

Commentary

A Review on the Policy and Practices of Therapeutic Drug Uses in Bangladesh

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ABSTRACT

Despite substantial progress in drug manufacturing, irrational drug use, inappropriate prescribing, inadequate access to essential drugs, and uncontrolled price are major problems affecting the total health care system badly of Bangladesh. This project is based on reviewing related literatures, newspapers articles and online searches using Pubmed and Google. Combinations of key words related to each of the subject areas were used. Websites of relevant institutions, government and non-government organisations were also searched. The obtained literatures were categorized and reviewed carefully. Most of the medications are prescribed inappropriately and polypharmacy is very common. Antibiotics are often prescribed irrationally without standard guidelines. Virtually, all the drugs are available without prescriptions and self-medications are highly common. Access to essential medicines is significantly less than that mentioned in the official documents. Price of essential medicines is not consistent and the drugs regulating authority does not have any control over pricing of drugs. Counterfeit medicines have deluged Bangladesh market with an estimated worth of US\$100-US\$150. Smaller drug manufacturers are engaged in the production substandard or fake drugs. Information on monitoring and reporting of adverse drug reactions (ADR) of the marketed drugs were not available. Management and utilisations of therapeutic drugs in Bangladesh is extremely vulnerable. The drug controlling authority should be more vigilant to ensure appropriate use and availability of medicines. Advanced studies are required to assess drug use patterns in the country.

KEY WORDS: Bangladesh, National Drug policy, Essential drugs, Rational drug use, Price of drugs.

INTRODUCTION

General Health matters of Bangladesh

Bangladesh is considered a developing country with more than 75% of the total (142 million) population living in rural areas. About 36% of the population continue to live below the national poverty line (<US\$1/day). Basic needs of living particularly health and education remain largely unmet and only less than 40% of the population has access to basic healthcare [1, 2]. Distribution of health workers (per 1000

population) in Bangladesh is physicians 0.26, nurses 0.14 and pharmacist 0.06. Per capita total expenditure on health only US\$ 2.84 in comparison to US\$ 30-40 per capita, the minimum required for essential health interventions in low-income countries [3]. Though majority of the population live in rural areas, the government healthcare system remains a very minor source of health care there [4]. Around 26% of professional posts in rural areas remain vacant and there is high rate of absenteeism (about 40%). Treatments in the rural areas are mainly (about 45%) provided by unqualified health personnel including medical assistants, mid-wives, village doctors, community health workers in comparison to that by qualified medical graduates (only 10-20%) [5]. Over-prescribing and inappropriate prescribing are very common in the country due to unethical practices of both health professionals and drug manufacturers [6].

Regulation of Therapeutic Drugs in Bangladesh

In response to WHO's essential drugs concept such as access to essential medicines, quality of all medicines and rational use of drugs [7], Bangladesh pioneered a National Drug Policy (NDP) in 1982. Main objectives of this policy were to ensure easy accessibility to essential drugs with affordable price, standard quality of drugs and rational use of drugs through appropriate prescribing and dispensing the health care professionals.

The Directorate of Drug Administration (DDA) under the Ministry of Health & Family Welfare, Government of the People's Republic of Bangladesh, is the drug regulatory authority of the country. Mission of the DDA is to ensure that the common people have easy access to useful, effective, safe and good quality essential and other drugs at affordable price. All matters related to drugs and medicines are regulated in Bangladesh by the Drugs Act 1940 and the rules made thereunder. In addition to that, the Government adopted the NDP in 1982 and The Drugs (Control) Ordinance, 1982 was promulgated to implement it. The Ordinance controls manufacture, import, distribution, sale, pricing, advertisement of all essential Allopathic drugs and medicines and for prohibiting production, sale and use of non-essential and unnecessary or less necessary drugs and medicines in the country. At present, the DDA has 33 district offices and all officers function as "Drug Inspector" pursuant to the drug laws. Besides, a number of

Committees, such as Drug Control Committee (DCC), Standing Committee for procurement and import of raw materials and finished drugs, Pricing Committee and a number of other relevant Committees. To test the quality of pre-registration and post-marketed drugs and medicines, there are two government Drug Testing Laboratories in the country, one in Chittagong under the direct administrative control of the DDA and the other in Dhaka under the control of the Institute of Public Health (IPH) of the Directorate General of Health Services [8].

