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The Social Costs of Graduating from Least Developed Country Status: Analyzing the impact of increased protection on insulin prices in Bangladesh

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ABSTRACT

In 2021, the United Nations Committee on Development Policy will consider whether Bangladesh should graduate from 'least developed country' (LDC) status. If graduation is granted, in 2024 Bangladesh would thus have to forego its exemption to intellectual property (IP) provisions of the World Trade Organization (WTO). Bangladesh has taken advantage of the policy space it was granted under the LDC exemption to the WTO to build a generic medicines industry that not only serves Bangladesh but also other LDCs. Under the WTO, Bangladesh will have to require patent protection of certain medicines. We draw on previous work and develop a model to examine how IP provisions in the WTO will impact the prices of insulin in Bangladesh and its subsequent impacts on welfare and poverty. We find that LDC graduation will trigger a significant jump in insulin prices that could cause a up to a 50 percent decline in the welfare of households with one or more members living with diabetes in Bangladesh, increasing the poverty rate of such households up to 36 percent and of those needing insulin up to 60 percent unless policy adjustments are carried out.

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1. Introduction

Members of "least developed countries" (LDC) are exempt from granting pharmaceutical patents till January 1, 2033 (WTO, 2015). In addition, LDC members also have the option of not filing patent mailbox applications and obtaining exclusive marketing rights until January 2033 (WTO, 2015). This implies that LDC member countries have freedom to reject a pharmaceutical patent application as long as the exemption is active. This temporary exemption is important to ensure access to essential medicines in least developed countries. The temporary exemption may facilitate local production of generic versions of many essential medicines among those LDC members who are capable and will also LDC members to import generic medicines.

However, once this temporary exemption is over, LDC members have to ensure patent protection and provide exclusive marketing rights for any patented medicines. This change may greatly restrict the access to essential medicines in low income countries. We use the case of Bangladesh's LDC graduation to carry out an ex-ante analysis of the impact of Bangladesh LDC graduation on the access to insulin, a lifesaving medicine for individuals with diabetes.

As an LDC, Bangladesh does not presently need to comply with global commitments under the World Trade Organization's 'Trade Related Intellectual Property Rights' (TRIPS) provisions (aka the "TRIPS Agreement"). Currently, Bangladesh can produce the generic version of any innovative drug and patent protection for pharmaceuticals is not allowed. In 2021, if certain conditions are met, the United Nations will recommend Bangladesh for graduation from the LDC category in 2024. Consequently, Bangladesh will not be able to produce medicines on patent in Bangladesh after graduation from LDC status. Household out-of-pocket expenditure as percentage of total health expenditure in Bangladesh was more than 67 percent in 2015, and of which more than 75 percent was on pharmaceuticals (MoHF, 2016). This implies that prices of some medicines may increase significantly after 2024, which places an even larger burden of health expenditure on households.

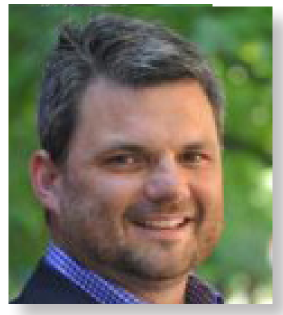
Higher prices of medicines can affect access to medicines in several ways. First, higher prices of medicines may force some households to stop taking medicines or take less than the recommended dose. Second, households may also reduce other forms of consumption such as food or spending on children's education to cope with the additional expenditure on medicines due to higher prices. Thus, higher prices of medicines not only affect the usage of pharmaceutical medicines, but may also reduce consumption of foods, education and other essential amenities, which are necessary to lead a healthy life. This paper estimates the impact of these different types of expenditure substitution. We estimate the changes in household welfare following the implementation of pharmaceutical patenting and stricter intellectual property rights (IPRs) that would potentially increase the prices of some medicines. For this purpose, we choose the market for insulin to estimate these aforementioned effects.

Insulin is a good tracer medicine to measure the effects of stronger IPR on access to medicines for several reasons. First, some types of insulin would still be under patent (in other countries) after Bangladesh's LDC graduation, which implies that IPR provisions will be a binding constraint on the insulin market. Second, the burden of diabetes is increasing in Bangladesh. Currently more than 10 percent of adults have diabetes (mostly type 2) and more than 70,000 deaths per year are attributable to diabetes or high blood glucose (WHO, 2016). This means that insulin is widely required to satisfy the health needs of the population. Finally, expenditure on insulin is mostly out of pocket (WHO, 2016). Thus, after Bangladesh's LDC graduation, the price of insulin may significantly increase, which will increase the health expenditure pressure on households with members having diabetes.

In this paper, we use household income and expenditure (HIES) data (BBS, 2016) and quadratic almost ideal demand system (QUAIDS) to estimate the household's substitution pattern among food, medicines and education for households with potential expenditure on insulin. In addition, we estimate the loss in household welfare and increase in household poverty resulting from the higher prices of insulins. Unlike other *ex-ante* studies that investigate the similar question for different medicines in some other LDC or developing countries, we use household level data to estimate elasticities of medicine demand and to perform welfare analysis.

There are several advantages of using household data rather than the market share data of different brand and generic medicines treating a condition or some aggregate sales and average price data. First, household data allows us to control many characteristics of household and individuals living in the household, which are important determinants of demand for medicines along with the price of medicine. Thus, controlling for those characteristics would enable us to estimate the demand parameters consistently and efficiently. Second, household data enables us to estimate the different types of substitution between medicines and other important expenditure items, such as food and education. Third, sales data of different brand or generic medicines are often proprietary and it can be very hard and expensive to get access to that data. Moreover, sales data may not be very representative, especially for LDCs. On the other hand, HIES data is available for most of the LDCs as well as most representative of the population. In addition, the HIES data is often publicly available. Thus, our paper provides an effective way to estimate demand parameters of insulin and perform household welfare analysis with household data of Bangladesh, which could also be applied for any other medicine and HIES of any other LDC to carry out the similar analysis.

The paper finds that the household's demand for insulin is highly price inelastic, even more inelastic than the household's demand for food. The own price elasticity of insulin is less than 1 in absolute value, which means that the price of insulin could increase more than 8 times its current price if a stronger IP regime facilitates an unregulated monopoly for insulin and this would have significant welfare effect for households with members who need insulin. We find that the aggregate annual expenditure of those households goes up on an average by USD 283 million and the welfare cost of the unregulated monopoly of insulin would vary from USD 54 million to USD 276 million under various estimation methods and measure of welfare. Moreover, the increase in insulin price will have a serious impact on household poverty. Poverty rates for households needing insulin could increase between 5 percentage points to up to 48 percentage points



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The rest of the paper is organized as follows: Section 2 provides some background on Bangladesh's LDC graduation and on the current status of IP regulation and pharmaceutical industry in Bangladesh, Section 3 is a discussion of relevant studies, Section 4 details the methodology and estimation techniques with description of data and its sources, Section 5 shows the estimation results along with household welfare and poverty analysis, Section 6 discusses some policy implications, limitations of our analysis, and our conclusions are in Section 7.

2. Background

Bangladesh is in the process of making its transition out from the group of "least developed" countries (LDCs) (United Nations, 2020). This involves a country meeting graduation thresholds under at least two of the following three pre-defined criteria: per capita income, human assets and economic vulnerability.[1] Decisions on inclusion into, and graduation from, the list of LDCs are made by the United Nations General Assembly (UNGA) based on recommendations by the Committee for Development Policy (CDP), a subsidiary body of the UN Economic and Social Council. The CDP, is among other things, mandated to review the category of LDCs every three years and monitor their progress after graduation from the category (Bhattacharya, 2009). In March 2018, the CDP found that Bangladesh met the criteria for graduation for the first time by satisfying all three criteria. If Bangladesh meets the graduation criteria for a second time at the next triennial review in 2021, the CDP may recommend Bangladesh for graduation from the LDC category in 2024 (WTO, 2018).

LDC classification accords a country duty-free access to the richer economies of the world, exemption from intellectual property rights enforcement for the time being, and other economic benefits (United Nations 2020). The impact of the loss of LDC privileges carries with it a three-year grace period from 2024 to 2027, during which time Bangladesh must prepare itself for graduation. The most visible trade related implication of LDC graduation is the loss of preferential market access, such as the loss of concessions granted to the LDCs under the global system of trade preferences (GSTP) among the developing countries (United Nations 2019). Since LDCs are also exempted for the trade-related aspects of intellectual property rights (TRIPS) agreement, graduation out of LDC status may have significant implications for intellectual property rights enforcement in Bangladesh, which will have to be addressed by the pharmaceutical and software industries, among others (United Nations 2019).

[1] Income criterion, based on a three-year average estimate of GNI per capita for the period 2011-2013, based on the World Bank Atlas method (under $1,025 for inclusion, above $ 1,230 for graduation as applied in the 2018 triennial review).

Human Assets Index (HAI) based on indicators of: (a) nutrition: percentage of population undernourished; (b) health: mortality rate for children aged five years or under; (c) education: the gross secondary school enrolment ratio; and (d) adult literacy rate.

Economic Vulnerability Index (EVI) based on indicators of: (a) population size; (b) remoteness; (c) merchandise export concentration; (d) share of agriculture, forestry and fisheries; (e) share of population in low elevated coastal zones; (f) instability of exports of goods and services; (g) victims of natural disasters; and (h) instability of agricultural production. **Source:** United Nations 2020

Bangladesh has a burgeoning manufacturing capability and a relatively self-sufficient pharmaceutical sector. Companies basically manufacture finished formulations by assembling known generic and, in some cases, patented products. Since pharmaceutical patents in Bangladesh were suspended in 2008, this created opportunities for local generic production of drugs patented outside Bangladesh, with a number of generic companies supplying the same drug. For example, local firms manufacturing drugs patented abroad include Incepta, Beximco, Beacon, Renata, Square, and Eskayef. Drugs patented abroad that are manufactured in Bangladesh include sofosbuvir, sitagliptin, linagliptin, vildagliptin, rivaroxaban, emphagliflozin (Islam et al. 2017). Some firms have been engaged in producing Active Pharmaceuticals Ingredients (APIs)--excipients and solvents that are used as raw material in producing the final drug formulations. R&D activity is, however, virtually nonexistent in the Bangladesh pharmaceutical industry as it is a branded generics market. Generic formulations represent the main business of the Bangladesh pharmaceutical industry. Presently, the market consists of approximately 8,000 generic products and 258 firms with manufacturing capability, in addition to imported patented products (Islam, et al., 2018). This local production supplies over 95 percent of Bangladesh's pharmaceutical needs and about 80 percent of these medicines are generics. The top 30 to 40 companies by value dominate almost the entire market in which the top 10 hold 70 percent of domestic market share, and the top two - Beximco and Square Pharma - capture over 25 percent of the market (Islam, et al., 2018). In brief, the Bangladesh pharmaceutical market can be divided as follows:

1. High-end products (Anti-cancer, insulin, vaccines etc.) produced by multinationals- if on patent, they are not patented yet in Bangladesh.

   These are essentially products specific to a niche market. The products are typically high priced and represent a small portion of the market. Medicines patented outside Bangladesh comprise less than 10 percent of the market at present. Profit margins in such products are very high.

2. Branded generics (Antibiotics, GI medicines)

   This represents broadest segment of the market, comprising products with relatively stable profits margins and brand name orientation. This segment is dominated by local manufacturers due to high brand loyalty observed in the market.

3. Low End generics

   This segment is small, price competition is very vigorous. The market share of each competitor depends on success of marketing strategy

4. Contract manufacturing (domestic and export)

   Locally, this segment is small as almost every firm manufactures its own products. The business usually comes from non-governmental organizations and other institutions like UNICEF to provide products such as saline, contraceptives and the like (Mohiuddin, 2018).

The dynamic nature of the Bangladesh pharmaceutical industry is in contrast to its long standing IP system. Patent rules and procedures are governed by the original Patents and Designs Acts of 1911. Bangladesh has not replaced or amended the 1911 Act. It only issued a Notification in 2008 that applications for pharmaceutical and agrochemical product patents were to be suspended pursuant to the Doha Ministerial declaration on TRIPS and public health, since LDC members of the WTO were allowed to exempt pharmaceutical products from patent protection. This waiver has been extended until 2033 by the TRIPS Council. Bangladesh can benefit from these transition periods but only if it retains LDC status (Chowdhury, 2018). As mentioned, some companies in Bangladesh are able to make high-end products like insulin to compete with multinationals (Mohuiddin, 2018)). This is important as Bangladesh ranks as one of the ten countries with the highest number of people with diabetes globally (IHME, 2019).

