

The Road to Free Insulin

ECUADOR CASE STUDY

September 2017

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This case study is part of a series entitled “The Road to Free Insulin: Country Case Studies” that was created for the ACCISS Study. They are aimed at understanding the role of government, clinicians, and civil society in enabling insulin to be provided free of charge in some contexts.

The Road to Free Insulin: Ecuador Case Study

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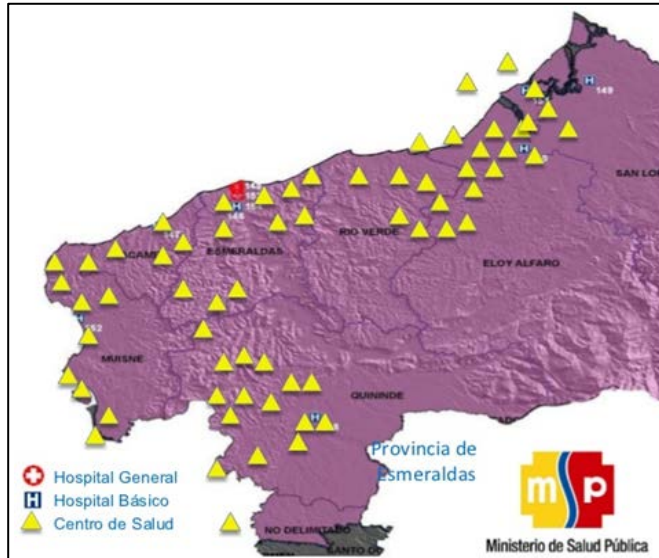
Background

Located on the pacific coast of South America, Ecuador is a country of about 15 million people (2010 census data). Its gross domestic product (GDP) in 2015 was US\$100.2 million. This number has increased substantially in the past five years, mainly as a result of the surge in oil prices. Even with the economic surge, in 2013, 26 percent of the population still lived below the poverty line (1). According to the World Health Organization (WHO) and the World Bank, Ecuador gave 9.2 percent of its GDP to health in 2014; this is a substantial increase from less than one percent in the beginning of the century.

The Ecuadorian Health system divides the country in nine zones and 139 districts. The idea is that every district should have various small health centres and one basic hospital (hospital basico), and every zone must have at least one general hospital (see Figure 1 for an example of the Provincia de Esmeraldas zone).

There is also a higher level of care that is called the national reference hospital, but this is only available in the big cities.

Figure 1. Map of health centers and hospitals in Provincia de Esmeraldas (2)

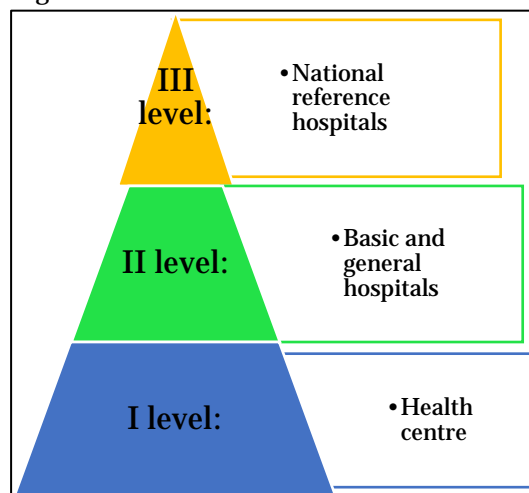


Ecuador's Health System

The country has three main health systems. The private sector and the public sector, which is divided into the Ecuadorian Social Security Institute (IESS), and the Ministry of Public Health (MSP). There is a separate health system for selected people, such as military and police personnel, called ISSFA¹ and ISSPOL², respectively. People who are work-dependent and have a salary are subscribed to the IEISS system as a requisite by law. This allows them to seek assistance at this Institute's health services any time. Every Ecuadorian can access the MSP system if they are not subscribed to the IEISS system. Basically IEISS, MSP, ISSFA and ISSPOL are regulated by the same laws but have different budgets.

