

Background

Diabetes Mellitus is a metabolic disorder caused by different factors characterised by a chronic high level of blood glucose with disturbances to carbohydrate, fat and protein metabolism resulting from defects in insulin secretion, insulin action, or both [1]. Type 1 diabetes is the consequence of a process destroying insulin-producing cells in the pancreas, and presents as an insulin-dependent, or ketosis prone, form of the disease. This is a life-long condition, affecting children, young people and adults worldwide. The disease is recognised by a loss of control over the use of the body's glucose and other fuels and is due to the destruction of insulin producing cells in the pancreas (pancreatic islet beta cells). Inadequate care leads to serious health complications such as blindness, kidney failure, nerve disease, limb amputation, heart attacks, strokes and premature death. In many African populations, the patterns of diabetes differ from those found in Caucasian populations, with a substantial proportion of patients losing weight and wasting, but without ketosis [2,3]. These patients, like those with ketoacidosis, require insulin for reasonable survival. We have used the term insulin-requiring diabetes, defined as a patient with onset at less than 30 years of age and requiring insulin within 12 months of onset, to cover both of these patterns. This term includes people with Type 1 diabetes or Insulin Dependent Diabetes Mellitus (IDDM).

Leonard Thompson, a Canadian child, was given his first injection of insulin on 11 January 1922 [4]. He was the first patient to be treated with insulin for Type 1 diabetes. Having survived some 2½ years from his diagnosis, he had done better than most Type 1 diabetic patients in the pre-insulin era. However three quarters of a century after its discovery, insulin is still not available on an uninterrupted basis in many parts of the developing world [5-7]. A survey in 25 countries in Africa found that in half of them insulin was often unavailable in the large city hospitals, while in only 5 countries was insulin regularly available in rural areas. In some countries, insulin is not included on the national formulary [8].

Before the discovery and purification of insulin, the average life expectancy for a patient with Type 1 diabetes was around 12 months [9]. Some studies suggest that the prognosis for a patient with Type 1 diabetes in sub-Saharan Africa may currently be just as poor [10-12]. The reasons for this are that patients with Type 1 diabetes need a continuing supply of insulin, syringes and monitoring, and a health care system able to provide these supplies to all parts of the country. In parallel to these supplies diabetes-trained health workers able to provide both clinical support and patient education are also essential. There have been no systematic studies in countries in sub-Saharan Africa of health care for patients with Type 1 diabetes.

In order to study such patterns, a clear analysis of the constraints to insulin access and diabetes care is needed. It is likely that increasing the supply of insulin through donations or other means is not sustainable and the root of the problems needs to be solved. This led to the development of the Rapid Assessment Protocol for Insulin Access (RAPIA).

Design

The RAPIA draws on the principles of Rapid Assessment Protocols (RAP) which have been developed and implemented in different areas. The method of RAP has been used extensively to assess services for communicable diseases, including

malaria, tuberculosis and STDs, for the purpose of developing interventions. The approach chosen here is to adapt existing protocols to suit the assessment of access to insulin [13-15].

The main principles of the RAP are:[16]

- Pragmatism – the methods should provide adequate information, without necessarily being ‘scientifically perfect’. Triangulation, or cross-checking between different sources of data is used to establish the validity and reliability of the data collected.
- Speed – the methods are intended to provide relevant information quickly, upon which decisions about health care interventions can be made.
- Use of multiple data sources – different methods are used to access different sources of data to get a balanced overview.
- Cost-effectiveness – the focus is on research instruments that provide information cheaply, and are not labour and time intensive. Where possible, use is made of existing data.

These were adapted through a thorough literature review on diabetes, chronic condition management and medicine supply in developing countries. This literature review was carried out using Medline. Articles were searched using the following Medical Subject Headings (MeSH) individually and in combination: Diabetes Mellitus, Type 1; Diabetes Mellitus; Insulin-Dependent; Diabetes Mellitus, Juvenile-Onset; Type 1 Diabetes Mellitus; Chronic Disease; Chronic Illness; Less-Developed Countries; Third-World Countries; Under-Developed Countries; Developing Nations; Less-Developed Nations; Third-World Nations; Under-Developed Nations; Africa South of the Sahara; Legislation Medical; Drug Therapy; Supply and Distribution; Insulin; Patient Care Management; Disease Management; Self Care; Self Management; Therapy; Guidelines and Practice Guidelines.

