

# World Journal of *Diabetes*

*World J Diabetes* 2020 August 15; 11(8): 322-369



**REVIEW**

- 322 Range of adiposity and cardiorenal syndrome  
*Pazos F*

**MINIREVIEWS**

- 351 Interstitial lung disease and diabetes  
*Rajasurya V, Gunasekaran K, Surani S*

**ORIGINAL ARTICLE****Observational Study**

- 358 Access to insulin delivery devices and glycated haemoglobin in lower-income countries  
*Klatman EL, Ogle GD*

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## Observational Study

## Access to insulin delivery devices and glycated haemoglobin in lower-income countries

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## Abstract

## BACKGROUND

Young people with type 1 diabetes in low-and-middle income countries face many challenges in accessing care, with various essential supplies needed for survival and long-term health.

## AIM

To study insulin delivery devices and glycated haemoglobin (HbA1c) testing.

## METHODS

A survey was conducted in 2019 of leading diabetes centres in 41 countries supported by the Life for a Child Program. The survey covered numerous aspects concerning availability and costs at all levels of the health system, local usage patterns and attitudes, obstacles, and other aspects.

## RESULTS

Thirty-seven countries returned the survey (90.2% response rate). Key findings included: Syringe use was most common (83.1%), followed by insulin pens (16.7%) and pumps (0.2%). 48.6% of public health systems did not provide syringes, even with a co-payment. Use of suboptimal syringe/needle combinations was common. Needles were generally reused in almost all countries (94.3%,  $n = 35$ ). Aside from donated supplies, there was variable access to HbA1c testing within public health facilities, and, when available, patients often had to cover the cost. Provision was further compromised by numerous problems including stock-outs, and challenges with understanding the test, equipment maintenance, and refrigeration.

## CONCLUSION

Large gaps exist for adequate access to appropriate insulin delivery devices and HbA1c testing. Public health systems in low-and-middle income countries should increase affordable provision. There are also needs for specific health professional

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training and diabetes education; elimination of customs duties and taxes; development of inexpensive, robust HbA1c testing methods that do not require refrigeration of testing supplies; differential pricing schemes; and other solutions.

**Key words:** Type 1 diabetes; Diagnostics; Glycated haemoglobin; Syringes; Insulin; Access

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**Core tip:** This study reviews access to insulin delivery devices and glycated haemoglobin testing supplies in 37 less-resourced countries. Although these two essential non-insulin supplies are required to effectively manage Type 1 diabetes, the study's results demonstrate that their access is largely insufficient within the health systems of the countries surveyed. Specific access barriers are summarised and recommendations to overcome these are advocated for by the authors.

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## INTRODUCTION

Care for people with type 1 diabetes (T1D) involves a number of essential supplies, including insulin and injection devices, blood glucose monitoring equipment, and glycated haemoglobin (HbA1c) testing. For insulin, many have thoroughly assessed access to care<sup>[1-9]</sup>. On a smaller scale, this has been done for blood glucose meters and test strips<sup>[10-12]</sup>. However, this has not yet been comprehensively done for insulin injection devices and HbA1c testing equipment.

Insulin can be injected *via* syringe, pen, or insulin pump<sup>[13]</sup>. In 2015, our group surveyed 71 countries, finding that there was no government provision of syringes in 12 countries and incomplete provision in 24<sup>[6]</sup>, necessitating families buying these out-of-pocket in private retail pharmacies. Only six countries had full government provision of insulin pens<sup>[6]</sup>. Measurement of HbA1c is an essential component of monitoring glycaemic control, providing crucial information on recent blood glucose control and the risk of developing long-term complications. Testing every three months is recommended in young people with T1D<sup>[14,15]</sup>, with HbA1c either being measured in a laboratory or in clinic by point-of-care testing (POCT). POCT is the most suitable method to inform treatment changes as it provides immediate results which can be discussed with the patient and used to guide any required changes in management<sup>[16]</sup>. However, access to either method can be poor in low-and-middle income countries (LMICs). In a study of 15 such countries, HbA1c testing was not available at all in two countries, free in one country, and required a co-payment in 12 countries, with 90% of families requiring assistance with the cost<sup>[17]</sup>. Even in major youth diabetes centres, POCT may not be available. Our group previously reported provision in 37% of low-income countries, and 50% of lower-middle income countries<sup>[6]</sup>.