The country is following a model called the Integral Health Attention Model (MAIS³). It is based on 'levels' of care depending on the complexity of the health request or condition. For example, in diabetes care, tests like HbA1c requires a higher level of care outside the primary care physician's office, but follow ups to this test are to be carried out by the primary care physician.

Figure 2. Levels of Care



¹ ISSFA: instituto de seguridad social de las fuerzas armadas

² ISPOL: Instituto de seguridad social de la policía Nacional

³ MAIS: Modelo de atención Integral de salud

This model aims to decongest hospitals and focuses more on the population's health needs. People initially entering into the health system with basic concerns start in level I. If capacity is limited, or needs are more complex, they are sent by reference for a higher level of attention. Sometimes capacity is saturated at higher levels but several private clinics have contractual agreements with the government and patients will be referred to those centres if there is limited availability. Figure 2 shows the various levels of care.

The MSP has created an essential medicine list (EML; Annex 1) based on the epidemiological knowledge in the country. The same institution uses this list and data provided from the health centres to purchase medicines. In 2015, the government created two procedures by which they would purchase medicines. The first procedure, called 'reverse auction', is initiated when a government sets a maximum price and opens the process up to auction. Pharmaceutical companies then offer competitive prices to the government and the lowest price is chosen for that specific medicine. This results in many companies selling different medications to the public sector. The other process they established is buying medicines directly from a catalogue and choosing the lowest price available. Companies participating in this process could be from anywhere in the world, but 80 percent of the time, national companies are chosen. The medicines must have a permit given by the MSP to assure quality. Additionally, they take samples of the medicines and send them to laboratories to assess if they have similar concentrations as the originals. According to one zone epidemiological director, acquisitions tend to be of medicines of the cheapest price available, so the purchasers choose from the catalogue if the offering price could not be lowered by the reverse auction process, and vice versa.

Diabetes in Ecuador

The lack of research in Ecuador has resulted in very limited epidemiological data about diabetes in the country. According to disease estimates and projections published in 2015 by the International Diabetes Foundation (IDF), diabetes prevalence in Ecuador is about 8.5 percent and will increase to 10 percent by 2040. The IDF estimates that the incidence of type 1 diabetes is 0.1/1000 and the prevalence is 0.4/1000 children (3–4). The CARMELA study, which investigated the prevalence of cardiovascular risk factors in Latin America, reported that in Quito, Ecuador's capital, the prevalence of diabetes reached 5.9 percent (5). According to information provided by the National Institute for Statistics and Census (INEC), diabetes is the second-most common cause of mortality in the country.

The average Ecuadorian's knowledge and awareness about diabetes and its risk factors has grown exponentially over the past few years due to physician training, a growing amount of organisations in the field, and an investment in public health. As part of this new trend, the government has created public policies that may help prevent and treat type 2 diabetes according to international guidelines. Unfortunately, type 1 diabetes has mostly been on the margins of these policies. In addition, according to the president from one diabetes non-governmental organisation (NGO) in Ecuador, a limited number of specialists practise in the paediatric endocrinology field. Several NGOs have been established to fill some of the gaps in care, particularly for children, and work specifically with children living with this condition. These organisations have sponsored projects aimed at creating awareness, educating patients and physicians, and providing many children better options for care.

The majority of diabetes specialists in Ecuador are concentrated in major cities and are not necessarily accessible to populations where diabetes is more prevalent. Consequently, the immediate management of diabetes falls to general practitioners or primary care physicians. In the past few years, the health ministry created guidelines for the treatment of chronic diseases and, in 2017, released its own diabetes management guidelines to be applied throughout the country. These guidelines state people with diabetes are only referred to endocrinologists by their general practitioner in cases of diabetes complications or tough management issues. After resolving the problem, people are then supposed to go back to their primary doctor with a counter-reference. In practice however, most of these people

continue to be managed by endocrinologists and/or internal medicine physicians, and do not go back to their general practitioner, according to one physician who works in one of the rural districts.

