Access to Care for Patients With Insulin-Requiring Diabetes in Developing Countries

Case studies of Mozambique and Zambia

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OBJECTIVE — The objective of this study was to assess the barriers to care for patients with insulin-requiring diabetes in Mozambique and Zambia.

RESEARCH DESIGN AND METHODS — We used the Rapid Assessment Protocol for Insulin Access to collect information through interviews, discussions, site visits, and document reviews. Government organizations, health facilities, care givers, and patients were asked about care for people with insulin-requiring diabetes. Between 100 and 200 interviews/discussions per country were undertaken in and around the capital city and the regional capital and in a rural area.

RESULTS — Insulin was present in both countries in sufficient quantities, although the financial burden for health services and patients meant that problems with supply exist. There are problems with quantification of needs and equitable distribution of insulin. Problems with availability of syringes and testing equipment were noted, particularly in Mozambique. This lack of tools and infrastructure for diagnosis and follow-up coupled with low levels of health care worker training and lack of diagnostic reagents resulted in a substantial risk of misdiagnosis or failure to detect diabetes. The estimated prevalence of insulin-requiring diabetes differs more than 10-fold between urban and rural areas in Mozambique and 4-fold between Mozambique and Zambia, suggesting that problems in diagnosis and care result in substantial worsening of prognosis for such patients.

CONCLUSIONS — Insulin is necessary but not sufficient to improve prognosis for diabetic patients. A Rapid Assessment Protocol methodology can be used to define problems in health care delivery for diabetes. Proper care for insulin-requiring diabetes necessitates health systems able to provide trained personnel, medicines in sufficient quantity, and diagnostic and monitoring facilities.

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Type 1 diabetes has been estimated to affect ~19,000 people in the world's poorest countries (1), but there are a lack of good data on the disease prevalence in developing countries and in particular in sub-Saharan Africa. The annual incidence of type 1 diabetes in East Africa was found to be 1.5 per 100,000 population aged 0–19 years (2) compared with 10.3 per 100,000 population in African Americans (3) and 18 per 100,000 population in the U.K. (4). However, the low prevalence of the condition may reflect poor prognosis as well as low incidence.

Type 1 diabetes is an expensive disease not only for patients but also for health systems. It has been estimated that the average annual cost of care for an East African patient with type 1 diabetes is $229, of which around two-thirds is for the purchase of insulin (5). This low prevalence and high cost mean that type 1 diabetes is likely to be low on the list of priorities for the ministries of health in sub-Saharan Africa.

Leonard Thompson, the first patient to be treated with insulin for type 1 diabetes, was given his first injection on 11 January 1922 (6). Three-quarters of a century after its discovery, insulin is still not available on an uninterrupted basis in many parts of the developing world (7–9). In consequence, the prognosis is likely to be poor for patients with type 1 diabetes in much of sub-Saharan Africa (10,11). There are, however, few detailed studies of patterns of diabetes care in these situations. We have investigated patterns of diabetes care in two African countries and related these to estimates of prevalence and prognosis.

RESEARCH DESIGN AND METHODS

— The International Insulin Foundation (IIF) was established to improve the prospects for type 1 diabetic patients in the world's poorest countries. To achieve these objectives, a clear analy-

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Abbreviations: IIF, International Insulin Foundation; RAPIA, Rapid Assessment Protocol for Insulin Access.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

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Table 1—*Questionnaires that make up the RAPIA*

Interviewees	Issues addressed in each RAPIA questionnaire
Macro	
Ministry of Health	Organization of delivery of diabetes care
	Resources available for diabetes and insulin
	National programs for diabetes and insulin
	Pricing of insulin
	Distribution of insulin
	Funding for insulin and diabetes
	Insulin tendering and purchase
Ministry of Trade	Trade issues (laws, barriers to trade)
	Trade infrastructure
Ministry of Finance	Funding of health system
	Taxes on insulin
	Funding for insulin and diabetes
Private sector	Pricing of insulin
	Distribution of insulin
National diabetes association	Issues with diabetes and insulin
Central medical store	Insulin tendering and purchase
	Insulin distribution and storage
	Insulin pricing
Meso	
Regional/district health organization	Issues with diabetes and insulin
	Organization of care for diabetics
Hospitals, clinics, health centers, dispensaries, etc.	Treatment and management of diabetics
	Access to appropriate tools to diagnose and treat patients
	Infrastructure present and/or lacking for insulin provision
Laboratory	Infrastructure present and/or lacking for proper diagnosis and follow-up
Pharmacy	Insulin distribution and storage
	Insulin pricing
Micro	
Health workers and traditional healers	Problems encountered in diagnosis and treatment of patients
	Training
	Infrastructure present and/or lacking
	Tools present and/or lacking
Patients	Diagnosis
	Access to treatment
	Cost of treatment

sis of the constraints to insulin access and diabetes care is needed. This led to the development of the Rapid Assessment Protocol for Insulin Access (RAPIA). The RAPIA studies the path of insulin and the availability of infrastructure, personnel, and resources to diagnose, treat, and care for patients with type 1 diabetes in a country and tries to identify barriers that may exist at different levels of the health system. It is used to collect information through interviews using a series of questionnaires, discussions, site visits, and document reviews from various stakeholders. The aim is to collect, analyze, and present data to evaluate and inform the development of health care services for diabetes management in these countries.