To address these gaps in knowledge about insulin delivery devices and HbA1c testing, the Life for a Child Program (LFAC)<sup>[18]</sup> undertook a survey of LFAC-supported health centres in 37 countries to assess current global access to these components of T1D care.

## MATERIALS AND METHODS

### Survey

This study was done *via* means of a survey. Survey questions covered provision, cost, and availability of HbA1c testing and insulin injection devices within respondent's countries. Availability of HbA1c testing and syringes/pens in national health systems

was estimated by the centre respondent on a scale of 100% being always available, 75% mostly available, 50% sometimes available, 25% rarely available, and 0% never available. The draft was finalised after peer review to four global T1D experts. Translations into French and Spanish were done by bilingual diabetes experts. The full survey is in Appendix A in the Supplementary materials.

### Survey respondents

The survey was sent to the senior lead in the main diabetes centres supported by the LFAC program in 41 countries. Four centres in four different countries did not return the questionnaire.

Responses were received from 37 countries: Azerbaijan, Bangladesh, Bolivia, Burkina Faso, Burundi, Central African Republic, Democratic Republic of Congo, Dominican Republic, Ecuador, Eritrea, Ethiopia, Ghana, Guatemala, Guyana, Haiti, India, Jamaica, Liberia, Maldives, Mali, Mauritania, Mexico, Nepal, Nigeria, North Korea, Pakistan, Philippines, Republic of Congo, Rwanda, Sri Lanka, St Lucia, Tajikistan, Tanzania, Togo, Uganda, Uzbekistan, and Vietnam. The geographic distribution of respondent countries was Africa (16 countries), Americas (nine), Asia (eight), Caucasus/Central Asia (3) and Western Pacific (1) with 44.4% being low-income countries, 33.3% lower-middle, and 22.2% upper-middle.

The types of respondents were as follows: 20 national diabetes association chiefs, five diabetes nongovernmental organisations doing extensive work in diabetes care, seven government hospitals, two senior endocrinologists, two Ministry of Health officials, and one mission hospital.

Costs were obtained in local currency and then converted to US dollar at the time. When prices and frequencies of HbA1c tests and insulin injections were reported as ranges, the mean values were used for analysis. When necessary, follow up questions were clarified by e-mail, or Skype. The open source mobile data collection program KoBo Toolbox (Cambridge, Massachusetts) was used for recording returned surveys. When all surveys were returned, data were inputted into Excel and descriptive statistics were derived. The *n* for all results is 37 unless otherwise stated.

## RESULTS

### Insulin delivery devices

Within the 37 centres, the average percentage of those injecting insulin *via* syringes was 83.1% and pens 16.7%. Only three countries had higher pen than syringe use: Vietnam (97%/3% respectively), Maldives (92%/0%) and Guyana (65%/35%), with Dominican Republic and Ecuador having an even split.

29 of the 37 centres (78.4%) provided syringes to enrolled patients. Of these 29, nine centres (31.0%) had to purchase these and twenty centres (69.0%) received donations. The mean cost to centres who had to purchase syringes was \$0.32 per syringe, ranging from \$0.04 in Uzbekistan to \$0.97 in Guatemala. Six centres charged patients for syringes, with a mean price of \$0.23. All of the centres that received donations provided these free-of-charge to patients. Only one centre that purchased syringes provided these free of charge to patients.

Respondents were asked to designate where young people could obtain insulin syringes outside of their centres. 45.9% of respondents (*n* = 17) stated they were provided only in private retail pharmacies, 21.6% (*n* = 8) in public health system and private retail pharmacies, 18.9% (*n* = 7) the public health system and private retail pharmacy and public health insurance, 5.4% (*n* = 2) only the public health system, 5.4% (*n* = 2) the public health system and public health insurance program, and 2.7% (*n* = 1) private retail pharmacies and public health insurance program. **Table 1** details the costs of syringes within these settings.