Based on these articles and discussions with different experts in the field a conceptual model was developed. This model comprised two paths, the path of insulin and the path of care.

The RAPIA protocol

The aim of the RAPIA is to investigate the possible barriers to insulin access that exist in a particular country. The framework of the RAPIA studies the path of insulin from its arrival in the country to the point that it reaches or fails to treat the patient effectively and thereby identify how and where the system works and/or fails. The questionnaires developed and the questions included in them tried to follow each level of this path from the beginning with the purchase and import of insulin to the country until the insulin reached or failed to reach the patient. In parallel the path of care was assessed from the highest levels of the health system, to regional/provincial organisations, hospitals, clinics and finally individual carers and patients.

All the stakeholders at different levels of the health system within a country were listed that would have an influence on these two factors. These two paths then served as the basis for the development of the questionnaires. Different questionnaires targeted at different stakeholders had overlapping questions in order to check for internal consistency.

The RAPIA is structured as a multi-level assessment of the different elements that influence the access to insulin and care for people with diabetes in a given country. The aim of RAPIA is to provide a practical field guide to assist teams in the collection, analysis and presentation of data to evaluate and inform the development of health care services for diabetes management in resource poor settings. It provides the tools to enable a research team to collect information on the structure and functioning of insulin supply services/practices and also to conduct an assessment of the quality of care currently provided to people with insulin-requiring diabetes. This information is gathered through the different questionnaires detailed in Table 1, site visits, document reviews and discussions.

The RAPIA is divided into 3 components (Table 1). The first is the Macro level which is aimed at the Ministerial levels, Private Sector, National Diabetes Association, Central Medical Store and Educators. Then the Meso level targeted at Provincial Health Officers, "Health Care Settings" (Hospitals, Clinics, Health Centres, etc.) and Pharmacies/Dispensaries. Finally a Micro level where Carers (Healthcare Workers and Traditional Healers) and people with diabetes are interviewed.

In each country the Meso and Micro levels of the protocol were implemented in 3 areas - the capital city, a large urban centre and a predominantly rural area and their respective surroundings. These three areas were chosen by local stakeholders to be representative of different geographical and socio-economic situations within the country. Local teams trained on how to use the tool carried out interviews. Data was then collected and entered into a database for analysis.

A visit to Mozambique, Zambia and Tanzania, with meetings at the Ministry of Health, in hospitals, with diabetes associations, clinicians and patients enabled the lead author to discuss the problems each person had with providing/obtaining care and insulin. This also enabled some questions to be tested and explore the issues surrounding diabetes care and insulin access in more depth in the field. The information gathered from these visits enabled the final development of the questionnaires and protocol. Following the development of the questionnaires these were tested with various people familiar with diabetes and/or healthcare in developing countries.

The questionnaires developed serve as a guide and can be adapted according to the structure of the country. In order to achieve the broad aim, the RAPIA has the following objectives:

- To provide a range of data collection tools, from which research teams can select those appropriate to their own situation
- To provide suggestions of data items to collect
- To provide suggestions on data sources, data collection, data analysis and data presentation for each of the tools presented.
- To collect opinions and perspectives of the different people interviewed rather than precise statistical data.

The RAPIA provides information in the categories of:

- Health service structure and functioning with regards to procurement of medicines, diabetes management
- Diabetes policies written and enacted

- Reported and observed practice for insulin-requiring diabetes management
- Availability of insulin, syringes and monitoring equipment
- Existence of distribution networks for insulin
- Insulin supply-related knowledge and attitudes amongst people with diabetes and their carers.
- Other problems that hamper the access to proper insulin and care

Table 2 shows the specific areas that the different RAPIA questionnaires target.

Implementation of the RAPIA

The Protocol was piloted in Mozambique and then refined with two further iterations in Zambia and Mali. Translations of questionnaires were made into local languages when necessary, with back translation to ensure precision. A copy of the RAPIA protocol is available from the lead author.

