MEDICINES IN HEALTH CARE DELIVERY

BANGLADESH

Situational Analysis:

13 – 25 September 2014

Report prepared using the WHO/SEARO workbook tool for undertaking a situational analysis of medicines in health care delivery in low and middle income countries

October 2014

CONTENTS

1. ABBREVIATIONS

ABC   ABC analysis – method for measuring drug consumption

ADR   Adverse Drug Reaction

AMR   Antimicrobial Resistance

BMA   Bangladesh Medial Association

BMDC   Bangladesh Medical and Dental Council

BDNF   Bangladesh National Formulary

CME   Continuing Medical Education

CMSD   Central Medical Stores Depot

CPD   Continuing Professional Development

DCC   Drug Control Committee

DIC   Drug Information Centre

DGDA   Directorate General of Drug Administration

DGHS   Directorate General of Health Services

DH   District Hospital

DRA   Drug Regulatory Authority

DSO   Drug Supply Organisation

DTC   Drug and Therapeutics Committee

GDP   Good Dispensing Practice

EDL   Essential Drug List

EDCL   Essential Drug Company Limited

EML   Essential Medicines List

GPP   Good Prescribing Practice

HOD   Head of Department

IPD	In-patient Department
M&E	Monitoring & Evaluation
MIC	Medicines Information Centre
MOH	Ministry of Health
MOHFW	Ministry of Health and Family Welfare
MOU	Memorandum of Understanding
NCL	National Control Laboratory
NDP	National Drug Policy
NGO	Non-Governmental Organisation
NMP	National Medicines Policy
OPD	Outpatient Department
OTC	Over-the-Counter
PHC	Primary Health Care
PV	Pharmacovigilance
QA	Quality Assurance
RUM	Rational Use of Medicines
SOP	Standard Operating Procedures
STG	Standard Treatment Guidelines
TOR	Terms of Reference
UHC	Upazila Health Complex
VEN	Vital, Essential, Non-essential – method for classifying drug importance
WHO	World Health Organization

2. EXECUTIVE SUMMARY

2.1. Introduction

A situational analysis was conducted in Bangladesh during 13-25 September 2014. The Terms of Reference were to examine medicines in health care delivery with respect to medicines supply, selection, use, regulation and policy. It was agreed that the WHO/SEARO workbook tool would be used and that a team of government officials, led by the Bangladesh Directorate General of Drug Administration (DGDA), facilitated by WHO/SEARO, would conduct the situational analysis.

The team members consisted of:

Dr Kathleen A Holloway, Regional Advisor Essential Drugs & Other Medicines, WHO/SEARO
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Mr A. A. Salim Barami, DGDA
Prof Dr Afsana Karim, Dhaka Medical College
Ms Mazeda Begum, CMSD
Mr Kh. Rashedul Haque, EDCL
Mr Md. Aziullah, DGDA
Mr Md. Akter Hossain, DGDA
Dr Md. Tanvir Islam, Delta Medical College
Dr Md Shafiqul Islam, NIPSOM
Dr Kim Sungchol, WHO/SEARO
Dr Selina Ahmed, WHO/WCO Bangladesh
Mr Faridur Rahman, WHO/WCO Bangladesh

The programme involved meetings with all the major government departments and other stakeholders involved in the management of medicines and visits to health facilities in two Divisions. A detailed program can be seen in section 3. A national strike took place during 2 days of the situational analysis, so a visit to an Upazila Health Complex and Community Clinic was rescheduled after the workshop. Some data collected from Manikanj district during a visit by Dr Holloway in June 2014 in preparation for the situational analysis was also used. During the visits to public health facilities and private pharmacies, drug stores were visited to collect data on stock availability for 21 selected essential drugs and drug management, outpatient dispensaries were visited to do a prescription audit, wards were visited to review in-patient drug management, and staff were interviewed to identify health and health care factors affecting drug management.

A one-day national stakeholder workshop was held on 24 September 2014 where findings were discussed and recommendations developed. The participants list can be seen in section 12. The findings were presented on behalf of the team by Dr Holloway, WHO/SEARO. Group work was done by participants to develop recommendations in the areas of medicines supply, selection, use, regulation and policy.

The words "medicine" and "drug" are used interchangeably in this report.

2.2. Medicines Supply

Drugs are supplied to the public sector in the same way as they were supplied in 2010. Government expenditure on drugs remains extremely low (about 0.36 USD/person/year). According to national policy, 70% of drugs are supplied by the Essential Drug Company Limited (EDCL), 25% by the Central Medical Stores Depot (CMSD) and the remaining 5% by local purchase. While most drugs supplied belong to the national Essential Drug List (EDL), an increasing proportion of non-EDL drugs are being supplied, one reason being that the EDL has not been updated since 2008. The EDCL remains efficient at supplying drugs and the efficiency of the CMSD has increased with reduction in lead times to one year. Availability of key essential drugs was 61-75% in hospitals and upazila health complexes and 100% in community health care clinics (according to a separate more limited list supplied). However, there are still complaints of stock-out and lack of sufficient budget to meet patient demand. The lack of pharmacists and the lack of any electronic drug management information system make it extremely difficult to monitor accurately consumption, stock-outs, and expiry and this lack of knowledge results in poor quantification and leads to stock-outs. Unfortunately, the recommendation in 2010 to establish an electronic drug management information system was not followed.

Recommendations are to:

• Increase government expenditure on essential drugs.

• Establish a harmonised, functional, electronic drug management information system, to monitor consumption, stock-out, expiry, etc. which is necessary to improve quantification:

  – recommended in 2010, but little progress;
  – DGHS/USAID/GTZ project 2010-2013 was planned but not executed:
  – start centrally & extend to district level initially:
  – employ a data-entry staff for this purpose at each hospital and district.

• Involve bachelor and diploma pharmacists in stock management, not just outpatient dispensing.

• Train staff in monitoring medicine consumption and quantification.

• Review the ward management of drugs.

2.3. Medicines Selection

The national EDL contains only 209 drugs and has not been updated since 2008. As a result, about half of all the drugs prescribed in public sector hospitals do not belong to the national EDL, despite national policy dictating that the majority of drugs used should belong to the national EDL. Many of the drugs supplied by the CMSD are non-EDL ones according to a list approved by the Directorate General of Health Services (DGHS) after discussion with senior doctors and civil surgeons. Even some of the drugs supplied by the EDCL are non-EDL ones. In addition, many patients are prescribed non-EDL drugs that are not available in public facilities and have to buy them from private pharmacies. Unfortunately, the recommendation in 2010 to revise the national EDL was not followed.

Recommendations were to:

- Revise the EDL:

  - include drugs for all levels of care;
  - classify each drug according to level of care, therapeutic class
  - have wide representation of specialists, generalists and pharmacists, and transparent process to improve acceptance.

- Implement the EDL:

  - Demand to EDCL and CMSD should follow the EDL;
  - Ensure all providers are sensitized/trained on the EDL;
  - Monitor compliance.

- Establish a transparent system to review all requests for non-EDL drugs:

  - Drug and Therapeutic Committee in each referral and district hospital could do this.

2.4. <u>Medicines use</u>

Irrational use of medicines remains a very serious problem. The percentage of drug prescribed by generic name in the public sector was 17% in tertiary hospitals, 48-59% in district hospitals (DHs) and upazila health complexes (UHCs) and 93% in community care clinics. The percentage of prescribed drugs belonging the EDL was 49% in tertiary hospitals, 57-65% in DHs and UHCs and 96% in community care clinics. The percentage of upper respiratory tract infection cases treated with antibiotics was 59-60% in UHCs and community clinics, but was impossible to measure in other facility types due to lack of recording of diagnosis and treatment in outpatient patient registers. From private pharmacies, it was found that for private practitioners, the percentage of drugs prescribed by generic name was only 6%, and the percentage of prescribed drugs belonging to the EDL only 27%.

There is little monitoring of medicines use and little implementation of policies to promote rational use of medicines, such as development of national standard treatment guidelines (STGs), establishment of hospital drug and therapeutic committees (DTCs), establishment of continuing medical education (CME) for all prescribers and public education campaigns on the safe and prudent use of medicines. Since 2010, the Community Health Clinic system has been established but so far this initiative has not managed to reduce overcrowding of patients in the public hospitals. The number of hours in the undergraduate curriculum on pharmacology appears to have increased, but there appears to be no greater clinical pharmacology or clinical pharmacy activities in the medical college hospitals.

Recommendations were to:

- Monitor drug use:

  - Prescription audit using diagnosis - by all teaching hospitals & district health offices;

  - Revise outpatient (OPD) patient registers to include drugs prescribed & revise dispensing slips to have one slip per patient;

  - Revise inpatient (IPD) dispensing procedures and documentation;

- Identify specific inappropriate practices that you want to change (e.g. overuse of antibiotics in upper respiratory tract infection) in order to target interventions to these practices.

- Analyse prescriber workload:

  - To ensure equal workload for all prescribers, which could lead to more prudent prescribing, better dispensing, less return of old patients so reducing OPD crowding (and possibly IPD admission/crowding);

  - Lobby central level for more staff and redistribution of staff according to workload & to match expertise with equipment.

- Establish a referral system to decrease overcrowding:

  - Encourage treatment of more non-communicable diseases at Upazila health complexes;

  - Consider higher registration fees if patients come to higher level facilities without referral.

- Develop and implement Standard Treatment Guidelines (STG):

  - should include OPD treatment of simple primary care conditions with emphasis on using of fewer medicines;

  - disseminate to every doctor and student and incorporate into CME.

- Update the Bangladesh National Formulary (BDNF):

  - incorporate it in undergraduate education and disseminate to all doctors.

- Establish Drug and Therapeutic Committees (DTC) in every hospital:

  - require them to monitor drug use, encourage CME, and report annually on activities to MOHFW.

- Strengthen continuing medical education (CME):

  - Incorporate prescription audit and feedback and ethics into CME;
  - Involve Bangladesh medical / pharmacy councils / associations;
  - Cover all cadres of prescriber and dispenser.

- Undertake Public Education:

  - Incorporate core pharmaceutical messages e.g. does my child need more than one medicine? Antibiotics not needed for simple coughs and colds through health education channels and the media.

2.5. <u>Medicines Regulation</u>

Since 2010 the national drug regulatory authority has been upgraded to Directorate General level – now being the Directorate General of Drug Administration (DGDA). Unfortunately, this has not resulted in an increase in human resources, which remain at similar levels to 2010. Despite this, the pharmaceutical sector continues to grow, with now over 29,000 products registered, over 800 manufacturing units and

over 100,000 drug retail pharmacies, to be managed by 226 staff. With such under-staffing the DGDA has great difficulty to fulfil all its obligations. The national control laboratory has been renovated, upgraded and re-equipped since 2010 and has greatly increased its drug testing capacity, now testing over 5000 drug samples per year.

Recommendations were to:

- Establish a new Medicines Act:

    - Already in process as draft was submitted in 2014.

- Strengthen the DGDA.

- Strengthen the Drug Control Laboratory (DCL), including the capacity to test traditional medicines (TRM)

- Make the registration process more stringent:

    - Stronger criteria e.g. bioequivalence studies, dissolution profiles, stability studies;
    - Stricter application of criteria;
    - More transparent process with less conflict of interest – decrease manufacturer presence;
    - Will help to reduce the number of products registered.

- Establish an over-the-counter (OTC) schedule.

- Expand the drug pricing controls to include all essential drugs.

- Consider regulation to limit the number of pharmacies.

2.6. <u>Medicines Policy and Coordination</u>

The national drug policy, coordination and structure remain similar to the situation in 2010. Many objectives of the 2005 national drug policy remain unfulfilled and many policies to promote rational use of medicines and to monitor medicines use are not implemented by any MOHFW department or unit. The process for establishing a Core Committee for Rational Use of Drugs as proposed in 2008 was not renewed.

Recommendations were to:

- Establish a permanent statutory committee to advise the Minister of Health on Pharmaceuticals with wide membership including laypersons, professional bodies …

    - Revive the Core Committee for Rational Use of Drugs

- Establish an Executive Division in MOHFW to carry out the statutory committee recommendations and:

    - To coordinate action between MOHFW departments (e.g. DGHS, DGDA, CMSD) and with EDCL and other Ministries (Finance, Trade)

    - To be responsible for monitoring drug policy implementation

    - To be responsible for promoting rational use of drugs: implementation of EDL, STGs, DTCs, monitoring drug use, pre-service training, CME, public education, school health programs, etc.

3. <u>PROGRAMME AGENDA</u>

Day	Date	Time	Places visited
1	Sat 13/9/14	Am	Orientation of assessment team
		Pm	Visits to Dhaka Medical College Hospital and nearby private pharmacies
2	Sun 14/9/14	Am	Visits to DG Health Services, National Control Lab, Centre for Medical Education
		Pm	Visits to Community Clinic Project, Management Sciences for Health
3	Mon 15/9/14	Am	Visits to Central Medical Stores Depot and Essential Drug Company Ltd.
		Pm	Visits to Gonoshasthaya Kendra Trust
4	Tues 16/9/14	Am	Visits to Bangladesh Pharmacy Council, Medical & Dental Council, and Pharmacy Faculty of Dhaka University
		Pm	Visits to Directorate General of Drug Administration
5	Wed 17/9/14	Am	Visits to District Hospital, Gazipur
		Pm	Visits to private pharmacies, Gazipur
6	Thurs 18/9/14	Am	Visits cancelled due to national strike, document review
		Pm	Visits cancelled due to national strike, document review
7	Fri 19/9/14	Am	Preparation for national workshop
		Pm	Preparation for national workshop
8	Sat 20/9/14	Am	Visits to Bogra Medical College and Hospital
		Pm	Visits to private pharmacies nearby Bogra Medical College Hospital
9	Sun 21/9/14	Am	Visits to Mohammad Ali Hospital in Bogra
		Pm	Visits to private pharmacies in Bogra town centre
10	Mon 22/9/14	Am	Visits cancelled due to national strike, preparation for workshop
		Pm	Visits cancelled due to national strike, preparation for workshop
11	Tues 23/9/14	Am	Visits to Upazila Health Complex in Tangail District
		Pm	Visits to Community Clinic in Tangail District
12	Wed 24/9/14	Am	National workshop
		Pm	National workshop
13	Thurs 25/9/14	Am	Visits to Upazila Health Complex in Gazipur District
		Pm	Visits to Community Clinic in Gazipur District

4. MEDICINE SUPPLY

4.1   Responsible Agents/Departments

Function/ Organisation	MOHFW	Other Agency	Name of Agency/MOHFW Department
Selection	√		DG Drug Administration, MOHFW, coordinates the national EML
Quantification	√		DG Health Services does this taking into account demand from health facilities, and in liaison with Central Medical Stores Depot for procurement and Essential Drug Company Ltd. for manufacture
Procurement	√	√	Central Medical Stores Depot (CMSD) under DGHS does central procurement, the Civil Surgeon Office do some local procurement for district facilities and hospitals also procure their own drugs
Pricing	√	√	DG Drug Administration coordinates prices for some essential medicines, but other drug prices are as decided by manufacturers
Storage	√		Health facilities and CMSD/MOHFW
Distribution	√		CMSD and EDCL as per health facility demand
Monitoring & evaluation	√		DG Health Services is supposed to monitor management of medicines in the public health facilities

4.2.   Drug availability

The only report published on the availability of essential drugs that could be found was the same one as found during the 2010 situational analysis. A study done in 2009 by the Centre for Medical Education, MOHFW, found that availability of key essential drugs was only 39% at Upazila health complex, and 17% at community health centres. Interview of patients revealed that only 28% of patients received all their drugs at the government facility, 58% patients received some of their medicines and that 14% received no drugs at the facility. Of those not receiving some or all of their drugs, half said that they would not buy them due to non-affordability. During the 2010 situational analysis there were many complaints of stock-out and the percentage of prescribed drugs dispensed in district and referral hospitals was 69-70%.