The RAPIA uses the principles of rapid assessment protocols, which have been used in areas such as infectious diseases, drug abuse, and nutrition for the purpose of applying preventive and therapeutic interventions (12–14). The aim of rapid assessment protocols is to rapidly collect the best possible information and not aim for scientific or statistical precision. These data can then be used to develop specific health care interventions (15). By using many different sources of data (such as documents, interviews, and site visits) a balanced overview is obtained. Triangulating, or cross-checking between data sources, provides internal validity and reliability of the data collected. The RAPIA used the process of triangulating across interviews with different stakeholders as well as among different sources of data. As an example, the frequency of insulin being out of stock in a setting would be ascertained from patients, health workers, and pharmacists. Similarly, patient numbers attending a facility would be ascertained from nurse and doctor records, clinic registers, and patient reports on frequency of follow-up. The RAPIA is structured as a multilevel assessment of the different elements that influence the access patients have to insulin and diabetes care in a given country (Table 1) and comprises between 100 and 200 interviews or discussions in each country. The framework studies the path of insulin from its arrival in the country to the point that it reaches or fails to treat the patient effectively, thus identifying how and where the system works and/or fails. The RAPIA also studies the availability of infrastructure, personnel, and resources to diagnose, treat, and care for patients with insulin-requiring diabetes.

The term "insulin-requiring diabetes" is defined as onset of diabetes at <30 years of age and a requirement for insulin within 12 months of onset. This term is used instead of the more common term "type 1 diabetes," both because scarcity of ketone testing causes difficulties with the term "ketosis prone" and because of differences in the spectrum of insulin-requiring diabetes among African and Caucasian patients (16,17).

The RAPIA is structured as a multilevel assessment of a health system and is divided into three levels. The macro level is aimed at ministries of health, finance, and trade; national diabetes associations; educational establishments; central medical stores; and private wholesalers of medicines and medical equipment. A meso level is designed for regional and district health offices, health facilities, including pharmacies and laboratories, and private clinics, pharmacies, and laboratories. Finally, information from interviews with health care workers, traditional healers, and patients comprises the micro level. The meso and micro levels are de-

signed to gather information in three distinct geographical locations: the capital city, a large city or urban area, and a predominantly rural area chosen by local partners to represent different geographical and economic situations. The latest version of the RAPIA is available from the authors.

Two countries were studied: Mozambique and Zambia. Both countries are highly indebted poor countries, so defined by the World Bank on the basis that debt repayment demands for such countries heavily exceed their ability to generate income, and, as a consequence, programs of social investment, including health, are suffering (18). The RAPIA in Mozambique comprised 76 interviews (including 25 health care workers, 7 pharmacists, and 18 patients) and another 30 informal meetings and discussions, and was carried out over a period of 3 weeks in April/May 2003. These interviews were carried out in three distinct geographical areas: Maputo (the capital), Beira (a regional capital), and Lichinga (a small town 2,200 km from Maputo in a rural area in northern Mozambique). In Zambia, surveys were conducted in hospitals and health centers in three provinces (Lusaka, Eastern, and Copperbelt). In total 182 interviews took place, including 60 health care workers, 25 pharmacists, and 38 patients, during September/October 2003.

The RAPIA process was conducted by three to eight local people supervised by the project coordinator (D.B.), with liaison to the ministries of health and national diabetes associations. The interviewers were selected and trained as a dedicated team to work in each province rather than evaluating services in the locality within which they were working. The process permitted the RAPIA teams to conduct the whole project in 3–8 weeks per country. In each instance the findings and recommendations were reported to the ministries of health and the national diabetes associations some 4 months after the protocols were completed.

RESULTS

Insulin supply and price

The essential drug lists of Mozambique and Zambia each included both short-acting insulin (Actrapid) and prolonged-acting insulin (Insulatard), 100 IU/ml. In addition Mozambique includes intermediate-acting and mixed insulin preparations in its formulary. Based on these formularies insulin should be available at hospitals and referral health centers. In Mozambique insulin was always present at only 20% of five hospitals studied, but at none of six health centers. In Zambia insulin was present at all 13 hospitals investigated but at only some referral health centers (42%).

