-to-reach areas that do not have doctors or, for that matter, any formal health facilities or providers (Kamat and Nichter 1998; Kafle et al. 1999; Chuc 2002; Chalker 2003; Goodman et al. 2007; Stanback et al. 2011; Wafula, Miriti, and Goodman 2012). Lack of professional training of any kind, as observed in this study for nearly half of the respondents, is very commonly seen in LMICs such as Lao People's Democratic Republic, Pakistan, and Vietnam (Rabbani et al. 2001; Stenson et al. 2001; Chuc 2002). Selling drugs without a prescription is also common in Pakistan (Rabbani et al. 2001) and India (Sabde et al. 2011), as it is in Bangladesh.

Lengthy and Costly Licensing Process

Approximately one-fifth of the sampled drug shops did not have drug licenses. Reportedly, the lengthy and costly licensing process discouraged them from getting a license. Such a barrier is important to remove on the way to enlisting the unlicensed drug shops under regulation and supervision.

First, one reason identified as contributing to the long process is that the license application, after field inspection by DS, has to be placed before the district drug committee for approval. Only then can it be sent to DGDA Dhaka for approval. The district committee meetings are few and far between. If this step could be waived and if the post-inspection application with

necessary notes could be sent directly to the DGDA, the delay could be cut short substantially. Second, the informal costs associated with getting a license over and above the required government fees discourage the owners of unlicensed drug shops. Respondents unanimously complained about this cost, which could be up to BDT 20,000 and more. Necessary measures should be taken to curb this cost and to expedite the process, thereby improving the image of DGDA.

Inspection Visits at Drug Shops

Because of constraints in time and resources (43 DSs and 3 DIs for 64 districts in the country), the shop visits are not regular and systematic. In the short time, the inspectors and superintendents can have a superficial inspection only. The regulators, especially at the grassroots, again and again emphasized the inadequacy of the current system because of a shortage of personnel and resources required for meaningful inspections of the drug shops. This shortage needs to be given immediate attention to regulate the market as well as to maintain a minimum level of supervision to prevent irrational use of drugs and to ensure that high-quality essential drugs are available to the poor at affordable costs.

Revisiting and Redesigning the Grade C Pharmacist Certificate Course

To position the drug dispensers in their proper place in the existing PHC system, the training curriculum for grade C pharmacist should be revisited and redesigned. This action is required for content and for pedagogical methods (an audiovisual element and a proactive and participatory approach). If Bangladesh is to develop the capacity for someone to become a first-line PHC worker, topics such as health education, first aid (e.g., accidents, drowning, snake and dog bites, burns, cardiopulmonary resuscitation), referral guides to higher levels of treatment, and so forth should be included.

The current course duration of three months may have to be increased to six months or even a year (with an increase in course fees) with provision for in-service training in licensed shops and government pharmacies. The curriculum should be standardized and then franchised to health institutes in the public and private sectors, including NGOs, for training the vast number of untrained dispensers in a reasonable amount of time.

Feasibility of Providing DOTS for TB Services from Drug Shops

Findings reveal that the respondents from retail drug shops are willing to provide DOTS-related services for TB. But to do so, drug sellers need relevant training for diagnostic referrals and subsequent services for diagnosed cases. The NTP and local authority need to be linked so both levels can track TB cases undergoing treatment and any change in the treatment regimen. Besides training, drug sellers should be paid for their time and efforts if such an approach is to succeed.

Feasibility of Developing an ADDO Model in Bangladesh

An ADDO approach to model retail drug shops such as tested in Tanzania is feasible in Bangladesh. This approach standardizes the drug shop's operation by staffing the shop with appropriately trained dispensers, by strictly enforcing regulations, and by providing supportive supervision. However, for the model's implementation, certain conditions have to be fulfilled. Qualitative data from regulators and other stakeholders revealed some of those conditions. They include, but are not restricted to (1) training a cadre of grade C pharmacists by using a revised and updated curriculum, (2) franchising the training to whoever possesses the resources and infrastructure to conduct it, (3) including elements of preventable PHC services and basic curative care services, (4) building community awareness on the importance of improving the quality of drug shop services and the rational use of drugs, and (5) creating supportive supervision for the ADDO model's effective functioning as a first-line PHC outpost.