Although Bangladesh has demonstrated exceptional progress in health outcomes over the past few decades (IHME, 2019), the growing burden of non-communicable diseases, in particular diabetes has become a major challenge for its health system (WHO, 2015). While a national plan for tackling non-communicable diseases (NCDs) exists and significant strides are made towards universal health coverage, current household expenditure on medicines is high (MoHFW, 2016). It is estimated that the 20 percent poorest households spent 13.5 percent of their income of health related expenditure (Afroz, et al., 2019). Moreover, the graduation of Bangladesh from LDC could result in an increase in medicines expenditure and hence, in more households experiencing poverty as a result of high health related expenditure.

A recent scoping review for Bangladesh (Biswas et al., 2016) found that a final estimate of diabetes prevalence obtained after pooling of data from individual studies among 51,252 participants was 7.4 percent, similar to the global prevalence noted above. For Bangladesh with 165 million inhabitants in 2020 (World Bank, 2020), this means 11.6 million people with diabetes, about half of them undiagnosed. Undiagnosed diabetes is higher in people of lower socio-economic status (Islam, et al, 2016). The prevalence of diabetes was higher in males compared to females in urban areas and vice-versa in rural areas. Analyses revealed an increasing trend of diabetes prevalence among urban and rural populations.

Type 2 Diabetes is the most common form of diabetes worldwide with over 90 percent of all cases (WHO, 2019). Management of diabetes type 2 includes diet, physical exercise and weight management (NIDDK, 2020). If necessary, patients with type 2 diabetes require medication such as oral anti-diabetes medicines and in some cases insulin (NIDDK, 2020). Patients with type 1 diabetes require insulin. Since patients with diabetes have a higher risk of developing cardiovascular diseases, they may also require additional medicines (NIDDK, 2020). Generally, insulin is more expensive than several commonly used oral anti-diabetes medicines that have been marketed for many decades and are available at low price generic recommended as first line pharmacological treatment for diabetes (WHO, 2015).

Diabetes has emerged as a major public health problem worldwide, especially in low-and-middle income countries (LMICs), where more than 80 percent of people with diabetes are living. The International Diabetes Federation (IDF) estimated that the global prevalence of diabetes among adults in 2013 was 8.3 percent, roughly 382 million people living with diabetes, and projected to increase beyond 592 million in less than

25 years, which might be a conservative estimate. Southeast Asia accounts for close to one-fifth of all diabetes cases worldwide and the prevalence of diabetes is estimated to increase by 71 percent in this region by 2035. The IDF Diabetes Atlas 5th edition projected that diabetes prevalence in Bangladesh will increase to more than 50 percent by next 15 years, ranking Bangladesh 8th in number of people with diabetes globally. The economic and human costs provoked by diabetes in a large population such as in Bangladesh will be substantial. This study estimates the effect of "graduation" out of LDC status and the attendant changes in intellectual property (IP) protection for pharmaceuticals on insulin price and its subsequent impacts on welfare and poverty in Bangladesh.

3. Literature review

This paper builds on an emerging body of literature on the impacts of trade and investment treaties on access to medicines. A full assessment of this literature can be found in Islam et al. (2019). This literature is commonly grouped into two categories—*ex-ante* analyses that examine the extent to which proposed policies might impact access to medicines, and *ex-post* analyses that examine the impact of trade and investment treaties that have already occurred. This paper falls in the *ex-ante* category, attempting to estimate the extent to which access to insulin will be jeopardized in Bangladesh under a scenario where it loses its exemption from the TRIPs agreement under the WTO if it 'graduates' from the LDC status in the coming years.

The majority of *ex-post* studies find that trade and investment treaties adversely impact access to medicines in developing countries, but to a lesser degree than do *ex-ante* studies. With respect to *ex-post* studies, some *ex-post* analyses look at the impacts of WTO related provisions, others at 'free trade agreements' (FTAs). Of the WTO studies, Kyle and Qian (2014) examined the impact of intellectual property rights (IPRs) in the TRIPS Agreement on the launch of new medicines, prices and sales using data from 59 countries of varying levels of development. They found that patented medicines have higher prices and quantities sold, and that new medicine launches were unlikely without patent protection. Other studies examine impacts from FTAs that have more stringent provisions than the TRIPS Agreement, particularly those of the United States. Examples of this literature are studies that examine the US-Jordan FTA and find that the FTA increased prices of essential medicines and delayed market entry of generics (Abbot et al., 2012)). Shaffer and Brenner (2009) examined the Central American Free Trade Agreement (CAFTA) found that CAFTA Reduced access to generics already on the market, delayed entry of other generics. Most recently, Trachtenberg et al (2020) found that the US-Chile trade agreement increased both the price and sale volume of biologics.

This present study builds on a set of *ex-ante* studies. *Ex-ante* studies predictably estimate adverse impacts given the underlying assumptions they deploy from economic theory. The outcomes that *ex-ante* studies predict reflect the models' underlying assumptions, which are rooted in economic theory. When a firm is granted a patent, economic theory predicts the firm will supply a restricted quantity at a higher price because the patent grants the producing firm a temporary monopoly over the product (Baker, 2016).

Akaleephan et al. (2009) used a trade liberalization framework and attempted to find effects on prices and quantities following a reduction in tariffs or other trade barriers- to estimate the potential cost savings in Thailand resulting from an absence of TRIPS-plus provisions and increased price competition between innovative and generic producers of 74 International Non-proprietary Name (INN) imported medicines. These authors found that a proposed US-Thailand treaty would increase medical expenses and reduce the entry of generic medicines.

Chaves et al. (2017) used the Intellectual Property Rights Impact Aggregate (IPRIA) Model to project the impact of TRIPS plus provisions of the Mercosur-EU FTA on the public expenditures and domestic sales of ARVs and Hepatitis C medicines in Brazil and reckoned that the treaty would increase medicine expenditures and decrease sales by domestic producers.

This present paper is similar to the work of Chaudhuri et al. (2006) and Dutta (2011) in terms of nature of research question being investigated. Chaudhuri et al. (2006) used a two-stage budgeting framework (using data from 1999 to 2000) to investigate the effects on prices and welfare when one or more domestic generics are withdrawn from the quinolone market[2] in India due to the TRIPS agreement of the WTO. That study found considerable consumer welfare losses from reduction in the variety of products available on the market after TRIPS. On the other hand, Dutta (2011) utilized a discrete choice structural model to estimate and conduct the analysis similar to Chaudhuri et al. (2006). Our approach in this paper is different from Chaudhuri et al. (2006) and Dutta (2011) as we use household data and estimate a QUAIDS model with one stage budgeting considering only broad expenditure categories such as food, medicine and education. Household data does not have granular information on medicine in terms of types (brand or generic) or manufacturer (domestic or foreign) and so this does not allow us to estimate demand parameters for a subgroup of medicines treating a certain condition. However, using household data to estimate the demand parameters of medicine (insulin) has several advantages, as we mentioned above, over the sales and average price data used in Chaudhuri et al. (2006) and Dutta (2011).

4. Methodology, estimation framework, data

To estimate the effect of graduating from LDC status on the prices of essential medicines such as insulin, we analyze the effect of introducing patent protection for pharmaceuticals in Bangladesh, such protection not being recognized under the current intellectual property laws. This introduction will potentially reduce competition in the pharmaceutical market, and even the market of innovative medicines might be monopolized by the patent holder if there is no further regulation of medicine prices. Hence, analyzing the effects of Bangladesh's LDC graduation on medicine prices is akin to estimating the effects on medicine prices due to the pharmaceutical market becoming more monopolized through new patent protection and withdrawal of generic versions of innovative medicines from the local market.

[2] Quinolones are a sub-segment of systematic anti-bacterials.

In this paper we estimate the demand for insulin in Bangladesh, as the burden of Type 2 diabetes is increasing in Bangladesh and prices of insulin may affect a large number of persons with Type 2 diabetes. We combine a variety of data sources to estimate the impacts of LDC graduation on insulin prices, welfare, and poverty in Bangladesh. To estimate the demand elasticities for pharmaceutical products and/or medicines, previous studies used market share data.

For example, Chaudhuri et al. (2006) and Dutta (2011) used IQVIA market share data of different brands/generics of quinolones in the Indian market to examine the impact of the WTO agreement in that country. The IQVIA market sales data of quinolones was representative of the Indian market. However, IQVIA market share data only covers 2 percent of total sales of medicines in Bangladesh, which is not be representative enough to carry out a rigorous demand parameter estimation. Hence, we use the household level expenditure data on medicine and other items instead of market share data. The household level data have the advantage of reporting the cost of medicines faced by the households rather than the price reported by the manufacturers, but the drawback of using household level data is that it does not provide quantity or price of medicines but rather the total cost of medicines per person monthly or annually.

Accordingly, for our estimation purpose we use Bangladesh's Household Income and Expenditure Survey (2016) for information on different categories of expenditures, such as food, medicines, education, household characteristics such as income, number of members, geography of residence, and household head's characteristics, such as age, gender, religion, employment status, employment sector. The summary statistics of these variables are provided in Appendix A, in tables A.1 and A.2. We select the households with at least one member with diabetes from HIES residing in any part of the country. The HIES (2016) was conducted by Bangladesh Bureau of Statistics (BBS) during the period of April 2016 to March 2017 (BBS, 2019). This newest HIES is the most extensive household survey in Bangladesh, which provides detailed household level information for about 46080 households covering all administrative areas of Bangladesh (BBS, 2019).

To ensure optimal representation of the population, the survey areas are divided into 20 strata, of which 8 are rural, 8 are urban and 4 are largest city areas namely Statistical Metropolitan Areas. These strata are further disaggregated into 2304 Primary Sampling Units (PSUs). We complement the HIES data with insulin prices from the Director General of Drug Administration (DGDA) of Bangladesh, where prices of all approved insulins and their respective strength are reported.

To measure the effects of stronger IPR on the use of insulin and consumption of other essential items, we model a households' decision problem of allocating income in broad expenditure categories, such as food, medicine, education and other. We estimate the parameters at this stage using a version of the quadratic Almost Ideal Demand System (QUAIDS) and household level information. The QUAIDS framework requires expenditure shares on these expenditure categories, price or price index, total household income and other household level controls, all of which is available in the HIES (2016). Here, we use the Poi (2012) specification of QUAIDS, which incorporates the demographic variables.

4.1 Demand

The QUAIDS model in our estimation framework is based on the following indirect utility function used in Banks, Blundell, and Lewbel (1997):

$$\ln V(\boldsymbol{p}, m) = \left[\left\{\frac{\ln m - \ln a(\boldsymbol{p})}{b(\boldsymbol{p})}\right\}^{-1} + \lambda(\boldsymbol{p})\right] \tag{1}$$

Where ln $a(\boldsymbol{p})$ is the transcendental logarithm function of prices or costs of individual expenditure items, p_i:

$$\ln a(\boldsymbol{p}) = \alpha_0 + \sum_{i=1}^{3} \alpha_i \ln p_i + \frac{1}{2}\sum_{i=1}^{3}\sum_{j=1}^{3} \gamma_{ij} \; ln\, p_i \ln p_j \tag{2}$$

And $b(\boldsymbol{p})$ is the Cobb-Douglas price aggregator, defined as:

$$b(\boldsymbol{p}) = \prod_{i=1}^{3} {p_i}^{\beta_i}$$

And $\lambda(\boldsymbol{p})$ is defined as:

$$\lambda(\boldsymbol{p}) = \sum_{i=1}^{3} \lambda_i \; ln\, p_i$$

Here we need to estimate parameters $\{\alpha_i, \beta_i, \gamma_i, \lambda_i\}$, except α_0 which is generally set to some value lower than the lowest value of *ln m* in the sample (Deaton & Muellbauer, 1980; Banks, Blundell, & Lewbel, 1997). The set of parameters satisfy some conditions:

$$\text{Adding up: } \sum_{i=1}^{3} \alpha_i = 1$$

$$\text{Homogeneity: } \sum_{i=1}^{3} \beta_i = 0$$

$$\text{Slutsky symmetry: } \sum_{j=1}^{3} \gamma_{ij} = 0, \sum_{i=1}^{3} \lambda_i = 0, \; and \quad \gamma_{ij} = \gamma_{ji},$$

Now, we specify the expenditure share equation of expenditure item i by applying the Roy's identity to equation (1):

$$\omega_i = \alpha_i + \sum_{j=1}^{3} \gamma_{ij} ln\, p_j + \beta_i \ln\left(\frac{m}{a(\boldsymbol{P})}\right) + \frac{\lambda_i}{b(\boldsymbol{p})}\left[ln\left\{\frac{m}{a(\boldsymbol{p})}\right\}\right]^2, \qquad i\epsilon\{1, 2, 3\} \tag{3}$$

Where ω_i is the household's budget share for expenditure category i, and where we only consider expenditure on three items: food (1), medicine (2) and education (3), ω_i is defined as:

$$\omega_i \equiv \frac{p_i q_i}{\sum_j p_j q_j} = \frac{p_i q_i}{m}, \qquad j\epsilon\{1, 2, 3\}$$

Here q_i is the quantity of item i and p_i is the price/cost of expenditure category j, m is the household income spent on food, medicine and education, and P is the overall price index of these three items. To estimate the system of equations of expenditure shares, we need to use a nonlinear estimation technique because of nonlinear price index $a(\boldsymbol{p})$. Some studies suggest using some linear approximation for this nonlinear price index (Deaton & Muellbauer, 1980). However, with modern computing power, we can now estimate this nonlinear price index using any standard computing software.