Many hospital directors and superintendents stated that the allocation for medicines purchase was insufficient. Most stock-outs related to intravenous fluids which are not supplied by either EDCL or CMSD, but are mostly supplied by the Institute of Public Health. By contrast, many store keepers did not report much serious difficulty with stock-outs, saying that they often had alternative medicines they could use. However, one storekeeper reported that he was instructed to supply less quantity to the wards than they actually demanded in order that there would always be some stock available for very poor patients or in an emergency. It was observed that many storekeepers did not know the stock condition of the outpatient dispensary or the wards and that a significant number of patients had to purchase their medicines from outside. In the OPD pharmacies, about 20-30% of medicines prescribed had to be purchased from outside pharmacies. One hospital OPD pharmacy had a list of which medicines were in and out of stock on public display. Observation in private pharmacies, situated near the entrance of hospitals, served mostly inpatients of the nearby hospital. In a few cases, it was observed that the patient was actually purchasing medicines that had been observed to be in stock in one of the wards. This may have occurred because of poor re-distribution of stock between wards and lack of knowledge about stock availability within the hospital by hospital staff.

Table 4.2.1 show some data on stock availability and stock-out. The percentage of prescribed drugs dispensed in district and referral hospitals is similar to levels seen in 2010.

Table 4.2.1: Summary of EML* drug availability from observation and record review in the health facility surveys:

Public Referral Hospitals	1	2			Average
% items out of stock	-	19/131=15%			15%
% key EML drugs available	82%	67%			75%
% prescribed drugs dispensed**	97%	51%			74%
Public District Hospitals	1	2			
% items out of stock	-	13/140=9%			9%
% key EML drugs available	54%	81%			68%
% prescribed drugs dispensed**	68%	76%			72%
Public Upazila Health Complex	1	2			
Facility Name					
% items out of stock	17/94=18%	11/128=86%			52%
% key EML drugs available	57%	64%			61%
% prescribed drugs dispensed**	72%	57%			65%
Community Health Clinic	1	2			
% items out of stock	14/30=47%	16/30=53%			50%
% key EML drugs available***	100%	100%			100%
% prescribed drugs dispensed**	100%	93%			96%
Private pharmacies	1	2	3	4	
% EML items out of stock	-	-	-	-	-
% key EML drugs available	-	-	-	-	-
% prescribed drugs dispensed**	75%	83%	87%	95%	85%

* Belonging to the national EML or the provincial / hospital formulary in decentralized systems
** From prescription audit done during the health facility survey
*** The availability is 43% if judged by the same list of key essential drugs used for other facility types.

The percentage of key EML drugs available was based on a list of 21 drugs chosen by the team from the EML, consisting of: caps/tabs of amoxicillin, ciprofloxacin, erythromycin, metronidazole, albendazole or mebendazole, atenolol, enalapril, ferrous/folic acid, glibenclamide, metformin, paracetamol, ibuprofen, omeprazole, diazepam, frusemide; oral rehydration solution; salbutamol nebulizer solution; antibiotic eye/ear drops; benzyl benzoate lotion; hydrocortisone injection and Normal Saline intravenous fluid. Some of the stock-out of EML drugs occurred because these drugs were no longer supplied by EDCL or CMSD. Each health facility had a number of non-EML drugs and followed its own list. Some facilities were unable to say what the total number of items purchased was, so the percentage of items out of stock could not be calculated.

4.3. Annual aggregate data of medicines distribution / consumption

Table 4.3.1: ABC analysis of top 24 items distributed in public facilities in 2013 by EDCL & CMSD

Source of data (government department/organization): EDCL and CMSD

Rank	EDCL Item Name/Strength	EML	Value ($)	CMSD Item Name/Strength	EML	Value ($)
1	Oral Rehydration Solution	√	1,763,915	5% D/saline IVI 500ml	√	930,224
2	Paracetamol tab 500mg	√	1,681,160	Cholera Saline 500ml	√	498,380
3	Antacid tab 650mg	√	1,414,517	Hartmann Sol. 500ml*		329,663
4	Metronidazole tab 400mg	√	1,198,387	Normal Saline 500ml	√	142,828
5	Amoxycillin cap 250mg	√	1,094,550	Cefixime tab/cap400mg*		114,559
6	Azithromycin tab 500mg*		809,481	Hydrocortis. inj 100mg	√	95,509
7	Amoxycilin syrup 100ml	√	807,243	Ceftriaxone inj 250mg*		92,698
8	Paracetamol susp 60ml	√	774,623	Omeprazole inj 40mg*		68,491
9	Amoxycilin cap 500mg	√	636,027	Cefuroxime tab 250mg*		51,379
10	Ciprofloxacin tab 500mg	√	561,424	Cefixime tab 200mg*		45,988
11	Benzoic & Salicylic ointment	√	549,028	Amoxycillin inj 500mg	√	39,633
12	Vit. B Complex tab	√	514,764	Flucloxacillin inj 250mg*		34,335
13	Omeprazole cap 250mg	√	422,435	Azithromycin cap 250mg*		32,569
14	Flucloxacillin cap 500mg*		420,670	Cefotaxime inj 250mg*		29,829
15	Ceftriaxone inj 1gm*		412,329	Cefuroxime syr 125mg/5ml*		29, 123
16	Penicillin V tab 250mg	√	397,598	Pantoprazole tab 20mg*		21,812
17	Ferrous & Folic tab	√	377,082	Oxytocin 5 I.U. inj	√	21,289
18	Ranitidine tab 150mg*		366,766	B Complex syrup 100ml*		21,058
19	Cefradine cap 500mg*		365,893	Cefixime syr 100mg/5ml*		20,842
20	Doxycycline cap 100mg	√	337,686	Sol. insulin inj 40 IU	√	20,133
21	Metronidazole IVI 500mg	√	327,221	Enoxaparin Inj 60mg*		20,128
22	Cloxacillin cap 500mg	√	236,173	Naproxen tab 500mg*		19,868
23	Benzyl benzoate 60ml	√	229,256	Clindamycin cap 300mg*		19,672
24	Levofloxacin tab 500mg*		164,953	Alum/Magnes. syr 200ml	√	19,535
Totals	Top 24 items cost 31% budget (non-EDL 5%); Antibiotics 44% & vitamins 4% of total budget			Top 24 items cost 82% budget (non-EDL 42%); Antibiotics 19% & vitamins 1% of total budget.		

* non-EML drugs

Table 4.3.2. ABC analysis of the top 24 items by EDCL and CMSD combined in 2013

Source of data (government department/organization): EDCL and CMSD

Rank	Item Name/Strength	Value ($)	% of total	Cumulative %	EML
1	Oral Rehydration Solution	1,763,915	2.96	2.96	√
2	Paracetamol tab 500mg	1,681,160	2.82	5.78	√
3	Antacid tab 650mg	1,414,517	2.37	8.15	√
4	Metronidazole tab 400mg	1,198,387	2.01	10.17	√
5	Amoxycillin cap 250mg	1,094,550	1.84	12.00	√
6	5% D/saline IVI 500ml	930,224	1.56	13.56	√
7	Azithromycin tab 500mg*	809,481	1.36	14.92	
8	Amoxycilin syrup 100ml	807,243	1.35	16.28	√
9	Paracetamol susp 60ml	774,623	1.30	17.58	√
10	Amoxycilin cap 500mg	636,027	1.07	18.64	√
11	Ciprofloxacin tab 500mg	561,424	0.94	19.58	√
12	Benzoic & Salicylic ointment	549,028	0.92	20.51	√
13	Vitamin B Complex tab	514,764	0.86	21.37	√
14	Cholera Saline 500ml	498,380	0.84	22.21	√
15	Omeprazole cap 250mg	422,435	0.71	22.91	√
16	Flucloxacillin cap 500mg*	420,670	0.71	23.62	
17	Ceftriaxone inj 1gm*	412,329	0.69	24.31	
18	Penicillin V tab 250mg	397,598	0.67	24.98	√
19	Ferrous & Folic tab	377,082	0.63	25.61	√
20	Ranitidine tab 150mg*	366,766	0.62	26.23	
21	Cefradine cap 500mg*	365,893	0.61	26.84	
22	Doxycycline cap 100mg	337,686	0.57	27.41	√
23	Hartmann Solution IVI 500ml*	329,663	0.55	27.96	
24	Metronidazole IVI 500mg	327,221	0.55	28.51	√
	Subtotal of top 24 items	16,991,066		28.51	
	Total EDCL sales and CMSD budget	59,596,027			

* Non-EML medicines

Overall the aggregate consumption data shows that, with a few exceptions, most high expenditure items are EML drugs as per government policy.

Analysis of this 2013 data reveals:

- Annual per capita government expenditure on medicines: 0.36 USD

- Number of items on national EML 209;

- Number of formulations on national EML: 318

- Number of top 24 items on national EML: 20 (if cholera solution is counted as an EML product)

- Percentage of total value due to antibiotics: 41%;   vitamins (multivitamins and B Complex): 4%

- Number of traditional medicine items supplied by CMSD: 197 (25 Ayurveda products, 152 Homeopathy products and 20 Unani products)

- Total proportion of CMSD budget spent on traditional medicines: 2%

- Total number of items on national procurement lists:
    - EDCL: 224 items (32% non-EDL items);
    - CMSD: 512 items (76% non-EDL items);

According to national policy, 70% of all medicines should be supplied by the EDCL, 25% by the CMSD, and 5% by local purchase. However, on analysis of 2013 data and assuming that 5% of the total drug budget was spent on local purchase, then in fact 82% of the allocated budget was spent on purchase from the EDCL and 13% from the CMSD. This lower percentage supply from CMSD may have come about from health facilities not spending all their budgets. One health facility reported that they had to return funds at the end of the fiscal year because CMSD had been unable to supply in time the ceftriaxone that they requested. In addition, the budget lines for supplying medicines are quite complex and it may be that some CMSD funds have not been included although all effort was made to include all budget sources, including those of line directors with the DGHS. A further reason for a greater proportion of the drug supply coming from EDCL may be that CMSD is now buying some drugs from the EDCL, which has won the competitive bid (and which does manufacture some non-EDL drugs). All the ABC analyses, shown here, had to be manually extracted and estimated. This demonstrates that no functional logistics management information system, with analytical capacity, is operating at the central level.

The top 10 causes of mortality in 2013 (DGHS/MOHFW 2014) were:

1. Birth asphyxia
2. Transport accidents
3. Acute myocardial infarction
4. Stroke, not specified as hemorrhage or infarction
5. Other septicemia
6. Complications and ill-defined descriptions of heart disease
7. Other chronic obstructive pulmonary disease
8. Heart failure
9. Pneumonia, organism unspecified
10. Bronchial asthma

The top 10 diseases with greatest incidence in 2013 (DGHS/MOHFW 2014) were:

1. Diarrhea
2. Assault
3. Pneumonia
4. Road traffic accident
5. Peptic ulcer
6. Bronchial asthma
7. Enteric fever
8. Viral fever
9. Poisoning
10. Hypertension

Comparison of the top 20 drugs by value with the top 10 causes of mortality and the top 10 diseases by incidence show that spending on essential medicines is quite appropriate since the top 20 drugs include IV fluids, ORS, amoxicillin which may be used for traffic accidents, acute diarrhoea and pneumonia respectively. The high use of metronidazole is likely to be related to the high incidence of acute diarrhoea although most diarrhoea does not need treatment with metronidazole. Similarly peptic ulcer is in the top 10 diseases drugs to treat it (omeprazole and ranitidine) are in the top 20 drugs. The absence of a bronchodilator drug in the top 20 drugs even though asthma features as one of the top 10 diseases suggests that asthma may be under-treated due to a lack of drugs, probably as a result of there being no bronchodilator on the national EML apart from salbutamol.

CMSD supplies a small amount of traditional medicines. In the 3 public facilities observed, only in the district hospital did the traditional practitioner dispense some traditional medicines (about 10 items) supplied by CMSD. In the two Upazila health complexes observed, patients had to buy their treatment from outside. In one of the complexes a pharmaceutical representative promoting traditional products was meeting with the traditional practitioner. In the NGO hospital visited, the ayurvedic practitioner was dispensing ayurvedic products that he had personally bought from the market. The Bangladesh government has just signed an MOU with India to import approximately 60 million USD worth of traditional medicine products from India. It is unclear how these products will be distributed.

4.4. Drug Procurement

4.4.1. National Public Sector Drug Procurement

National policy dictates that public sector medicines will be purchased from EDCL (70%), CMSD (25%) and local sources (5%). While EDCL generally supplies EDL drugs, CMSD also supplies non-EDL drugs and medical equipment (which is the greater part of its operations). Both CMSD and EDCL mentioned that they were satisfied with the quality of drugs and were paid promptly by government operations. EDCL operations are briefly described in section 4.10 on drug manufacturing. All drugs produced for government, whether by EDCL or other manufacturers, are colour coded in red and green and marked with "for use only in government facilities" in order to cut down on pilferage. However, one respondent mentioned that marking actual tables would be needed to really stop all pilferage.

The CMSD is the government procurement unit for all medical supplies and it operates with 221 staff, 180 based in Dhaka and 21 at Chittagong port. CMSD supplies medicines to 64 civil surgeons (in charge of health facilities below the level of district hospital), district hospitals, and the public health programs operated by 9 line Directors in the Directorate General of Health Services. Referral and specialist hospitals generally do not procure from the CMSD. At the time of the last situational analysis in 2010, CMSD had been supplying drugs for about a year, and it had been found that the quality of medicines had improved and the price of some products had greatly reduced, as compared to previously when health facilities had procured elsewhere. Tertiary hospitals are not obliged to procure from the CMSD, but they are obliged to purchase from about 40 manufacturers pre-qualified by the CMSD.

CMSD has various funds including reimbursable project aid, direct project aid and government development and revenue budgets. Procurement is done annually on their own quantification estimates based on past supply, with adjustments made by the DG Health Services, who ultimately approves the procurement plan. A national bidding process is used or an international bidding process if the cost of any single item or package is more than 300 000 USD. There are extensive written SOPs, following the Public Procurement Act of 2006 and the Public Procurement Rule of 2008, which does not have any separate requirement for drugs. CMSD also use the World Bank Procurement Guidelines (2010). It was mentioned that the procurement process has greatly improved since 2010 resulting in reduced lead times (from 18 months in 2010 to 12 months currently). Nevertheless, the procurement process involves 19 steps with an overall lead time of 45-60 weeks (as opposed to a 12-week lead time for EDCL to manufacture items). Taking into account poor quantification by health facilities and long lead times, procurement is often done for 2-3 years estimated requirement.

Challenges mentioned concerning procurement included:

- "locking" of product specifications due to WHO pre-qualification requirements,
- difficulty to harmonize quality, budget and procurement guidelines;
- high bid prices due to unseen collusive practices;
- difficulty to take strong measures for supplying poor quality medicines, since 80% of the payment has already been made before receipt.

The process of sample testing for quality is problematic. Since Bangladesh has no WHO-prequalified laboratory, batch samples of some drugs are sent abroad for testing, during the post-shipment inspection process. It is unclear how much batch sampling for quality testing is done and what laboratories are used for nationally produced products.

4.4.2. Provincial/District/Health facility Drug Procurement

While health facilities are able to order drugs as per need from EDCL and CMSD, according to their allocated budgets, in practice all funds are controlled centrally and only 5% of allocated budgets is available for local purchase by health facilities at the district level and below. Most health facilities use this budget to purchase intravenous fluids from the Institute of Public Health (IPH), since EDCL does not manufacture such products and CMSD does not generally procure them for civil surgeons and district hospitals, only for line directors. Up to 25,000 Taka worth of drugs in district hospitals and 15,000 Taka worth of drugs in Upazila Health Complexes may be purchased without tender. Above this tendering must be done. Such procurement is management by Civil Surgeons and District Hospital Superintendents. No local purchase is done for the Community Health Clinic whose drugs are purchased centrally.

Specialist and tertiary hospitals may spend 25-30% of their budget on local purchase from 40 manufacturers prequalified by the CMSD. Procurement is managed by the hospital directors and is by tendering according to the procurement rules.

All health facility drug stores were managed by store keepers with the exception of some medical college hospitals. While diploma pharmacists were generally present in all facilities, mainly in the outpatient dispensary, they were not generally involved in store management or procurement. The store keepers managed the stores and issued drug orders to the senior management but were not involved in the procurement process. Most storekeepers undertook quarterly ordering and mentioned making 2-3 emergency orders per year.