Overview of the prevailing drugs market

Bangladesh drug market is flooded with over 8,000 formulations compared to 117 essential drugs and 100 supplementary drugs listed on the essential drug list. Among 231 allopathic drug manufacturers, top 30 companies are considered as large scale units and these are enjoying major share of the total market [8]. Interestingly, Bangladesh owns about 70.9% of generic medicines in terms of total sales among the 48 least developed countries of the world [9]. At present there are about 30,000 illegal [10] and more than 70,000 illegal drugstores according to the Bangladesh chemist and druggist association, Bangladesh. These are alleged to sell substandard or fake, poor quality, smuggled and adulterated medicines. Most of them are selling medicines without registered doctors' prescription [11].

The paper was undertaken with the recognition that bringing a review of available literatures within a short time frame presenting useful information to anyone interested in researching, implementing or comparing data in this area. This review may not provide answers to all questions but may provide detailed and considerable amount of information on drug use patterns, prescribing behaviours of the medical practitioners, access to essential medicines, antibiotic prescribing practice, compliance or non-compliance with standard prescribing practice and cost of medications in Bangladesh. It also includes what has been done till date, what is going on and what needs to be done, in the aforementioned fields.

METHODS

This project is based on reviewing related literatures, newspapers articles from 1995 to the end of July 2006. Because available documents showed that drug use studies were never looked into adequately, this long period was considered to make this paper more precise with valuable information. Internet searches were performed using Pubmed and Google search engines. Combinations of key words used for each of the subject areas based on project objectives beginning with 'base' of drug use, price of drugs, prescribing patterns, essential drugs and rational drug use. To these were added Bangladesh, rural areas, urban areas, and associated terms such as graduate doctors, non-graduate doctors, quacks (village doctors), government health facilities etc. Further, titles were identified as cited in the reference sections of each found literatures and were

accessed accordingly for required information. As well, specialty areas and links were searched for academic institutions, respective national and international NGOs and various research foundations of Bangladesh. Web sites of national organisations such as, drug administration, health ministry, physicians, pharmacists and other health care professions care were also searched, including their publications, search engines and links. The collected resources were categorized according to the subject areas. Literatures from individual groups were reviewed extensively to extract important information for this paper.

RESULTS

Prescription Patterns of Drugs

In reality, there is no mechanism or legislation exists in the country for assessing the competence of prescribing medical practitioners. No legal action is taken against them even if a serious mistake leads to a fatal outcome. The relatives of the victim accept it as fate, and no complaint is lodged. A medical practitioner can prescribe anything from vitamins to vincristine, for anything from the common cold to cancer [12]. Inappropriate prescriptions are readily available due to poor consulting period (a mean of only 54 seconds!) of doctors in Bangladesh [13]. It is estimated that more than half of medicines are inappropriately prescribed, dispensed or sold [14]. Moreover, polypharmacy is very common among the rural medical practitioners with antibiotics and vitamins prescribed widely [4].

The prescription procedure of antibiotics in Bangladesh is less than ideal as prior identification of the pathogens and its sensitivity to the drug is rarely determined before the drug is prescribed [15]. The situation is very alarming in the rural areas. For example, one survey conducted among rural medical practitioners with an average of 11 years' experience showed 60% of antibiotics prescriptions written based on the symptoms alone [16]. All antimicrobial agents were prescribed mainly on the patient's complaints, and all available antibiotics were prescribed in inappropriate doses and duration as has been showed in another similar survey [17].

Children are mostly affected by inappropriate antibiotics prescribing in Bangladesh. In a study it was showed 26% of purchased drugs were antibiotics for children aged 0-4 year(s) and 48% of antibiotics were purchased in quantities of less than a single day's dose [18]. Pneumonia and diarrhoea are the two most common infectious diseases among children in Bangladesh with the annual deaths of about 230,000 children due to diarrhoea [19]. But the percentages of appropriate antimicrobial treatment of pneumonia, and diarrhoea were 57.1% and 67.8% respectively as shown in one study [20]. Misuse of drugs in the treatment of acute diarrhoea among under-five children is highly prevalent and WHO-recommended treatments were seen in only 26.7% of cases and metronidazole was

prescribed in all 38.6% cases [21]. Multiple and inappropriate antimicrobial drugs is the most common treatment errors in dysentery with failure to recommend use of oral rehydration solution [22]. Over-statements and misinformation is very common in Bangladesh, which greatly influences doctors' prescribing behaviours. Currently, drug companies are the only organisations in Bangladesh to provide information to health personnel and the information supplied is often not consonant with recommendations from public health bodies [23]. Along with bribe in the form of cash, a large number of doctors accept various gifts including free air ticket for foreign trips, computers, mobile phones, air conditioners, table lights, telephones, towels, calendars, paperweights, pens and what not. Ultimate result is prescriptions of inappropriate or unnecessary and expensive medicines [24].