4.2 Demographics

Household and household head characteristics can be incorporated into the QUAIDS framework using the scaling techniques first used by Ray (1983). Poi (2002), using this scaling technique, introduces the demographic variables into the QUAIDS model. Suppose **Z** is the vector of demographic variables, which includes the set of household controls such as location, and household head's characteristics, such as age, education, sex, religion, etc. We denote the expenditure function by $e(\boldsymbol{p}, u)$. Ray's scaling method decomposes the expenditure function into a scaling function, which depends on prices, level of utility and demographics, and an expenditure function, which depends on prices and level of utility only. More specifically:

$$e(\boldsymbol{p}, u, \boldsymbol{Z}) = m_0(\boldsymbol{p}, u, \boldsymbol{Z}) \times e(\boldsymbol{p}, u)$$

Here the scaling function $m_0(\boldsymbol{p}, u, \boldsymbol{Z})$ takes the following form:

$$m_0(\boldsymbol{p}, u, \boldsymbol{Z}) = \overline{m}_0(\boldsymbol{Z}) \times \phi(\boldsymbol{p}, u, \boldsymbol{Z})$$

Where $\overline{m}_0(\boldsymbol{Z})$ is the part of scaling function that depends on demographics only, that is, a larger family will have a larger expenditure on food compared to a smaller family and a family with more school-aged children is likely to have higher educational expenditure than a family with no school-aged child. The second part $\phi(\boldsymbol{p}, u, \boldsymbol{Z})$ accounts for interaction between consumption pattern and the demographics, that is, a family with a member with diabetes may consume different types of food compared to a family with no such member. Ray (1983) parameterize $\overline{m}_0(\boldsymbol{Z})$ and $\phi(\boldsymbol{p}, u, \boldsymbol{Z})$ as follows:

$$\overline{m}_0(\boldsymbol{Z}) = 1 + \rho' \boldsymbol{Z}$$

$$\phi(\boldsymbol{p}, u, \boldsymbol{Z}) = \frac{u \prod_{j=1}^{3} p_j{}^{\beta_j} \left(\prod_{j=1}^{3} p_j{}^{\eta_j' Z} - 1 \right)}{\frac{1}{u} - \sum_{j=1}^{3} \lambda_j \; ln\, p_j}$$

Where ρ and η are vectors of parameters to be estimated. Hence, the expenditure share equations specified in (3) become:

$$\omega_i = \alpha_i + \sum_{j=1}^{3} \gamma_{ij} ln\, p_j + (\beta_i + \eta_j' \mathbf{Z}) \ln \left(\frac{m}{\overline{m}_0(\boldsymbol{Z}) a(\boldsymbol{P})} \right) + \frac{\lambda_i}{b(\boldsymbol{p}) c(\boldsymbol{p}, \boldsymbol{z})} \left[ln \left\{ \frac{m}{\overline{m}_0(\boldsymbol{z}) a(\boldsymbol{p})} \right\} \right]^2 \quad (4)$$

Where $c(\boldsymbol{p}, \boldsymbol{z}) = \prod_{i=1}^{3} p_i{}^{\boldsymbol{\eta}_i' \boldsymbol{z}}$ and we have an additional adding-up condition: $\sum_{i=1}^{3} \eta_i = 0$.

4.3 Construction of price indices

The QUAIDS model in our paper uses broad expenditure items, such as food, medicine (insulin), and education. These expenditure categories are a sum of many other expenditure items. For example, food is sum of food and beverage, whereas food is classified into different items, such as grains, pulses, fish, milk and dairy, sweetmeat, oils and fats, fruits, spices, etc. Each of these food items is further disaggregated into finer types, for instance, food grains include expenditure on rice, wheat, flour, and others, and each of these items is even further disaggregated (e.g., rice is classified into fine, medium, coarse, beaten, pop, and puffed). The HIES (2016) provides information on prices and quantities of each of these finer expenditure items. Thus, we construct a price index for food, which is the weighted average of each of these finer expenditure items under food, where the weight is the share of monthly total food expenditure for each of these items.

For medicine, we use only chronic medicine expenditure for individuals who suffer from only diabetes and no other chronic disease. About half of the households in our sample have only one member suffering from diabetes. For households with more than one member with diabetes, we use average medicine expenditure for these households, that is, sum the total expenditure on medicines for diabetes and divided this by the total number of household members with diabetes. These average monthly expenditure on chronic medicines is used as the price of medicines, where the total monthly expenditure on diabetes medicines by the household is used to calculate the share of medicine expenditure share. For education, households face a variety of costs, including admission fees, tuition fees, annual session fees, registration fees, and examination fees among others. We sum all the costs related to education for each individual in a household and then divide this sum by the number of members attending school in the household. This is then used as the price of education, whereas the total household expenditure on education is used to calculate the share of education expenditure.

4.4 Elasticities

With the price indices in hand, we then move to estimate elasticities. The uncompensated price elasticity of demand for good i with respect to the price of good $j(\epsilon_{ij})$ is derived in Poi (2012) and given by:

$$\epsilon_{ij}^{h} = \frac{d\ln q_i}{d\ln p_j} = -\,\delta_{ij} + \frac{1}{\omega_i}\left(\gamma_{ij} - \left[\beta_i + \eta_i'\boldsymbol{Z} + \frac{2\lambda_i}{b(\boldsymbol{p})c(\boldsymbol{p},\boldsymbol{Z})}\ln\left\{\frac{m}{\overline{m}_0(\boldsymbol{Z})a(\boldsymbol{p})}\right\}\right] \times \left(\alpha_j + \sum_k \gamma_{ik}\ln p_k\right) - \frac{(\beta_j + \eta_j'\boldsymbol{Z})\lambda_i}{b(\boldsymbol{p})c(\boldsymbol{p},\boldsymbol{Z})}\left[\ln\left\{\frac{m}{\overline{m}_0(\boldsymbol{Z})a(\boldsymbol{p})}\right\}\right]^2\right)$$

Where $\delta_{ij} = 1$ if $i = j$, and 0 otherwise, and h is the index for households. The expenditure or income elasticity for good i (μ_i) is derived as:

$$\mu_i^h = \frac{d\ln q_i}{d\ ln\ m} = 1 + \frac{1}{\omega_i}\left[\beta_i + \eta_i'\boldsymbol{Z} + \frac{2\lambda_i}{b(\boldsymbol{p})c(\boldsymbol{p},\boldsymbol{Z})}\ln\left\{\frac{m}{\overline{m}_0(\boldsymbol{Z})a(\boldsymbol{p})}\right\}\right]$$

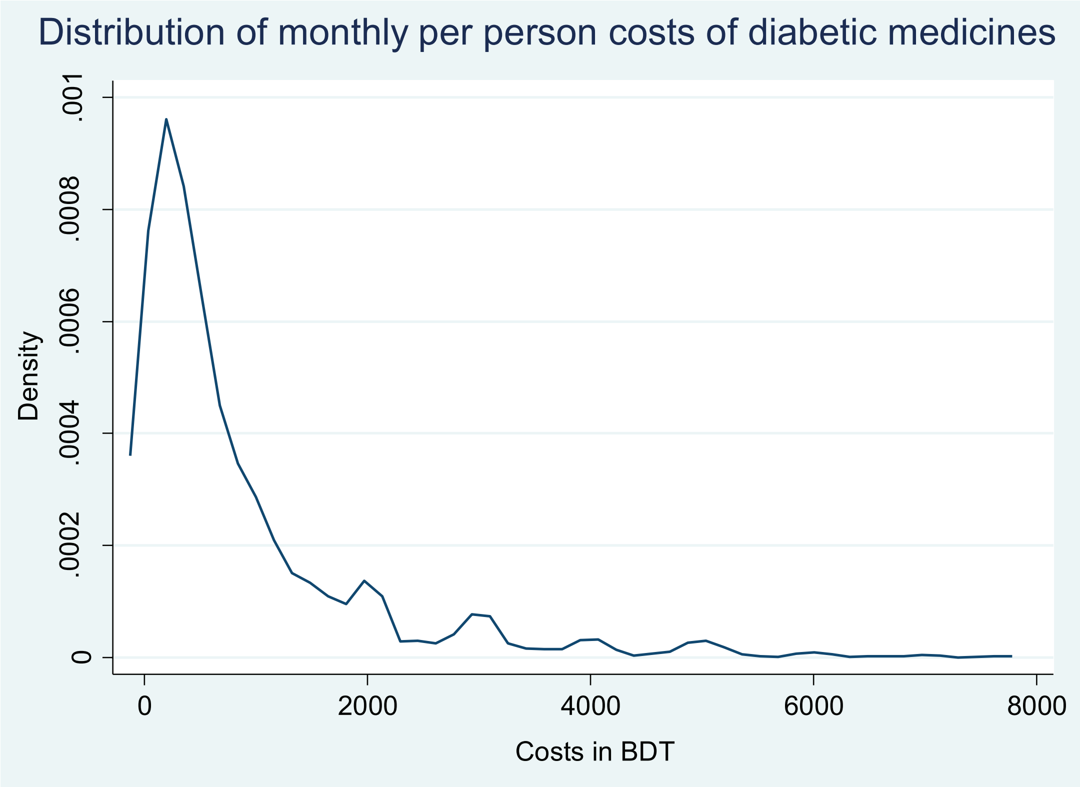
The formula for price elasticities here are at the household level. To find the price elasticities at market level, we need to aggregate the individual price elasticities as follows:

$$E_{ij} = \sum_h \epsilon_{ij}^h \frac{p_i^h q_i^h}{\sum_h p_i^h q_i^h}$$

Here $p_i^h q_i^h$ is total expenditure on item i by household h, and $\sum_h p_i^h q_i^h$ is the total expenditure on item i by the all households.