4.5. Allocation of budget for medicines in the public sector

The drug budget allocation to each health facility is based on the number of beds per facility, multiplying by a factor of 2000, 3000 or 3500 for Upazila health complexes, district hospitals and tertiary hospitals, respectively, plus some adjustment for past consumption. It is determined by the DG Health Services. An exact formula could not be shared. It was admitted that since bed occupancy is 150% or even 200% the drug allocation is insufficient. CMSD mentioned that they compiled an annual need based on past consumption and submitted it to DGHS who then adjusted it and approved it prior to tendering. They further stated that the allocated budget was one-tenth of the real need. Some hospital directors also stated that the allocation was well below need and that they had to "ration" certain drugs to ensure availability for the very poor and in the case of emergencies. These end-user perceptions are consistent with the finding from analysis of sales and purchase data from EDCL and CMSD, respectively, that government expenditure on medicines in 2013 was about 0.36 USD/person/year (see section 4.3), which is well below what is recommended by WHO.

4.6. Drug quantification in the public sector

Quantification is done according to past consumption. Civil surgeons, district hospital superintendents, tertiary hospital directors and DGHS line directors calculate their estimates needs and submit to DGHS. CMSD and EDCL also supply data on past supply. Within DGHS data is compiled and matched with allocations. However, the process is unclear and does not appear to result in adequate amounts to meet demand. The CMSD complained that quantification done by civil surgeons and line directors was poor and uncoordinated and that this resulted in under-stocking and sometimes over-stocking. The lack of any electronic drug management information system means that all stock management must be done manually and that there is no system of tracking drugs or estimating accurately length of stock-outs and amounts of expiry. Thus any quantification methods based on past consumption are unlikely to match real need. None of the storekeepers appeared to take buffer stock into account when making orders, merely ordering the amount they had previously used, when stocks ran out (or nearly ran out). Store keepers were also often unaware of stock levels in the OPD dispensary and in the wards.

4.7. Drug Management and Distribution in the public sector

4.7.1. Drug Management and Distribution from the central national level

Drugs are ordered by each facility quarterly from EDCL, and annually from CMSD, within the allocated budget "pull system". Local drug purchase (5%) is adhoc. The drugs are distributed quarterly from the EDCL or from the local manufacturers used by CMSD according to health facility demand (which must be within their budgetary allocation). Only in the case of imported drugs, are drugs stored in the CMSD warehouse from where they are distributed to health facilities. EDCL does have a warehouse from which it distributes drugs to health facilities. CMSD mentioned that sometimes they cannot supply all of the demands on time as requested by health facilities. There is no ordering schedule to ensure timely, equal distribution of ordering from health facilities throughout the year.

In the case of community health clinics, a "push" system operates, drug kits being supplied quarterly directly from EDCL, as instructed by the Community Health Project under DGHS and in collaboration with EDCL. In the two CHCs visited there was no stock-out of the drugs supplied in the kits. One CHC mentioned that some drugs were out of stock after 2 months and that they had to do without for about a month before the next kit came. It was also stated by the CHC inspectors that sometimes they did re-distribute drugs that had limited shelf life between CHCs.

In the 2010 situational analysis, DGHS had mentioned that they were going to establish an electronic drug management information system, starting centrally and working down to district level in order to improve quantification and stock management and that there was USAID and GTZ support for this. However, no progress on this appears to have happened. Rather a new electronic health management information system has been started but this will not help with drug management. Management Sciences for Health has been supporting logistics management for family planning products in recent years since when there has apparently been no stock-out for these products. However, this system has not been extended to medicines in general.

4.7.2. Drug distribution between and within health facilities in the public sector

There is little redistribution of medicines between facilities and districts (with the exception of CHCs) and indeed most facilities complained that they ran out of stock rather than having too much of it. However, without an electronic drug management information system it is very difficult to be able to communicate about short-dated drugs in one facility and a near stock-out situation in another facility. Drug stores were often cramped and poorly ventilated. The store keepers often had little knowledge of the stock situation on the wards or in the outpatient dispensary. Stock was generally well maintained in the OPD dispensary under the charge of diploma pharmacists. However, in the wards, drugs were much less well managed, with poor storage conditions and poorly maintained stock records. Nevertheless, the nurses often knew what was in stock and stated that they often asked for more than they needed because store keepers will often supply less than they ask. Likewise one storekeeper mentioned that s/he often supplied less than was asked for on instruction from the Hospital Director in order to keep stock in readiness for emergencies.

The record keeping for actual dispensing of medicines to inpatients was poor and in some circumstances dangerous. There were no individual patient records for administration of medicines. Rather the nurses wrote out a list of medicines for each dosing period, from all the patient records, with the bed number of the patient who must be given the concerned drug. There was no written indication on the patient notes of

whether each dose of each medicine was actually given. In a scenario of more than 90 patients looked after by 3 nurses, such a system could easily result in the wrong drug being given to the wrong patient. Supposing mobile patients swapped beds? Furthermore, such a system is vulnerable to pilferage since there is no way of checking whether all the drugs stored on the ward are used for the inpatients. It was noticed on one occasion that drugs seen on the ward were later bought in outside pharmacies near to the hospital for hospital inpatients.

4.7.3. Human resources

It was mentioned that, with the exception of the DG Drug Administration (drug regulatory authority), there are only 8-16 bachelor pharmacy positions in the public sector in Bangladesh, and not all the posts are filled. Thus, drugs are being managed centrally and peripherally without sufficient pharmacy expertise. Without such expertise, it will be difficult to establish and operate any electronic drug management information system, quantification is likely to remain problematic, clinical pharmacy cannot be introduced into hospitals, and many activities to improve drug management, such as review of ward drug management procedures, monitoring of consumption, establishment of functional Drug and Therapeutic Committees, are unlikely to be done. Furthermore, dedicated data-entry personnel are needed to run an electronic drug management information system. While the investment in establishing such a system may seem large it would pay dividends many times over in efficiencies in drug management gained.

4.8. Patient Flow in the Health Facilities

The health sector comprises tertiary, secondary and other hospitals at the district level and above (126 hospitals with 28,978 beds), 483 primary health care health facilities at the upazila level (19,855 beds) and 13,500 community health clinics. Recently one traditional medicine practitioner has been posted in each district hospital and also in some Upazila Health Complexes. A similar patient flow operates at all levels except the CHCs where patients do not pay any registration fee and where there are no beds. While there was generally about 10 medical officers handling outpatients in Upazila Health Complexes and more than this in district hospitals doctors, there was generally one traditional medicine practitioner per district hospital and Upazila Health Complex.

Patients register, paying a 5-10 Taka registration fee, and then go to the general Medical Officers, or specialist outpatients, or the emergency room. Where patients go after registration is decided by the registration staff and the patient. If the general medical officers feel that a patient needs referral, they can refer to the specialist if one is there or directly to the ward. Similarly, emergency room patients may be referred to the ward or discharged. All patients needing any kind of injection are referred for admission with the exception of patients requiring tetanus toxoid, rabies vaccination, childhood immunization and local anaesthetic for minor wound suture. All medicines dispensed from the hospital are free of charge.

In outpatients, patients are given a prescription, with a separate slip recording the drugs to be dispensed from the OPD dispensary. The slips with the drugs recorded are then given to the pharmacy where the drugs are dispensed. The OPD pharmacies keep these slips to count up the quantity of drugs dispensed each day. In some facilities there is one slip per drug and in others one slip per patient. In Dhaka Medical College, there is a separate slip for each drug and patients must go to a separate counter with each slip to get the required medicine. This latter arrangement may help to ensure that the correct drugs are dispensed to the patients, in the context of huge crowding and very short dispensing times, but it does not help to

facilitate patient understanding of how to take their medicines. About 10-35% of prescribed drugs are not available from the OPD dispensary so patients must go to private outside pharmacies to purchase these.

In the OPD, most doctors kept a register of patients seen. The younger doctors in Upazila Health Complexes and Community Care Clinic staff maintain these registers fairly well, recording diagnosis and treatment. However, the older doctors in the Upazila Health Complexes and all doctors in higher facilities do not maintain the registers well, often only recording patient name and/or number and no diagnosis or treatment. Medical officers generally had to see 100-200 patients per day in tertiary hospitals, 100-150 patients/day in district hospitals, and 30-50 patients/day in Upazila health complexes. Specialists generally saw less patients than this, about 30 patients per day, though more complex cases. Where Traditional Medicine practitioners were established (3 Unani practitioners seen in 3 public facilities and one ayurvedic practitioner seen in one NGO facility), the number of patients seen per traditional medicine practitioner per day was similar to the number pf patients seen per allopathic doctor per day. Community Health Care Providers (CHCPs) in CHCs saw 20-30 patients per day. Some outpatient diploma pharmacists and pharmacy assistants had to dispense to more than 200 patients per day each.

Inpatient records consist of one sheet of paper with history, examination and diagnosis recorded and with any lab tests etc. attached. There is no individual patient dispensing record sheet. There was an acute shortage of nurses in all tertiary and district hospitals, with bed occupancy of 150-200%, patients lying on mattresses on the floor, and generally more than 15 patients to each nurse in the morning shift (which is better staffed than other shifts). By contrast, bed occupancy in Upazila Health Complexes was less than 100% and there were generally less than 10 patients to each nurse in the morning shift.

Inpatient beds are generally free. However, it was mentioned that there are also private beds and rooms available in some hospitals. For example, one hospital was charging 75 Taka per bed per day plus food at 125 Taka per day. Private cabins were also available at 150 or 200 Taka per day plus food at 150 Taka per day. Private beds for operations were available at 500 Taka per day and private rooms for operations were also available at 500-2000 Taka per day, depending on whether surgery was major or minor.

There was huge crowding of patients in both the OPD and the IPD wards in district and tertiary hospitals, making it extremely difficult for staff to work. Indeed, one-minute OPD consultations are likely to result in more IPD admissions than necessary simply because there is not the time to assess and manage a patient thoroughly in the OPD. This in turn leads to greater ward crowding. One hospital mentioned that the workload was so great in the wards that nurses could no longer record the dispensing of oral treatments on the dosing forms where the bed number of patients needing specific drugs was recorded.

Many tertiary and district hospitals mentioned that patients bypass the lower health care facilities and indeed there was much less crowding in the OPD and the IPD at Upazila Health Complexes. It was also mentioned that many common conditions such as hypertension or diabetes were not generally treated at Upazila Health Complexes, which did not even stock some medicines such as, for example, anti-diabetic medicines. This seems a waste of resources since there appear to be many qualified young doctors, who could easily treat such patients, posted at these complexes.

4.9. <u>Insurance</u>

There is no health insurance for the majority of the population.

4.10. Drug Manufacturing

The Essential Drug Company Limited (EDCL) is the government-owned manufacturing company and it supplies 70-75% of all medicines used in public sector hospitals and Upazila health complexes and all drugs used in community care clinics. It has four manufacturing units and sales in 2012-13 were 398.55 crore Taka and production 390.28 crore Taka. They mostly supply government although they do supply ICCDRB and are starting to export to Bhutan, Sri Lanka and Mynamar through bilateral government agreement. The EDCL has its own drug testing laboratory and everyone seemed satisfied with the drug quality. They purchase APIs for paracetamol, amoxicillin and flucloxacillin locally and rest from China, Europe and India. Occasional poor quality API supplied by China and causing delays in manufacture was reported in the 2010 situational analysis, but seems to no longer be a problem.

Although policy dictates that EDCL only supply drugs on the EDL, they do in fact supply a number of non-EDL drugs. Indeed of 224 items that they manufacture, 32% are not on the EDL. This is may partly be due to exports to Bhutan, Myanmar and Sri Lanka (although this has only just started) but is also due to demand from line directors in the DGHS and civil surgeons, who are increasingly using non-EDL drugs, the EDL not having been updated since 2008 (although an update is now in process). In fact competing manufacturers do not want the EDL to be updated or expanded because of a fear of prices controls on an increased number of medicines. The EDCL has started undertaking market surveys annually, asking civil surgeons what products they would like to purchase. In this way they decided to manufacture 30 new non-EDL items in the previous year.

Apart from the EDCL there are about 270 private allopathic manufactures in Bangladesh of which the top 10 are reported to be of world class stature and thought by some to be better than EDCL. Forty of these manufacturers are approved by CMSD for public hospitals to purchase from in open tender.

4.11. Drug management in the private sector

Thirteen private pharmacies were visited in four areas - two areas were near the entrance of two medical college hospitals and two areas were in town-centres away from the hospitals. The pharmacies tended to be situated in groups, sometimes of about 20 shops or more particularly near hospitals, all in fierce competition with each other. Pharmacies near to hospitals tended to serve IPD and OPD patients who could not get their medicines from the hospitals. It was mentioned that supplying medicines to patients at night was problematic because hospital drug stores are closed and so inpatients often have to buy medicines from outside pharmacies at high prices. Pharmacies in town-centres away from hospitals tended to serve patients getting prescriptions from private GPs.

On interviewing pharmacy staff it was found that the average number of patients served per day varied from 20 to 350 patients per day and the number of items stocked varied between 350 to more than 5000, of which there were between 2 and 50 traditional medicine items in 5 of the pharmacies. Sales per day varied from 5000 Taka to 1 Lakh per day. Reported profit margins varied hugely with some pharmacy owners saying they only made 4% profit (1000 Taka per day), others stating that the mark-up was 12% and one pharmacy owner's account sheet over 5 days showing a 26% profit margin.

Pharmacy shops bought mostly directly from 20-50 manufacturers, most of whom visited every few days to sell small quantities to maintain the pharmacies' stock levels. Some pharmacies also bought from wholesalers. A number of pharmacy shop staff had no pharmacy qualification although many of them had a

diploma or certificate in some other subject. Many such staff were alone in the pharmacy. Many of the pharmacies did not have good storage conditions. The small quantities of stock supplied by manufacturers to such pharmacy shops on an almost daily basis means that none of these shops is likely to stock 200 units of any one batch of product, thus precluding analysis testing of these products by the DGDA.

Summary status including progress, changes and problems in drug supply since the last situational analysis

Drugs are supplied to the public sector in the same way as they were supplied in 2010. Government expenditure on drugs remains extremely low (about 0.36 USD/person/year). According to national policy, 70% of drugs are supplied by the Essential Drug Company Limited (EDCL), 25% by the Central Medical Stores Depot (CMSD) and the remaining 5% by local purchase. While most drugs supplied belong to the national Essential Drug List (EDL), an increasing proportion of non-EDL drugs are being supplied, one reason being that the EDL has not been updated since 2008. The EDCL remains efficient at supplying drugs and the efficiency of the CMSD has increased with reduction in lead times to one year. Availability of key essential drugs was 61-75% in hospitals and upazila health complexes and 100% in community health care clinics (according to a separate more limited list supplied). However, there are still complaints of stock-out and lack of sufficient budget to meet patient demand. The lack of pharmacists and the lack of any electronic drug management information system make it extremely difficult to monitor accurately consumption, stock-outs, and expiry and this lack of knowledge results in poor quantification and leads to stock-outs. Unfortunately, the recommendation in 2010 to establish an electronic drug management information system was not followed.

4.12. **Medicines Supply: Recommendations**

- Increase government expenditure on essential drugs.

- Establish a harmonised, functional, electronic drug management information system, to monitor consumption, stock-out, expiry, etc. which is necessary to improve quantification:

    – recommended in 2010, but little progress;
    – DGHS/USAID/GTZ project 2010-2013 was planned but not executed:
    – start centrally & extend to district level initially:
    – employ a data-entry staff for this purpose at each hospital and district.

- Involve bachelor and diploma pharmacists in stock management, not just outpatient dispensing.

- Train staff in monitoring medicine consumption and quantification.

- Review the ward management of drugs.

5. MEDICINE SELECTION

5.1. <u>National Essential Drugs/Medicines List (EDL/EML)</u>

From review of the national EDL:

- Responsible government department or agency: Directorate General Drug Administration, MOHFW

- Date of publication of latest EDL: 2008

- Previous publication dates: 1982

- Number of active pharmaceutical ingredients (APIs) in current EDL: 209

- Number of formulations for all APIs : 318

- Number of products (incl. all brand names and formulations) registered in the market: >25,000

- Categories by level of use in national EDL: no categorization.