The Provision of Free Insulin

After the new constitution was written in 2008, the public sector provides medications for free to those in the public system. In order to obtain these medications, they must be included in the country EML, unless it is specifically requested by a physician. It also should be prescribed by a physician working in the MSP system. In Ecuador, insulin is on the EML but only two types are included: NPH (intermediate-acting insulin) and regular (short-acting insulin). Until 2014, lispro and glargine were also included on the list, but the public health ministry decided to take both out, arguing that data did not demonstrate a clinical advantage in comparison to regular and NPH and were both more expensive.

Policies regarding free access to insulin are the same policies that govern free access to other medications. Certain zones and their populations go to one specific public health centre and appropriate referral centres. Every health centre has a director who requests the medicines that their population needs via the online National Public Procurement Service catalogue (catalogo.compraspublicas.gob.ec). The pharmaceutical company should then deliver the products in less than 15 days. Normally, every four months the health ministry signs new contracts with pharmaceutical companies that can sell medicines to every district at a prefixed price. For example, Annex 2 shows the current contract for NPH. According to the director of an urban zone, the disadvantage of this system is that when the area of care they are assigned requires expenses above US\$7000, the process requires approximately three months, while a smaller purchase will be delivered faster allowing for immediate distribution.

Currently, most districts are getting NPH and regular insulin from Leterago SA and Pharmabrand for US\$3.04 and US\$4.05 for a 10ml vial, respectively. These numbers can change with every auction. Last year, the health ministry approved an order (Annex 3) that states that strategic drugs, even if not on the EML, cannot be more expensive in the private sector or bought by the government for more than the maximum of what the order says. This includes all types of insulin.

All health centres and hospitals are required to report monthly to a local administrator with information, including diagnoses, medicines and amounts used, and epidemiological data. Based on this, every district buys a certain quantity of medicines for each disease reported in that area, plus 25 percent extra for stocking purposes, directly from pharmaceutical companies. They do this every month or every time medication supplies run low. Each area has its own budget assigned by the MSP and all expenses are adjusted to it.

People with chronic conditions can be prescribed enough medicines for three months, but according to the director of medicines in one rural district, physicians often prefer to give only one or two months of dosage; otherwise their centre can risk running out of medicines. At every follow up, a patient should receive an insulin refill. There is no limit to the amount they are given; instead, doctors will calculate prefixed doses and their need within those few months and prescribe based on this amount.

According to one district administrator, there is sometimes a period in which they have run out of medicines and patients are unable to receive refills. This is mainly due to the time the auctioning process takes. In the 17th district, for example, they ran out of insulin just once, and this was due to contract delays. In conclusion, the major delays in the purchase of medicines are the result of administrative delays.

According to Quito's preventative taskforce chief, there is not enough money to buy all the supplies needed for people to manage their diabetes at home (including syringes, test strips, glucometers, etc.). The taskforce therefore decided to purchase certain amounts of supplies

for each health centre to serve people living with diabetes. While syringes are given to insulin users to take home (amounts calculated by the physician), other supplies can only be used at the health centre itself. For example, people must go to these centres to get their glucose measured with a glucometer. Laboratory tests are provided for free, but not all tests are available in every health centre. For example, HbA1c is only performed at higher level centres that handle more complex health needs. These centres are located in cities, so some people must travel to get these tests.

History of the Provision

In 2004, the Congress approved a code called prevention, protection and integral attention for people with diabetes (Annex 4). The code states that the government will assure protection, prevention, diagnosis, treatment and control of the complications of diabetes. Every Ecuadorian citizen and foreign citizen that has lived in the country for over five years can access this program. In 2004, medicines were not free. Children, people living with disabilities, or elderly people could pay 50 percent less for medicines. In practice, most of what was written in this code never became a reality.