Both countries benefit from the Novo Nordisk LEAD Initiative, which provides insulin to the governments of less developed countries at a price not exceeding 20% of the average price in the industrialized countries of North America, Europe, and Japan (19). Insulin was exempt from any taxes and duties in both countries. The cost for insulin purchased by both national health systems was between $4.30 and $4.60 per 10-ml U100 vial including freight costs. In Mozambique, the cost of insulin purchased through a local private wholesaler was between 25 and 125% more expensive ($5.47–$9.91 per 10-ml U100 vial). In Zambia, insulin from private wholesalers was 85–125% more expensive depending on manufacturer. Local purchase was necessary only when need was underestimated for international purchases through tender.

Mozambique and Zambia have regulations in place for patients to receive free or subsidized insulin even though these are neither standardized nor clear to patients. In both countries the price to the patient varied from being free of charge in the public sector to costing >$15.00 per 10-ml U100 vial in the private sector. The average cost to the patient in the public sector was $1.13 per vial in Mozambique and $2.00 in Zambia. Assuming a daily insulin dose of 35 units, the annual cost of purchasing insulin for the health service in these countries is ~$56.03. This is ~40 times the annual public sector pharmaceutical spending per patient in these countries.

There are substantial problems with quantification of insulin needs and ordering at different levels of the health system in these countries. In Mozambique, for example, Maputo Province represents only 11.3% of the total population, yet it receives 77.3% of the total amount of insulin ordered by Mozambique. These problems result in part from orders being based on past consumption rather than on numbers of patients. As both countries purchase a year's supply of insulin at a time, this leads to trouble with stock management and results in some insulin passing its expiration date. No problems with the cold chain were observed in either country, but some logistical problems exist with regards to transportation of insulin, especially to rural areas.

Access to syringes

There are problems with quantification of syringes and testing strips, which are often in short supply in the public sector, meaning that they are purchased in the private sector at high prices. Patients paid from $0.15 to $1.50 per syringe in Zambia and $0.04 to $0.20 per syringe in Mozambique. Patients in rural areas had the most difficulty in accessing syringes. In Zambia a total of 6,242 syringes had been distributed to patients in the public sector from January to October 2003. This quantity is sufficient for only 240 patients, assuming they replace their disposable syringes every 14 days. In discussions with an employee of a private company that sells syringes in Zambia, he stated that he was selling 1,000 insulin syringes a month in Lusaka and that demand far outweighed supply, because of inadequate supplies available through the public sector. Furthermore, there is little standardization of syringes, with 40- and 100-unit/ml syringes both being available.

Diagnostic tools

Only wealthy patients own their own glucose meter. Some patients have their glucose concentrations monitored without charge in public health facilities. Others, depending on whether they have one or more tests per month or their own glucose meter, pay anywhere from $0.20 to $50 per month for their monitoring. Only 6% of health centers visited during the implementation of the RAPIA in Mozambique had facilities to test blood glucose compared with 25% in Zambia. Besides high costs and lack of consumables and laboratory equipment, there was also a shortage of trained staff.

Health care worker and patient knowledge about diabetes

Health care workers in Mozambique and Zambia rarely encounter patients with insulin-requiring diabetes. This lack of familiarity and lack of tools for proper diagnosis mean that diabetes in many patients is likely to be missed or misdiag-

nosed. Diabetes in patients presenting in a coma may be misdiagnosed as cerebral malaria or HIV/AIDS.

In neither country was there a system of referral pathways and treatment guidelines, so that even if diabetes was diagnosed in patients correctly, their referral and treatment may be suboptimal. This is especially true in areas remote from main hospitals.

Low levels of health care worker knowledge about diabetes lead to poor understanding of their condition by patients. Misconceptions about diet and a low level of understanding regarding insulin use leads to poor diabetes management and frequent complications. A shortage of health care workers exists in both countries. This is particularly true in rural areas, and this shortage combined with strong traditional beliefs results in many people accessing health care only through traditional healers.

Table 2—*Comparison of prevalence and life expectancy between Mozambique and Zambia*

Location	Prevalence of insulin-requiring diabetes per 100,000 population	Estimated life expectancy*	
		0–14 years	15+ years
Mozambique			
National	3.5	3.5	5.2
Capital	9.1	3.8	20
Urban	5.0	2.1	11.1
Rural	1.4	0.6	2.9
Zambia			
National	12.0	11.2	16.7
Capital	18.0	18.0	27.0
Urban	12.6	13.0	19.0
Rural	9.5	9.0	14.0

*Estimated life expectancy assumes incidence of insulin-requiring diabetes of 1 per 100,000 per year for 0–14 and 0.67 per 100,000 per year for 15+ (ref. 4) and uses the method described in the text.