- Number of persons involved in drafting the latest EDL:

    o Core team: 11 senior experts from Director and <u>Assistant Director DGDA</u>, Representative of <u>DGHS (formerly head of medicine of Dhaka medical college hospital)</u>, <u>Chairman of BCSIR</u>, <u>Dean and Faculty of Pharmacy Dhaka University</u>, Deputy Secretary of Public Health MOHFW, President Bangladesh Pharmaceutical Society, Representative Bangladesh Association of Pharmaceutical Industry, <u>Representative Bangladesh Pharmacy Council</u>, Representative Consumer Association of Bangladesh, and Representative Bangladesh Chemist and Druggist Society;

    o Sub-committee of the core team were 5 members of the above core team, as underlined above;

    o Experts: Heads of Departments of the major medical schools.

- Specialties represented (including general practice): Unknown whether all specialties including general practitioners were represented.

- Geographic representation of experts: Unknown

- Consistency with national STGs? No National STGs for most common conditions.

5.2. Other Medicine Lists

Central procurement

The EDCL has a list of drugs it manufactures and this list contains 224 items of which 32% do not belong to the EDL.

The CMSD has a procurement list of about 512 drug items of which 72% do not belong to the EDL and which is agreed with the DGHS.

The DGDA has a primary health care list of 117 drugs for price control, of which 24 drugs are not on the EDL. Of the 183 formulations, 51 are not on the EDL. This list was produced in 1993 and appears not to have been updated with the revised 2008 EDL.

Districts and Hospitals

Civil Surgeons and Hospital Directors follow their own lists with regard to local purchase and purchase from CMSD. Each hospital has a slightly different list from within the EDCL and CMSD lists.

Bangladesh National Formulary

The Bangladesh National Formulary (BDNF) 2006, produced by the DGDA, is a comprehensive formulary with all the drugs on the market listed and each drug described in the style of the British National Formulary. It contains information on EDL and non-EDL drugs. However, some information may be out of date since it has not been updated since 2006.

5.3. Development / updating of national EDL

The situation with regard to development and updating of the national EDL has not changed since 2010 since the 2008 national EDL has not yet been updated. Briefly, the national EDL has only has 209 chemical entities, including vaccines, and is missing many of the drugs needed in hospitals e.g. Cephalosporins. While some people may feel that the EDL is only for use in primary health care and acute care, this is not mentioned in the EDL booklet itself. Furthermore, the EDL does contain some medicines for chronic diseases such as diabetes mellitus (Glibenclamide, Gliclazide, Metformin, Soluble Insulin) and hypertension (Amlodipine, Atenolol, Hydrochlorthiazide, Methyldopa, Nifedipine, Enalapril) and cancer (methotrexate, cyclosphosphamide). There are also some surprising inconsistencies. For example, while there is no 5% dextrose for intravenous infusion, there is human immunoglobulin and peritoneal dialysis solution.

The National EDL was produced by 11 persons, mainly pharmacists with apparently little representation from the medical profession, neither specialists nor generalists. Furthermore, the committee of 11 persons included representatives from the pharmaceutical industry and the chemists and druggist society and it is not certain what their role would have been in selecting essential medicines from the perspective of efficacy and safety and, indeed, they may have had a conflict of interest in this role. The criteria used for selecting drugs, the sources of evidence are not known, and the process is not transparent. In these

circumstances it is not surprising that many doctors do not feel that EDL contains the drugs they need and in many hospitals, many non-EDL drugs are purchased, some which may not be the optimal, most cost-effective drugs.

The Bangladesh National Formulary 2006, by contrast, had 74 contributors representing all disciplines plus an editorial board of 14. With this degree of representation in the development process, there is much more chance of acceptance and use by the medical profession and prescribers. However, it appears to have been poorly promoted as few doctors in facilities had a copy or had heard of it.

The non-EDL drugs that are included in the CMSD and EDCL lists appear to be chosen according the number of requests from civil surgeons, hospital directors and superintendents, and DGHS line Directors. Civil surgeons and hospital directors and superintendents decide on what drugs to order/purchase on the basis of opinions from the senior doctors and heads of clinical departments.

The need to update the national EDL was acknowledged by many government staff and it was mentioned that there had been resistance from the pharmaceutical industry to update the EDL because of price controls for EDL medicines.

5.4. Implementation of EML

National policy has ensured that the majority of medicines produced by the EDCL and comprising 70% of the drugs supplied to public health facilities belong to the national EML. Nevertheless, the national EDL is increasingly perceived as being out of date and not relevant to hospitals, which are increasingly purchasing non-EDL drugs through the CMSD and through local purchase. As mentioned previously even the EDCL is manufacturing non-EDL drugs. The ability to purchase non-EDL at district level and below is limited to those non-EDL drugs procured by CMSD and also limited due to budget constraints. However, medical college hospitals have more freedom since they are able to use 30% of their budget on purchases outside of the EDCL and CMSD lists.

No copies of the national EDL were seen in the health facilities and it did not appear to be relevant to the health staff. While medical students are taught about the EDL, they see many other non-EDL drugs being used in their clinical studies.

There are no previous reports on EDL implementation. One report in 2009 documented poor availability (as mentioned in section 4) but the percentage of drugs prescribed that belong to the EDL has never been measured. Consumption data were not available at regional/ hospital level, but implementation of the EDL was reviewed during the health facility survey by observing stock availability and doing a prescription audit at health facilities. Availability of key EDL drugs was 61-75% in public health facilities at upazila health complex level and above. Some of the non-availability was due non-use by the facility as the concerned drugs had been "superseded" by other non-EDL ones which are supplied by the CMSD. In particular, erythromycin had been completely superseded by azithromycin. In the CHCs visited there was 100% availability (although the list of key EDL drugs was reduced as compared to the list used for other facilities and availability would have been 43% if the same list was used as for other levels).

Prescription review during the situational analysis showed that in public sector OPD the percentage of prescribed drugs belonging the national EDL was 49% in medical college hospitals, 57% in district hospitals, 77% in Upazila Health Complexes and 97% in community health clinics. By contrast, the percentage of prescribed medicines belonging to the national EDL in the private sector as judged by review of prescriptions in private pharmacies was only 27%. Thus nearly half of all drugs prescribed in public sector hospitals do not belong to the EDL.

ABC analysis of 2013 supply data (section 4) shows that 6 of the top 24 drugs by value were non-EDL drugs and that 6 of the top 24 drugs manufactured by EDCL were non-EDL ones and 16 of the top 24 drugs procured by CMSD were non-EDL ones. Table 5.4.1 shows findings of EML implementation as observed at the facilities.

Table 5.4.1: EDL (EML) drug availability and use from observation and record review in the health facility surveys

Public Referral Hospitals	1	2			Average
% key EML drugs available*	82%	67%			75%
% prescribed drugs belonging to the EML**	63%	36%			49%
EML available in pharmacy? Yes/No	No	No			No
Public District Hospitals	1	2			
% key EML drugs available*	54%	81%			68%
% prescribed drugs belonging to the EML**	64%	51%			57%
EML available in pharmacy? Yes/No	No	No			No
Public Upazila Health Complex	1	2			
% key EML drugs available*	57%	64%			61%
% prescribed drugs belonging to the EML**	79%	52%			65%
EML available in pharmacy? Yes/No	No	No			No
Community Health Clinic	1	2			
% key EML drugs available*	100%	100%			100%
% prescribed drugs belonging to the EML**	96%	96%			96%
EML available? Yes/No	No	No			No
Private pharmacies	1	2	3	4	
% key EML drugs available					
% prescribed drugs belonging to the EML**	33.3	27.4	26.1	20.6	26.8
EML available in pharmacy? Yes/No	No	No	No	No	No

* Belonging to the national EML – please see also the section on drug supply under drug availability
** From prescription audit done during the health facility surveys

5.5. __Summary status including progress, changes and problems__ in drug selection since last situational analysis

The national EDL contains only 209 drugs and has not been updated since 2008. As a result, about half of all the drugs prescribed in public sector hospitals do not belong to the national EDL, despite national policy dictating that the majority of drugs used should belong to the national EDL. Many of the drugs supplied by the CMSD are non-EDL ones according to a list approved by the Directorate General of Health Services (DGHS) after discussion with senior doctors and civil surgeons. Even some of the drugs supplied by the EDCL are non-EDL ones. In addition, many patients are prescribed non-EDL drugs that are not available in public facilities and have to buy them from private pharmacies. Unfortunately, the recommendation in 2010 to revise the national EDL was not followed.

5.6. __Drug Selection: Recommendations__

- Revise the EDL:

    - include drugs for all levels of care;
    - classify each drug according to level of care, therapeutic class
    - have wide representation of specialists, generalists and pharmacists, and transparent process to improve acceptance.

- Implement the EDL:

    - Demand to EDCL and CMSD should follow the EDL;
    - Ensure all providers are sensitized/trained on the EDL;
    - Monitor compliance.

- Establish a transparent system to review all requests for non-EDL drugs:

    - Drug and Therapeutic Committee in each referral and district hospital could do this.

6. MEDICINE USE

6.1. **Responsible Agents/Departments**

From discussion with senior MOH officials

Function/ Organisation	MOHFW	Other Agency	Name of Agency/MOH Department
Monitoring medicines use in hospitals	√		Directors of Hospitals are responsible but it is infrequently done.
Monitoring medicines use in Primary care	√		Director of Essential Service Delivery (ESD) is responsible but it is infrequently done.
Development of national STGs	√		DGHS. Only the vertical disease control programs have produced Standard Treatment Guidelines (STGs).
Development of national formulary	√		DGDA.
Drug Information Centre	√		No drug information centre, although the DGDA has proposed to provide information through their website.
Provision of independent drug information		√	Only literature and web-based information available.
Monitoring Hospital DTCs	√		DGHS responsible but there are few functional hospital Drug and Therapeutic Committees (DTCs) and no monitoring.
Monitoring Hospital quality of care	√		DGHS and Directors of Hospitals are responsible.
Monitoring DTCs in provinces/districts	√		DGHS responsible but there are no functional district (DTCs) and no monitoring.
Undergraduate education for health professionals	√	√	Director of Medical Education, Centre for Medical Education (CME) and Bangladesh Medical & Dental Council (BMDC) under Ministry of Health & Family welfare (MOHFW) are responsible.
Continuing medical education for health professionals	√	√	MOHFW runs refresher training for some topics, medical schools run education activities for their staff, medical association and pharmaceutical industry for private doctors and specialists
Public education on medicines use	√		Bureau of Health education under DGHS is responsible. Medical Education and Health Manpower Development within the DGHS does little public education on medicines use.
Implementing generic policies	√		DGHS and DGDA would be responsible but generic policies are not implemented.

6.2. Past prescription surveys

Since the situational analysis done in 2010, few published surveys have been found. The table from the 2010 report, updated with results from the 2010 situational analysis is given below for reference. These studies show widespread irrational use of medicines and in one study (Rahman 2009) that public education can improve use.

Table 6.2.1: Reports of medicines use surveys done in the last 10 years

Reference	Study type	Survey year	Findings
Holloway KA 2010 Situational analysis, WHO/SEARO.	Public Hospital Public PHC Private pharmacies	2010	Hosps: 3.1 drugs/patient; 61% patients received ABs, 69% drugs dispensed. PHCs: 2.4 drugs/patient; 35% patients received ABs. Pharmacies: 3.1 drugs/patient; 28% patient received ABs; 712 BT/patient
Begum et al 2014	Public Tertiary hospital inpatients	2009	38% patients received ABs and 14% of prescriptions were found to be irrational
Rahman MS 2009	Community self-medication; Public education campaign intervention	2009 control group 2009 interv group	No change in control group and no change in prescribing by doctors. 13% reduction in no drugs/patient 10% reduction in patients getting ABs 25% reduction in patients getting VIT
Shapna Sultana et al 2010	Public tertiary hospitals outpatients	2009	Prescribing for hypertension – polypharmacy, only brand name prescribing, most prescriptions without patient instructions
Hoque et al 2007 Arifeen et al 2004 Arifeen et al 2005	Public PHC; IMCI intervention	2000 baseline 2005 post-intervention	STGPX 11% ; INAPPAB 48-72% STGPX 78% ; INAPPAB 9% Reduced IMR
Mamun et al 2006	Private drug sellers	?	60% patients received ABs, half without prescription, & all sold in inappropriate doses & duration,
Rahman Z, Nazeen R & Begum M, 2009	Private doctors	2005	Average of 3.81 drugs/patient, 72% patients received ABs, 50% drugs from EML, 58% patients received proper instructions.
Rahman Z et al 2005	Public & private hospital inpatients	2004	8-84 days AB prophylaxis for hysterectomy, all contrary to STGs
Larson et al 2006	Private informal providers	2003	% childhood diarrhoea cases treated with ORS 56% & AB 35%
Rahman MS et al 2007	Public & private hospital outpatients	2003	Private hosp used NSAIDs that are more potent, expensive and have more side effects than public hospitals
Islam et al 2007	Hospital inpatients; Prescription audit & feedback interv	2003	AB prophylaxis for Caesarian Section reduced from 8 to 7 days and AB costs reduced by 2/3.
Akter et al 2005	Public & private hospital pediatric inpatients	2002	Unnecessary multi-AB practice, more in private than public hospitals

STGPX = % cases treated in compliance with standard treatment guidelines;
INAPPAB = % cases treated unnecessarily with antibiotics;
NSAID = Non Steroidal Anti-Inflammatory Drugs; interv = intervention;
IMCI = Integrated Management of Childhood Illness; ORS = Oral Rehydration Solution;
AB = Antibiotic; STG = Standard Treatment Guidelines; VIT = Vitamins.

6.3. <u>Current prescribing practices</u>

A prescription survey in public facilities was done reviewing 30 prescriptions from general medical officers on the day of the visit to each facility. Care was taken to select only primary care type cases in the hospitals. Data for general prescribing indicators was collected prospectively from prescriptions as patients came to the OPD pharmacy for the medicines to be dispensed. Data could not be collected retrospectively from the medicines slips that are kept in the pharmacy because medicines to be purchased outside are not recorded on these slips, which are kept only for the purposes of counting dispensed stock. In addition, 30 prescriptions for upper respiratory tract infection were reviewed in Upazila Health Complexes and Community Health Clinics where prescribers were keeping a record of diagnosis and treatment in the OPD patient register. In the case of Dhaka Medical College Hospital, prescriptions were only collected from the acute General Medical Officer Unit and all other outpatients (general medicine, paediatric) prescriptions, which may also contain acute primary care type cases, were excluded.

In private pharmacies, data was collected from 30 patients as they came to the pharmacy to purchase medicines. There were no records kept in the pharmacy so the only means of collecting data was from patients. Since patient flow was slow in the pharmacies, different members of the team collected data from individual patients attending different shops within the same area and the results are presented as an average for a cluster of 3-4 shops in one area (four areas being visited in total). The cost per prescription was based on the cost of all drug items prescribed not on what the patient actually paid – which was often less for fewer drugs.

A visit was made by the WHO to Manikanj district two months prior to the situational analysis in order to determine sources of data. Since the situational analysis was disrupted for several days by nation-wide strikes, data from Manikanj district was also included in the survey results, mainly with regard to one Upazila Health Complex and Community Health Clinic data.

The results of the prescription survey done during this situational analysis are shown in tables 6.3.1 (public sector) and 6.3.2 (private sector) below.

Overall, the average number of drugs prescribed per patient and the percentage of patients receiving one or more antibiotics was similar in 2014 to the results found in 2010 at the levels of district hospital and below. The number of drugs prescribed per patient and antibiotic use appeared to have decreased in Dhaka Medical College Hospital in 2014 as compared to 2010 but this is likely to reflect a different sampling procedure, since this time only acute medical officer prescriptions were reviewed, unlike in 2010 when general OPD prescriptions were reviewed. Nevertheless, the acute medical officer unit in Dhaka Medical College Hospital demonstrated admirably low use of antibiotics.