Eighteen countries (48.6%) stated that they believed young patients receiving private treatment in the respective country mostly used syringes, while sixteen (43.2%) stated pens. One respondent (2.7%) stated both, and two (5.4%) did not answer. In no country were pumps the most common delivery mechanism for private patients.

The commonest syringe volume used in countries was 1 cc/mL [95.5% response rate (*n* = 35), 42.9% (*n* = 15) using these]. The commonest needle size used was a needle length of 3/16 inch (5 mm) [89.1% (*n* = 33) response rate, with 48.5% (*n* = 16) using these]. The commonest needle gauge was 28 needle gauge [86.4% (*n* = 32) response rate, with 43.8% (*n* = 14) using these]. Specific challenges were reported by individual countries: In Ecuador, syringes were free in the public health system but the respondent noted the lengths available were inappropriately long for paediatric cases

**Table 1 Syringe provision and costs**

Setting	% of settings where syringes are free of charge	Mean (range), range, costs of a syringe to the patient (for systems not providing for free)
Public health system	47.4	\$0.27, \$0.04 (Uzbekistan)-\$0.97 (Tajikistan)
Private retail pharmacy	0.0	\$0.29, \$0.07 (Eritrea)-\$1.25 (Bolivia)
Public health insurance program	50.0	\$0.19, \$0.10 (Burundi)-\$0.28 (Nigeria)

Table 2 provides further details.

74.3% ( $n = 26$ ) of respondents indicated that patients preferred pens, 20.0% ( $n = 7$ ) syringes, and 5.7% ( $n = 2$ ) both. The most common injection site was thighs, followed by stomach. Table 3 provides further detail. The most common age that centres educated patients with the tools to begin self-administering insulin injections was 10 years old, followed by eight years old. Table 4 provides further detail. In Ecuador, Jamaica, Pakistan, Tajikistan, and Tanzania, respondents noted that this would vary on an individual patient basis. Respondents from Philippines and St Lucia did not answer.

In terms of needle reuse, respondents noted that patients mostly tended to use their needle more than once, but less than five times before disposal, with 35 centres responding (see Table 5).

As a result of needle reuse, 13.9% ( $n = 5$ ) of respondents stated infection issues were “common”, 33.3% ( $n = 12$ ) “not uncommon”, 30.6% ( $n = 11$ ) had seen 1-2 isolated cases, and 22.2% ( $n = 8$ ) had not seen any infections. The centre in Ethiopia commented that an interrupted syringe supply had led to extensive reuse and more painful injections were reported. The respondent from Rwanda stated that lipohypertrophy was sometimes seen but this may have been due to inappropriate injection technique.

For lipohypertrophy, 5.4% ( $n = 2$ ) stated this was very common, 18.9% ( $n = 7$ ) common, 43.2% ( $n = 16$ ) not uncommon, 18.9% ( $n = 7$ ) had seen 1-2 isolated cases, and 13.5% ( $n = 5$ ) had never seen it.

62.5% ( $n = 20$ ) of respondents stated they believed improper disposal of insulin syringes/pens was a problem in their country, whilst 37.5% ( $n = 12$ ) did not. 52.7% of respondents ( $n = 19$ ) noted that there was official national guidance on the safe disposal of needles, whilst 47.2% ( $n = 17$ ) stated there was not.

Most respondents (74.3%,  $n = 26$ ) noted that young people experience feeling stigmatized when injecting their insulin with syringes in public. Two respondents did not answer.

### HbA1c testing

Of the 37 countries, 83.8% ( $n = 31$ ) provided HbA1c testing at the centres and 16.2% ( $n = 6$ ) did not. Of the 31 centres that did provide testing, 22 (71.0%) provided POCT, eight (36.4%) used laboratory analysis, and one (3.2%) both methods. When provided, the average annual frequency of HbA1c testing for young people with T1D was  $3.0 \pm 1.58$  (mean  $\pm$  SD), with a range of 1-4 tests.

Of the 31 centres that provided testing, 20 (65.5%) had to pay for HbA1c test cartridges/laboratory reagents, and 11 (35.5%) received these by donation from LFAC. The mean cost to the centre when purchased was \$6.89 (range \$2.20 in Sri Lanka - \$14.80 in St Lucia). Eighteen (58.1%) provided tests free-of-charge to young people with T1D, and for the 13 centres that did charge, the mean cost was \$9.34 per test (range \$2.36 in Mexico-\$18.50 in St Lucia).