4.5 Econometric issues

The HIES (2016) does not provide any information on whether a household with a person who is living with diabetes needs to purchase insulin for that member, so to estimate the demand parameters and elasticities for insulin demand, we construct a sample which has the highest probability of including the households that purchase insulin. For this purpose, we use the maximum retail price of each registered insulin to estimate the cost per daily dose (DDD) as defined by WHO, and then calculate the monthly cost of insulin for an individual. Firstly, we estimate the bounds on insulin cost per month for an individual and our calculation shows that the monthly cost of using only insulin lies between BDT 436 to 1925. Secondly, for the purpose of this study we assume that the individuals who use only non-insulin diabetes medicines using the lower bound of the above mentioned price interval of insulins. That is, individuals whose monthly cost of diabetes medicines is below BDT 436 are assumed to use only non-insulin diabetes diabetes medicines. The distribution of costs of diabetes medicines is shown below:



From the distribution of costs of diabetes medicines, we obtain that around 35 percent of observations (424 out of 1211) are below the lower bound BDT 436. Thus, the proportion of households using only insulin, insulin plus non-insulin, or expensive non-insulin medicines is about 65 percent. Hence our sample for the analysis is the 35 percent of households with at least one member with diabetes in which per person costs of medicines are between BDT 436 and 1925. Here, we don't include households with members suffering from diabetes along with other chronic illnesses. Our assumptions seem plausible given that recently, Mohiuddin (2019) found that about 15 percent of patients patient with diabetes use only insulin, whereas Islam et al. (2017) found that about 41 percent of patients with diabetes use insulin in Bangladesh (Islam, et al., 2017; Mohiuddin, 2019)

Since our sample includes only those households which have at least one member with diabetes and per person costs of medicines between BDT 436 and 1925, the bounds on the cost of medicines ensures that our sample includes almost all the households spending on insulin, however, this does not ensure the exclusion of households whose expenditures on medicine fall within the bounds but these expenditures are not on insulin. This may introduce a sample selection bias into our estimation. To minimize this bias, we perform a Heckman type correction for selection bias. This correction is performed in two stages: In the first stage we estimate the following Probit model:

$$Prob\ (D = 1|X) = \Phi(X\theta) \tag{5}$$

Where X is the vector of explanatory variables that includes different individual characteristics such as age, gender, education, ethnicity, etc., and individuals' household characteristics such as household income, location, religion, household head's education, age, gender, etc., θ is a vector of unknown parameters, and Φ is the cumulative distribution function of the standard normal distribution. Here vector X could be same as Z or different than Z, that is, we can use the variable vector Z in place X, or we could use a subset of Z with some other control variables to construct X. The indicator variable D is defined as:

$$D = \begin{cases} 1, if\ monthly\ cost\ of\ diabetic\ medicine\ is\ less\ than\ BDT\ 436 \\ 0,\ \ otherwise \end{cases}$$

Estimation of this Probit model yields results that can be used to predict the probability for each individual with diabetes that uses only non-insulin diabetes medicines given the various individual and household characteristics. We use this estimated Probit model to predict the probability that an individual uses only non-insulin diabetes medicines for our sample, individuals with diabetes with monthly costs more than BDT 436. These predictions will be unbiased and consistent if the error terms in the Probit model are uncorrelated with control variables and are normally distributed. After estimating this Probit model, we obtain the correlation between the predicted values and the residuals of the model and this correlation is almost 0 (-0.0004). So, we can maintain the assumption that the error terms of Probit model and the set of control variables are uncorrelated. Assuming that these assumptions are satisfied, we estimate the probabilities that the individuals using only insulin or insulin with other non-insulin medicines in our sample using the estimated Probit model:

$$Prob\ (D = 0|X) = 1 - \Phi(X\hat{\theta}) \tag{6}$$

Using these estimated probabilities, we estimate the inverse Mills' ratio as follows:

$$\xi\big(X\hat{\theta}\big) = \frac{\Phi(X\hat{\theta})}{1-\phi(X\hat{\theta})} \tag{7}$$

Where ϕ is the probability density function. After estimating the inverse Mills' ratio, we estimate the QUAIDS model, where now Z includes $\xi(X\hat{\theta})$as an additional control along with other control variables described above. Assuming that the error terms are jointly normal, we estimate the QUAIDS model including Mills' ratio as an additional demographic variable.

Second issue in the estimation of QUAIDS model is that the costs of diabetes medicines might be correlated with other unobserved individual or household characteristics (Islam et al., 2019). To overcome this problem, we construct an instrumental variable (IV) for the cost of diabetes medicines. To construct this IV, we argue that cost of diabetes medicines of an individual might be correlated with unobserved individual and household characteristics, but these unobserved characteristics are orthogonal to cost of medicines of individuals residing in the same geographic area. Thus, we use the average cost of medicines in the smallest geographic unit of HIES as the IV for cost of diabetes medicines as price or cost of diabetes medicines are correlated within a same geographic region, but orthogonal to a specific individual's or household's characteristics, where the average is calculated by leave-one-out method. That is, IV for the cost of medicines for individuals in household *h* residing in the region *r* is the average of cost of medicines for all individuals residing in the same region *r* except members of household *h*. Let's call this IV as IV_1, so IV_1 is given by:

$$IV_{1hr} = \frac{\sum_{h\epsilon r\backslash h} p_{dhr}}{N_r} \tag{8}$$

Where IV_{1hr} is the IV for cost of medicines of individuals in household h in the region r, p_{dhr} is the cost or price of diabetes medicines of an individual in household h in the region r, $\sum_{h\epsilon r\backslash h} p_{dhr}$ is the sum of cost of diabetes medicines of all individuals in region r except the diabetes individuals with diabetes in household h, and N_r is the total number of diabetes individuals with positive cost of medicines in region r.

Another issue in estimating the demand parameters is that error terms u may be spatially correlated as costs of diabetes medicines are generally correlated with the types of health care provider such as public hospitals, private hospitals, pharmacy, etc., and we have certain types of health care providers in a given region (Islam et al., 2019). This may introduce heteroscedasticity in the QUAIDS model and hence reduce the efficiency of the estimators. To eliminate the heteroscedasticity due to spatial correlation in error terms u, we cluster the standard errors at the Union/Ward level, which is the lowest administrative unit in Bangladesh.

4.6 Computing counterfactual price changes

To determine the range of potential increases in the prices of insulin following Bangladesh's graduation from LDC, we use estimated demand elasticities to compute the ranges of markups and marginal costs based on the current prices of insulin and insulin market structure. Since the expenditure items in our QUAIDS model is defined broadly, i.e. food, medicine, and education, it is expected that the price elasticities of demand would be very low and hence it would be impossible to determine the insulin prices under the monopoly market structure ensured by the stronger IP laws as a consequence of LDC graduation as a monopoly's equilibrium output is always at the elastic part of the market demand curve. Hence, to compute the counterfactual prices of insulin under monopoly market structure, we need to estimate the slope of the demand function of insulin so that we can use this slope to estimate the price elasticities of demand at different points on the demand curve. This estimated elasticity is then used to derive the optimal monopoly markup. Here we assume that the market demand for insulin is linear in insulin prices and estimate this linear demand function by estimating the following regression equation:

$$\omega_2 = \varphi_0 + \varphi_1 p_2 + \varphi_2 \bar{\omega} + Z'\Omega + \mathrm{u} \tag{9}$$

Where ω_2 is the household expenditure on insulin, p_2 is the price of insulin faced by the household, $\bar{\omega}_2$ is the minimum level of income necessary to ensure subsistence level of food consumption for the household. $\bar{\omega}$ is calculated by multiplying the household size and the national lower poverty level income as reported in the final report of HIES 2016 (BBS, 2019), Z' is the vector of household and household head's characteristics, u is the error term, and φ_0, φ_1, φ_2, Ω are parameters to be estimated. Here the main parameter of interest is φ_1, which then is used to calculate the slope of the insulin demand curve with respect to insulin price as follows:

$$\frac{d\omega_2}{dp_2} = \frac{d(p_2 q_2)}{dp_2} = q_2 + p_2 \frac{dq_2}{dp_2} = \hat{\varphi}_1$$
$$\bar{b} = \frac{dq_2}{dp_2} = \frac{\hat{\varphi}_1}{\bar{p}_2} - \frac{\bar{q}_2}{\bar{p}_2} \tag{10}$$

Where $\bar{b}$ is the slope of the demand curve evaluated at the average price and quantity of the insulin. We also verify the estimate of slope of inverse demand curve using the own price elasticity of insulin demand obtained from our QUAIDS model as follows:

$$0 = p_2 + q_2 \frac{dp_2}{dq_2} = 1 + \frac{1}{E_{22}} \tag{11}$$

$$\frac{dp_2}{dq_2} = 1 + \frac{1}{E_{22}} - \frac{\bar{p}_2}{\bar{q}_2} = \frac{1}{\bar{b}} \tag{12}$$

Where we use the fact that at the midpoint of the demand curve, marginal revenue is 0. Once we have the estimated slope of the insulin demand curve, we can estimate the price elasticities of the insulin demand curve:

$$E_{22} = \bar{b}\frac{p_2}{q_2} \tag{13}$$

Now, we can find the elasticities at different points of the demand curve. With these estimated elasticities, we can find the optimal markup for the monopoly. In addition to simulating the counterfactual markup and price under monopoly market structure, we also use the average insulin price in Pakistan, where the pharmaceutical market is less regulated and strong IP laws govern the market (Basant, 2007). Nevertheless, most of the insulins are very affordable in Pakistan compared to rest of the south Asian countries and the main reason that a stronger IPR regime did not lead to exorbitant price increases for insulin is the provision of significant supply of insulin from the public sector (Ewen et al., 2019). In Pakistan the state has subsidized the price directly, which lowers the market prices of similar insulins by creating a competitive pressure on private suppliers. The reason that we choose current insulin prices in Pakistan as another counterfactual price is: (1) this provides an interesting scenario where strong IP laws coexist with public sector participation, which enables greater access to insulins, and (2) the size of the economy of Pakistan is comparable to Bangladesh economy. Thus, we use the simulated insulin price under monopoly market and average insulin prices in a neighboring country Pakistan to measure the welfare effect of stronger IPR regime in Bangladesh with no LDC status.

4.7 Welfare analysis

To have insights into the welfare effects of a stronger IPR regime in post-LDC Bangladesh under two counterfactual prices: simulated prices under monopoly market structure and prices in a less regulated neighboring country Pakistan, we use a number of measures of welfare as elaborated by Araar and Verme (2016). Our first measure is the consumer surplus (CS), defined as the difference between willingness to pay and market price of insulin. The measure of CS is given as follows:

$$CS = \int_{p_2}^{p_{2'}} D(p_2)dp_2 \tag{14}$$

Where p_2 and $p_{2'}$ are the current and counterfactual prices of insulin, $D(p_2)$ is the demand function of insulin. Here to estimate the CS we need to know the Marshallian demand function $D(p_2)$. For a linear demand system and moderate change in prices, CS can be estimated using the following equation:

$$CS = -x_2\Delta p_2(1 + 0.5E_{22}\Delta p_2) \tag{15}$$

For the problem concerned in this paper, the price changes could be significantly higher and so the above formula will provide highly overstated estimate for CS. Araar and Verme (2016) derived an approximation CS formula for a large price changes:

$$CS = -x_2 \Delta p_2 (1 - 0.5 \Delta p_{22} / (1 + \Delta p_2)) \tag{16}$$

CS as a measure of welfare is somewhat restrictive as it assumes that marginal utility of real income is constant and there is no distributional effect of price changes. It also captures only the partial equilibrium effects and does not perfectly measure the change in welfare if the changes in prices are large. However, CS is a straightforward and easy to estimate welfare measure, which would be a good standard to compare with other measures of welfare. The next two welfare measures that we estimate are Compensating Variation (CV) and Equivalent Variation (EV). These measures are defined as follows:

$$CV = e(p_2, v^0) - e(p_{2'}, v^0) = \int_{p_2}^{p_{2'}} h(p_2, v^0) dp_2 \tag{17}$$

$$EV = e(p_2, v^1) - e(p_{2'}, v^1) = \int_{p_2}^{p_{2'}} h(p_2, v^1) dp_2 \tag{18}$$

Where v^0 and v^1 are levels of generic indirect utility before and after the implementation of a stronger IPR regime, respectively, e(.) is the generic expenditure function, and h(.) is the Hicksian demand function. Here the CV is the monetary compensation required to bring the consumer back to the original utility level after the price change and the EV is the monetary change required to obtain the same level of utility after the price change (Araar & Verme 2016). One computational problem in calculating CV and EV is that we need to know the indirect utility level before or after the changes in prices. One solution to this computational problem is to derive the CV and EV from CS as given in Chipman and Moore (1980):

$$CV = \left(1 - e^{-CS/m}\right)m \tag{19}$$

$$EV = \left(e^{CS/m} - 1\right)m \tag{20}$$

Where m is the income level. In addition to these measures of welfare, there are two simple straightforward measures of welfare: Laspeyers Variation (LV), which is defined as the exact change in income necessary to purchase the initial bundle of goods at prices after and before the change in the IPR regime and is defined as:

$$LV = e(p_2', X^0) - e(p_2, X^0) \tag{21}$$

Where X^0 is the initial bundle of good purchased before the change in prices. The second measure is the Paasche Variation (PV), which is defined as the exact change in income required to purchase the final bundle of goods at prices after and before the change in the IPR regime and is given by:

$$PV = e(p_2', X^1) - e(p_2, X^1) \tag{22}$$

Where X^1 is the final bundle of goods purchased after the change in prices due to change in the IPR regime. To estimate the LV or PV, we just need the information of quantity purchased before or after the change in the policy regimes and the associated changes in prices, whereas to estimate the other measures of welfare requires some knowledge or assumptions on the demand function or the utility function.