Injections are generally not prescribed in OPD and all injections are only dispensed in the inpatient wards. Therefore, prescription of injections was not investigated in most facilities. Nevertheless, injection use was explored in Manikanj district hospital prior to the situation analysis. It was found that about 6% of OPD patients received an injection, either in the emergency room or in the ward, and were sent home the same days. The injections were mainly ant-rabies or tetanus toxoid. It was mentioned that anti-rabies injection could not be given at the Upazila Health Complex or below so injection usage would be less there. Compared to other countries, injection use in the public sector is admirably low.

Table 6.3.1: Results of the 2013 situational analysis prescription survey in public sector

Public referral hospitals	1	2		Average
Average number of drugs per patient	2.5	2.8		2.7
% patients prescribed antibiotics	8.1	29.1		18.6
% patients prescribed injections	-	-		-
% patients prescribed vitamins	8.1	10.9		9.5
% drugs prescribed by generic name	15.3	19.4		17.4
% prescribed drugs belonging to the EML	62.6	35.5		49.1
% URTI patients prescribed antibiotics	-	-		-
Average cost per prescription	-	-		-
Public district hospitals	1	2		Average
Average number of drugs per patient	3.1	2.5		2.8
% patients prescribed antibiotics	53.1	55.0		54.1
% patients prescribed injections	-	-		-
% patients prescribed vitamins	12.5	16.7		14.6
% drugs prescribed by generic name	50.5	45.4		48.0
% prescribed drugs belonging to the EML	63.6	50.7		57.2
% URTI patients prescribed antibiotics	-	-		-
Average cost per prescription	-	-		-
Public Upazila Health Complexes	1	2	3	Average
Average number of drugs per patient	2.0	3.3	1.7	2.3
% patients prescribed antibiotics	20.0	48.4	30.0	32.8
% patients prescribed injections	-	-	-	-
% patients prescribed vitamins	36.7	32.3	6.7	25.2
% drugs prescribed by generic name	60.7	40.8	75.0	58.8
% prescribed drugs belonging to the EML	78.7	51.5	-	65.1
% URTI patients prescribed antibiotics	55.6	36.7	86.7	59.7
Average cost per prescription				-
Community health clinics	1	2	3	Average
Average number of drugs per patient	1.6	1.8	1.9	1.8
% patients prescribed antibiotics	16.8	28.2	22.5	22.5
% patients prescribed injections	-	-	-	-
% patients prescribed vitamins	15.0	15.4	25.0	18.5
% drugs prescribed by generic name	86.7	93.6	100.0	93.4
% prescribed drugs belonging to the EML	95.6	95.7	-	95.7
% URTI patients prescribed antibiotics	65.0	66.7	44.4	58.7
Average cost per prescription				

Table 6.3.2 Results of the 2013 situational analysis prescription survey in private sector

Private-for-profit pharmacies	1	2	3	4	Average
Average number of drugs per patient	1.7	2.3	4.1	3.1	2.8
% patients prescribed antibiotics	27.6	35.1	30.3	40.0	33.3
% patients prescribed injections	41.4	45.9	24.2	0.0	27.9
% patients prescribed vitamins	3.4	13.5	30.3	27.3	18.6
% drugs prescribed by generic name	9.8	7.1	4.5	4.1	6.4
% prescribed drugs belonging to the EML	33.3	27.4	26.1	20.6	26.8
% URTI patients prescribed antibiotics	-	-	-	-	-
Average cost per prescription (Taka)	172.25	291.27	791.65	282.60	384.44

Review of all overall prescribing shows widely differing prescribing patterns across different facility types. There was very high public sector prescribing by brand name and high use of non-EDL drugs, this being greatest in medical college hospitals, high in district hospitals, and moderate in Upazila health complexes. In Community Health Clinics, most prescribing was by generic name and nearly all medicines prescribed belonged to the EDL, although there was some prescribing for outside drugs, mostly but not always during times of stock-out. Between 10-25% of patients received vitamins (B Complex or multivitamins) rates being highest in the Upazila Health Complexes and lowest in the Medical College Hospitals.

Antibiotic use in district hospitals is high and much higher than in the other levels of health care. While district hospitals may have to see more serious communicable disease cases than at the other levels of health care, antibiotics are likely to be overused. The percentage of upper respiratory tract infection cases treated with antibiotics in Upazila Health Complexes and Community Health Clinics at around 60% is also very high and represents substantial overuse of antibiotics, as the majority of upper respiratory tract infection is caused by viruses not bacteria.

Prescribing in public sector facilities was done by medical doctors, with the exception of Community Health Clinics, where paramedical staff generally of 3 months training undertook the prescribing. On discussion with OPD doctors, most general medical officers in district and medical college hospitals saw 100-200 patients per doctor per day, while those working in Upazila Health Complexes saw up to 50 patients per doctor per day. Seeing 100-200 patients per day in crowded circumstances, with 1-2 minute consultations, is likely to result in over prescription on medicines, and may result in over-admission, since there is insufficient time in the OPD to assess patients properly. The Upazila Health Complexes were less crowded and not treating certain non-communicable chronic diseases such as diabetes. This is surprising because the doctors would be able to offer such treatments and it would result in such patients not going to the district hospitals, where over-crowding is very serious. Despite the problems of patient crowding and short consultation times, most doctors did not feel there was very much irrational prescribing.

In the private sector, prescribing was very different depending on whether the pharmacy was serving hospital inpatients or general practitioner cases, who often had chronic disease. Pharmacies serving hospital inpatients on average sold fewer drugs per patient and many more injections as compared to pharmacies, which served the patients of private practitioners. The average amount paid per patient for their drugs in private pharmacies was less than that found in 2010 but this is likely to represent a sampling difference.

One traditional practitioner was posted in the District hospitals and Upazila Health Complexes visited – mainly a Unani doctor. In one district hospital and one Upazila Health Complex visited, the Unani traditional medicine practitioner had been working for some time and they tended to see the same number of patients per doctor as the allopathic doctors. In another Upazila Health Complex, the Unani doctor had only just started working and was only seeing 5-10 patients per day. The Unani doctors mentioned that their patients suffered from cough, joint pain, diarrhea, indigestion, skin diseases, urinary problems, and weakness – which is similar to the patients treated by the allopathic doctors. The Unani practitioners in public sector facilities were not offering procedural-based treatments. One had oral treatments to dispense but the others gave prescriptions for patients to take to outside pharmacies. In one private NGO hospital, an ayurvedic practitioner was posted and he was offering procedural-based treatments as well as ayurvedic oral therapies.

6.4. Dispensing Practices

6.4.1. Health Facility Outpatients

Dispensing in the OPD pharmacies of public facilities was generally done by diploma pharmacists or pharmacy assistants under the supervision of diploma pharmacists. In district hospitals and medical college hospitals, where patient crowding was extreme, each dispenser may have to dispense to more than 200 patients per day. Patient-dispenser interaction time was less than 1 minute in all facilities visited and often only a matter of seconds, sometimes without any verbal instructions given. There was no labelling on any medicine dispensed (apart from what is written on the manufacturers' packaging).

Patients were given prescriptions by the OPD doctors, plus medicines slips for the medicines to be dispensed from the facility. One-third or more of the medicines prescribed were for outside purchase so they were not written on the slips. The pharmacists generally only saw the slips and not the prescriptions, so even if they had the time, they would not have been able to advise the patients on how to take all their medicines. In the case of Dhaka Medical College Hospital, one separate slip was given per medicine to be dispensed from the hospital, and the patients had to queue in separate lines for different medicines. While this system may ensure that the correct medicines are dispensed, it also makes it extremely difficult to educate patients on how to take their medicines during the dispensing process. The medicine slips were used to count the quantities of medicines dispensed, this information being used to calculate quantities to order from the store. The OPD dispensary records were generally well maintained.

Since patients keep their prescriptions which contain many medicines not dispensed, and since many doctors do not keep OPD patient registers properly, prescription audit could only be done prospectively by examining patients prescriptions as they exit from consultations or as they wait for medicines to be dispensed at the OPD dispensary.

6.4.2. Health Facility Inpatients (wards)

Inpatient management of medicines was sub-optimal. Storage conditions were often poor, items being stored in boxes and cupboards in a haphazard manner. Documentation concerning drug stocks and dispensing were poor. In many facilities it was found that stock records were poorly kept and not

reconciled against actual stock. Nurses managed medicines in the wards unsupported by any diploma pharmacists. Despite poor record keeping and storage conditions, the nurses often knew what was in stock.

Dispensing records of medicines to patients was poor. There were no individual patient medicine record sheets. The system involved the doctor writing a prescription for drugs in the patient's record sheet, which is contained within a folder marked with the patient's bed number. For each dispensing round, the nurses drew up a list of all the drugs to be dispensed by reviewing all the patient folders and then marking down which bed number required which medicine. The medicines would then be dispensed according to this hand-written sheet, but in general no signature on the sheet would be made to record that the medicine had actually been given. Since patients did not have identifiers and some were ambulant and could move to other beds, it is possible that the wrong medicines could be given to the wrong patients. This could also occur If the nurse was distracted during the dispensing round – medicines could be forgotten or the wrong ones given. In Dhaka Medical College, it was stated that the patient crowding was so great and the workload was so extreme, that the dispensing of oral medicines was not recorded at all.

Since individual inpatient dispensing records are not kept, inpatient drug utilization review cannot be done. Even if one did manage to match patient bed numbers with patient records, one could still not be sure whether drugs had actually been given or not.

6.4.3. Private Pharmacies

Dispensing in pharmacies was sometimes done by certificate level pharmacists of 2 months training and sometimes by laypersons, some of whom had higher education in other fields. Many pharmacy owners either had certificate training or employed an assistant who had such training. Most pharmacies operated very long days so there are likely to be frequent periods, when the pharmacist is not there to dispense. Even though there is less patient crowding in the pharmacies, dispenser-patient interaction time was generally less than one minute, instructions to patients was minimal and no drug labelling was done.

Few pharmacies issued bills or kept any kind of records. Therefore prescription audit could only be done by reviewing patient prescriptions as they came to the pharmacy and observing what patients bought.

6.5. <u>Policies to promote rational use of medicines</u>

6.5.1. Monitoring and supervision of prescribing/dispensing by supervisors

No monitoring, prescription audit or drug utilization review has been or is being done on a regular basis. The pharmacology departments in various medical colleges have undertaken adhoc research studies involving prescription audit. However, these appear few and have not been used to instigate change.

6.5.2. Standard Treatment Guidelines (STGs)

There are no national standard treatment guidelines covering the majority of health conditions. There are a few guidelines for the vertical disease control programs. Some medical college hospitals have antibiotic guidelines, although it is not clear to what extent these are updated and followed.

6.5.3. National Formulary

The Bangladesh National Formulary (BDNF) 2006, 3rd Edition, produced by the DGDA, is a comprehensive formulary with all the drugs on the market listed and each drug described in the style of the British National Formulary. It was produced with wide input from the medical professions and does cover EDL and non-EDL drugs, indications, contra-indications, side effects, drug interactions, generic names, brand names, drug schedules, and drug costs. However, it does not appear to be used in pre-service or in-service training or by practicing doctors. It was not seen in any health facility or mentioned as being used by any doctor. Since it is now 8 years old, it should be updated. It was mentioned that a 4th edition is currently being drafted.

6.5.4. Drug information Centre

There is no national drug information centre.

6.5.5. Independent drug information

Independent drug information is not distributed by the MOHFW, except with regard to a few clinical guidelines from the vertical disease control programs. Medical colleges have libraries, internet access and pharmacology departments who can provide independent drug information but it is unclear to what extent these resources are used by practicing clinicians, who have little spare time outside of their clinical duties. Medical representatives are allowed to visit clinicians in the public facilities after 1 pm and do so. A medical representative was even found visiting a Unani doctor in one public facility.

6.5.6. Drug and Therapeutics Committees (DTCs)

There are no functional DTCs in hospitals or districts, only drug review committees who meet to decide local purchase.

6.5.7. Undergraduate education on medicines use

Medicine

The time devoted to undergraduate education in pharmacology appears to have increased in recent years from 60 hours to 200 hours total over the 3rd and 4th years, followed by examination. In Dhaka Medical College it was stated that 300 hours teaching was provided. The pharmacology course includes teaching on the Essential Medicines Concept and the Essential Medicines (Drug) List (EML), and also INRUD-type prescription audits and critiquing of prescriptions, which are recorded in a workbook, which is examined. However, the student prescribing information does not appear to be more widely discussed in the hospitals. Problem-based learning approaches appear not to be used.

The Centre of Medical Education, MOHFW, teaches educational methods and oversees curricula changes which must then be approved by the Bangladesh Medical and Dental Council. The Centre for Medical Education visits all medical colleges and operates a peer review of their performance in conjunction with the Bangladesh Medical and Dental Council.

The Director of the Centre for Medical Education felt that pharmacology training should be extended to the 5th year of medical training as the good prescribing practices learnt in pre-clinical years get eroded by the final clinical year and subsequent clinical practice. In 2010, it was mentioned that the Centre for Medical Education was trying to introduce 15 days training on clinical pharmacology during the general medicine the pre-registration time, but this does not appear to have taken place.

Pharmacy

Pharmacy education is of three types – Masters in pharmacy studied over 4-5 years (category A), Diploma in pharmacy studied over 3-4 years (category B) and Certificate in Pharmacy studied over 2 months (category C). The universities control the education of categories A and B, with some oversight by the Bangladesh Pharmacy Council. The DGDA, together with the Bangladesh Pharmacy Council and the Bangladesh Chemists and Druggists Association manages the drug seller training. Category A pharmacists mainly work in the pharmaceutical industry, category B pharmacists in public health facilities and category C in pharmacy shops.

Paramedical prescribers

Community health clinic providers (CHCP) receive 3-month training in prescribing and other health work through the Community Health Clinic Project under the DGHS, MOHFW. There is a network of supervisors, including community health medical officer (3 years training) and health inspectors, all of whom may prescribe. Usually, a supervisor visits once a week to supervise and see patients him/herself in the community health clinics. Refresher training is operated by the MOHFW but how often is unclear. One CHCP had only had one refresher training in 3 years.

6.5.8. Continuing Medical Education on medicines use

There is no regular Continuing Professional Development (CPD) and whatever adhoc seminars there are do not include prescribing. In medical college hospitals, each department organizes regular lectures and seminars and also "Grand Ward Rounds" but internal prescription audit is generally not done.

Some Medical Officers in public facilities stated that they had attended refresher training organised by one of the vertical disease control programs of the MOHFW in the last year. Other public sector doctors stated that they had not attended any refresher training for years. No training involved general prescribing. There is no continuing medical education for private GPs. Pharmacology departments are not involved in organising any refresher training or seminars on prescribing for practising doctors.

The Bangabandhu Sheik Mujib University (BSMMU) is in charge of post graduate curricula. Postgraduate pharmacology students in some medical colleges do undertake prescription audits and some of these have been published. However, these studies do not appear to have been discussed more widely or led to action to improve prescribing. Postgraduate pharmacy students in Dhaka University are also undertaking studies various aspects of clinical pharmacy such as prescription audits and monitoring of adverse drug reactions.

There is no licensing requirement for doctors to do continuing medical education nor is there any system of accreditation for continuing medical education operated by the Bangladesh Medical Council. Likewise, there is no licensing requirement for pharmacists to do continuing medical education nor is there any system of accreditation for continuing pharmacy education operated by the Bangladesh Pharmacy Council.

6.5.9. Public Education on the safe and prudent use of medicines

While public education on maternal child health issues and other public health subjects has been widespread and successful in Bangladesh, there appears to have been no wide public education campaigns, and indeed very little public education done, on the safer and prudent use of medicines. Since so many

people use private pharmacies without prescription, public education is extremely important. The channels of communication with the community are well established, so it should be relatively easy to introduce some important core messages on safe use of medicines e.g. do not use antibiotics for coughs and colds, asking the doctor whether my child needs more than one medicine, etc.

6.5.10. Generic Policies

There are no policies on generic prescribing which is extremely low. Generic substitution is undertaken in the public sector and also in the private sector although officially it is not allowed.