Each interview had as its main aim to obtain the person's perspective on the problems faced by people with diabetes in the given country in gaining access to insulin and proper diabetes care, rather than seeking precise statistical information. Through the overlap in the areas of questioning above and by using other sources of information (site visits, discussions and document reviews) the information gathered can be cross-checked and triangulated between different sources and types of information. These different interactions also allowed for new sources of information to be identified and used accordingly.

The RAPIA provides a variety of information with regards to health service structure and functioning with regards to procurement of medicines and diabetes management. It also looks at any policies with regards to diabetes and chronic conditions and studies how they are enacted. With regards to insulin, the RAPIA looks at its availability, price and distribution. This is also done for related supplies such as syringes and testing equipment. In looking at the entire health system the RAPIA is also able to identify other problems that hamper the access to proper insulin and care.

The RAPIA Process

In each country the following steps were carried out to ensure a successful project. A few months before the start of the RAPIA, the lead author visited the specific country in order to garner local support, establish contacts, identify RAPIA teams and prepare training, translate questionnaires, obtain any necessary official credentials, and identify 3 areas of study with local partners. He then prepared the RAPIA and other materials accordingly, while in parallel local partners identified key people to interview and organised logistics.

The lead author then returned and began the RAPIA, in the following sequence: training local teams, contacting necessary interviewees, carrying out interviews, site visits, document reviews and discussions, providing feedback to local partners as the work progressed, and debriefing the local teams to get their impressions.

The findings were written up for distribution to local partners, and a meeting was arranged to present and discuss the findings and develop an Action Plan. In Mozambique and Zambia these were done with the input of Dr. Kaushik Ramaiya, President of the IDF Africa Region and a Tanzanian diabetologist.

Figure 1 shows a diagrammatic representation of the process.

Mali, Mozambique and Zambia were chosen due to their geographical, historical and socio-economic differences. Implementing the RAPIA in these three Highly Indebted Poor Countries (HIPC) was to see how a sustainable solution could be found to the issues of access to insulin and proper diabetes care under extreme conditions of scarce resources in the health sector.

Mozambique was chosen as a pilot country due to strong local support. DB together with a team of local interviewers from the diabetes association carried out the RAPIA in Mozambique over a period of almost 2 months. In total 76 interviews and approximately another 30 informal meetings and discussions were held in three distinct geographical areas in Mozambique - Maputo, Beira and Lichinga and their surroundings.

In collaboration with the Diabetes Association of Zambia (DAZ) and the support of the Central Board of Health, DB carried out the RAPIA in Zambia with a team of local interviewers, patients and carers from the diabetes association. Over a period of a month, 182 interviews and approximately another 40 informal meetings and discussions were held in three provinces in Zambia – Lusaka, Copperbelt and Eastern Province and their surroundings.

Together with Santé Diabète Mali (SDM), a local NGO, and the support of the Ministry of Health, and the Direction Nationale de la Santé, Dr. A. Nientao, DB carried out the RAPIA in Mali. Over 7 weeks 110 interviews and approximately another 40 informal meetings and discussions were held in 4 distinct areas of Mali – District of Bamako (City of Bamako), Sikasso (City of Sikasso and Cercle of Kadiolo), Timbuktu (City of Timbuktu) and Mopti (Cercle of Douentza).

Results were obtained in these three countries on the following:

- Estimates of prevalence for diabetes in different areas of the country
- Estimates of life expectancy in different areas of the country
- Purchase procedures, pricing, distribution, supply and availability of insulin throughout the country
- Purchase procedures, pricing, distribution, supply and availability of syringes throughout the country
- Levels of care in different facilities with regards to diabetes care
- Availability and cost of diagnostics
- Levels of healthcare worker training
- Role and activities of the diabetes associations
- Policies regarding diabetes
- Role of traditional healers
- Other barriers to care and insulin, for example travel, distance and cost

This data enabled the preparation of three country specific reports (available on www.access2insulin.org) highlighting the problems identified during the RAPIA and proposing concrete actions to address them. These reports were presented to local stakeholders and with the input of external experts and the IIF clear Action Plans were

developed. A more comprehensive review of the data from Mozambique and Zambia have been published elsewhere [12].