78.4% of respondents ( $n = 29$ ) stated that HbA1c testing was provided in some level(s) of their respective national health systems - see Table 6. Eight countries had no provision of HbA1c testing in the public health system.

Respondents were asked whether they thought the education/support provided at their centre was adequate, and whether they thought patients were provided with the knowledge and strategies to help guide improvements in their glycaemic control. Thirty-five centres responded, with 27 (77.1%) stating that it was adequate and eight (22.9%) that it was inadequate. This question was also asked about the public health system, with 23 centres responding. Six respondents (26.1%) stated the education/support was adequate, and 17 (73.9%) inadequate.

The mean  $\pm$  SD cost of an HbA1c test within a private laboratory was \$15.42  $\pm$  \$12.46, range \$4.00 in Vietnam-\$28.85 in Mexico (reported for 34 countries). This compared to an average cost of \$10.87  $\pm$  \$1.09 (range \$9.74-\$11.92) in public health

**Table 2 Syringe volume and needle length and gauge**

Syringe volume ( <i>n</i> = 37)				
	1 mL/cc	0.5 mL/cc	0.3 mL/cc	
Percentage	42.9 ( <i>n</i> = 15)	34.3 ( <i>n</i> = 12)	22.9 ( <i>n</i> = 8)	
Needle length ( <i>n</i> = 33)				
	5/16" (8 mm)	3/16" (5 mm)	1/8" (4 mm)	
Percentage	36.4 ( <i>n</i> = 12)	48.5 ( <i>n</i> = 16)	15.2 ( <i>n</i> = 5)	
Needle gauge ( <i>n</i> = 32)				
	28	29	30	31
Percentage	43.8 ( <i>n</i> = 14)	15.6 ( <i>n</i> = 5)	15.6 ( <i>n</i> = 5)	25.0 ( <i>n</i> = 8)

**Table 3 Injection sites encouraged by diabetes centres**

Injection sites	Number (%) of centres
Thighs	36 (97.2)
Stomach	35 (94.5)
Back of arm	21 (56.7)
Buttocks	19 (51.3)
Front of arm	12 (32.4)
Other	1 (2.7)

**Table 4 Ages recommended to begin self-administration of insulin injection**

Age (yr)	Number (%) of centres
≤ 5	3 (10.0)
6	4 (13.3)
7	2 (6.7)
8	6 (20.0)
9	2 (6.7)
10	9 (30.0)
11	1 (3.3)
≥ 12	3 (10.0)

**Table 5 Needle reuse**

Times needle used before disposal	Number ( <i>n</i> %) of centres
Single use	2 (5.7)
Two to four	18 (51.4)
Five to nine	10 (28.6)
Ten or more	5 (14.3)

settings, when it was available there. 41.4% of country respondents (*n* = 37) stated that HbA1c testing was covered in one or more health insurance program within their respective country.

Survey respondents were asked to identify the main challenges in providing HbA1c testing at their centres. Thirty-two centres responded. Table 7 shows the number of

**Table 6 Glycated haemoglobin provision within the 29 countries that had some public health provision**

Provision	Frequency of provision in defined setting	Measurement methods			Costs per test			Availability
		POCT	Laboratory analysis	Both	Number (percentage) providing at no cost to patient	Mean cost to patient (when not provided for free)	Range of cost to patient	Mean availability (when provided)
Primary health care facility	6 (20.7)	3	3	0	2 (33.3)	\$10.95	\$6.44 (Dominican Republic)-\$17.41 (Philippines)	62.5%
District and regional hospitals	27 (93.1)	7	15	5	4 (14.8)	\$9.74	\$4.00 (Ethiopia and Uzbekistan)-\$27.75 (St Lucia)	67.5%
Tertiary hospital	26 (89.7)	4	18	4	9 (34.6)	\$11.92	\$4.00 (Ethiopia)-\$29.00 (Central African Republic)	75.5%

POCT: Point-of-care testing.