5. Results

5.1 Price and expenditure elasticities

Table B.1 in the appendix reports the parameter estimates of our QUAIDS model. The estimated uncompensated price elasticities and expenditure elasticities are reported in the table 5.1. Here all these elasticities are the average elasticities across all households in the sample. The price elasticities are reported in panel A and are denoted as E_{ij}, where subscript *i* denotes the expenditure item *i* and *j* denotes the price of expenditure item *j*. The elasticities E_{11}, E_{22}, and E_{33} are own price elasticities of food, medicine (insulin), and education, respectively. Here all of these own price elasticities are negative as expected

Table 5.1: Uncompensated price and expenditure elasticities of major expenditure items in Bangladesh.

	Not corrected		Corrected	
	OLS	IV	OLS	IV
A. Price elasticities				
E_{11}	−0.995***	−0.994***	−0.995***	−0.996***
E_{12}	−0.023***	−0.023***	−0.022***	−0.019***
E_{13}	−0.011***	−0.002***	−0.012***	−0.016***
E_{21}	−0.069***	−0.046***	−0.069***	−0.020***
E_{22}	−0.491***	−0.893***	−0.499***	−0.961***
E_{23}	−0.225***	0.193***	−0.227***	0.194***
E_{31}	0.033***	−0.094***	0.034***	−0.144***
E_{32}	−0.468***	0.317***	−0.467***	0.353***
E_{33}	−0.291*	−1.339***	−0.269	−1.030***
B. Expenditure elasticities				
E_1	1.023***	1.031***	1.023***	1.039***
E_2	0.216***	0.067	0.235***	0.252***
E_3	1.160***	1.163***	1.135***	0.865***

Source: Estimates of QUAIDS model using HIES 2016 data.

Note: ***p<0.01, **p<0.05, *p<0.1.

and highly statistically different from 0. The estimate of own price elasticity of food, E_{11}, is consistently estimated across different models, E_{11} ranges from 99.4 percent to 99.6 percent under different specifications. However, the estimates of elasticities of insulin and education are significantly different in different specifications. The own price elasticities of insulin vary from 49.1 percent to 96.1 percent, whereas the own price elasticities of education vary from 26.9 percent to 133.9 percent under various specifications. However, we think that the estimates of elasticities are the most reasonable under IV estimation, especially with correction for sample selection bias, where insulin has inelastic demand ($E_{22} = -0.961$), food has almost unit elastic demand ($E_{11} = -0.996$), and education has slightly elastic demand ($E_{33} = -1.03$).

The cross-price elasticities show interesting demand patterns as well. The cross-price elasticities between food and medicine (insulin), E_{12} or E_{21}, are always negative under all specifications and statistically different from 0. This indicates that food and medicine are complement to each other and increase in prices of one of these expenditure items lead to lower demand for both of these items. The cross-price elasticities of education with food or medicine are not consistent across various specifications, E_{13} is always negative, whereas E_{31} is negative under IV estimation but positive under OLS estimation and all of these cross-price elasticities are statistically different from 0. Similarly, E_{23} and E_{32} are negative under OLS estimation but positive under IV estimation. Thus, the relationship between education and food might be weakly complementary whereas the relationship between education and medicine seems to be weakly substitutable.

Expenditure elasticities are all positive indicating that all of these expenditure items are normal goods. The expenditure elasticities of food are very consistently estimated under the different specification, narrowly vary from 102.3 percent to 103.9 percent, are significantly different from 0. This shows that an average household will increase the expenditure on food if its income goes up and this increase is slightly more than one-to-one proportion. So, food for an average household in Bangladesh is slightly luxurious item. The expenditure elasticities of insulin vary from 6.7 percent to 25.2 percent under various specifications and this satisfies the prior expectation that household may increase the expenditure on medicine when it receives more income but this increase would be significantly less than one-to-one proportion. Similarly, the expenditure elasticities of education are mostly greater than 1 indicating education is also a slightly luxurious item for an average household in Bangladesh.

For estimating the welfare effects of stronger IPR provisions for pharmaceutical industry, especially for insulin market, in Bangladesh, we use only the own and cross-price elasticities of medicine (insulin).

5.2 Marginal costs and markups

We use the insulin's own price elasticities and the current market structure of insulin in Bangladesh to compute the marginal costs and markups. These marginal costs are then used to estimate the equilibrium under a counterfactual monopoly scenario, which is supposed to prevail in the market for insulin in Bangladesh following her graduation from the LDC status. Currently, insulin is supplied by a number of producers and domestic pharmaceutical firms are also allowed to produce insulin. Hence, currently the market for insulin in Bangladesh is oligopolistic and to find the markups in this market, we assume that marginal cost of producing insulin is constant and same for all producers. Now, if there are *n* firms in the market with same marginal cost, c, the profit maximization of firm *i* is:

$$\pi_i = [P(Q) - c]Q_i$$

where $P(Q)$ is the inverse market demand and Q_i is the quantity of firm *i*. The first order profit maximization condition implies that:

$$\frac{P-c}{p} = -\frac{1}{n}\frac{Q}{P}\frac{dP}{dQ} = -\frac{1}{nE_D}\,.$$

The current insulin market in Bangladesh is to some extend competitive. There are seven domestic producers of insulin supplying 50 different insulin products in Bangladesh (DGDA 2019). The differences in these products are in terms of dosages size and the producers. In addition, there are six foreign producers, which have registered 65 insulin products in Bangladesh (DGDA 2019). The licenses of products of two foreign producers have expired as of 2019. Hence, currently there are 11 suppliers of insulin in Bangladesh. Thus, the markup is given by the following formula $\left(\frac{1}{1-\frac{1}{11*E22}}\right)$. The marginal costs are calculated by using the bounds of insulin prices, which is paid by a household for one month of insulin supply. We use the maximum retail prices reported by DGDA to estimate this monthly expenditure on insulin, which is found to be between BDT 436 and BDT 1925. Using the estimated markups and the bounds on the monthly expenditure on insulin, we estimated the upper and lower bounds of marginal costs for one-month supply of insulin. The estimated markups and bounds of marginal cost of one-month insulin supply are reported in the table 5.2.

From the table 5.2, we can see that the current markups range from 1.104 to 1.227 reflecting the fact that current market is characterized by some competitive forces as the markups are around 110 percent of marginal cost (MC) when we use the elasticity

Table 5.2: Implied markups under current market structure of insulin

	Not corrected		Corrected	
	OLS	IV	OLS	IV
Markups	1.227	1.113	1.223	1.104
MC (Upper bound) BDT	1568.59	1729.03	1574.3	1742.9
MC (Lower bound) BDT	355.27	391.61	356.57	394.76
P_{22} (Upper bound) BDT	1924.66	1924.41	1925.57	1924.16
P_{22} (Lower bound) BDT	435.92	435.86	436.09	435.82

Source: Estimated using HIES 2016 and DGDA data.

under IV estimation with sample selection correction. Only considering the OLS estimates of elasticities, the markup would be at most 123 percent of the MC. The upper and lower bound of MC ranges from BDT 1569 to 1743 and BDT 355 to 395, respectively. These bounds reflect the end user MC rather than the MC at the production level. Thus, these are the MCs of all value added of insulin production: from production to final purchase by the households.

5.3 Demand function of insulin and counterfactual prices

We estimate the insulin demand function as specified in regression equation (9) using the IV for insulin prices. The reason that we use IV for insulin prices instead of insulin cost faced by the household is that the total monthly expenditure on insulin by the household is directly proportional to the cost of insulin faced by the household. The result of the regression equation (9) is reported in appendix in table B.3. The estimates of the coefficient of insulin price (p2IV) are negative under the estimation strategy of not correcting or correcting for sample selection bias. We use the estimate of the coefficient of p2IV in regression equation corrected for sample selection bias and this estimate is $\hat{\varphi}_1 = -0.147$. Then the estimated slope coefficient, $\bar{b} = -0.00141$, is given by:

$$\bar{b} = \frac{dq_2}{dp_2} = \frac{\hat{\varphi}_1}{\bar{p}_2} - \frac{\bar{q}_2}{\bar{p}_2} = \frac{\hat{\varphi}_1}{\bar{p}_2} - \frac{\bar{p}_2\bar{q}_2}{\bar{p}_2{}^2} = \frac{-0.1475}{884.16} - \frac{973.33}{884.16^2} = -0.0014,$$

where 973.33 is the average monthly household expenditure on insulin and 884.16 is the average of monthly price of insulin, both are in BDT. Now, the elasticity of insulin demand at the average price and quantity of insulin is given by:

$$E_{22} = \bar{b}\frac{\bar{p}}{\bar{q}} = \bar{b}\frac{\bar{p}^2}{\bar{p}\bar{q}} = -0.00141 \times \frac{884.16^2}{973.33} = -1.13399.$$

Using this elasticity of insulin demand measured approximately at the mid-point of the insulin demand curve, we can find the maximum markups of insulins which will enjoy a monopoly market under stricter IPR laws in Bangladesh following her graduation from LDC status. The maximum markup is thus given by:

$$\left(\frac{1}{1 - \frac{1}{E22}}\right) = \frac{E_{22}}{1 + E_{22}} = 8.46.$$

This markup shows that under an unregulated monopoly, the insulin price could be more than 8 times higher compared to current insulin prices, where the current markup of insulin in Bangladesh ranges from 1.1 to 1.23. Using the estimated markup under an unregulated monopoly and the upper and lower bounds of MC as reported in Table 5.2, we estimate maximum possible counterfactual prices of insulin, which are reported in the following table 5.3.1. These counterfactual prices show the most extreme situations of increase in insulin prices in Bangladesh following her graduation from the LDC status and enforcing strong IPR laws. Thus, these provide some bounds on the prices of insulin in a worst case scenario.

Table 5.3.1: Markup and bounds on maximum counterfactual prices of insulin under monopoly

	Not corrected		Corrected	
	OLS	IV	OLS	IV
MC (Upper bound) BDT	1,568.59	1,729.03	1,574.3	1,742.9
MC (Lower bound) BDT	355.27	391.61	356.57	394.76
P_{22}(Upper bound) BDT	13,270.27	14,627.59	13,318.58	14,744.93
P_{22}(lower bound) BDT	3,005.58	3,313.02	3,016.58	3,339.67
ΔP_{22}(Upper bound) BDT	11,345.61	12,703.18	11,393.21	12,820.77
ΔP_{22}(Lower bound) BDT	2,569.67	2,877.16	2,580.5	2,903.86

Source: Estimated using HIES 2016 and DGDA data.

In table 5.3.1, first two rows are the estimated marginal costs under different econometric specifications, which are the same as in table 5.2. Using the markup of 8.46, we estimate the counterfactual upper and lower bounds of insulin prices corresponding to lower and upper bounds of MCs, which are reported in the third and fourth rows of table 5.3.1. Here the upper and lower bounds of insulin prices are larger under IV estimation compared to OLS. In addition, we use the correction for sample bias in our estimation, we get slightly larger counterfactual prices. Counterfactual prices of insulin in our estimation varies approximately from 3006 BDT to 14745 BDT. These prices are the cost of insulin for households for one month. Since the average per household income in HIES 2016 is 15945 BDT (BBS, 2019), some households would require to use almost all of its monthly income to purchase the monthly supply of insulin under an unregulated monopoly scenario.

The last two rows show the magnitudes of increase in insulin prices under an unregulated monopoly cases, where the row of upper bound increase in insulin prices is the difference between the counterfactual upper bound of prices as reported in the third row of table 5.3.1 and the current upper bound of prices as reported in the third row of table 5.2. Similarly, the increase in insulin prices for lower bound is also calculated and shown in the last row of table 5.3.1. Considering the upper bound, the counterfactual prices of insulin could rise more than 12000 BDT under an unregulated monopoly, whereas for the lower bound counterfactual prices, an unregulated monopoly prices of insulin could be 2500 to 3000 BDT higher than the current prices of insulin.