Discussion

Besides providing valuable information on patients' access to insulin, syringes, monitoring and care which was then used to help these three countries improve the care for people with diabetes, the RAPIA was able to sketch a picture of the health care system and its ability to treat patients with insulin-requiring diabetes. In all countries where this tool was used the involvement of local stakeholders resulted in the process acting as a catalyst in bringing diabetes to the attention of the health authorities. The RAPIA also raised the profile of diabetes associations and awareness around diabetes and non-communicable diseases (NCDs) in countries where most funding and projects are focused on communicable diseases.

It has been proposed that illnesses such as Type 1 diabetes may represent a 'tracer' condition for effective health care systems [17], such that the management of patients with Type 1 diabetes could act as a yardstick against which the components of a fully functioning and effective health care system might be judged. A system with such components – including continuing supplies of drugs, diagnostic facilities, health worker training and retention, and patient education – are vital in the management of other NCDs and of the chronic communicable diseases such as tuberculosis and HIV/AIDS. Improvements in health care systems are, then, a vital component of improving health and health care across sub-Saharan Africa. Therefore the RAPIA besides enabling health planners to assess their health system with regards to insulin-requiring diabetes could use this tool for an assessment of the capacity of their health system to deal with all chronic conditions.

It is intended that the RAPIA be freely available for use by health system planners, in Ministries, NGOs and international organisations, in other countries in Africa and elsewhere. The latest version of the RAPIA is available from the lead author, and discussions are proceeding with WHO divisions in Geneva and in Africa, as well as with the International Diabetes Federation, to disseminate the tool more widely for assessing health services for diabetic patients in resource poor countries.

Abbreviations

DAZ – Diabetes Association of Zambia
HIPC – Highly Indebted Poor Countries
IDDM – Insulin Dependent Diabetes Mellitus
IIF – International Insulin Foundation
MeSH – Medical Subject Headings
NCDs – Non Communicable Diseases
RAP – Rapid Assessment Protocol
RAPIA – Rapid Assessment Protocol for Insulin Access
SDM – Santé Diabète Mali

Competing Interests

No competing interests.

Author's contributions

DB drafted the manuscript, edited and revised the contents, MdC and JY edited and revised and reviewed the manuscript, DB, MdC and JY all contributed to the conceptual development of the project.

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Table 1 – Questionnaires that make up the RAPIA

Level	Issues Addressed in each RAPIA questionnaire
MACRO	
- Ministry of Health	- Organisation 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 Organisation	- Issues with diabetes and insulin - Organisation of care for people with diabetes
- Hospitals, Clinics, Health Centres, Dispensaries, etc.	- Treatment and management of people with diabetes - 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

Taken from [12]

Table 1 – Target areas of each RAPIA questionnaire

Target questions with regards to insulin and diabetes care	Questionnaires														
	Ministry of Trade	Ministry of Finance	Ministry of Health	Private Sector	National Diabetes Association	Central Medical Store	Educators	Regional Health Organisation	Regional Central Medical Store	Hospitals, Clinics, Health Centres, etc.	Laboratories	Pharmacies	Health Workers	Traditional Healers	Patients
Funding for diabetes care and insulin		X	X			X		X	X	X					X
Taxes and Import restrictions on insulin	X	X	X	X	X	X			X			X			
Labour Resources			X					X		X					
Organisation of care			X		X			X		X			X	X	X
Supply of insulin and related supplies (cost, mark-ups, taxes, “black market”)	X		X	X	X	X		X	X	X	X	X	X		X
Infrastructure			X	X		X		X	X	X	X	X	X		
Tools for monitoring and administration diabetes care			X		X			X		X	X		X		X
Training			X		X		X						X	X	
Awareness and education			X		X		X				X	X	X	X	X
Prevalence, Incidence number of cases seen			X		X		X	X		X	X	X	X	X	
Process of care (from diagnosis to treatment)			X		X			X		X	X	X	X	X	X

Figure 1 – Stages of the RAPIA

