Insulin access in the developing world: problems and solutions

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Introduction

The discovery of insulin by Banting and Best in 1921 revolutionised the treatment and outcome of type 1 diabetic patients. Prior to the discovery of insulin, the prognosis for these patients was universally fatal, often within 12 months of diagnosis. Sadly, this is not dissimilar to the current prognosis faced by many type 1 diabetic patients in developing countries.[1,2] Indeed, in rural Mozambique, the life expectancy for a child with type 1 diabetes may be as short as 7 months from diagnosis.[3] The poor access to insulin is undoubtedly a major contributing factor to such awful prognoses.

The epidemiology of type 1 diabetes is poorly defined in the developing world. This is particularly true for Africa where published rates of type 1 diabetes are only found in three countries: Nigeria, Tanzania, and Zambia. Extrapolations from these imperfect estimates suggest there are around 39 000 children under 14 with type 1 diabetes in Africa, which translates to a relatively low prevalence of 12 in 100 000 (see Figure 1).[4] The low prevalence in Africa and some other regions of the world could be the result of genetic variations, under-diagnosis and, as mentioned above, bleak prognosis.

Insulin access

Insulin access is a major problem for many people in the developing world. The extent of this problem was illustrated in a survey by International Diabetes Federation (IDF) in 2002, which found that none of the countries surveyed in Africa had uninterrupted supply of insulin, and in many other poor regions of the world, such as South and Central America, access is also a significant problem.[5]

There are many causes for the poor access. In the same survey done by IDF, the cost of insulin was the most commonly cited reason. However, there are other factors involved in the poor access to insulin, such as unavailability in the regional areas, transportation problems, imbalance between demand and supply, poor quality insulin, and in the case of type 2 diabetic patients, preference (rightly) given to those with type 1 diabetes (see Figure 2).[5]

True cost of insulin

The cost of insulin *per se* is rather meaningless. It must be

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put into the context of a country's national health budget and the incomes of the population. For example, in Mozambique and Zambia, assuming a daily requirement of 35 units, the cost of a year's supply of insulin for a single patient was calculated to be US$56.03 for the health service.[3] This figure may seem trivial in a developed country, but for developing countries like Mozambique and Zambia it represents around 40 times the annual public sector pharmaceutical spending per patient. Looking at it from the opportunity cost perspective, the treatment of one insulin-requiring diabetic patient in a developing country may deprive 75 others of potentially lifesaving antimalarials or antibiotics.[6] Type 1 diabetes is an expensive disease to treat and in the developing countries, health ministries are faced with the chilling but valid question: should valuable resources be diverted to buy insulin for the few patients that desperately need it or should it be used in other areas that can help even more patients? The high opportunity cost combined with the low prevalence undoubtedly plays a significant part in the low priority set for the provision of insulin.

As a result of the poor availability of insulin in the public sector, many patients are forced to buy insulin from the private sector where the prices are many times more expensive. In a study looking at the affordability of insulin in the private sector, Mendis and colleagues calculated the number of days an individual would need to work to buy a month's supply of insulin, assuming a daily dose of 40 units of intermediate acting insulin.[7] The wage was based on the lowest paid government worker in the various low- and middle-income countries (see Figure 3). In Malawi, a month's supply of insulin would cost the worker nearly 20 days of wages, which translates
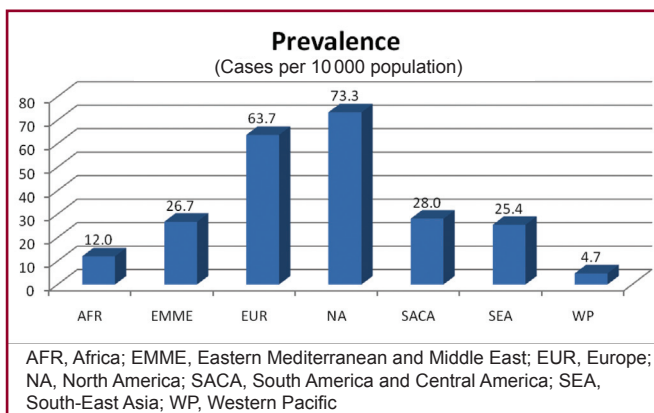