**Table 7 Main challenges in providing glycated haemoglobin testing**

Challenge	Number (%) of centres reporting this challenge
Cartridge cost	23 (70.9)
Stockouts	22 (68.8)
Maintenance of testing machine	21 (65.6)
Machine cost	18 (56.3)
Adequate supplies	15 (46.9)
Trained staff	15 (46.9)
Refrigeration	11 (34.4)
Adequate oversight of supplies	9 (28.1)
Other challenges	8 (25.0)

respondents reporting each pre-defined potential challenge. Further information is in Appendix B of Supplementary Material.

Thirty-one respondents answered a question about whether they had experienced an interruption in being able to provide testing due to stock-outs of cartridges /reagents. Twenty-eight respondents (90.3%) stated they had and three (9.7%) had not. The length of interruption ranged from one month in Eritrea to 36 mo in St. Lucia, with a mean of 10.5 mo. Respondents reported that various alternate methods of assessing overall blood glucose control were used in the stock-out periods. These included sending patients to public or private external health facilities. Others said they reviewed patients' glucose measurements (random, fasting, postprandial, or those recorded within logbooks), while a number said they relied on anthropometric measurements and general wellbeing. Some respondents said they had no alternative methods in place.

Respondents were asked to whether they knew of young people with T1D who had forgone HbA1c testing due to cost or other barriers. Thirty-four responded, 76.5% ( $n = 26$ ) stated "yes" 23.5% ( $n = 8$ ) stated "no".

Further details on barriers to HbA1c testing for patients are presented in Appendix C in the Supplementary materials.

## DISCUSSION

This study of leading childhood and adolescent diabetes centres in 37 LMICs demonstrates that there are many challenges to the provision and accessibility of adequate insulin-delivery devices and HbA1c testing.

Insulin syringes were by far the most common delivery mechanism, with pens more commonly used in only three countries, and pump use was uncommon, even for private patients. In 48.6% of countries there was no government provision of syringes at all, with 20 countries (54.0%) fully or partly relying on donations from LFAC or other sources.

Insulin delivery *via* a pen or pump is preferred when there are adequate resources to support this<sup>[13]</sup>. Insulin doses are more precise, with both routes providing convenience and greater patient control<sup>[19]</sup>. The stigma of using a needle and syringe in public, reported by 74.3% of countries in the current study, can be profound and also reduce treatment compliance. However, both pens and pumps are more expensive options than using syringes. Insulin pens, whether disposable or refillable, use cartridge insulin (which is generally more expensive)<sup>[15]</sup>, and pumps have the substantial added cost of the device itself and the ongoing consumables.

Even when available, insulin syringes were usually expensive, with prices up to \$0.97 per syringe, and mean prices to patients of \$0.23. This is consistent with a previous study our group did in 25 countries which found that the median cost of a syringe to the T1D patient/family was \$0.20, and aside from being provided for free in St Lucia, costs ranged from \$0.10 in Nepal to \$0.56 in Central African Republic<sup>[17]</sup>. Syringe costs can also vary markedly within a country – a study by Beran *et al*<sup>[9]</sup> found a range of \$0.15-\$1.50 in Zambia and \$0.04-\$0.20 in Mozambique.

The current study found a range of syringes were available in different countries. Syringes are needed for many purposes in medicine. For people with diabetes, the type of syringe/needle combination is important. The recommended syringes for T1D are plastic fixed needles<sup>[13]</sup>, with short needle lengths<sup>[19]</sup> (4 mm) to limit risks of intramuscular injections that lead to bleeding, bruising and pain<sup>[19,20]</sup>. Fine gauges (32-gauge) are recommended to encourage correct site rotation and thereby reduce the development of lipohypertrophy, which can cause insulin absorption problems and unexpected hypoglycemia<sup>[20]</sup>. Syringes should also have small unit markers to help accurately deliver doses in younger children.

Smaller volume syringes make dosing more accurate and therefore more effective and safer. This is especially an issue for younger children who may only be receiving a couple of units of insulin per injection – an inadvertently high dose can lead to a life-threatening hypoglycaemic episode. 1 mL/cc syringes, used in 42.9% of the surveyed countries, are often too big - 0.5 mL/cc and 0.3 mL/cc syringes should also both be available<sup>[13]</sup>.