6.6. **Summary status including progress / changes / problems** in medicines use since last situational analysis

Irrational use of medicines remains a very serious problem. The percentage of drug prescribed by generic name in the public sector was 17% in tertiary hospitals, 48-59% in district hospitals (DHs) and upazila health complexes (UHCs) and 93% in community care clinics. The percentage of prescribed drugs belonging the EDL was 49% in tertiary hospitals, 57-65% in DHs and UHCs and 96% in community care clinics. The percentage of upper respiratory tract infection cases treated with antibiotics was 59-60% in UHCs and community clinics, but was impossible to measure in other facility types due to lack of recording of diagnosis and treatment in outpatient patient registers. From private pharmacies, it was found that for private practitioners, the percentage of drugs prescribed by generic name was only 6%, and the percentage of prescribed drugs belonging to the EDL only 27%.

There is little monitoring of medicines use and little implementation of policies to promote rational use of medicines, such as development of national standard treatment guidelines (STGs), establishment of hospital drug and therapeutic committees (DTCs), establishment of continuing medical education (CME) for all prescribers and public education campaigns on the safe and prudent use of medicines. Since 2010, the Community Health Clinic system has been established but so far this initiative has not managed to reduce overcrowding of patients in the public hospitals. The number of hours in the undergraduate curriculum on pharmacology appears to have increased, but there appears to be no greater clinical pharmacology or clinical pharmacy activities in the medical college hospitals.

6.7. **Medicines use: Recommendations**

- Monitor drug use:

    - Prescription audit using diagnosis - by all teaching hospitals and district health offices;

    - Revise outpatient (OPD) patient registers to include drugs prescribed and revise dispensing slips to have one slip per patient;

    - Revise inpatient (IPD) dispensing procedures and documentation;

    - Identify specific inappropriate practices that you want to change (e.g. overuse of antibiotics in upper respiratory tract infection) in order to target interventions to these practices.

- Analyse prescriber workload:

  - To ensure equal workload for all prescribers, which could lead to more prudent prescribing, better dispensing, less return of old patients so reducing OPD crowding (and possibly IPD admission/crowding);

  - Lobby central level for more staff and redistribution of staff according to workload & to match expertise with equipment.

- Establish a referral system to decrease overcrowding:

  - Encourage treatment of more non-communicable diseases at Upazila health complexes;
  - Consider higher registration fees if patients come to higher level facilities without referral.

- Develop and implement Standard Treatment Guidelines (STG):

  - should include OPD treatment of simple primary care conditions with emphasis on using of fewer medicines;

  - disseminate to every doctor and student and incorporate into CME.

- Update the Bangladesh National Formulary (BDNF):

  - incorporate it in undergraduate education and disseminate to all doctors.

- Establish Drug and Therapeutic Committees (DTC) in every hospital:

  - require them to monitor drug use, encourage CME, and report annually on activities to MOHFW.

- Strengthen continuing medical education (CME):

  - Incorporate prescription audit and feedback and ethics into CME;
  - Involve Bangladesh medical / pharmacy councils / associations;
  - Cover all cadres of prescriber and dispenser.

- Undertake Public Education:

  - Incorporate core pharmaceutical messages e.g. does my child need more than one medicine? Antibiotics not needed for simple coughs and colds through health education channels and the media.

7. MEDICINE REGULATION

7.1. Responsible Agents/Departments

From discussion with senior MOH officials

Regulatory function	DRA	Other Agency	DRA/MOH department/Name of Agency
Drug Schedules	√		DGDA
Licensing & Inspection of drug outlets	√		DGDA
Drug registration	√		DGDA
Pharmacovigilance	√	√	DGDA and focal points in 30 medical colleges and 30 manufacturing units
Drug quality testing	√		National Control Laboratory, Dhaka, and Central Drug Testing Laboratory, Chittagong, under DGDA
Drug promotion	√		DGDA
Drug pricing	√	√	DGDA fixes prices for 117 essential drugs, other drug prices fixed by manufacturers
Health professional licensing/accreditation		√	Professional councils (BMDC, Pharmacy Council, Nursing Institute, Unani & Ayurvedic Board, Homeopathic Board)
Health facility/hospital licensing/accreditation	√		DGDA licenses pharmacies, DGHS licenses hospitals and health facilities

7.2. Pharmaceutical sector

From discussion with national drug regulatory authority

- Number of products on the market: 29,670
  - 23,970 allopathic, 2539 unani, 2170 ayurvedic, 750 homeopathic, 250 herbal products
- Number of generic products on the market: 2,285
  - 1,280 allopathic, 345 unani, 299 ayurvedic, 322 homeopathic, 39 herbal products
- Number of manufacturers: 852 among which 127 are non-functional or suspended
  - 273 allopathic, 266 unani, 205 ayurvedic, 79 homeopathy, 29 herbal
- Number of wholesaler outlets: 1,700
- Number of retailer outlets: 110,509;
  - 107,687 allopathic outlets (some of which also sell traditional medicines, although they are only legally allowed to do so if they have a separate licence for selling traditional medicines)
  - 627 unani, 445, ayurvedic, 1750 homeopathic outlets
- Number of blood transfusion centres supported by the Safe Blood Transfusion Program: 208
- Enforcement of regulations in 2013:
  - 646 prosecutions
  - 42 million Taka in fines
  - 163 people imprisoned

7.3. <u>Current Medicines Legislation</u>[1] **(key documentation)**

a) Summary of Laws/Regulations in place:

Name of Law or Regulation	Year
Drug Act	1940
Bengal Drug Rules	1945, 1946
Drug Control Ordinance	1982
Drug Control Ordinance Amendment Act	2006

b) Coverage: *indicate with Y (Yes) or N (No)*

Area / Activity Covered?	Y/N	Document Name
Establishment & functioning of National MRA	√	
Medicines marketing authorisation	√	
Medicines scheduling	√	
Licensing of medicines handling premises, personnel & practices	√	
Licensing of prescribers	x	Medical Council
Mandatory CME for prescriber licence renewal	x	Does not exist
Licensing of pharmaceutical personnel	x	Pharmacy Council
Mandatory CME for pharmacy licence renewal	x	Does not exist
Regulatory inspections/ enforcement activities	√	
Medicines quality	√	
Medicines packaging & labelling	√	
Medicines promotion	√	
Post-market surveillance/ pharmacovigilance	x	Contained in draft Law 2014 which covers all aspects of regulation and is submitted to Ministry of Health & Family Welfare
Collection of fees	√	
Clinical trials	x	Contained in draft Law 2014 which covers all aspects of regulation and is submitted to MOHFW
Generic substitution	x	Code of Marketing Practices 1994 does not allow this.
TRIPS-related issues	x	Not applicable until 2016
Transparency & accountability[2]	x	Citizens Charter 2008 covers freedom of information and contains a standing order that no file can be kept without action for > 3 days
Banning of unsafe medicines	√	

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[1] Medicines regulation issues may be covered in more than one law and may have multiple associated regulations, so ensure that all relevant documentation is identified & obtained for review.
[2] Includes provisions for the MRA to define and publish its policies and procedures, publicly account for its decisions, conduct and actions, and follow a regulatory code of conduct.

7.4. __National Regulatory Authority for medical products__

* Name of National Drug Regulatory Authority: Directorate General of Drug Administration (DGDA), under the Ministry of Health and Family Welfare (MOHFW).

* Total number of staff: 370 posts, 226 in post, which is similar to the situation in 2010
    o technical staff (list different types): 143 posts, 80 in post
    o non-technical staff: 227 posts, 146 in post
    o DGDA estimate that they need 700 posts

* Website address: http://www.dgda.gov.bd

* Number of quality-control (drug testing) laboratories: 2

* Annual report of activities: Yes;
    o Reference: Directorate General of Drug Administration Annual Report 2013 (in Bengali)

* Annual Budget last year: Bangladesh Taka 49,295,000 (approx. USD 640,195) (DGDA 2013)

* Written SOPs for the following key regulatory procedures?

Key procedure	Written SOP? (Yes/No)	SOP Seen? (Yes/No)
Product dossier evaluation	No	Vaccines only
Registration of medicines	No	Flow chart only
Inspection of manufacturing premises	Yes	No
Inspection of retail premises	No	No
Sampling for Quality Control testing	Yes	No
Medical product recall or withdrawal	Yes	No

* Position in hierarchy of government structure:
    o DGDA is under the MOHFW and not independent. It has been upgraded from Directorate to Directorate General since 2010.

* Decentralised capacity:
    o Number of branch offices: 48; Number of technical staff in each office: 1
    o Functions of branch offices: Drug outlet inspection, Drug Manufacturing Unit inspection
    o Functions outsourced to public health authorities: None

- Technical committees to advise the DGDA:
    - Project Evaluation Committee to advise on the establishment of new pharmaceutical industry;
    - Drug Control Committee to advise on drug registration;
    - Technical sub-committee to support to Drug Control Committee;
    - Technical Committee for Price Fixation of Medicines;
    - Standing Committee for Import of Pharmaceuticals including raw materials & finished products;
    - Vaccine committee to advise on manufacturing, toxicology and clinical trials;
    - Clinical trial committee;
    - Technical sub-committee of Drug Control Committee for Herbal Medicine;
    - District Drug Licensing Committees;
    - Advance ADR Advisory Committee.

7.5.   Drug Schedules

There are two schedules in practice:

(1) narcotics and psychotropics, controlled drugs, which are only available on prescription in hospitals and drug outlets with special license;
(2) all other drugs which are easily available over-the-counter without prescription, although officially all are only supposed to be available with prescription.

According to the 1940 Drug Act, there is provision for an over-the-counter (OTC) schedule as well as a prescription-only schedule. Unfortunately, this has not been applied during the registration process for many years and so there are thousands of products on the market without a specific OTC or prescription-only schedule applied. In addition, some anti-cancer drugs are only available in certain hospitals.

In 2010 recommendation was made to establish an OTC list but this has not been acted upon.

7.6.   Regulation and inspection of drug outlets

Retail outlet licenses should be renewed 2-yearly and effort is made to inspect all retail outlets once every 2 years. Manufacturers should be visited at least annually and more often in case of problems e.g. non-compliance with GMP. In 2013, the number of inspections done was 51,000 for retail pharmacies, 6000 for wholesalers, and 800 for manufacturers.

There is a written SOP for inspection of manufacturers but not for inspection of retail pharmacies. With only 143 technical staff, it must be extremely difficult to complete so many inspections and the quality of inspections could be compromised.

In some of the retail pharmacies visited, unqualified staff were dispensing drugs unsupervised by any pharmacist and some drugs were stored in sub-optimal conditions. It was mentioned that in rural areas, most retail pharmacies were staffed by unqualified persons. While this is against the regulations which state that a category C pharmacist or above must be present in a pharmacy, DGDA cannot enforce this as they are unable to do sufficient inspections due to lack of staff.

7.7.   Drug Registration

Drug registration remains unchanged from 2010 and is under the control of the Drug Control Committee (DCC) of 21 members who meet 2-3 times per year. The DCC only decide upon new molecules that are not already on the market. For new products of molecules that are already on the market (i.e. a me-too product for a molecule already approved by the DCC), whether the manufacture is local or the product is to be imported, the DGDA can issue a license for marketing authorisation without referral to the DCC, provided the manufacturer can provide proof of satisfactory quality as determined by examination of dossier of documents and inspection of the premises.

For new molecules, not on the market, the DCC will only consider them for registration, for importation, if they are already registered in UK, USA, Australia, France, Germany, Switzerland or Japan. The Technical sub-committee of 15 members will consider the dossier of documents and the evidence concerning efficacy, safety, usefulness and quality (which involves checking the adequacy of manufacture) and make a report to the Drug Control Committee who will then take a decision by consensus.

The number of products on the market was felt to be excessive in 2010 and the number of products has increased from 18,687 to 29,670 in a 4-year period. There seems to be no way of restricting registration of new products if a manufacturer can prove his product is equal to others already on the market in terms of quality. Having such a huge number of products on the market creates a huge regulatory burden, which cannot be fulfilled with current resources and could compromise patient safety (from the perspective of drug quality and overdosing on the same molecule by patients who are unaware that different brands and combinations may contain the same molecule).

A number of respondents felt that the drug registration process was too easy, not taking into account dissolution profiles, stability or bioequivalence studies. Others respondents mentioned that there was over-representation of the pharmaceutical industry in the DCC and that these members may have conflict of interest. Furthermore, it was mentioned that some government members were sometimes absent from committee meetings, that other government members sometimes represented other organizations and also had links with the pharmaceutical industry, and that some members were only members by virtue of the position they held and were not technically qualified. Most respondents strongly felt that there should be less or no representation from the pharmaceutical industry and that all persons sitting on the Drug Control Committee should not only represent a certain organization but should also be technical qualified and should attend regularly.

All respondents felt that it would be good to reduce the number of products on the market and that this could be done by:

(1) Ensuring DCC member had no conflict of interest;
(2) Making the requirements for registration stricter;
(3) Increasing the registration fee to 1000 USD and preferably 2000-5000 USD (and reinvesting this money into the DGDA rather than sending it all to the Treasury).

7.8.   Pharmacovigilance

The DGDA coordinates pharmacovigilance through a recently established network of 30 manufacturers and 30 Medical College Hospitals and a Committee, which has met twice. So far 46 adverse events have been

reported and after investigation, 23 Adverse Drug Reactions (ADRs) were confirmed. On the basis of these reports, 3 manufacturers have been asked to add minor warnings on their package inserts. In addition, 5 molecules have been banned followed international drug alerts. Currently there are 100 adverse drug event reports pending for investigation. In 2010 only 19 ADRs had been reported and now 4 years later, only 46 adverse drug events have been reported – a very small number for the size of the population and pharmaceutical sector in Bangladesh. It is hoped that this new initiative will manage to increase the reporting of adverse events and ADRs which must undoubtedly be happening but are generally going unreported at present.

7.9. Drug Promotion

Advertising of drug products is not allowed in Bangladesh without the prior approval of the licensing authority. There is no standing committee for drug promotion and it is monitored in an adhoc way by staff – who follow up on any reports on adverts that they see in the newspapers or that are reported to them.

Other forms of drug promotion such as done by Medical Representatives of the pharmaceutical industry are not monitored and are considerable. Although, medical representatives are not allowed on the premises of public facilities before 1pm, they come after 1pm, visiting traditional practitioners as well as allopathic ones. The fact that some pharmacies are visited every few days by the same company indicates the saturation of information from the pharmaceutical industry coming to retailers and private GPs – much more than any refresher training could counter. In these circumstances, it is not surprising that prescribers are influenced much more by the industry than by any independent literature. Requiring manufacturers to disclose how many medical representatives they have and how much expenditure they have for drug promotion may help to elucidate this problem and then control it.

7.10. Drug Price controls

The DGDA operates price controls for 117 essential drugs, which belong to the primary health care list of 1993. The Price Fixation Committee set the maximum retail price for these drugs based on the cost of the raw material and packaging plus a mark-up of 150% to 340%, depending on the formulation. For all other drugs, the pharmaceutical industry sets the price. All imported drugs are subject to import duty and VAT.

The price fixation committee consisted of 16 members, including representatives from DGDA, MOF and the pharmaceutical industry. It was reported that the pharmaceutical industry does not want the national EDL to be revised and expanded for fear of prices controls on more drugs. There is no monitoring of prices.

7.11. Drug Testing Laboratories

The DGDA has two Drug Testing Laboratories - a new National Control Laboratory in Dhaka, and another smaller laboratory in Chittagong. The Dhaka National Control Laboratory was renovated and re-equipped with modern equipment, sufficient to undertake all routine tests, following the situational analysis done in 2010. There are SOPs for most procedures.

Currently, there are 74 staff (64 technical staff and 10 non-technical) in the Dhaka laboratory and 17 staff (7 technical and 10 non-technical) in the Chittagong laboratory. The government has recently approved 158 posts from an application requesting 236 posts.

The laboratories get samples from the DGDA and also from the Institute of Public Health which manufactures intravenous fluids and vaccines. In the last 3 years, 87% of their samples have come from the market and 13% from the manufacturers.