Uses of Prescription Drugs

The drug use studies involving outcomes, adverse reactions and bioavailability in Bengali population has never been seriously looked into in Bangladesh [25]. Like all other developing countries, irrational and inappropriate use of medicines is very common in Bangladesh [23]. Recent study showed that about half of the antibiotics were sold without any prescriptions, and even ordinary people without any knowledge of medicine asked the drug seller for specific antibiotics [17]. Almost every drug store salespersons illegally recommends and sells prescription medicines people often do not buy all the drugs as prescribed for them because of financial constraint. Moreover, self-medication is a common practice among laypeople [4]. Unjustified combination of vitamins and minerals are still extensively available violating the principles of NDP, which restricts the production and marketing of these types of combination products. Recently, many pharmaceutical manufacturers have launched one such combination containing 32 ingredients including selenium, vanadium, molybdenum, tin and other less important or unnecessary minerals. But the socio-demographic conditions of Bangladesh clearly outweighs the justification of this type of combination products as most of the nutritional deficiencies are caused due to Vitamin A or B-complex, iron, calcium, iodine, or zinc deficiency. Deficiencies due to selenium, vanadium or tin are seldom diagnosed in Bangladesh, if ever. British pharmacopoeia clearly indicates that there is no justification for prescribing multiple ingredient vitamin preparation [14]. As single agent Vitamin A and ergometrine are dispensed inappropriately in more than 60% of the cases [26]. In addition, drug like syntocinon (a hormonal injection which is given to pregnant women to ease labour) is being sold or used indiscriminately in home deliveries in rural Bangladesh, which is readily available without prescription there [27]. The NDP clearly indicates that no company can market a drug of similar benefits as of the existing one with minor chemical difference. But at present, there are

captopril, cilazapril, enalapril, fosinopril, lisinopril, perindopril, and ramipril in use in Bangladesh [28].

Over the Counter (OTC) Drug Uses

In real sense, there is no 'prescription only drug' in Bangladesh at present. One can get any drugs from anywhere. Only need is money; no prescription indeed [12]. Over the counter (OTC) drugs have emerged recently as drugs of serious misuse across Bangladesh, and other neighbouring countries. One report estimates that there are four million drug misusers in the South Asian region, with Bangladesh accounting for nearly 500,000 [29]. Self-medications in a population with low literacy level like Bangladesh are very challenging, which poses risks such as incorrect diagnosis, absence of knowledge of alternative treatments, irrational use of drugs and neglecting side effects and drug interactions. Study showed that around 30-40% of disadvantaged population including the women, elderly, ethnic minorities, poor / ultra-poor undertake self-medications for managing illness [5].

Availability and Accessibility of Essential Drugs

A health system only functions well with sustained availability of essential drugs, as patients tend to bypass facilities that can not provide drugs [30]. Though the official documents showed that about 80% of the people of Bangladesh had sustainable access to affordable essential drugs in Bangladesh [31], there are numerous evidences of frequent and persistent unavailability of essential drugs in the government health facilities. For instance, one study conducted in four district hospitals and one medical college hospital showed that only 8% of household reported outpatients reported receipt of the prescribed medicines from the facilities. Some 42% of hospital interviewed outpatients got all the prescribed medicines. Most of the inpatients (86%) reported paying for medicines from outside [32]. As with rural areas, unavailability of essential drugs the urban government health facilities are often very common. One report showed that two large hospitals (Sir Salimullah Medical College and Mitford Hospital) in the capital (Dhaka) city had been operating without essential medicines for eight weeks [33]. Theft and illegal sale of essential medicines from the government hospitals are very common. Officials in-charge of hospital drug stores sell these drugs to local pharmacies instead of supplying to the poor patients.