Figure 1 The prevalence of type 1 diabetes in children under 14 living in different regions of the world. Data extracted from **Diabetes Atlas**[4]
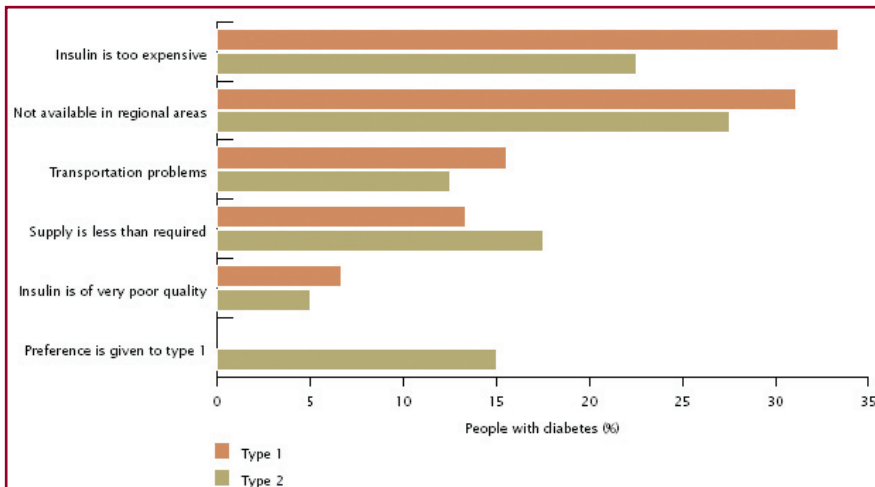
Figure 2 Causes cited by patients for the lack of access to insulin[5]

to two-thirds of their monthly income, making it highly unaffordable. Similarly, for other countries like Nepal and Sri Lanka, the cost of insulin equates to between one-fifth and one-quarter of the worker's income. Unfortunately, the true picture is probably much worse given the large number of people living below the poverty line in these countries whose income is a great deal less than that of the lowest paid government worker.
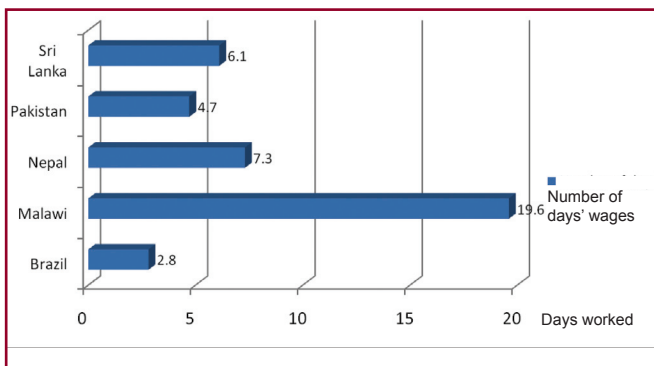

Figure 3 The affordability of insulin in some low- and middle-income countries in terms of the number of days a lowest paid government employee would need to work to buy a month's supply of insulin[7]

The 'RAPIA' system
Although poor affordability is a major issue, there are other causes for poor access to insulin. In order to clarify the various contributing factors, the International Insulin Foundation (IIF) devised the Rapid Assessment Protocol for Insulin Access (RAPIA).[8] It studies the path of insulin from its arrival into the country to reaching (or failing to reach) the patients. In addition, RAPIA also assesses the availability of infrastructure and human resources for diabetic care. It collects information through interviews, group discussions, site visits, and document reviews from the relevant stakeholders.

There are three levels in the assessment. At the macro level, officials from the health, finance, and trade ministries are interviewed. National diabetic associations and insulin wholesalers from the private sector are also included at this level. The meso level refers to regional health organisations, hospitals, health clinics, laboratories, and pharmacies. Lastly, at the micro level, individual patients and health workers are consulted.

So far, RAPIA has been carried out in three African countries: Mali, Zambia, and Mozambique.[3,9-11] These countries are defined as highly indebted, poor countries by the World Bank because their debt repayment greatly exceeds their income, and consequently, their ability to fund social investments like health programmes is restricted. The findings from these countries demonstrate significant problems with insulin access (see Table 1) and highlight the other contributing factors beside costs; they also raise a number of issues related to diabetic care.