Conclusions

The important role of drug shops in promoting public health in the LMICs such as Bangladesh cannot be overemphasized (Smith 2009). Now those drug shops are numerous, employ untrained salespersons, and are legally allowed to sell prescription-only drugs. Given the critical shortage of human resources for health (HRH) and the inequitable distribution of qualified HRH in Bangladesh—especially in remote areas (Ahmed et al. 2011)—it is essential to develop the drug shops as an integral part of PHC and to ensure the delivery of a minimal level of quality care, products, and information to the people. Because the number of drug shops is large, the problem of geographical accessibility can easily be overcome and will increase the outreach of services to the disadvantaged population (HIP 2013).

Evidence from both Asia (Chuc 2002; Syhakhang 2002; Chalker 2003) and Africa (Wafula and Goodman 2010) suggests that it is possible to train the attendants, salespersons, and dispensers at drug retail outlets to improve dispensing practices, to promote rational use of drugs, and to treat and manage common illnesses and injuries. This path to improvement must be given serious consideration by the DGDA, the DGHS, and the DGFP (Directorate General of Family Planning), to facilitate Bangladesh's journey toward effective UHC by developing model drug shops beyond 2015.

RECOMMENDATIONS

Immediate and Short-Term Measures

- Create **a crash program to train** the vast number of **dispensers in unlicensed shops within** a short time, such as **a maximum of one year**.
    - Encourage PPPs (including nonprofit NGOs) to play a significant role in franchising the certificate course for grade C pharmacists.
    - Include a certificate course for grade C pharmacists in existing public and private health institutes.
- **Make the drug licensing process user-friendly, efficient, and inexpensive** so that the unlicensed drug shop owners are encouraged to become licensed after fulfilling the requirements.
    - Abolish the district drug committee, and fast-track the licensing process.
    - Conduct awareness-building campaigns about the necessity and benefits of fulfilling the requirements for a drug license and, ultimately, having a drug license.
    - Make transparent the exact amount of fees required for applying and getting a drug license to all owners of drug shops through a DGDA circular.
    - Investigate each and every case of irregularity.
- **Make shop inspections regular, comprehensive, supervised** (by district DGDA), and problem solving—not punitive.
    - Do not allow any compromise with basics; a DGDA-approved checklist should be meticulously followed during shop inspection and records kept by the DS/DIs of shop inspections by DS/DIs, and include checks during shop visits.
- **Increase the capacity of the DGDA with more personnel and improved logistics** so that shop inspections can be conducted countrywide, year round, and on a regular and planned schedule. Such inspections will keep the drug-shop owners alert to not breach the laws.
- **Develop amicable relationships between DGDA officials and other stakeholders** to effectively implement regulations, and makehigh-quality essential drugs available at the people's doorsteps.

Long-Term Measures

- **Revise the contents, forms, and duration of the grade C certificate course** to develop a standard curriculum that also includes basic PHC services (first aid and health

education, including TB and TB DOTS) for these to work as PHC outposts in remote rural areas.

- **Increase the technical capacity of DGDA** (e.g., establish more drug-testing laboratories) to discourage marketing of counterfeit, expired, and poor-quality drugs.

- **Develop the capacity of the dispensers** by training and giving monetary incentives **to be providers for TB DOTS.**

- **Ensure strict adherence to GMP for all pharmaceuticals** and for maintaining the standard and quality of drugs.

- **Understand that requirements** to be fulfilled **for ADDOs in Bangladesh** include the following—

    - Ensure the presence of a pharmacist who is well trained in the revised curriculum in the drug shop.
    - Conduct an extensive information, education, and communication (IEC) campaign to build awareness of the public and the pharmacy stakeholders on the irrational use of drugs and their harmful effects (e.g., antimicrobial resistance, MDR TB, etc.).
    - Include the health professional associations in developing ownership of the ADDO process.
    - Encourage the critical role of CAB and the similar associations as pressure groups for the rational use of drugs.

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APPENDIX A: LIST OF DOCUMENTS REQUIRED TO APPLY FOR A DRUG LICENSE, INCLUDING FEES AS MENTIONED BY RESPONDENTS

1. Application letter along with Form 7
2. Copy of trade license
3. Bank payment receipt or treasurer receipt (payment of fees for metropolitan area BDT 2,500 and for outside metropolitan area BDT 1,500)
4. Copy of S.S.C. certificate or educational certificate
5. Copy of pharmacist registration certificate
6. Copy of voter ID card
7. Shop rental agreement between owner and renter
8. Copy of nationality certificate
9. Copy of a passport-size photo (two respondents mentioned that two copies of the photo were needed.)
10. Bank solvency certificate (This certificate was mentioned by two respondents.)
11. Tax certificate copy (This copy was mentioned by only one respondent.)
12. Approval document from committee (This document was mentioned by all respondents.)
13. Birth certificate (One respondent mentioned this certificate.)