The results of drug testing in the Dhaka Laboratory in the last 3 years are shown below:

Year	Samples received	Samples tested	Samples found to be sub-standard
2011	3813	2673	111 (4.2% failure)
2012	4250	2434	64 (2.6% failure)
2013	5457	4531	145 (3.2% failure)

Of the 145 samples found to be sub-standard, 112 were allopathic medicines and 33 traditional medicines. All the failed allopathic samples came from the market but only 8 of the failed traditional medicine products came from the market, the other 25 coming from pre-registration applications. During 2013, in the Chittangong laboratory, 893 samples were received, 466 samples tested, and 23 found to be substandard.

Many respondents mentioned that many more samples need to be tested and that many more should be sampled randomly from the manufacturers. The NCL mentioned that they plan to increase the number of samples tested to 10,000 per year but that a greater number than this would require more laboratory space as well as a greatly increased workforce. They also mentioned that testing the quality of traditional medicine products was much more difficult than for allopathic medicines and that they a separate drug testing laboratory for traditional medicines is needed.

7.12. Licensing and accreditation of health professionals

The Bangladesh Medical and Dental Council (BMDC) licenses doctors and dentists, the Bangladesh Pharmacy Council licenses pharmacists of all categories, and the Bangladesh Nursing Council licenses nurses. All the councils are under the MOHFW. There are 69,300 doctors registered with the BMDC but only about 50,000 are currently working in Bangladesh. The BMDC also licenses medical assistants of which there are 6,843. The State Medicine Faculty of Bangladesh provides registration of the paramedics. Community Health Care Providers (CHCP) who run the community clinics are trained by DGHS. They are allowed to provide medicines of common ailments as per guidelines provided by DGHS.

The Medical and Pharmacy councils are established by parliamentary ordinance and are responsible for licensing all practising members, providing oversight of the undergraduate curricula, training and examination, including regular inspection of training institutions every 1-5 years. The Medical Council also controls admission of students to medical schools and oversees specialization of doctors. The pharmacy council controls the examination for B and C category pharmacists, though not of A grade pharmacists.

The Councils also investigate cases of misconduct although very few doctors or pharmacists have had their licenses revoked. Only 4 doctors have had their license revoked in 10 years. A major problem of investigating complaints is that the complainant provides insufficient information, e.g. the wrong address of the doctor or no patient record.

Registration for doctors is 1500 Taka for the first 5 years after qualification and pre-registration and then 1000 Taka 5-yearly. Registration for pharmacists is 500 Taka for A-grade pharmacists and 250 Taka for B and C grade pharmacists every 5 years. There is no system currently for accreditation and relicensing according to performance or continuing medical education done for either doctors or pharmacists.

The Medical Council has recently initiated an electronic, web-based system for recording the registration of doctors, which also includes a photo. This has proved very useful for identifying fake doctors – only the previous week 10 people had been arrested for falsely posing as doctors. There is no similar system for pharmacists. The Medical Council is governed by a Board of 65 members who are elected every 3 years and who sit on different committees. While training for specialization may be designed by the various specialist colleges, all curricula must be approved by the Council.

7.13. Licensing and accreditation of health facilities and pharmacies

Private pharmacies are granted 2-year licenses by the DGDA, according to checklist of criteria. The DGDA tries to inspect all facilities once every 2 years.

Private hospitals and clinics are regulated by the DGHS, and granted annual licenses dependent upon a successful inspection by an inspection team, which includes the divisional chief, the district civil surgeon and a clinical consultant. The team uses a checklist which requires collection of information on the physical facility, equipment and staffing, but does not require any information on drug use. The Hospital Director under the DGHS coordinates licensing of private facilities. Licenses for private Medical Colleges and hospitals require liaison with the Medical Council also.

7.14. Summary status including progress / changes / problems in medicines regulation since last situational analysis

Since 2010 the national drug regulatory authority has been upgraded to Directorate General level – now being the Directorate General of Drug Administration (DGDA). Unfortunately, this has not resulted in an increase in human resources, which remain at similar levels to 2010. Despite this, the pharmaceutical sector continues to grow, with now over 29,000 products registered, over 800 manufacturing units and over 100,000 drug retail pharmacies, to be managed by 226 staff. With such under-staffing the DGDA has great difficulty to fulfil all its obligations. The national control laboratory has been renovated, upgraded and re-equipped since 2010 and has greatly increased its drug testing capacity, now testing over 5000 drug samples per year.

7.15. <u>Medicines regulation: Recommendations</u>

- Establish a new Medicines Act:

    – Already in process as draft was submitted in 2014.

- Strengthen the DGDA.

- Strengthen the Drug Control Laboratory (DCL), including the capacity to test traditional medicines (TRM).

- Make the registration process more stringent:

    – Stronger criteria e.g. bioequivalence studies, dissolution profiles, stability studies;
    – Stricter application of criteria;
    – More transparent process with less conflict of interest – decrease manufacturer presence;
    – Will help to reduce the number of products registered.

- Establish an over-the-counter (OTC) schedule.

- Expand the drug pricing controls to include all essential drugs.

- Consider regulation to limit the number of pharmacies.

8. MEDICINE POLICY AND COORDINATION

8.1. <u>National Medicines Policy</u>

Bangladesh has a National Medicines (Drug) Policy Document that was first formulated in 1982 and revised in 2005. There are 18 objectives and policy areas covering laws and regulation, the national drug regulatory authority (DGDA), drug registration, drug production, drug procurement, drug distribution and storage, drug sales, drug pricing, drug quality assurance, manpower of manufacturing units, drug information and monitoring and essential drugs.

Some objectives have been met, particularly with regard to increasing manufacturing capacity. However, other objectives have not been met, such as regulation of drug promotion, improving access to essential medicines, ensuring rational use of medicines, improving price controls, implementation of WHO GMP guidelines, proper monitoring of ADRs and strengthening the drug regulatory authority.

There is no national drug policy implementation plan or budget. The DGDA mentioned that the policy needed revision. A national committee and its sub-committee have been working for the past few years to revise the National Drug Policy and it was mentioned that a draft revised document is now near finalisation.

8.2. Summary of medicines policies in place to promote rational use of medicines

Policy	Implementation status
National Medicines Policy (NMP)	Official document 2005, but some important aspects of it are not implemented
National Essential Medicines List (EML)	National EML (EDL) 2008, which is used in the public sector for drug procurement
National Standard Treatment Guidelines (STGs)	No national STGs for common diseases, only some STGs for the vertical disease control programs
National Formulary manual	Bangladesh National Formulary 2006, which is currently being updated
National government unit dedicated to promoting rational use of medicines	No government unit, but there has been intermittent discussion since 2010 of resurrecting the process for forming a National Core Committee for the Rational Use of Drugs under the Chairmanship of DGHS
Monitoring medicines use	No official monitoring done, but some adhoc research studies done by students of clinical pharmacology and pharmacy
Drug and Therapeutic Committees (DTCs)	No functional DTCs in hospitals or districts, only drug review committees for drug purchase
National Drug Information Centre (DIC)	None
Generic Policies	No generic prescribing. Some generic substitution done
Health insurance	Most of the population is not insured
Payment for medicines by patients	Registration fees of 5-10 Taka in public sector OPD, but no fees for drugs. However, one-third of patients must buy their medicines from private pharmacies
Provider revenue from medicines	None in the public sector
Undergraduate training on pharmacology & prescribing	Training on the essential medicines concept, EDL and prescribing is done.
CME training on pharmacology & prescribing	Adhoc continuing medical education (CME) for most public sector prescribers and no CME for most private prescribers
Public education on medicines use	No public education campaigns on the safe and prudent use of medicines
Pharmacovigilance	Network of 30 manufacturers and 30 medical college hospitals to undertake pharmacovigilance just formed, and 46 adverse drug events reported and production & marketing of 5 molecules stopped.
Regulation of drug promotion	Adhoc monitoring of advertisments which are not allowed (except for ORS and family planning items)
National strategy to contain Antimicrobial Resistance	No national strategy to contain antimicrobial resistance, but some discussion ongoing since 2010 to form a committee and develop a strategy
Over-the-counter availability of prescription-only medicines including antibiotics	All medicines, including antibiotics but excluding controlled drugs, are easily available over-the-counter.

8.3. Coordination of medicines-related policies within the Ministry of Health

8.3.1. Ministry of Health Organogram

Source: DGHS/MOHFW 2014.

Bangladesh Ministry of Health Hierarchy of Personnel and implementing authorities

Key: MOHFW=Ministry of Health and Family Welfare; DGHS=Directorate General Health Services; DGFP=Directorate General Family Planning; NIPORT=National Institute of Population Research & Training; DGDA= Directorate General Drug Administration; HEU= Directorate General of Health Economics Unit; HED= Directorate General of Health Engineering Department; DNS= Directorate General of Nursing Services; RCHCIB=Revitalisation of Community-based Healthcare Project; EDCL=Essential Drug Company Ltd.; TEMO=Transport & Equipment Maintenance Organisation; NEMEW=National Electro-medical & Engineering Workshop.

8.3.2. Coordination within the Ministry of Health

Departments within the MOHFW with medicines-related functions include:

- DGDA – regulation of drugs;
- DGHS – regulation of health services, allocation of drug budget, quantification, DTCs, STGs;
- EDCL – manufacture of essential drugs

Under the DGHS are the following departments:

- Administration
- Hospitals and Clinics
- Central Medical Stores Depot (CMSD)
- Finance Department
- Homeo, Unani and Ayurvedic medicine
- Management Information System
- Primary Health Care
- Disease Control
- Myco-bacterial disease control
- Planning, Research and Development
- Medical education and Health Manpower Development
- Dental Department

Problem policies that fall between different departments within the MOHFW:

- EDL is developed by the DGDA, but is only partially followed by the CMSD and the DGHS;
- Drug budget allocation and quantification requires coordination between the DGHS, CMSD and EDCL;
- Public education requires coordination between different departments within the DGHS, particularly Medical Education and Health Manpower Development, but may also require coordination with other departments under the DGHS, such as Public Health or Non-communicable diseases for the distribution of specific messages related to medicines use. It may also require coordination with other Directorate Generals such as the Revitalization of Community-based Healthcare Project (responsible for community clinics where much prescribing is done) or DGDA (responsible for pharmacy retail outlets where much self-medication occurs) or DGFP (responsible for planning services where contraceptive medication is promoted).
- No department is monitoring drug use, encouraging DTCs, developing general national STGs, running a Drug Information Centre, managing continuing medical education (outside the vertical disease control programs).

It is not clear how coordination is managed or which department will take up the functions currently not done. In 2008 there was a proposal to have a "Core Committee for Rational Use of Drugs" under the chairmanship of the DGHS. Consultative meetings were held (sponsored by WHO) – one each with the professional bodies, the prescribers and health managers and civil society organizations. All meetings agreed with the need for a core committee on Rational Use of Drugs. Following this it was proposed to have a National Committee for Rational Use of Drugs under the chairmanship of the DGHS, with the Member Secretary being the Coordinator of the program to promote rational use of medicines, in the Department of Pharmacology, Bangabandhu Shiekh Mujib Medical University.

The terms of reference for this committee were to:

- " Facilitate cooperation among policy makers, regulators, prescribers, medical educators, medicine sellers, dispensers and consumers (patients and care givers) in initiating, developing, carrying out and monitoring measures directed towards ensuring rational use of medicines in Bangladesh;

- Conduct a review of the following issues to explore the present situation and suggest the opportunity:
    - Course and curriculum of health related disciplines
    - Content of the continuing medical education;

- Establish sub-committees to provide advice or to assist in the performance of its functions, e.g.
    - Undergraduate and post graduate medical education
    - Continuing medical education."

It was proposed that the committee meet every 3 months and a proposed membership list was drawn up. The document was due to be submitted to the MOHFW for endorsement but, unfortunately, it was never endorsed and the process was halted.

8.4.   Other Ministries with medicines-related functions

Other Ministries involved in medicines-related policies include:

- Ministry of Finance and Treasury – provides budget (which may not be enough) for:
    - human resources employed in all sectors of the MOHFW;
    - public sector medicines supplied by the EDCL and CMSD and local drug purchase.

- Ministry of Trade and Industry – sets rules (which may not always serve the public health interest) for:
    - Medicines prices and mark-ups outside the 117 essential drugs;
    - Duties and taxes on the importation of medicines;
    - The fees for licensing of importer and drug outlets and the ruling that disallows any kind of limitation on the number of drug outlets, particularly retail pharmacy shops;
    - The ruling that disallows any limitation on the registration of medicines.

- Ministry of Education – sets training programs and curricula for health professionals:
    - May not give the same importance to some topics as would the MOHFW in determining health service delivery needs.

- Public Services Commission (human resources) - decides on the number of posts in MOHFW:
    - May not assign posts as MOHFW needs e.g. there are very few posts for bachelor pharmacists in the public sector outside the DGDA;
    - The chief of specialist departments may not be filled by a specialist from that field e.g. the DGDA chief need not be a pharmacist though some DGDA staff feel the position should be reserved for a pharmacist.

Coordination between the MOHFW and other Ministries with regard to pharmaceuticals is sometimes not well managed due to lack of a coordinating unit. Problem policies, requiring intervention by other ministries, include:

- Excessive numbers of drug products, especially me-too products, are on the market, resulting in extra regulatory burden, because limits cannot be placed on new products of molecules already existing on the market due to trade rules concerning competition.

- Excessive number of pharmacies in Bangladesh, resulting in extra regulatory burden (such that the DGDA cannot inspect all pharmacies regularly and such that many pharmacy outlets are not staff by pharmacists), because limits cannot be placed on new pharmacies due to trade rules concerning competition.

- Excessive number of manufacturing plants, resulting in extra regulatory burden, including for traditional medicines because limits cannot be placed on new manufacturing plants due to trade rules concerning competition. Even though there are some non-functional licences which could be cancelled (so reducing the number and allowing for better monitoring) the workload involved in inspecting all manufacturing plants is so heavy that maintenance of an active list is difficult.

- Lack of category A pharmacists in the human resource plan, but without them, quantification and efficient procurement sufficiently in advance cannot be done.

- Lack of clinical pharmacology and clinical pharmacy departments and activities in the clinical setting, without which good pharmaceutical care cannot be introduced and which will require coordination between different directorates/departments within the MOHFW and the Ministry of Education.

- Lack of sufficient drug budget to meet demand although coordination between MOHFW and MOF is good since MOF does pay promptly for the procurement of medicines.

8.5. **Summary status including progress / changes / problems** in medicines policy since last situational analysis

The national drug policy, coordination and structure remain similar to the situation in 2010. Some important objectives of the 2005 national drug policy remain unfulfilled and some policies to promote rational use of medicines and to monitor medicines use are not implemented by any MOHFW department or unit. The process for establishing a Core Committee for Rational Use of Drugs as proposed in 2008 was not renewed.

8.6. Medicines policy and coordination: Recommendations

- Establish a permanent statutory committee to advise the Minister of Health on Pharmaceuticals with wide membership including laypersons, professional bodies …

    – Revive the Core Committee for Rational Use of Drugs

- Establish an Executive Division in MOHFW to carry out the statutory committee recommendations –

    – A new Directorate

    – To coordinate action between MOHFW departments (e.g. DGHS, DGDA, CMSD) and with EDCL and other Ministries (Finance, Trade);

    – To be responsible for monitoring drug policy implementation;

    – To be responsible for promoting rational use of drugs: implementation of EDL, STGs, DTCs, monitoring drug use, pre-service training, CME, public education, school health programs, etc.

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10. PERSONS MET DURING THE SITUATIONAL ANALYSIS

All the persons attending the national workshop plus the following additional people were met.