For the Pakistan price counterfactual we use the average insulin prices reported in Ewen et al. (2019), where the insulin prices for a number of low and middle-income countries including Pakistan were surveyed in 2016. Since our sample is from HIES 2016, we use the insulin prices in Pakistan as reported in Ewen et al. (2019). These prices are shown in table 5.3.2.

In table 5.3.2, we only show the average insulin prices in the private sector: private pharmacy and hospital/clinics as reported in Ewen et al. (2019) but the public sector insulin price is very similar to private sector price for any specific type of insulin.

Table 5.3.2: Insulin prices in Pakistan in 2016 (1000 IU in USD).

	Cartridge				Vial	
	Private retail pharmacies		Private hospital/clinics		Private retail pharmacies	
	Original brand	Biosimilar	Original brand	Biosimilar	Original brand	Biosimilar
Short-acting human	5.81	4.5	5.81	4.72		
Intermediate-acting human	5.81	4.67				
30/70 human	5.15	4.48			5.82	7.89
Glargine analogue	28.6	20.65				

Source: Calculated using Table 2 in Ewen M, et al. (2019).

However, the Glargine analogue insulins are only available in private sector, particularly at the private retail pharmacies. The average insulin prices in Pakistan in 2016 ranges from about USD 4.5 to USD 7.89 except the glargine analogue. Using the BDT/USD exchange rates in June 2016 from Bangladesh Bank,[3] the central bank of Bangladesh, these average prices corresponds to BDT 352.8 to 618.58, whereas the average monthly cost of insulin per person in Bangladesh is about BDT 884.16. Since 1000 IU of insulin are approximately the monthly supply of insulin for an individual, so the average monthly insulin cost for most types of insulin are significantly higher in Bangladesh than of that in Pakistan. However, the long-acting insulins namely glargine analogues average prices are USD 20.65 to 28.65, which corresponds to BDT 1618.18 to 2246.16, which are higher than the average monthly insulin cost in Bangladesh. Here we use the price of original brand of glargine analogue in Pakistan as the counterfactual price of insulin in Bangladesh under a stricter IPR laws. To estimate the upper bound of price increase and loss in welfare, we take the difference between this price, BDT 2246.16 and the current monthly average cost of insulin per person Bangladesh, BDT 884.16, which implies a 154 percent increase in monthly cost of insulin in Bangladesh.

5.4 Welfare analysis

One of the important implications of Bangladesh's graduation from LDC status is the increase in expenditure by impacted households on essential medicines such as insulin, which will be protected under a stronger IPR regime. The increase in expenditure is straightforward to calculate and these are estimated using a fixed basket of three goods: a composite good namely 'food', medicine, and education. Hence, the welfare measures of the change in expenditure, LV and PV, are the same in this scenario. That is, we use the same quantities of these goods before and after the change in prices of insulin following the graduation, and so our measure of LV and PV are same. In addition, we measure the CS as outlined in equation (16), which then used to estimate the CV and EV. Here CV and EV both allow the change in the quantity of goods in response to an increase in insulin prices. These welfare estimates are reported in the table 5.4.1.

[3] The BDT/USD exchange rate for the month of June in 2016 is 78.4. https://www.bb.org.bd/econdata/exchangerate.php

Table 5.4.1: Annual aggregate welfare losses under an unregulated monopoly and neighbor price (in Millions of BDT and USD)

		Upper bound		Lower bound		Average price	Pakistan price counterfactual
		OLS	IV	OLS	IV		
LV=PV	BDT	38,431.08	43,244.52	8,704.44	9,795.12	22,248.72	4,581
	USD	490.2	551.64	111	124.92	283.8	58.44
CS	BDT	19,217.28	21,624	4,353.96	4,899.24	11,126.04	2,292.24
	USD	245.16	275.76	55.56	62.52	141.96	29.28
CV	BDT	22,581	25,965.72	4,508.28	5,095.44	12,185.4	2,334.36
	USD	288	331.2	57.48	65.04	155.4	29.76
EV	BDT	16,650.84	18,422.88	4,208.76	4,716.12	10,220.04	2,251.32
	USD	212.4	234.96	53.64	60.12	130.32	28.68

Source: Estimated using HIES 2016.

The welfare loss estimates in the table 5.4.1 are aggregate national level estimates. These welfare loss estimates are the aggregate welfare loss of all households with cost of medicine (diabetes) between BDT 440 and 1930, and these aggregates are weighted by the population weight of each household. The first two columns in table 5.4.1 show the welfare loss for the counterfactual increase in insulin prices with the correction for sample selection bias. Thus, the welfare losses under the column header 'Upper bound' correspond to upper bound price changes in columns 3 and 4 of table 5.3.1. Similarly, the welfare losses in columns 3 and 4 in table 5.4.1 correspond to lower bound price changes in columns 3 and 4 of table 5.3.1. The welfare estimates in column 5 of table 5.4.1 is calculated for the counterfactual price increase from the average price of BDT 884.16, that is, we use the estimated markup of 8.46 to find the counterfactual average price and then use the increase in prices to estimate the welfare losses as reported in column 5. The welfare loss estimates in the last column, column 6, of table 5.4.1 is calculated by using the originator's price of long-acting insulin glargine analogue in Pakistan, which is USD 28.6 or equivalently BDT 2246.16, and then we use the difference between this price and the average price of BDT 884.16 to estimate the welfare losses of column 6. All of these estimates of welfare loss show the worst case scenario, that is, the maximum welfare losses under an unregulated monopoly as a result of stronger IPR after Bangladesh graduation from LDC status.

The first row of table 5.4.1 is the measure of aggregate increase in household expenditures due to an increase in insulin prices following Bangladesh's graduation from LDC status. Here Laspeyers Variation (LV) and Paasche Variation (PV) measures are the same as we use the same composition of goods before and after changes in insulin prices. Here the upper bound of the aggregate increase in households' expenditure under an unregulated monopoly ranges from 490 to 550 million USD per year, whereas the lower bound ranges from 111 to 125 million USD per year. The aggregate increase in household expenditure would be significantly lower just about 58 million USD per year if the insulin prices in Bangladesh stay at a similar level of insulin prices in Pakistan.

The second row of table 5.4.1 reports the aggregate losses in consumer surplus (CS) under different econometric specification and counterfactual scenarios. CS is the difference between the value of consuming some quantity of a good and the price paid for this quantity of good. The upper bound of the loss in CS for an unregulated monopoly ranges from 245 million USD to 276 million USD per year, whereas the lower bound ranges from 55 million USD to 63 million USD per year. The loss in CS under the Pakistan price counterfactual is much lower at about 29 million USD. These figures are considerably lower than the corresponding figures of LV or PV. The reason that figures of loss in CS are lower than the figures of LV or PV is that under LV or PV we use the same quantities of goods before and after the change in the price of insulin whereas in CS the optimal quantity of each good would be different after the increase in insulin price from quantities of goods bought at the initial prices. Since the counterfactual price of insulin would be significantly higher than the initial price of insulin, the utility maximization implies that households will consume lower quantity of insulin when all other prices and income of households are constant and thus the losses in CS would be lower than the losses in LV or PV.

Compensating variation (CS) and equivalent variation (EV) are two most commonly used measures of welfare of a price change. Here CV is the amount of money that a household needs to be compensated to achieve the initial level of utility or the bundle of goods at the new prices whereas EV is the amount of money needed to obtain the new level of utility or new bundle of goods at the initial prices. For an increase in price of insulin, the relationship among loss in CS, CV and EV are as follows: CV > loss in CS > EV. From the figures in the table 5.4.1, we can see that these relationships are satisfied. From the figures in third (CV) and fourth (EV) rows in table 5.4.1, the annual aggregate loss in welfare under an unregulated monopoly as a result of stronger IPR laws in Bangladesh following her graduation from the LDC status will range from 288 million USD to 60 million USD. However, under the Pakistan price counterfactual, the annual loss in welfare would be around 29 million USD.

The welfare effect of an increase in insulin prices at the household level is shown in the table 5.4.2. Table 5.4.2 reports the increase in household expenditure and the increase in expenditure as a percentage of household average income per year for three counterfactual scenarios: largest upper bound estimate (Upper bound IV), smallest lower bound estimate (Lower bound OLS) and Pakistan price counterfactual estimates of increase in households' expenditure as a result of Bangladesh's transition to a non-LDC status.

The annual welfare impacts of stronger IPR laws could be from $58 million across impacted households (Pakistan subsidized price counterfactual) to an upper bound of $550 million across impacted household under an unregulated monopoly as reported in table 5.4.1. According to a review of the literature (Biswas et al. 2016), the incidence of people with diabetes in Bangladesh is estimated to be 4.5 to 35 percent of the population with the 'pooled preference' being 7.4 percent. The average number of people in a household in Bangladesh is 4.06 (BBS, 2019). The cost per impacted household would therefore be from 19.7 dollars per household in a year to 187 dollars per household in a year or a 3 to 31 percent decline in affected household incomes.

Table 5.4.2: Household level Welfare Analysis of Insulin increases in Bangladesh

	Incidence of diabetes (range of estimates according to Mohiuddin)			
	Total	**4.5%**	**7.4%**	**35%**
Population (2016)	161,356,000	7,261,020	11,940,344	56,474,600
Households		1,788,429	2,940,971	13,910,000
	Aggregate welfare	**Dollars per household per year**		
Increase in expenditure and welfare per household	58,000,000	32.4	19.7	4.2
	111,000,000	62.1	37.7	8.0
	550,000,000	307.5	187.0	39.5
	Average income per household	**Welfare as % of household average income**		
Impact per affected household (percent)	602	5%	3%	1%
		10%	6%	1%
		51%	31%	7%
Bangladesh GDP 2016	**Welfare as % of GDP**			
221,000,000,000	0.03%			
	0.05%			
	0.25%			

Source: HIES (2016), WDI (2016) and authors' calculation.

5.5 Poverty impact

Increase in the price of insulin as a result of stricter IP laws will also have significant impact for poverty incidence for households that require access to lifesaving insulins for the members with diabetes living in those households. To show the effect of a price rise in insulin on household poverty, we estimate the rate of poverty at the household level for the households with members with diabetes, especially with members needing insulin. Table 5.5.1 shows the absolute number of people and households and rates of poverty under upper and lower poverty lines at the overall national level, households with persons having diabetes and households with members requiring insulin.

Table 5.5.1: Initial level of poverty.

			Lower poverty line			Upper poverty line		
	Total household (Million)	**Total population (Million)**	**Hholds count (Million)**	**Head count (Million)**	**Poverty rate (%)**	**Hholds count (Million)**	**Head count (Million)**	**Poverty rate (%)**
1. Overall national	39.33	159.58	5.07	20.59	12.90	9.55	38.78	24.30
2. Households with diabetes	1.05	4.25	0.13	0.52	12.20	.21	0.84	19.73
3. Households needing insulin	0.38	1.54	0.03	0.11	7.23	0.04	0.18	11.80

Source: HIES 2016 final report and authors' calculation.

The first row of table 5.5.1 shows national level estimates. The second row shows the estimates of poverty for households with a member with diabetes. Similarly, the third row shows the estimates of poverty for households needing insulin. The first two columns of table 5.5.1 show the absolute number of households and individuals for three different populations: national, households with a person with diabetes and households needing insulin. Thus, there were 39.33 million households or 159.58 million people in Bangladesh as reported by the HIES (2016), whereas the number of households with at least one member with diabetes is 1.05 million to which 4.25 million individuals with diabetes belong. Among all the households with such members, there are 0.38 million households that require insulin for at least one member and there are about 1.54 million individuals with diabetes in those households that need insulin.