TimeLine

Licenses are issued over a duration ranging from a minimum of 10 days to a maximum of 6 months after the application is completed. Most respondents mentioned that drug shop licensing process takes from one to two months. Most of them mentioned that it was difficult to know how long the application process would take.

The time varies depending on the meeting time at upazila level.After receiving a minimum of 10 to a maximum of 20 applications, the upazila committee meets. The applications are then returned to DGDA head office in Dhaka for approval. One respondent mentioned that “the time depends on DG [directorate general] sir.”

Types of Licenses

Two respondents mentioned that, at present in Bangladesh,drug shop licenses are given in two categories—

- Wholesaler:The license application should be submitted directly to the DGDA head office in Dhaka. The DG gives the wholesaler the license directly from Dhaka.

- Retail seller: The retail drug shop application should be submitted to the upazila drug office.

Application Fees

Discipline	Area	Fees (BDT)
Allopath	Within metropolitan or city corporation(*pourashava*) area	2,500
	Union or village level	1,500
Ayurveda/Unani/ Homeopath/ Herbal/Biochemical	Within metropolitan or city corporation(*pourashava*) area	2,000
	Union or village level	1,000

Renewal Fees

The drug shop license needs to be renewed every two years. To renew, the drug shop owner needs to submit all the necessary papers except the chalan receipt. The following table shows the renewal fees.

Discipline	Area	Fees (BDT)
Allopath	Within metropolitan or city corporation (*pourashava*) area	1,800
	Union or village level	700
Ayurveda/Unani/Homeopath/Herbal/ Biochemical	Within metropolitan or city corporation (*pourashava*) area	1,500
	Union or village level	700

Fine for Renewal Fees

If shop owners are late to renew the drug shop license, they are fined, one respondent said. A fine for delay to renew is BDT 100 within 1 to 3 months, BDT 200 within 3 to 12 months, and BDT 500 after 12 months. At the union and village level, the fine is BDT 100, BDT 150, and BDT 200,for those same time periods. Wholesaler/depot fees are BDT 10,000, and renewal fees are BDT 2,000.

APPENDIX B: INSPECTION CHECKLIST FOR VISIT TO RETAIL DRUG SHOPS

The following items are checked during a retail drug shop inspection—

- Drug shop license: Does the shop have a DGDA-approved drug shop license? Has the license been renewed? Is the license displayed publicly?
- Trade license: Does the shop have a trade license?
- Signboard: Is there a signboard in front of the shop?
- Pharmacist: Does a registered pharmacist work in the shop?
- Unregistered medicine: Are there any medicines without a DAR (drug administration registration number)? If the DAR number is not mentioned clearly, then that lack must be noted. If the DAR number is absent, then according to Form 4, the medicines are removed. If such medicines without numbers are present in small volume, then the shop is given verbal warning; if such medicines are present in large volumes, the authorities file a case against the shop.
- Substandard and expired medicine: Check the manufactured and expiration date. Determine if those medicines are sold and if the expired medicines are kept in a separate box marked “not for sale.”
- Medicines from other countries: Check for any smuggled medicine from other countries, for example, India.
- Record-keeping system: Check to see (a) if the shop keeps drugs records, (b) if the invoices are maintained, and (c) if the shop uses a register book.
- Storage: Does the shop have proper storage facilities?
- Samples: Take sample drugs from the shop, and send them to Dhaka or Chittagong for lab tests. On the basis of the lab report, appropriate actions are taken, including filing a case, if necessary.
- Refrigeration system: Does the shop have proper refrigeration to keep medicine (biological medicine), and is the refrigerator working properly?
- Good display systems: Does the shop have appropriate display systems and keep medicines stocked?
- Food supplements: Are such supplements sealed properly and quality checked? If the findings are not satisfactory, then the supplements must be identified using Form 5 and sent to Dhaka or Chittagong for a lab test. On the basis of the lab reports, actions are taken and a case is filed, if necessary.
- Shop environment: Is the shop clean? Does the shop have enough light and air space? Is the floor clean and not damp?