Quantification
A major difficulty identified in all three countries is the lack of accurate figures for the number of diabetic patients, and where they are located. Consequently, the quantification of insulin is based on past consumption which is a very inaccurate method of assessing needs and leads to frequent imbalance between demand and supply. For example, in Mozambique, where there are severe shortages of insulin in many regions of the country, 77% of the imported insulin is located in the capital city which has only 11% of the national population.[3] This may, of course, reflect the large number of diabetic patients

Table 1 Insulin availability in different countries

Country	Insulin access
Mali	Insulin is available mainly through private pharmacies which are more expensive than the public sector, where insulin is not available on an uninterrupted basis.[9]
Mozambique	Insulin availability is limited to provincial and central hospitals. Public sector pharmacies often lack insulin and patients are forced to use the more costly private pharmacies which have better insulin availability.[10]
Zambia	Insulin availability is good in hospitals, being present in all 13 hospitals studied, but only 42% of the local referral health centres are found to have insulin. Patients often do not know where they can obtain insulin, and may go to distant regional hospitals when they could have gone to their local clinics. Furthermore, patients are frequently charged high prices for their insulin when regulations allow them to have it for free.[3,11]

seeking care in the capital city, or perhaps this is where they come for their insulin. However, given the large size of the country, the authors believe mismanagement is a more likely explanation. In addition to the problem of quantification, the lack of information about disease prevalence also hampers resource and priority allocation for diabetes.

Procurement
Mozambique and Zambia procure insulin mostly through national tenders but on occasions also directly from local suppliers, which are more expensive. Mali purchases insulin directly from wholesalers based in France which, again, is more expensive compared with tenders. Both Mozambique and Zambia benefit from the Novo Nordisk LEAD (Leadership for Education and Access to Diabetes care) initiative which allows the public sectors from the 50 least developed countries, as defined by United Nations, to obtain insulin at no more than 20% of the average price in developed countries.[12] Even so, the cost of insulin is still significant; for example, it represents 10% of the drug budget in Mozambique.[10] Unfortunately, Mali has not joined the LEAD initiative which would have reduced the cost of insulin by two-thirds.[9] In addition, supply of insulin is also hindered by the poor coordination and communication between the Central Medical Stores and the Medicine Importation Agency with the end-users of insulin.

Social regulations
In Mozambique and Zambia insulin is exempt from any taxes.[3,10,11] Regulations in these countries enable patients to obtain insulin freely or at subsidised prices. Sadly, these regulations are confusing, poorly enforced, and not well known to patients. Furthermore, insulin is frequently unavailable in the public sector, and so few patients benefit from these regulations. In Mali, no such assistance is available and diabetic patients are responsible for the full cost of insulin with 2.5% tax added.[9]

Diabetes care
Diabetes care is mostly centered around urban areas and patients from rural regions are often neglected. Such inequalities are clearly shown by the great variations in the prevalence of diabetes and prognosis between rural and urban areas (see Table 2).[3] The lack of facilities and skilled health workers in the rural areas are likely to have resulted in mis- and/or under-diagnosis leading to the perceived low prevalence and the poor prognosis. It is interesting to note the much better prognosis is seen in Zambia compared with Mozambique despite similar national indices of poverty. The various factors contributing to this difference may include access to insulin, syringes

and testing materials, training of healthcare workers, availability of diabetes guidelines, and costs for individuals with diabetes. Furthermore, the advocacy and caring role played by the diabetes associations will also influence the outcome.

The scarcity and cost of allopathic healthcare mean that many diabetic patients seek help from traditional healers who are generally more accessible and affordable. In Zambia and Mozambique, these healers are an integral part of the health system, and many are able to recognize the classical symptoms of type I diabetes; they would normally refer the patients to hospital when their conditions are not improving.[3] Traditional healers would welcome closer partnership with allopathic health workers and learning more about diabetes.