The next three columns show the poverty estimates under the lower poverty line, which is BDT 2365 according to the HIES (2016). Here the lower poverty line is equivalent to the food poverty line, and the upper poverty line is above the food poverty line, where the food poverty line is the cost of acquiring a basket of food that provides 2122 calories per person per day (BBS, 2019). Thus, a household that is categorized as extremely poor or falling below the lower poverty line where the household's total expenditure is less than or equal to the food poverty line and similarly, a household is defined as moderately poor or under the upper poverty line if the household's food expenditure is less than or equal to the food poverty line. There are 20.59 million people living in 5.07 million households who are under the lower poverty line, which is about 12.9 percent of the total population. Among the 1.05 million households with at least one member with diabetes, 0.13 million households are below the lower poverty line, which is about 12.2 percent of all households with at least one member with diabetes. Analogously, 0.03 million households out of 0.38 million households needing insulin are below the lower poverty line, which is about 7.23 percent. From these poverty estimates, we can see that the poverty rate is relatively lower for households with members living with diabetes, especially for households needing insulin.

The last three columns report the poverty estimates for the upper poverty line, which is BDT 2765 according to the HIES (2016). There are 38.78 million individuals living in 9.55 million households under the upper poverty line, which is about 24.30 percent of total population. Under the upper poverty line, the poverty rate for the households with at least one person with diabetes is about 19.73 percent, and for the households needing insulin is about 11.80 percent. That is, out of all households with at least one member with diabetes, 19.73 percent of households are below the upper poverty line and similarly, out of all households needing insulin, 11.80 percent households' income are below the upper poverty line. Here the pattern of poverty is very similar under the lower and upper poverty line.

To estimate the effect of increase in insulin prices on household poverty, we use the counterfactual price increase, estimated using OLS and IV with correction for sample selection bias, as reported in the last two columns and rows of table 5.5.2. We also estimate the effect on poverty for an increase in average price and increase in counterfactual Pakistan price as used in our welfare estimation. Under these different counterfactual price scenarios, we estimate the household poverty rates, which are shown in the table 5.5.2.

Table 5.5.2: Poverty rates after the increase in insulin prices

	Upper bound		Lower bound		Average price	Pakistan price counterfactual
	OLS	IV	OLS	IV		
A. Lower poverty line						
Overall national	13.32	13.35	13.00	13.01	13.17	12.94
Households with members with diabetes	28.35	29.58	16.20	16.74	24.53	14.04
Households need insulin	51.85	55.25	18.27	19.76	50.71	12.31
B. Upper poverty line						
Overall national	24.70	24.74	24.40	24.40	24.57	24.37
Households with members with diabetes	35.24	36.84	23.94	24.0 1	33.61	22.90
Households needing insulin	54.64	59.05	23.43	23.59	61.32	20.56

Source: HIES 2016 final report and authors' calculation.

Panel A of the table 5.5.2 shows the poverty rates under various counterfactual price scenarios when household poverty is estimated using lower poverty line. The first four columns show the poverty estimates for price changes corresponding to last two rows and columns of table 5.3.1. Here the overall national level of poverty rate ranges from 13.00 to 13.35 percent, which indicates an increase in poverty rates ranging from 0.05 to 0.41 percentage point from the initial level of poverty rates. Similarly, the poverty rates for households with persons having diabetes range from 16.20 to 29.58 percentage points or equivalently an increase ranging from 4.0 to 17.38 percentage points. Poverty rates for households needing insulin are much higher under the various counterfactual price scenarios than the initial level of poverty rates. Poverty rates for these households range from 18.27 to 55.25 percentage points, which indicates a significant increase ranging from about 11 to 48 percentage points under various counterfactual price scenarios.

The column under 'average price' shows the poverty rates for a 7.46 times increase in insulin price from the initial average price of BDT 884.16, where the markup is 8.46. Under this counterfactual price scenario, the overall national poverty rate rises to 13.17, a 0.27 percentage point increase in poverty rate. However, the poverty rates for households with members with diabetes and households needing insulin rise significantly from 12.20 to 24.53, and 7.23 to 50.71 percentage points, respectively, which show that the poverty rate for households with a member having diabetes doubles while the poverty rate for households needing insulin increases about 7 times from their initial level. The last column in table 5.5.2 in panel A shows the poverty estimates for the Pakistan price counterfactual, where the average insulin prices rise about 154 percent under the policy regime similar to current policy regime of IPR in Pakistan. In this Pakistan price counterfactual, as if many types of insulin are provided by the public sector in a similar manner in Pakistan, the impact on national level poverty is very minimal, poverty rate increases from 12.90 to 12.94 percentage points or just a 0.04 percentage point increase in poverty rate. Similarly, in this counterfactual price scenario, the poverty rate for households with a member with diabetes increases moderately, from 12.20 to

14.04 percentage point or equivalently 1.86 percentage point increase in poverty. However, even with a Pakistan-like subsidy, the poverty rate for households needing insulin still increases about 5 percentage points from 7.23 to 12.31 percentage points. Poverty estimates under the upper poverty line as reported in panel B in table 5.5.2 are very similar to those under the lower poverty line as in panel A.

The absolute numbers of households that would fall below the lower and upper poverty line as result of increasing price in insulin along with the percentage increase from the initial level are reported in the table 5.5.3.

Poverty estimates in the table 5.5.3 are reported only for the largest upper bound (IV estimates with correction for sample selection bias) and smallest lower bound (OLS estimates with correction for sample selection bias) of price changes and the price change under the Pakistan counterfactual policy regime. Panel A of table 5.5.3 provides the poverty estimates for lower poverty line and Panel B for upper poverty line. Three rows show the estimates at three level of aggregation: total national level, households with a member with diabetes and households needing insulin. The first column reports the initial figures of households under the two poverty lines. Initially, there are about 5.1 and 9.6 million people below the lower and upper poverty lines at the national level, respectively. The numbers of households that fall below the lower poverty line are about 5.3 and 5.1 million for the upper and lower bound of an unregulated monopoly counterfactual scenario, which are about 3.59 and 0.83 percent higher than the initial level. For Pakistan price counterfactual the increase is much smaller, only about 0.38 percent increase from the initial level of poverty.

Among all the households with at least one member with diabetes, about .13 million households are currently estimated to be below the lower poverty line, which increases to 0.31, 0.17 and .015 million under the three counterfactual scenarios, respectively.

Table 5.5.3: Absolute level of household poverty before and after the increase in insulin prices and percentage change.

	Households in poverty before price increase	Households in poverty after price increase			% increase in household poverty rates from the initial level		
		Upper bound monopoly	Lower bound monopoly	Pakistan price	Upper bound monopoly	Lower bound monopoly	Pakistan price
A. Lower poverty line							
Overall national	5,070,399	5,252,506	5,112,266	5,089,670	3.59	0.83	0.38
Households with diabetes	1,27,856	309,963	169,723	147,127	142.43	32.75	15.07
Households needing insulin	27,424	209,531	69,291	46,695	664.04	152.67	70.27
B. Upper poverty line							
Overall national	9,551,217	9,730,437	9,595,314	9,584,433	1.88	0.46	0.35
Households with diabetes	206,783	386,003	250,880	239,999	86.67	21.33	16.06
Households needing insulin	44,748	223,968	88,845	77,964	400.51	98.55	74.23

Source: Authors calculation using HIES 2016.

These increases represent a rise in poverty rates ranging from 15.07 to 142.43 percent from the current level of poverty for these households. Out of all households that require insulin, about 0.03 million of them fall below the lower poverty line, which increases by more than 660 percent to 209,531 under the upper bound and about 153 percent to 69,291 under the lower bound of an unregulated monopoly counterfactual scenarios. Under the Pakistan price counterfactual scenario, the number of households that fall below under the lower poverty line is 46,695, which is about 70 percent higher than the initial level. The pattern of increases in the poverty rates are similar under the upper poverty line. Even though the absolute numbers of households that fall under the upper poverty line are larger than those under the lower poverty line, the percentage increase in poverty rates show the opposite pattern under these two poverty lines and the reason is that the initial numbers of households that are below the upper poverty line are much larger than that of below the lower poverty line.

Table 5.5.3 reports the numbers of households that are below the lower and upper poverty lines and the percentage increase in poverty from the initial level of poverty under the various counterfactual price increase scenarios. We also estimated the poverty rates as a fraction of total households for three different aggregate levels. These estimates are shown in the table 5.5.4.

The first column of table 5.5.4 shows the initial level of poverty rates. Overall, there are 12.90 and 24.30 percent of total households below the lower and upper poverty lines. After the increase in insulin price under a stricter IPR policy regime, the fraction of total households that fall below the lower poverty line ranges from 12.95 to 13.35 under these three counterfactual scenarios, or an increase in poverty rates ranging from 0.05 to 0.45 percentage points. Similarly, among all the households with at least one person with diabetes, the fraction of households that will be under the lower poverty

Table 5.5.4: Poverty rates before and after the increase in insulin prices and percentage change.

	Household poverty rate before price increase	Households poverty rates after price increase			Percentage point increase in household poverty rates		
		Upper bound monopoly	Lower bound monopoly	Pakistan price	Upper bound monopoly	Lower bound monopoly	Pakistan price
				A. Lower poverty line			
Overall national	12.90	13.35	13.00	12.95	0.45	0.11	0.05
Households with diabetes	12.20	29.58	16.20	14.04	17.38	4.00	1.84
Households needing insulin	7.23	55.25	18.27	12.31	48.02	11.04	5.08
				B. Upper poverty line			
Overall national	24.30	24.74	24.40	24.37	0.46	0.11	0.08
Households with diabetes	19.73	36.84	23.94	22.90	17.10	4.21	3.17
Households needing insulin	11.80	59.05	23.43	20.56	47.26	11.63	8.76

Source: Own calculation using HIES 2016.

line increases from an initial 12.20 percentage points to somewhere between 14.04 to 29.58 percentage points, where the increase in poverty rates ranges from1.84 to 17.38 percentage points. We can see a very substantial increase in the household poverty among the households needing insulin. Here under the three different counterfactual scenarios, the fraction of households that fall below the lower poverty line among all the households needing insulin ranging from 12.31 to 55.25 percentage points from an initial poverty rate of 7.23 percentage points, which indicates an increase in poverty rates ranging from 5.08 to 48.02 percentage points for those households. We have a very similar pattern in increase in poverty rates when we use the upper poverty line instead of lower poverty line.

6. Discussion and conclusion

This paper built on previous theoretical and empirical insights in order to estimate the potential impact of Bangladesh's LDC graduation on that country's population living with diabetes in general and insulin users in particular. To date, few if any studies deploy an *ex-ante* partial equilibrium framework that estimates price changes due to trade policy change, and then links those results to household behavior models and data. We model, and then estimate, the potential impact of LDC graduation on the price of insulin in Bangladesh and then link those price changes. Following those estimates, we then estimate demand elasticities and link them to Bangladeshi household data to determine the impacts of those potential price changes in household wealth.

While this paper draws on some of the core theoretical and empirical articles in this literature, it has significant policy ramifications as well. Bangladesh has a high incidence of diabetes and insulin users, as well as a fairly thriving domestic industry that supplies those treatments to patients in need. We find that prices of insulin would increase significantly in Bangladesh due to LDC graduation and the subsequent requirement to comply with the intellectual property provisions of the WTO. What is more, such price changes would also have significant welfare impacts for the population. LDC graduation will trigger a significant jump in insulin prices that could cause a 5 to 50 percent decline in the welfare of households with diabetes in Bangladesh, increasing the poverty rate of households with diabetes from 20 to 36 percent and of those needing insulin from 11 to 60 percent unless policy adjustments are carried out.

Our estimates of the impact of increases in insulin prices under a stronger IP regime on household welfare and poverty in Bangladesh after her graduation from the LDC group has important data limitations. These limitations emanated from the lack of detailed expenditure information on medicines by the individuals with diabetes. The HIES 2016 of Bangladesh does not provide disaggregated data on types of diabetic medicines, i.e., whether an individual with diabetes needs insulin or non-insulin medicines as well as no information on the quantity of medicines per day or per month. To construct the sample for our analysis, we needed to infer the households needing insulin from the expenditure on medicines for chronic disease reported in HIES and compare this expenditure to an interval constructed using administrative data on monthly insulin cost. It is likely that there would be some households needing insulin but not included in our sample if the households' monthly expenditure on medicines fall below the lower bound of the cost of insulin constructed using administrative data. Similarly, there would be some households which do not need insulin but expenditure on medicines by those households fall within the interval. In the prior scenario, our household welfare and poverty estimates would be underestimated and in latter scenario, these would be overestimated. Hence, without additional information on medicine expenditure by the households with members living with diabetes, we could not determine the direction of bias that our constructed sample may induce.