Consistent with international guidelines<sup>[13,19,21]</sup>, injections were most commonly given in the thighs, stomach, back of arm and buttocks. However, the front of the arm was also used in 32.4% of countries. The median age of children starting to give their own injections was 8-9 years with 43.3% of countries delaying this to 10 or older.

Manufacturers and guidelines direct single use of needles<sup>[13,19]</sup>. We found that, given cost and limited availability, reuse of syringes was practised by necessity in all but two countries. (Even if syringes could be purchased at \$0.20 each, three injection per day would be an annual cost of \$219). Reuse is however common even in well-resourced countries<sup>[13]</sup>. Other studies have found that some reuse can generally be done safely<sup>[17]</sup>, occur without risk of infection<sup>[13,22]</sup> and be cost-effective<sup>[22]</sup>. The current study found that infections at the injection site were common in almost half the countries surveyed, but 14.3% of countries had reuse of ten times or more, and a further 28.6% at five to nine times.

Reuse should not be encouraged when needles become blunt (due to increased pain) or if there are patient hygiene concerns, and sharing between patients must not occur<sup>[13]</sup>. One study noted that reuse of a single syringe more than five times poses risks for the development of lipohypertrophy<sup>[23]</sup>, however this may just be due to associated lack of site rotation, as commented by one of the respondents in the current study. The East African Diabetes Study Group advises that if needles are reused, this should not exceed five times and that they should be discarded if injections become more painful<sup>[24]</sup>. Provision by the Life for a Child Program is similar at four syringes per week.

Appropriate disposal of syringes was a common problem, as it is globally, posing accidental needlestick risks to the public<sup>[20]</sup>. Used needles should be disposed in specific sharps containers or opaque plastic containers for garbage collection<sup>[13]</sup>. The East African Diabetes Study Group notes there are many barriers that make disposal challenging in less-resourced settings, including lack of knowledge, misconceptions that sharps disposal containers are for illicit drug-users, and fear of revealing diabetes status. This results in various inappropriate current disposal practices such as in pit toilets or burning them<sup>[24]</sup>. Appropriate local recommendations are essential so that injuries to those with T1D, their families, waste handlers, and members of the

community are minimized<sup>[24]</sup>, but this was lacking in most countries in the current survey, and where was official guidance, many respondents said that these were designed for use by health professionals in hospital settings, and not for patients.

This study has demonstrated a legion of challenges for access to HbA1c testing, including availability of test equipment and disposables, cost, and numerous logistic and technical issues. HbA1c is an essential component of providing an “Intermediate Care” level which substantially reduces morbidity and mortality, and is cost-effective<sup>[15,25]</sup>. Without such testing, health professionals and patients are blind to information about medium-term blood glucose control, and whether the patient is meeting the recommended target or is exceeding this by a variable margin. Understanding for the health professional and patient is impaired, and diabetes education is severely hampered. Audit of clinical outcomes, and benchmarking efforts are virtually impossible.

Care is further compromised in LMICs by the frequent lack of access to supplies for self-monitoring of blood glucose, which limits blood glucose monitoring to clinic visits<sup>[6,11,26]</sup>. A study in Guinea concluded that inadequate access to HbA1c was the main precursor for poor glycaemic control<sup>[27]</sup>.

HbA1c testing was available in 31 of the 37 centres surveyed, and in 22 of these it was POCT. Eleven centres (all providing POCT) were reliant on donations from LFAC, with the other centres purchasing supplies. HbA1c testing was completely unavailable in Liberia and North Korea. Availability of testing was patchy in most countries at all levels of the health system, and particularly outside major hospitals, as has been noted by others<sup>[26]</sup>, with this resulting in either impaired management or lengthy and costly travel times for patients in rural areas<sup>[26]</sup>.