Other issues
The other issues identified by RAPIA include those that were mentioned previously, such as transport problems[3] and the quality of insulin, especially generic version which are often perceived as less effective than the more costly branded insulin.[9] Access to syringes is a major problem in government facilities and patients are forced to turn to the expensive private sector in which there is also shortages.[3,9-11] In addition, due to the unreliability of insulin supply, many patients will reduce their daily insulin dosage to make their supply last longer. Interestingly, the maintenance of cold chain is not an issue in either Mozambique or Zambia,[3] but is a problem in the public sector of Mali.[9]

Possible solutions
It is obvious that insulin access is a complex problem with no simple answer, and any successful solutions will need to address the many different factors involved. Furthermore, different countries will have their unique set of challenges depending on the state of their health system and their socioeconomic circumstances. Consequently, each country will require a unique set of interventions. Nevertheless, there are a number of components that will be important in making up a successful solution (see Figure 4).

Table 2 Prevalence of insulin-treated diabetes in Zambia and Mozambique, with estimated life expectancy

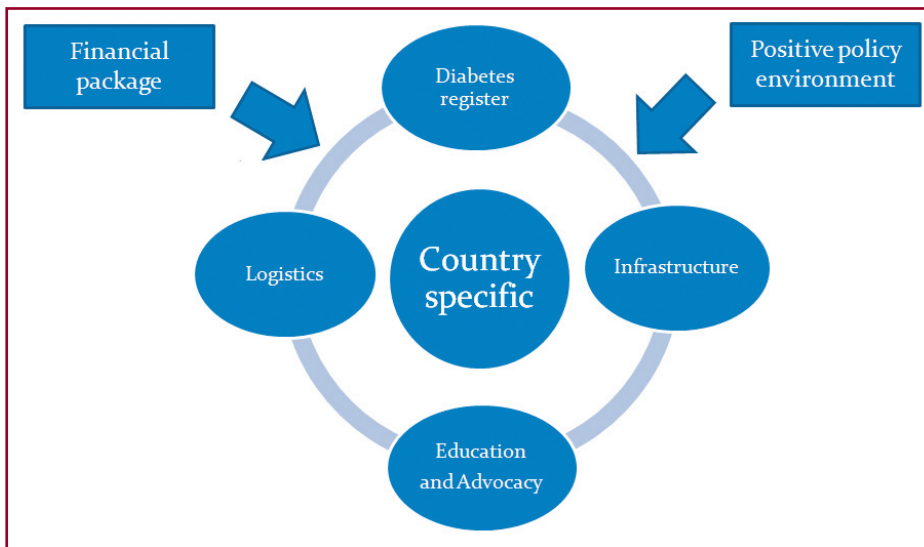| Country	Insulin-treated diabetes prevalence (per 100 000)	Estimated life expectancy (y) Below 14 years	Over 15 years
Mozambique			
National average	3.5	3.5	5.2
Urban	5.0	2.1	11.1
Rural	1.4	0.6	2.9
Zambia			
National average	12.0	11.2	16.7
Urban	12.6	13.0	19.0
Rural	9.5	9.0	14.0

Figure 4 *Some of the important components in solving the problem of insulin access. See text for further discussion of each component.*

Diabetes register

As discussed above, the absence of data regarding the number of patients needing insulin and where they are located, result in major difficulty in quantification and distribution of insulin. To solve this problem, a diabetic register is needed at different levels of the health system. This would provide information regarding the amount of insulin needed and how it should be distributed. Furthermore, an accurate description regarding the extent of the problem will assist in resource allocation and advocacy.

Financial package

Without a sustainable financial package, any interventions are doomed to failure. The donations of insulin by various charities such as Insulin for Life[13] are highly commendable and have an important role in emergency situations but are unlikely to offer a long-term solution to insulin access. Furthermore, the LEAD initiative by Novo Nordisk offering equity pricing to least developed countries is very welcome, but has had limited effect on insulin availability for reasons such as lack of information to eligible countries, exclusion of poor and populous countries like India and Nigeria, and exclusion of the private sector, from which many patients purchase their insulin due to poor availability in the public sector.[14] Some authors have, therefore, commented on the risk of producing 'islands of philanthropy'[14] with such schemes and distracting 'attention from the underlying issues of patent protection and rising drug costs'.[15]