Another data limitation in HIES is that it seems to underrepresent the fraction of population suffering from diabetes. In the HIES 2016, there are 186,078 individuals included in the survey but only 2,238 individuals are reported to be living with diabetes, which is about 1.2 percent of the sample. However, it has been estimated that about 10 percent of population are suffering from diabetes, half undiagnosed (WHO, 2016). Hence, we would expect about 5 percent of the individuals in our sample to report a diagnosis of diabetes. The underrepresentation of individuals with diabetes in HIES would also cause a downward bias in estimation. Thus, in this case our estimated effects of increase in insulin price on household's welfare and poverty are conservative estimates, which signifies the fact the true welfare cost of a stricter IP regime in Bangladesh after her graduation from LDC group would be significantly higher.

That said, this paper should not be the last word on this subject for Bangladesh, but rather it should start a discussion. As noted earlier this analysis suffers from a lack of data availability in a transparent manner. Better data collection and dissemination will be paramount to a better understanding of these issues in economics in general and Bangladesh in particular.

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Appendix A: Summary statistics

Table A.1 : Summary statistics: mean and standard deviation of household and household head's characteristics

	All households with at least one member with diabetes			Households needing insulin		
	Observations	Mean	Std. Dev	Observations	Mean	Std. Dev
Household size	1210	4.41	1.86	424	4.38	1.69
Average Age	1210	34.90	12.26	424	35.14	11.57
Head age	1210	51.51	13.06	424	51.49	12.80
Monthly income	1205	22646.15	19213.00	422	24547.93	21098.18
Monthly food expenditure	1209	9232.69	6518.35	424	9368.45	4855.21
Monthly education expenditure	1104	411.49	622.53	388	461.21	699.26
Monthly medicine expenditure	1125	1061.15	2598.68	424	884.16	368.71

Table A.2 : Summary statistics: proportions of household and household head's characteristics

		All with at least one member with diabetes		Households needing insulin	
		Observations	Proportion (%)	Observations	Proportion (%)
Location	Rural	618	51.07	202	47.64
	Urban	592	48.93	222	52.36
House ownership	Doesn't own a house	104	8.6	32	7.55
	Own a house	1106	91.4	392	92.45
Religion	Non-muslim	143	11.82	48	11.32
	Muslim	1,067	88.18	376	88.68
Members attending school	0	392	32.37	134	31.6
	1	389	32.12	139	32.78
	2	297	24.53	106	25
	3	98	8.09	35	8.25
	More than 3	35	2.9	10	2.36
Members older than 60 years	0	661	54.63	231	54.48
	1	418	34.55	146	34.43
	2	129	10.66	46	10.85
	3	2	0.17	1	0.24
Members with NCD	1	643	53.41	217	51.3
	2	449	37.29	168	39.72
	3	83	6.89	32	7.57
	More than 3	29	2.41	6	1.42
Household head's employment status	Unemployed	269	22.25	96	22.64
	Employed	940	77.75	328	77.36
Household head's employment sector	Agriculture	252	20.83	87	20.52
	Industry	129	10.66	51	12.03
	Service	829	69	286	67

Appendix B: Additional tables

Table B.1: Coefficients of QUAIDS model.

	Not corrected		Corrected	
	OLS	IV	OLS	IV
α				
α_1	0.5410***	0.4763***	0.5363***	0.4481***
α_2	0.2951***	0.4063***	0.2902***	0.2926***
α_3	0.1639***	0.1174	0.1735***	0.2593***
β				
β_1	0.0314***	-0.0073	0.0239***	-0.0190
β_2	0.0016	0.0030	0.0093	0.0178
β_3	-0.0330***	0.0043	-0.0332***	0.0012
γ				
γ_{11}	0.0366***	0.0193**	0.0367***	0.0260***
γ_{21}	-0.0180**	-0.0197***	-0.0172**	-0.0152**
γ_{31}	-0.0186***	0.0004	-0.0194***	-0.0108**
γ_{22}	0.0353***	0.0093	0.0346***	0.0031
γ_{32}	-0.0173***	0.0104***	-0.0175***	0.0120***
γ_{33}	0.0359***	-0.0108**	0.0369***	-0.0012***
λ				
λ_1	0.0005***	-0.0010**	0.0005***	-0.0008
λ_2	0.0010***	0.0011***	0.0010***	0.0009*
λ_3	-0.0015***	-0.0001	-0.0015***	-0.0001
η				
$\eta_{\_Hsize\_1}$	-0.0003*	-0.0025*	-0.0003	-0.0008
$\eta_{\_Hsize\_2}$	0.0005***	0.0014*	0.0004**	0.0004
$\eta_{\_Hsize\_3}$	-0.0001	0.0011	-0.0002	0.0004
$\eta_{\_AvgAge\_1}$	0.0000	-0.0001	0.0000	0.0003
$\eta_{\_AvgAge\_2}$	0.0000	-0.0001	0.0000	-0.0002
$\eta_{\_AvgAge\_3}$	-0.0000**	0.0001	-0.0001**	-0.0001
$\eta_{\_NumSch\_1}$	0.0018***	0.0077**	0.0018***	0.0068***
$\eta_{\_NumSch\_2}$	-0.0010***	-0.0023	-0.0011***	-0.0003
$\eta_{\_NumSch\_3}$	-0.0007***	-0.0054***	-0.0007***	-0.0065***
$\eta_{\_old60\_1}$	0.0001	0.0034	-0.0001	-0.0024
$\eta_{\_old60\_2}$	-0.0002	-0.0008	0.0000	0.0018
$\eta_{\_old60\_3}$	0.0000	-0.0026	0.0001	0.0006
$\eta_{\_NumNCD\_1}$	-0.0003	-0.0022	-0.0004	-0.0008
$\eta_{\_NumNCD\_2}$	-0.0002	0.0011	-0.0001	0.0000
$\eta_{\_NumNCD\_3}$	0.0005**	0.0011	0.0005**	0.0008

Table B.1: Coefficients of QUAIDS model (continued)

	Not corrected		Corrected	
	OLS	IV	OLS	IV
$\eta_{\_HeadAge\_1}$	-0.0000	0.0000	0.0000	-0.0001
$\eta_{\_HeadAge\_2}$	0.0000	0.0000	-0.0000	0.0001
$\eta_{\_HeadAge\_3}$	0.0000	-0.0001	0.0000	0.0000
$\eta_{\_HeadEmpl\_1}$	-0.0002	0.0052	-0.0007	-0.0048
$\eta_{\_HeadEmpl\_2}$	0.0001	-0.0016	0.0006	0.0044
$\eta_{\_HeadEmpl\_3}$	0.0001	-0.0036	0.0001	0.0004
$\eta_{\_HeadSector\_1}$	0.0002	-0.0012	-0.0000	0.0005
$\eta_{\_HeadSector\_2}$	-0.0001	0.0005	0.0001	-0.0002
$\eta_{\_HeadSector\_3}$	-0.0000	0.000703	-0.0001	-0.0003
$\eta_{\_HeadMuslim\_1}$	-0.0004	-0.0016	-0.0001	0.0071
$\eta_{\_HeadMuslim\_2}$	-0.0005	-0.0017	-0.0008	-0.0080*
$\eta_{\_HeadMuslim\_3}$	0.0009	0.0033**	0.0009***	0.0009
$\eta_{\_House\_1}$	0.0005	0.0050	0.0007	0.0053
$\eta_{\_House\_2}$	0.0000	-0.0027	-0.0001	-0.0028
$\eta_{\_House\_3}$	-0.0005*	-0.0024	-0.0006	-0.0025
$\eta_{\_Urban\_1}$	-0.0023***	-0.0047	-0.0019***	0.0018
$\eta_{\_Urban\_2}$	0.0041***	0.0105**	0.0036***	0.0014
$\eta_{\_Urban\_1}$	-0.0018**	-0.0058**	-0.0016*	-0.0032**
$\eta_{\_IMR\_1}$			0.0058	0.0108
$\eta_{\_IMR\_2}$			-0.0056	-0.0120
$\eta_{\_IMR\_3}$			-0.0002	0.0012
ρ				
$\rho_{\_Hsize}$	0.0030	-0.0019	0.0024	-0.0003
$\rho_{\_AvgAge}$	0.0101	0.0004	0.0067	0.0002
$\rho_{\_NumSch}$	0.0068	-0.0055	-0.0189	0.0003
$\rho_{\_old60}$	-0.0694	0.0141	-0.0406	-0.0010
$\rho_{\_NumNCD}$	0.0457	0.0245	0.0239	-0.0009
$\rho_{\_HeadAge}$	-0.0011	0.0002	-0.0029	0.00004
$\rho_{\_HeadEmpl}$	0.0486	0.0457	0.1660	0.0268
$\rho_{\_HeadSector}$	-0.0370	0.0170	0.0620	0.0020
$\rho_{\_HeadMulim}$	-0.4274	-0.1024	-0.5500	-0.7402***
$\rho_{\_house}$	-0.6616	-0.9513***	-0.5106	-0.2634***
$\rho_{\_Urban}$	23.2489	6.3000	20.1897	0.0615
$\rho_{\_IMR}$			-0.0747	-0.0036

Source: Authors' estimation using HIES 2016.

Table B.2: Suppliers of Insulin in Bangladesh

Suppliers of insulin in Bangladesh	
Domestic producers (50 products)	**Import (65 products)**
1. Advanced Chemical Industries Limited	1. Eli Lilly & Company, USA (License expired as of 2016)
2. Aristopharma Limited	2. Lilly France S.A.S
3. Beximco Pharmaceuticals Ltd.	3. Novo Nordisk A/S
4. Drug International Ltd.	4. Novo Nordisk Producao Pharmaceutica do Brasil Ltd. Brazil.
5. Incepta Pharmaceuticals Ltd.	5. Novo Nordisk Production SAS (Expired as of 2018)
6. Popular Pharmaceuticals Ltd.	6. Sanofi Aventis Deutschland
7. Square Pharmaceuticals Ltd.	

Source: DGDA, Bangladesh.

Table B.3: Estimates of insulin demand equation.

	Dependent variable is total expenditure on insulin			
	Not corrected		Corrected	
	Coefficient	Std. Err.	Coefficient	Std. Err.
p2IV	-0.123	0.271	-0.147	0.275
$\bar{\omega}$	0.008	0.014	0.006	0.014
old60	88.509	55.805	93.978	56.796
NumNCD	125.666	52.992	126.676	53.508
HeadAge	1.858	2.946	1.618	3.028
HeadGender	-186.252	152.363	-214.373	165.380
HeadEduc	6.252	7.728	7.030	7.804
HeadEmpl	141.626	106.990	164.389	122.803
Urban	113.408	69.944	102.537	74.248
HeadMuslim	94.847	106.212	89.027	107.377
IMR			-167.260	305.312
N	314		312	
Adj R2	0.031		0.028	

Source: Authors' estimation using HIES 2016.

Table B.4: Welfare loss per year under an unregulated monopoly (Million)

			Not corrected		Corrected		Average price	Pakistan price counterfactual
			OLS	IV	OLS	IV		
Upper bound	LV=PV	BDT	38270.51	42849.81	38431.07	43244.57	22248.76	4581.02
		USD	488.14	546.55	490.19	551.59	283.79	58.43
	CS	BDT	19136.94	21426.59	19217.22	21623.97	11126.07	2292.19
		USD	244.09	273.30	245.12	275.82	141.91	29.24
	CV	BDT	22470.51	25682.63	22580.96	25965.67	12185.34	2334.34
		USD	286.61	327.58	288.02	331.19	155.43	29.77
	EV	BDT	16590.68	18279.80	16650.84	18422.85	10220.00	2251.38
		USD	211.62	233.16	212.38	234.99	130.36	28.72
Lower bound	LV=PV	BDT	8667.90	9705.11	8704.43	9795.17		
		USD	110.56	123.79	111.03	124.94		
	CS	BDT	4335.64	4854.24	4353.90	4899.27		
		USD	55.30	61.92	55.53	62.49		
	CV	BDT	4488.65	5046.77	4508.23	5095.45		
		USD	57.25	64.37	57.50	64.99		
	EV	BDT	4191.65	4674.38	4208.71	4716.12		
		USD	53.46	59.62	53.68	60.15		

Source: Authors' simulation using estimated price changes.

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