In 2008, Ecuador changed its constitution (Annex 5) to include several policies for health (e.g., “Every citizen has the right to health and the state should assure it.”) Based on this, they impelled a model created in the 1980s, called MAIS (Annex 6). The country prioritised the wellness of people by changing the curative mindset of health personnel to focus on disease prevention and health promotion. For example, Ecuador instituted policies regarding sugar and carbohydrate uses, such as labeling high sugar content products, taxes for those products, and forbidding the advertising of sugar containing products for children. In the upcoming months, the general assembly will approve the organic health code (Annex 7), which states, “the government should assure access and availability to qualified medications and its rational use, prioritising public health interests rather than economics”. With those concepts in mind, they began prioritising three aspects: infrastructure, equipment, and human resources. This includes assuring progressive gratuity for public services.

In the past eight years the Ecuadorian health system has changed policies significantly. According to the director and medication expert for the MSP, all these policies have changed as a result of the political change in the country, not as a result of a particular individual or organisation. Whenever a new policy or regulation is in the making, the government calls private and public personnel implicated in diabetes and allows them to participate in the process. The people responsible for ensuring these policies are fulfilled are the physicians working for the MSP, especially in primary care, because they well know how patients are being treated, and if they are getting the insulin they need.

Challenges/Lessons Learned

Having certain medications free of charge helps to offset the burden of diabetes and is particularly lifesaving for those living with type 1 diabetes. Unfortunately, insulin is not the only requirement for living a healthy life with diabetes. Insulin users also need test strips, syringes, a glucometer and, most importantly, knowledge. The lack of knowledge is as dangerous as the lack of insulin itself.

Most developed countries manage diabetes with a team comprised of endocrinologists, diabetes educators, nutritionists and psychological support. In Ecuador, it is difficult to find one complete team. There are few diabetes educators. NGOs, have had to take on the role of education in type 1 diabetes. Not surprisingly, these organisations are also centralised in the three main cities, but have several projects in which they try to cover other areas.

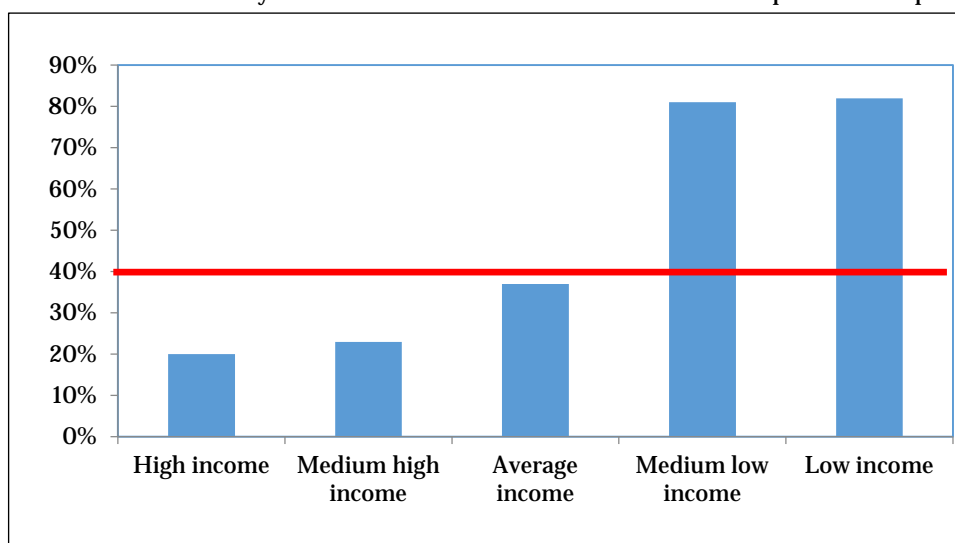
While managing diabetes is challenging for everyone, it can be even more challenging for those with minimal education. The Ecuadorian Juvenile Diabetes Foundation (FDJE), based in Quito and Guayaquil, is an NGO that provides education to families living with type 1 diabetes. They also support a group from a fishing village called Santa Elena where they have

low incomes and, for unknown reasons, a high prevalence of type 1 diabetes. Every four months, these families receive teaching experiences adapted to their cultural and educational level. As a result, they have achieved better control of the disease in their children.