Different schemes have been established to address the problems of payments by patients. In Zimbabwe, the revolving fund has been tried, where the initial drugs are donated and the money from the sale of these drugs is put back into the fund to purchase more medicines. Some of the money in the fund is also used to provide medicines freely to patients who would otherwise not be able to afford them. Unfortunately, revolving funds are generally unsustainable.[16] Another approach is the prepayment scheme where families pay a fixed amount each year allowing them to have access to drugs and medical treatments.[17] Such an arrangement has been found to increase health service usage and improve the financial accessibility of healthcare as well as quality of care. However, the success of the scheme is dependent on subsidies to pay the premiums of low-income groups and integration into the government system to afford better protection for small risk pools.[18]

Whatever means a country chooses to address the issue of payments, the emphasis must be on sustainability and affordability. There must be some form of safety net to ensure the poorest section of the population has access to life saving medicines. Unfortunately, the implementation of such safety nets is dependent upon an adequate health budget, which is simply unrealistic in many developing countries given their levels of incomes and debt repayments. In consequence, the role of advocacy, as will be discussed below, is vital.

Positive policy environment

A positive policy environment in this context refers to any policies and regulations that allow easier insulin access for patients. They include tax exemption for materials related to diabetes treatment, (enforced) regulations allowing free or subsidised access to insulin, and price control of insulin in the private sector. Additionally, the prequalification policy of WHO for HIV and TB medications may be expanded to include generic insulin as a guarantee of quality, thus improving users' confidence.

Logistics

The logistics component is concerned with distribution of insulin, especially to remote rural regions. Patients from these regions have the most difficulty in accessing insulin; their poor prognosis is a testament of such difficulty. The accurate quantification of insulin needs in the different regions, as mentioned above, serves as the first step in the correct distribution of insulin. The second step requires the establishment of transport and cold chain networks to provide a reliable and accessible supply of insulin. The transport of insulin may be linked to the establishment of mobile clinics described below.

Also included in the logistic component is the procurement process. A more efficient system like using tenders or pooled procurement will result in significant savings.[3,9-11] Further savings may also be possible by joining the Novo Nordisk LEAD initiative.

Infrastructure

Infrastructure includes not only the physical buildings and equipment, but also the human resources. There are severe shortages of all these in the developing world, and the problems are particularly acute in the remote rural regions. The simple answer of building more hospitals, buying more equipment and training more health workers is not feasible given the financial constraints. Creative approaches are needed to improve access for rural patients. Examples include the closer integration of traditional healers with allopathic healthcare and regular outreach mobile clinics to rural areas.

The health system set up in many developing countries is geared towards acute infectious diseases, with little attention paid to non-communicable chronic conditions, like diabetes. However, these chronic diseases are becoming more common in developing countries and together with infectious diseases, they formed the so-called 'double whammy'. There is, therefore, a need for additional focus in managing chronic conditions which means, among other things, better record keeping and instigating preventative health measures.

Education and advocacy

There is a poor understanding of diabetes among the general population, diabetes patients, and, disturbingly, health workers.[3,14] Education of these groups is, therefore, needed. World Diabetes Day (14th November) can be used to raise awareness among the general population (and government). Patients can be educated through appropriate teaching materials suitable for their age and literacy, while education programmes need to be rolled out for health workers, including traditional healers. Furthermore, there is an urgent need for guidelines and protocols regarding diabetes management, the absence of which has often delayed commencement of insulin.

Advocacy, often by national diabetic associations, plays a major role in promoting insulin access, and with the better quantification of insulin needs, advocates can accurately promote the problem to politicians and international donors. Furthermore, the issue of poverty, which is the underlying cause of so many problems in developing countries besides insulin access, must be addressed. Advocacy in poverty elimination through various schemes including debt elimination and fair trade is therefore imperative.

Conclusion

Insulin access is a major problem in many parts of developing countries, and in consequence, the prognosis for many type 1 diabetic patients in these regions is poor. There are many barriers to insulin access with costs being a major factor. Using RAPIA, investigators are able to study the path of insulin from its arrival into the country to it reaching or failing to reach the patients. The barriers they have identified are inaccurate insulin needs quantification, inefficient procurement procedures, non-enforcement of subsidy regulations, inaccessible healthcare, transport problems, and poor confidence in generic insulin.

There is no simple answer to the complex problem of insulin access. Any solution will need to be tailored to the individual country which will have its own unique set of challenges. Nevertheless, the components that are important in any solution include sustainable financial packages, diabeties register,s positive policy environments, logistics, infrastructure, education, and advocacy.

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