The importance of traditional beliefs

Traditional healers are an integral part of the health care systems in Mozambique and Zambia. National associations exist to represent the healers, and at the ministry of health in each country a division deals with the role of traditional medicine within the health system. Many traditional healers stated that they cared for diabetic patients for a certain time and if their condition did not improve within that time frame they would then send the patients to allopathic facilities.

Many traditional healers had heard of diabetes and knew at least that the disease was characterized by excessive thirst and urination. In both countries they also stated that they would welcome closer collaboration with allopathic medical personnel and learning more about diabetes.

Estimates of prevalence and prognosis

The RAPIA enabled rough estimates of prevalence to be calculated. In both Mozambique and Zambia numbers of patients were determined based on interviews with health care workers and from patient registers. If there was more than one facility treating patients in the same area, unless patients reported visiting more than one institution, it was assumed that there was no overlap. Official government population statistics were used as the denominator. The national prevalence was calculated using the respective proportion of populations living in rural and urban areas and the capital city and applying the calculated prevalence to this population. In Mozambique the estimated prevalence of insulin-requiring diabetes was 3.5 per 100,000 population and for Zambia it was 12.0 per 100,000 population. These figures compare with estimates of type 1 diabetes prevalence by the International Diabetes Federation of 5.2 per 100,000 for Mozambique and 4.8 per 100,000 for Zambia (4).

From these prevalence estimates and by using an estimate of diabetes incidence of 1.5 per 100,000 per year (2), it is possible to estimate life expectancy for patients with insulin-requiring diabetes, both nationally and by geographical location. This life expectancy varied from 0.6 years for a child in rural Mozambique to 27 years for an adult living in the capital city in Zambia (Table 2). The prevalence and life expectancy estimates mirror differences in the quality of care, availability of diagnostic tools, and availability of insulin between and across these two countries, with prognosis in rural Mozambique being particularly poor.

CONCLUSIONS — No previous study has examined in systematic fashion the patterns of diabetes care across countries in sub-Saharan Africa. Furthermore, studies of type 1 diabetes prevalence in sub-Saharan Africa are few (20,21) and neither a representative diabetes survey nor diabetes registry is available in the countries assessed. The RAPIA was developed to provide a situational analysis of insulin-requiring diabetes to be able to make recommendations to the national ministries of health and diabetes associations. In both Mozambique and Zambia local stakeholders were actively involved in the assessment. This resulted in the process acting as a catalyst in bringing diabetes to the attention of the health authorities, making the RAPIA an effective tool for advocacy.

The RAPIA has suggested that management of patients with insulin-requiring diabetes in these countries is problematic, particularly outside the catchment area of the major referral hospitals. Insulin availability at a national level did not appear to be a constraint to care. Nevertheless, in Mozambique, the availability of insulin to patients, particularly outside the capital, was a major barrier. Insulin is necessary, but not sufficient, for the survival of a patient with insulin-requiring diabetes. The dearth of health care available for most insulin-requiring diabetic patients outside the capital cities, particularly in Mozambique, also included intermittent availability of supplies needed for diabetes care such as syringes, urine and blood reagent strips, and, perhaps most crucially, little experience in management of diabetes by most health care workers. The nonavailability of blood or urine glucose testing facilities at the majority of health units raises the likelihood that the major contribution to the "missing patients" is failure of diagnosis at presentation.

The Mozambique study showed marked differences in diabetes care and in diabetes prevalence in the capital city and in other parts of the country. These estimates seem to be approximately two to

three times higher for Zambia than for Mozambique, and the urban-rural variation appears substantially lower in Zambia. It is improbable that the Mozambique findings represent differences in incidence in different parts of the country. The size of the country and the distances involved make it unlikely that patients would travel substantial distances for their care. The lower numbers of diabetic patients in other towns and rural areas are likely to represent poorer prognosis away from centers of excellence. The higher priority of diabetes care in national health care planning in Zambia may be attributed, in part, to the active advocacy and educational role played by the Diabetes Association of Zambia.

As stated by former U.S. President Bill Clinton, "Until we build the human and physical infrastructure needed to deliver effective treatment, programs will not succeed" (22). Although he was referring to HIV/AIDS, the same is true for diabetes. A system with such components including continuing supplies of drugs, diagnostic facilities, health worker training and retention, and patient education is vital in the management of diabetes. Improvements in health care systems are, then, a vital component of improving health and health care for patients with many chronic conditions across sub-Saharan Africa.

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