Many changes have occurred in Ecuador over the past 20 years. Fifteen years ago, diabetes was barely on the radar. Today, insulin is given free by the MSP and several organisations try to provide analogues for some children. In the near future, it would be beneficial for Ecuador to begin following the best available diabetes treatment guidelines and the examples set by neighbouring countries, like Colombia, Argentina and Brazil. (6-7).

In Ecuador, if a person runs out of insulin, they must purchase insulin from a pharmacy and pay for it out-of-pocket. A study of economic impact in the country found that diabetes expenses can still take the majority of a family's income in some regions of the country, as shown in Figure 3. (8)

Figure 3. The percentage of health expenditures of the participating families is shown, the red line shows the 40 percent indicated by WHO for the catastrophic expenditure (9)



Another issue with the current system is having such independency between districts in buying medicines. In this system, it is highly likely that several places will fail in getting all medicines needed by its population, as reported by a rural district director.

A problem must be understood before it can be solved. Ecuador still does not have any epidemiologic data for type 1 diabetes, specifically, and only limited information on type 2 diabetes. To start building a stronger base of knowledge for this disease, academia is now looking to several projects to create epidemiological data.

While the policy changes in the country are positive, it seems policies and changes being made are more for type 2 diabetes, and type 1 diabetes is barely seen as a public or political issue. More must be done to improve the lives of all of those living with diabetes in Ecuador.

References

1. CIA World Factbook, Ecuador : <https://www.cia.gov/library/publications/the-world-factbook/geos/ec.html>
2. Ministerio de Salud Publica *salud.gob.ec*
3. Patterson C, Guariguata L, Dahlquist G, Soltész G, Ogle G, Silink M. Diabetes in the young: A global view and worldwide estimates of numbers of children with type 1 diabetes. *Diabetes Res Clin Pract.* 2014;103(2):161–75.
4. Guariguata L, Whiting DR, Hambleton I, Beagley J. Global estimates of diabetes prevalence for 2013 and projections for 2035. *Diabetes Res Clin Pract* [Internet]. 2013;103(2):137–49. Available from: <http://dx.doi.org/10.1016/j.diabres.2013.11.002>
5. Schargrodsky H, Hernández-Hernández R, Champagne BM, Silva H, Vinueza R, Silva Ayçaguer LC, et al. CARMELA: Assessment of Cardiovascular Risk in Seven Latin American Cities. *Am J Med.* 2008;121(1):58–65.
6. Salud O De. POS. 27 dic. 2013. Colombia. 2013;
7. Ley N 23753. Modificación. Argentina. 2013;2.
8. Borja I (dir), Mantilla Jácome MP. *Impacto económico de la Diabetes Mellitus tipo 1 estudio de caso de la Fundación Diabetes Juvenil Del Ecuador, año 2015.* Tesis (Magíster en Salud Pública), Univ San Fr Quito, Col Posgrados; Quito, Ecuador, 2016 [Internet]. 2016; Available from: <http://repositorio.usfq.edu.ec/handle/23000/6177>
9. Borja I (dir), Mantilla Jácome MP, Translated from Figure 8.

Links with relevant information

<https://www.cia.gov/library/publications/the-world-factbook/geos/ec.html>

<http://www.ecuadorencifras.gob.ec/resultados/>

<http://portal.compraspublicas.gob.ec/sercop/medicamentos-de-calidad/>

<http://portal.compraspublicas.gob.ec/sercop/repertorio-de-medicamentos/>

<http://www.who.int/countries/ecu/en/>

<https://catalogo.compraspublicas.gob.ec/producto/3555>

<http://datos.bancomundial.org/indicador/SH.XPD.TOTL.ZS>

www.fdje.org

<http://data.worldbank.org/data-catalog/world-development-indicators>

Annexes (Available online only)

1. Basic Drug Chart (Essential Medicines List)
2. Leterago SA contract for Novolin N
3. Maximum Prices for Essential Medicines in Ecuador
4. Code for Prevention, Protection and Integral Attention for People with Diabetes
5. Ecuador Constitution (2008)
6. MAIS Manual
7. Organic Health Code Project