- Price: Are the medicines overpriced?
- As per prescription: Are medicines sold per prescription?
- Manufacturer's retail price: Is the MRP for essential medicines mentioned in the medicine packet?
- IP: Is the IP mentioned in the packet for nonessential drugs?
- Sample medicine: Are sample medicines (government medicine) sold?
- Temperature: Does the temperature control system of the shop meet standards?
- Department goods: Are products such as tissue paper and baby food stocked?
- Supplier: From where does the shop purchase its medicine, and does it have the receipts from suppliers?
- Narcotics: Does the shop sell pethidine type medicine?
- Illegal activities: Does the shop conduct or contribute to any activities that are contrary to the country's drug laws?

APPENDIX C: LIST OF KEY INFORMANTS

Central level: 4				
#	**Institution**	**Name of the officer**	**Duty station**	**Contact details**
1.	DGDA	Md. Ruhul Amin Director	Dhaka	01777971404 ruhulamin1961@gmail.com
2.		Md.Eyahya Asst. Director		01711190824 eyahya65@gmail.com
3.	Pharmacy Council of Bangladesh(PCB)	K. K.Saha Secretary		01199078052 info@pcb.gov.bd
4.	Bangladesh Chemist and Druggist Samity (Association)	Abdul Hai Vice President		01819218405

#	**District**	**Name of the officer**	**Duty station**	**Contact details**
Dhaka division 6				
1.	Tangail	Md. Abdul Malek Superintendent of Drugs	Tangail	01728052447 md.malekbiodu@gmail.com
2.	Jamalpur	Md. Sakhawat Hossain Razu Akanda Superintendent of Drugs	Jamalpur	01554903980 razu_sh86@yahoo.com
3.	Kishoregong	Mst. Fuara Eyasmin Superintendent of Drugs	Kishoregong	01712527980 fuaran54@gmail.com
4.	Narshingdhi	Gulshan Jahan Superintendent of Drugs	Narshingdhi	01711950490 gjriima@yahoo.com
5.	Madaripur	Md. Nurul Alam Superintendent of Drugs	Madaripur	01714218525 mnalam00@gmail.com
6.	Gazipur metropolitan	Md. Fazlul Huque Inspector of drugs	Gazipur	01717228672 fazluvet@gmail.com
Chittagong division: 2				
7.	Noakhali	Tanvir Ahmed Superintendent of Drugs	Noakhali	01717637236 tahmed.dvm@gmail.com
8.	Chittagong metropolitan	Md.Shaikh Ahsan Ullah Senior Superintendent of Drugs	Chittagong	01674888037 atkmahbub@gmail.com
Barisal division: 2				
9.	Patuakhali	Md. Masud Rana Superintendent of Drugs	Patuakhali	01676398397 masudrana_bmb@yahoo.com
10.	Barisal metropolitan	Md. Shafikur Rahman Superintendent of Drugs	Barisal	01818244711 shafikurpr@gmail.com
Khulna division: 3				
11.	Satkhira	Md. Rehan Hassan Superintendent of Drugs	Satkhira	01911025305 rehan.pharm@gmail.com
12.	Khulna metropolitan	Mahmud Husain Superintendent of Drugs	Khulna	01828160197 mahmudda12@gmail.com
13.	Chuadanga	S.M. Sultanul Arefin Superintendent of Drugs	Chuadanga	01553750967 emonarefin12@yahoo.com
Rangpur division: 4				
14.	Dinajpur	Md. Rafiqul Islam Superintendent of Drugs	Dinajpur	01914724210 mithu_bmb@yahoo.com

#	District	Name of the officer	Duty station	Contact details
15.	Lalmonirhat	B.M. Zahid Haider Superintendent of Drugs	Lalmonirhat	01712885478 bmzh2116@gmail.com
16.	Kurigram	Mst. Nargis Akter Superintendent of Drugs	Kurigram	01718353609 nargisvet@gmail.com
17.	Rangpur metropolitan	Md. Tauhidul Islam, Superintendent of Drugs	Rangpur	01716623113 tauhidulpharm@yahoo.com
Rajshahi division: 2				
18.	Chapai Nawabganj	Sikdar Kamrul Islam Superintendent of Drugs	Chapai Nawabganj	01673202270 dgdacapa@gmail.com
19.	Pabna	Md. Razibul Habib Superintendent of Drugs	Pabna	01718423453 mrhjewel@gmail.com