Price of Available Drugs

The stated aim of the NDP is to ensure that common people can get the essential and necessary drugs easily and to ensure the quality and safety of these essential drugs. It identified 150 essential drugs for controlled pricing. Since 1993, the number of the price-controlled essential drugs has been reduced to 117 primary health care drugs [30]. Maximum retail price (MRP) of the essential drugs will be fixed by the Directorate, Drug Administration, according to

the existing drug policy. In case of others, company price is approved by the same authority. Price of essential drugs in Bangladesh is virtually uncontrolled. The drug regulating authority does not negotiate the price rather only approves the prices sought by the pharmaceuticals companies [34].

Recently, a strong syndicate of top 20 drug manufacturers has pushed up the prices of medicines almost double than the previous ones of some 18 varieties of essential drugs immediately before declaration of revised drug policy to legalize the price hike [35]. Wilderness of price discrimination has become rampant now a days. For example, the price of ciprofloxacin tablets ranges from Tk. 8-Tk. 14 (US\$ 0.11-0.2) per tablet. But one mid-level company supplies the same medicine to medical college/university hospitals at Tk 2.5 (US\$ 0.04) per tablet. The supplied tablets have been tested subsequently and proved to be of standard quality. Obviously, the actual production cost of this antibiotic is less than Tk. 2.5 per tablet. But amazingly, some companies are making a profit of not less than Tk 12 (US\$ 0.17) for per tablet [34]. Another example of uncontrolled price can be evident for dexamethasone eye drop, which is available at Tk. 24-Tk. 90 (US\$ 0.34-1.29) per 5ml. Again, for diclofenac eye drops are available at Tk. 40-Tk. 200 (US\$ 0.57-2.86) [36].

Quality of Marketed Drugs

One media report showed that among all the pharmaceutical manufacturers only 20 to 25 companies are producing quality medicines in the country [37]. The situation clearly raises a question about the role of the remainder manufacturers. They are mainly involved in the production of fake/substandard or imitating renowned brands of various drugs. At present, spurious drugs have been flooded all over Bangladesh. Another testing conducted by the drug regulating body found 69% paracetamol tablets and 80% ampicillin capsules as substandard from some small manufacturers [38]. In its annual testing of 5000 drug samples in 2004, the Public Health and Drug Testing Laboratory (PHDTL) detected 300 drugs that are either counterfeit or of very poor quality. Significantly, these include many popular antibiotics and lifesaving drugs [39]. Similar report in 1999 from the drug regulating authority mentioned that 102 drugs out of 6517 registered drug samples found below standard. In 1998, it was 260 out of 5920 registered drug samples [40]. Because of scarce drug testing facilities, many of the drugs are entering into the market without any valid quality assessment procedures. Besides, there are many brands existing in the market having active ingredients less than the specifications. A recent assay involving 15 brands of ciprofloxacin showed that 47% of the collected samples containing active ingredient less than the required specification [38]. Apart from fake or substandard drugs, the use of date-expired or drugs with tampered dates in Bangladesh can not be ignored. This is of especially alarming in the rural areas due

to high rate of illiteracy. But regretfully, increased number of renowned private hospitals in the capital city (Dhaka) have been fined by a mobile in charge of possessing least 15 life-saving medicines with expired dates [41]. Appropriate storage conditions of drugs are very important in tropical countries like Bangladesh as heat, light or moisture may degrade the drug molecules easily. But most drug manufacturers in the country lack suitable storage facilities and enclose medicines in such low quality foils that it is impossible for them to retain their potency up to indicated shelf-life [39]. Use of counterfeit or substandard drugs is very threatening to human life. Along with substantial damage of health, they can even kill. For example, contaminated paracetamol elixir with di-ethylene glycol killed around 223 children in Bangladesh in 1992 [42]. Adulteration of antibiotics poses risks not only to human body but also for the environment. Along with the risk for therapeutic failure, counterfeit antibiotics can produce chance of potential antibiotic resistance [13].