Data from the 2015 Assessing National Capacity for the Prevention and Control of Noncommunicable Disease Global Survey<sup>[28]</sup> found that HbA1c testing was substantially less available than insulin provision and clinic blood glucose measurement in all country income levels except for High-income countries (see collated data extracted from this study in Figure in Appendix D of the Supplementary Materials). Also demonstrating this lack of availability are a Ugandan study which found testing was only available in 43.2% of hospitals (63.6% in private and 23.7% in public hospitals)<sup>[29]</sup>, and a study in Cameroon which found the test was available in 50% of urban hospitals and 0% of rural hospitals<sup>[30]</sup>.

POCT was only available at any level of the public health system in 37.8% of countries. This is despite it being the preferred method of testing in T1D as the immediate availability of results permits the health professional and the patient to discuss the HbA1c level and decide on management adjustments, and is noted to be even more beneficial in rural settings<sup>[31]</sup>.

The costs reported were a little lower than those reported in previous studies: \$4.90–\$20.00 with a mean \$9.75 in 12 countries<sup>[17]</sup>, and in Ethiopia, where it was reported to be \$13.00 per test<sup>[32]</sup>. Another study found that one HbA1c test cost 12.6 d of wages in Cameroon<sup>[30]</sup>. Costs in the current study were higher in private laboratories.

Further challenges were reported. HbA1c test supplies require refrigeration, and maintaining the cold-chain to the health facility and then refrigerating the (often quite bulky) supplies there is often a problem. Some respondents reported difficulties with using the equipment due to inadequate training. There is often no supplier in the country, increasing the risk of stock-outs and making machine service difficult or impossible. Some centres surveyed felt that healthcare professionals at their centres were inadequately educated in how to interpret and use patient results. Some respondents noted inefficiencies within their respective governmental agencies to procure sufficient stock, and noted a lack of commitment from their governments towards investment in diabetes care.

Several respondents also cited high import taxes and tariffs levied on HbA1c reagents and machines and resultant delays in customs clearance. Such taxes and tariffs have been raised by other researchers as further deterring national procurement officials from procuring machines and reagents as the higher costs would be usually passed on to patients who face further difficulty in affording them<sup>[26]</sup>. This issue of higher taxes and duties on diagnostic tests as opposed to essential medicines is also seen with self-blood glucose monitoring supplies<sup>[10]</sup>.

It should be noted that, due to various limitations of HbA1c as a measure of medium-term glucose control, alternative methods (such as time-in-range and glycaemic variability) have been proposed and are now being used in highly-resourced T1D care settings, using metrics derived from continuous glucose monitoring devices<sup>[33,34]</sup>. However, currently these devices are prohibitively expensive for less-resourced situations. HbA1c is also critical in the management of the much

larger problem of Type 2 diabetes, and also now has a substantial role in diagnosis and screening of Type 2<sup>[35]</sup>. Therefore, availability of this test will remain a critical issue in diabetes care in LMICs for the foreseeable future.

In conclusion, public health systems in LMICs are frequently unable to provide access to appropriate injection devices and HbA1c testing for people with diabetes. Furthermore, the cost of private purchase is often prohibitive, even if these components of care are available. This compromises the level of care that can be provided. Many countries are currently reliant on international donations. Implementation of HbA1c testing is further compromised by challenges with providing education, refrigeration, and equipment maintenance.

Based on these findings, we make the following recommendations: (1) National health systems with limited resources should provide appropriate fine-gauge and short-length insulin syringes for people with T1D, including smaller volume syringes for younger children. (2) Provision of reusable pens and cartridge insulin is preferable where resources permit. Equivalence of prices for vial and cartridge insulin would allow use of reusable pens as the ideal delivery method in LMICs, and also eliminate one of the extra costs associated with insulin pumps. (3) Reuse of syringes by individual patients is not optimal but is generally safe as long as there is appropriate personal hygiene. It should be restricted to five uses of a particular syringe, with patients being warned about early signs of infection. Inspection of injection sites, and site rotation should be checked at each clinic visit. (4) Practical guidelines should be in place for each country re syringe disposal. (5) HbA1c testing, preferably four times per year, is a mandatory part of T1D care in any country, unless supplanted by continuous glucose monitoring devices measuring time-in-range. (6) POCT for HbA1c testing is optimal. (7) The ideal HbA1c testing device for less-resource settings would be an accurate easy-to-use, battery power option, robust, minimal maintenance machine with battery power as an option that uses inexpensive testing supplies that have a long shelf life and do not require refrigeration. (8) Health professional training and patient/family diabetes education is critical for effective use of HbA1c testing. (9) Companies should consider differential pricing arrangements for these components of care for lower-income countries. And (10) Finally, customs duties and taxes increase the price and decrease availability of these components of care. This area warrants further study, and advocacy is needed country-by-country to eliminate these charges – these essential medical devices and diagnostics should be treated the same as essential medicines<sup>[10]</sup>.