	Name	Designation and Affiliation
1	Asir Uddin	Team Leader, Health Systems Strengthening, Management Sciences for Health (MSH)
2	Dr Abu Zahid	Team Leader, Procurement, MSH
3	Dr Afsana	Technical Adviser to DGDA, MSH
4	Dr. Josephine Aimiuwu	Management Sciences for Health, MSH/SIAPS
5	Dr Zubayer	Country Program Director, MSH
6	Prof Laila Parveen Banu	Gonoshasthaya Medical School, Dhaka
7	Prof Afsana Karim	Head of Pharmacology, Delta Medical College, Dhaka & Editor of BDNF
8	Dr Md. Nasser Shahrear Zaheeda	SEARPharm Forum Member
9	Hospital Administrator	Shaheed Ziaur Rahman Medical College Hospital, Bogra
10	Pharmacist	Shaheed Ziaur Rahman Medical College Hospital, Bogra
11	Rosina Akhtar	Community Health Care Provider, Pukhuria Community Clinic, Manikanj district
12	Nurun Nahaa	Family Welfare Assistant, Pukhuria Community Clinic, Manikanj district
13	Kagendra Chandra Sharkar	Health Assistant, Manikanj district
14	Md. Khalilur	Health Instructor, Manikanj district
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12. WORKSHOP SLIDE PRESENTATION

Medicines in Health Care Delivery in Bangladesh
Situational Analysis: 13-25 September 2014

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Dr Selina Ahmed, WHO/WCO Bangladesh
Mr Farid Rahman, WHO/WCO Bangladesh

Agenda of the workshop

AM
- Presentation by situational analysis team with discussion of findings, identification of main problems and possible solutions
- Group work to discuss solutions and develop recommendations to implement solutions
  - include main activities, who will do them, and in what time frame

PM
- Presentation of group work with plenary discussion and finalization of recommendations
  - Road map for MOHFW, stakeholders and WHO to follow

Terms of Reference

- To conduct a rapid assessment of medicines in health care delivery covering drug supply, selection, use, regulation and policy,
  - In liaison with national counterparts nominated by the MOHFW;
  - Taking into account progress made since the last situational analysis done in 2010

- To report on the findings and develop an action plan in a workshop of government officials and other stakeholders.

Mission: 13 – 25 September, 2014

- **13 Sept:** Orientation of team; visits to Dhaka Medical College & Hospital, private pharmacies
- **14 Sept:** Visits to DGHS, NCL, Centre Medical Education, Community Clinic Project Office, MSH
- **15 Sept:** Visits to CMSD, EDCL, Gonoshasthaya Kendra Trust
- **16 Sept:** Visits to Bangladesh Pharmacy and Medical & Dental Councils, Pharmacy Faculty of Dhaka University, DGDA
- **17 Sept:** Visits to District Hospital, private pharmacies, Ghazipur
- **20 Sept:** Visits to Bogra Medical College/Hospital, private pharmacies
- **21 Sept:** Visits to Mohammad Ali Hospital, private pharmacies, Bogra
- **22 Sept:** Preparation for workshop
- **23 Sept:** Visits to Upazila Health Complex & Community Clinic, Tangail
- **24 Sept:** National Workshop
- **25 Sept:** Visit to Upazila Health complex & community clinic, Ghazipur

Objectives of the workshop

- Review the situational analysis findings
- Identify the main priority problems to be addressed, in 5 areas:
  - Drug supply, Drug selection, Drug use, Drug regulation, Drug policy
- Formulate recommendations to resolve / address the priority problems in each area
- Develop an action plan to implement recommendations
  - What activity?
  - Who will do it?
  - Timeline?

Mission findings

- Extensive health care system, with substantial infrastructure, trained hardworking health care personnel and good health indicators, and...

- Some areas of progress since last situational analysis in 2010, but some serious problems remain in all areas of drug management

- Some problems can be addressed by existing resources and capacity and others need substantial coordinated effort by all partners.

Drug supply

- Drugs supplied to health facilities by govt. according to an allocated budget decided by DGHS and MOHFW
- Pull system - health facilities "order" drugs according to past procurement and within the agreed allocation
- EDCL supply: registration for making 224 items (32% non-EDL), supplies 70% of health facility drug budgets
  - Only 43 of 209 EDL drugs supplied, no IV fluids supplied
  - 82% budget in 2013
  - 3 months lead time
- CMSD supply: purchase >200 items, 64% (non-EDL), according to a DGHS drug list, supply 25% of health facility drug budgets
  - 13% budget in 2013
  - Also supply drugs of vertical disease control programs
  - 1 year lead time
- Local purchase: 5% budget
  - mostly for IV fluids from Institute Public Health

Drug Supply: recommendations

- Establish harmonised, functional, electronic drug management information system, to monitor consumption, stock-out, expiry which is necessary to improve quantification
  - recommended in 2010, but little progress
  - DGHS/USAID/GTZ project 2010-2013 was planned
  - start centrally & extend to district level initially
  - employ a data-entry staff for this purpose at each hospital & district
- Involve bachelor & diploma pharmacists in stock management, not just OPD dispensing
- Train staff in monitoring medicine consumption and quantification
- Review ward management of drugs

Drug availability

- **Situational analysis 2014**
  - Availability of 20 key EDL drugs 54-82%
  - Non-availability mostly due to non-use / non-purchase
  - Complaints of stock-out in some facilities, mostly for non-EDL drugs and IV fluids
  - % prescribed drugs dispensed 51-97% in district
- **Situational analysis 2010**
  - % prescribed drugs dispensed 69-70% in district/referral hospitals
  - Many complaints of stock-out
- **Study 2009 by Centre for Medical Education**
  - Availability of key essential drugs 39% in upazilla health complexes and 17% at community health centre,
  - 28% patients received all their drugs from the health facilities, 58% some of their drugs, 14% none of their drugs

Drug selection

- National List of Essential Drugs (EDL) 2008
  - 209 items, including items for all levels of health care, including hospital care drugs, e.g. methotrexate, mannitol, ketamine, chlorambucil, bleomycin, dopamine, pethidine, suxamethonium, tamoxiphen, etc.
- New EDL in process but not yet published
- EDCL "follows" EDL but 32% of its items are non-EDL
  - have started manufacturing new items according to market survey & civil surgeon request
- CMSD items – 36% EDL, 64% non-EDL
  - As per demand of civil surgeons & line directors of DGHS
- OPD prescribing survey 2014: 36-76% prescribed drugs on EDL in public hospitals

Health facility stock management

- All drug supply manual, no electronic LMIS system
  - Difficult to assess stock condition concerning stock-outs and expiry
- Store keepers manage drug supply in most health facilities, diploma pharmacists generally only dispense
- Drug ordering quarterly from EDCL, annually from CMSD
- No systematic drug quantification
- Some health facility stores have inadequate space, shelving, temperature & humidity control
- Ward management of drugs sub-optimal
  - Poor storage conditions – boxes, jars, cupboards
  - Poor recording systems – stock records, requisition forms, patient records, dispensing records according to bed-number form
  - Due to overcrowding and workload only the dispensing of injectable, not oral drugs, to patients is recorded on patient records in some hosps

Top drugs by value supplied by EDCL in 2013

	Drug name	USD		Drug name	USD
1	ORS	1,763,915	13	Omepraz cap 250mg	422,435
2	Paracetamol tab 500mg	1,681,160	14	Fluclox cap 500mg	420,670
3	Antacid tab 650mg	1,414,517	15	Ceftriaxone inj 1gm	412,329
4	Metronidaz tab 400mg	1,198,387	16	Pen V tab 250mg	397,598
5	Amoxycilin cap 250mg	1,094,550	17	Ferrous & Folic tab	377,082
6	Azithromyc tab 500mg	809,481	18	Ranitidine tab 150mg	366,766
7	Amoxycilin syr 100ml	807,243	19	Cefradine cap 500mg	365,893
8	Paracetamol susp 60ml	774,623	20	Doxycyclin cap 100mg	337,686
9	Amoxycilin cap 500mg	636,027	21	Metronidaz IVI 500mg	327,221
10	Ciproflox tab 500mg	561,424	22	Cloxacilin cap 500mg	236,173
11	Benzoic & Salicyl oint	549,028	23	Benzyl benzoate 60ml	229,256
12	Vit B Complex tab	514,764	24	Levfloxacin tab 500mg	164,953
Top 24 items cost 31% budget (non-EDL 5%). ABs cost 44%, vits 4%					

Top drugs by value supplied by CMSD in 2013

#	Drug name	USD	#	Drug name	USD
1	5% D/saline IVI 500ml	930,224	13	Azithromy cap 250mg	32,569
2	Cholera Saline 500ml	498,380	14	Cefotaxime inj 250mg	29,829
3	Hartmann Sol. 500ml	329,663	15	Cefurox syr 125mg/5ml	29, 123
4	Normal Saline 500ml	142,828	16	Pantoprazole tab 20mg	21,812
5	Cefixime tab/cap400mg	114,559	17	Oxytocin 5 I.U	21,289
6	Hydrocortis. inj 100mg	95,509	18	BComplex syr 100ml	21,058
7	Ceftriaxone inj 250mg	92,698	19	Cefixim syr 100mg/5ml	20,842
8	Omeprazole inj 40mg	68,491	20	Sol. insulin inj 40 IU	20,133
9	Cefuroxime tab 250mg	51,379	21	Enoxaparin Inj 60mg	20,128
10	Cefixime tab 200mg	45,988	22	Naproxen tab 500mg	19,868
11	Amoxycillin inj 500mg	39,633	23	Clindamycn cap 300mg	19,672
12	Flucloxacilin inj 250mg	34,335	24	Alum/Magn syr 200ml	19,535

Top 24 items cost 82% budget (non-EDL 42%), ABs cost 19%, vits 1%

Drug use indicator survey

Medicines (drug) use indicator	Referral hospital n=2	District hospital n=2	UPZ HC n=2	Comm HC n=2	Drug Retailer n=4
Av.no.drugs/patient	2.7	2.8	1.8	1.8	2.8
% patients given ABs	18.6	54.1	25.0	19.7	33.3
% URTIs given ABs	-	-	71.2	50.6	-
% patients given INJs	-	-	-	-	27.9
% patients given VITs	9.5	14.6	21.7	20.0	18.6
% generic drugs	17.4	48.0	67.9	93.4	6.4
% EML drugs	49.1	57.2	89.4	97.8	26.8
% drugs dispensed	73.9	72.0	84.0	100.0	85.0
Av.cost/Px (Taka)	-	-	-	-	384.44

Drug Selection: recommendations

- **Revise the EDL:**
  - include drugs for all levels of care
  - classify each drug according to level of care, therapeutic class
  - have wide representation of specialists, generalists & pharmacists, and transparent process to improve acceptance
- **Implement the EDL**
  - Demand to EDCL & CMSD should follow the EDL
  - Ensure all providers are sensitized/trained on the EDL
  - Monitor compliance
- **Establish a transparent system to review all requests for non-EDL drugs**
  - Drug & Therapeutic Committee in each referral hospital & district

Health worker views

- **Nurse**
  - We can only record the dispensing of injectable drugs to patients, not oral ones, because of the excessive workload
- **Doctor**
  - How can I make a proper diagnosis in one minute?
- **Pharmacist**
  - We are not involved in drug stock management. We just do dispensing. There are too many patients to be able to give good instruction to each one.
- **Storekeeper**
  - We often run short of intravenous fluids. On order from the Director, I have to deliver less quantity than the wards demand in order to save stock for poor people and emergencies.

Drug use

- Few prescribers use STGs
- Prescribing principles taught in medical school in 3-4th years but undermined by clinical studies and later work
- CPD adhoc and does not include prescribing principles or therapeutics
- Huge overcrowding in OPD and IPD public hospitals
  - Some doctors see 150-200 patients /day
  - 1-2 minutes per consultation,
  - < 30 secs dispenser-patient interaction time
  - Less overcrowding in Upazilla Health Complexes & Community Clinics where prescribers saw about 30 patients /day
  - No referral system

Drug use: recommendations (1)

- **Monitor drug use**
  - Prescription audit using diagnosis
  - Revise outpatient (OPD) patient registers to include drugs prescribed & revise dispensing slips to have 1 slip per patient
  - Identify specific inappropriate practices that you want to change (e.g. overuse of antibiotics in upper respiratory tract infection) in order to target interventions to these practices
  - Should be done by all teaching hospitals & district health offices
- **Analyse prescriber workload**
  - To ensure equal workload for all prescribers, which could lead to...
  - More prudent prescribing, better dispensing, less return of old patients so reducing OPD crowding (and possibly IPD admission/crowding)
  - Lobby central level for more staff and redistribution of staff according to workload & to match expertise with equipment
- **Establish a referral system to decrease overcrowding**

Drug use: recommendations (2)

- **Standard Treatment Guidelines (STG)**
  - Develop STGs to include OPD treatment of simple primary care conditions and to emphasize use of fewer medicines
  - Disseminate to every doctor & student & incorporate into CME
- **Drug and Therapeutic Committees (DTC)**
  - Establish DTCs in every hospital and require them to monitor drug use, encourage CME, and report annually on activities to MOHFW
- **Continuing medical education (CME)**
  - Incorporate prescription audit and feedback and ethics into CME
  - Involve Bangladesh medical / pharmacy councils / associations
- **Public Education**
  - Core pharmaceutical messages e.g. does my child need more than one medicine? Antibiotics not needed for simple coughs and colds through health education channels and the media

Drug regulation: recommendations

- Strengthen the DGDA
- Strengthen the DCL, including the capacity to test TRM medicines
- Make the registration process more stringent
  - Stronger criteria e.g. bioequivalence, studies, dissolution profiles, stability studies
  - Stricter application of criteria
  - Make process more transparent with less conflict of interest – decrease manufacturer presence
  - Will help to reduce the number of products registered
- Establish OTC schedule
- Expand the drug pricing controls

Drug regulation (1)

- **Directorate General Drug Administration (DGDA) of Bangladesh executes:**
  - Drug Act and Rules 1940 to 2006
- **DGDA under-resourced**
  - Has 226 staff, 80 technical, in post (out of 370 sanctioned posts)
  - Manages a sector consisting of >25,000 products; 270 allopathic drug and > 500 herbal/ayruveda/unani/homeopathic manufacturing units; >1,700 wholesalers; >110,000 retail shops
  - Asking for vacant posts to be filled & more sanctioned posts
- **National Drug Control Laboratories**
  - 2 labs with 90 staff, 71 technical, in post (out of 185 posts)
  - 4,531 samples tested of which 145 (3.2%) failed in 2013
- **646 Prosecutions in 2013**
  - 42 million Taka fines; 163 people sent to prison

National Drug Policy

- First established in 1980s, revised in 2005
- Policy covers
  - Laws, regulation, drug regulatory authority, drug registration, drug quality assurance
  - Drug manufacturing, distribution, storage, sales, prices
  - Drug information and monitoring of essential drugs
- Manufacturing objectives met but others not
  - Policy implementation not monitored
  - Many policies to promote rational use of medicines not in place
- National Core Committee for Rational Use of Drugs
  - Revival of previous proposal suggested in 2008, but not followed
- National Antibiotic Resistance initiative
  - Formed recently, starting work in few medical college hospitals

Drug regulation (2)

- **Outlet inspections**
  - Carried out 51,000 drug outlet inspections in 2013
- **Drug Schedules**
  - Act allows for prescription-only and OTC schedules as well as a narcotics schedule, but in practice no distinction is made between OTC and prescription-only schedules
- **Monitoring of drug promotion**
  - Only ORS and contraceptives can be advertised.
  - Adhoc monitoring done
- **Adverse Drug Reaction Monitoring**
  - 46 adverse events of which 23 were confirmed ADRs in 2013-14
- **Drug Price Controls**
  - Only 117 essential drugs have price controls (cost of manufacture plus 150-300% mark-up)
  - "Manufacturers do not want the national EDL increased for fear of greater price controls"

Drug policy & coordination: recommendations

- **Permanent statutory committee to advise the Minister of Health on Pharmaceuticals with wide membership incl. laypersons, professional bodies …**
  - Revive the Core Committee for Rational Use of Drugs?
- **Executive Division in MOH to carry out the statutory committee recommendations –**
  - A new Directorate?
  - To coordinate action between MOHFW departments (e.g. DGHS, DGDA, CMSD) & with EDCL & other Ministries (Finance, Trade)
  - To be responsible for monitoring drug policy implementation
  - To be responsible for promoting rational use of drugs: implementation of EDL, STGs, DTCs, monitoring drug use, pre-service training, CME, public education, school health programs, etc.

Group work

- Each group to draft 3-5 recommendations with practical steps including
    - What will you do?
    - Who will do it?
    - In what time line?
- Groups
    - Drug supply
    - Drug selection
    - Promoting rational drug use
    - Drug regulation
    - National structure and drug policy