Some statistics, however, show marked improvement in the health sectors of Bangladesh particularly in family planning and immunizations. As an integral part, drug management is still remaining in primitive level even after the implementation of the NDP more than two decades before. Availability of studies relating drug management is almost rare. Only one large scale baseline study on drug use patterns, prescribing behaviours, access to essential drugs and consulting time has been carried out in 1991. Except some institutional surveys, there are no such studies in the country till now. Thousands of unnecessary drugs are present in the market including many multivitamin and mineral preparations. Illegal drugstores are prevalent elsewhere that accounts more than the legal ones. Due to lack of any controlling mechanism prescribing practices of the medical practitioners are very rampant everywhere in the country. About half of the medications are prescribed inappropriately and polypharmacy is very common. Antibiotics, vitamins and minerals are widely prescribed. Irrational prescribing practices are predominant in the rural areas. Standard treatment guidelines are not often practiced specially in acute diarrhoea in under-five children. As with other developing countries, indiscriminate use of drugs and self-medications are highly prevalent in Bangladesh. Virtually, all the drugs are available without prescriptions at present. Access to essential medicines is significantly less than that mentioned in the official documents. Availability of essential drugs in the government health settings are scarce both in rural and urban areas.

Price of essential medicines is not consistent. Wide variations of prices are existent within brands of the same drug molecules. The drug regulating authority does not have any control over pricing of drugs and drug manufacturers are manipulating this opportunities. Counterfeiting of drugs in Bangladesh has flourished because of poor supervision

and control and unethical practices of most of the officials of drug regulating authority [43]. Among the total 245 pharmaceutical manufacturers only top 20 leading manufacturers are producing good quality medicines in the country and most others are engaged in the production substandard or fake drugs. Substandard or fake versions of life-saving drugs are alarmingly prevalent in Bangladesh markets. In some cases, it is around 70% to 80%. The value of fake and contraband drugs the market is estimated to be around US \$100- US\$150 million in Bangladesh [39]. Despite this situation, the liable authority believes that most of the counterfeit drugs are entering in the country from neighbouring countries particularly from India [10]. Though article 17 of the Drug (Control) Ordinance, 1982 says: "Whoever manufactures or sells any sub-standard drug shall be punishable with rigorous imprisonment for a term which may extend to five years, or with fine which may extend to one lakh taka, or with both", unfortunately, there is no single instance of any legal prosecution till date against any illegal traders in the country [40]. Though it was a vital directive in the NDP, no documents pertinent to monitoring and reporting of adverse drug reactions (ADR) of the marketed drugs in Bangladesh have been found during this review work. The ADRM section of the official website of Drug Administration was found 'under construction' though it was launched two years back. Because of lack of primary data sources, some information in this review has been quoted from the online versions of renowned national English newspapers. No data/information on adverse drug reactions (ADRs) or post-marketing surveillance of marketed drugs in Bangladesh has been reported in this paper due to unavailability of the same.

Patterns of drug prescribing, uses, availability, affordability and dispensing in Bangladesh are very crucial at present. The existing systems should be reformed in order to ensure better utilisations of therapeutic drugs in the country. The following recommendations can be suggested based on the present study:

- 1) An interdisciplinary approach involving physicians, nurses, pharmacists, economists, sociologists, communication specialists, manufacturers and others should address the problem of inappropriate use of drugs.
- 2) The policy makers, manufacturers and the medical professionals should be committed to uphold the status of public health systems of the country through the implementation of the noble objectives of the NDP.
- 3) The drug regulating authority should increase drug testing facilities and manpower in order to control the quality of all the medicines available.
- 4) The price controlling mechanisms should be stricter to ensure easy affordability of essential medicines in the country.
- 5) The primary health care systems of the country need to be aware to improve drug utilisations in the rural areas. The government should be more concern to eliminate substandard drugs from rural areas.
- 6) The government should ensure a steady supply of good quality essential medicines in the government health care facilities.
- 7) Post-marketing surveillance and adverse drug reactions monitoring should be initiated for all the currently marketed drugs.
- 8) Mass media like radio, television and newspapers can be used to create awareness and to educate the consumers about dos and don'ts of rational drug uses.
- 9) Participation of local and international NGOs are necessary to promote high quality and rational use of drugs.
- 10) Drug sellers should be trained properly to minimize inappropriate drug dispensing and recommendations.

Drug use studies in was never given proper importance. This review pointed out many alarming situations in respect to drug prescribing, uses, quality and availability in Bangladesh. Obviously, these all may pose substantial health hazards to the public health systems of the country. Greater commitments are required from the drug regulating authority, drug manufacturers and health care professionals to ensure effective and sound drugs management and utilisation mechanisms.

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