## ARTICLE HIGHLIGHTS

### **Research background**

People with type 1 diabetes, especially those that are young, require tools beyond insulin to help them improve their glycaemic control and avoid acute and long-term complications. These include insulin delivery devices and glycated haemoglobin (HbA1c) testing. Presently, many low-and-middle income countries (LMICs) have difficulty in providing adequate access to these two supplies. Therefore, this study investigates these barriers and provides recommendations for overcoming them. This is essential to helping health systems in LMICs make progress towards providing appropriate type 1 diabetes care to all in need.

### **Research motivation**

With regards to insulin delivery devices and HbA1c testing, study authors sought to investigate the range of access challenges for patients, health care providers, and health systems. Authors further endeavoured to understand the specific challenges associated with provision, costs, availability, usage details, and perceived hardships.

### **Research objectives**

As no existing studies have comprehensively looked into access of solely non-insulin supplies, study objectives were to do this for non-insulin essential devices within LMICs. This study was able to fulfil and apply this objective to 37 countries. By accomplishing this, future recommendations can be provided to help countries improve access to these supplies.

### **Research methods**

A survey was completed by senior leads of diabetes centres supported by the Life for a

Child Program. These included 37 LMICs within Africa, the Americas, Asia, Caucasus/Central Asia, and Western Pacific. Respondents ranged from national diabetes association chiefs, diabetes nongovernmental organisations, government hospitals, senior endocrinologists, Ministry of Health officials, and a mission hospital. Survey questions covered provision, cost, and availability of HbA1c testing and insulin injection devices.

### **Research results**

For insulin injection devices, results demonstrated that roughly half of the surveyed health systems provided syringes for insulin use. Further, a number of respondents noted that their patients used syringes with suboptimal practice surrounding reuse, site rotation, and disposal. For HbA1c testing, provision across the surveyed countries was more wide-ranging. Testing was not always available even in the countries where it was provided within public health settings. In these instances, patients could only access tests at private pharmacies, where they received no financial assistance. A number of respondents noted that, as health care providers, they faced many challenges in providing testing to patients including maintaining supply stock, maintenance, and health professional education.

### **Research conclusions**

This novel study shows that access to appropriate insulin delivery devices and HbA1c testing in LMICs is largely inadequate. For insulin delivery devices, poor access was largely due to lack of provision in health systems, stigma associated with syringes, cost, and inappropriate needle lengths, sizes, and gauges. For HbA1c testing, poor access for patients mainly stemmed from lack of availability and high purchase costs, and the taxes and tariffs levied of testing equipment within health systems. Sustaining maintenance and supply stock were further challenges. Research findings could serve as material to help patients, health care professionals, and civil society organisations advocate for increased provision of non-insulin essential diabetes supplies.

### **Research perspectives**

When people with diabetes cannot access insulin delivery devices, challenges arise associated with needle reuse, infection, and disposal. Further, inadequate access to HbA1c testing is problematic for people with diabetes, and also challenging for their health care providers, as the information derived can help to promote effective self-management and mitigate the risk of developing complications. Learning from the findings of this study, the authors encourage health systems to focus on provision of affordable and appropriate needle gauges, lengths and sizes, and accurate information on needle reuse and disposal. For HbA1c testing, it is essential that available and affordable testing be available within health systems, whereby health professionals and patients are appropriately education on usage. Preferential pricing arrangements, and reduction or elimination of taxes and tariffs are also ways to help improve access to these two supplies. Increased access means that health care providers can provide the resources necessary to enable patients to effectively lead their Type 1 diabetes self-management and mitigate risks of developing complications.

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