

RESEARCH ARTICLE

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Availability and pricing of insulin and related diagnostics in South Africa

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ABSTRACT

Background: In South Africa (SA), most patients rely on the government for free healthcare. Some choose to subscribe to a medical insurance scheme. If insulin is unavailable in government or otherwise unaffordable, non-adherence may occur, which can increase complications of the disease.

Methods: Data on availability and pricing of insulin and related diagnostics was collected from SA pharmacies via an online survey. Co-payments levied on insulin by the biggest medical aids were extracted from formularies. Affordability of these items was then assessed. An adapted methodology from the World Health Organization/Health Action International tool was used. **Results:** There was fairly high availability of insulin in the public sector, with the exception of long-acting insulin which respondents claimed was difficult to find; however, long-acting insulin glargine was available in most private sector pharmacies. Point-of-care (POC) blood glucose testing was free in the public sector but offered in only 31.25% of pharmacies. Patients pay a minimum of USD 40.4 (over 3 days' wages for the lowest paid government worker (LPGW)) for a months' supply of the cheapest insulin, needles and test strips. Insulin in SA was cheaper than 5 other countries, except Australia.

Conclusion: Overall, there is a good availability of insulin and related diagnostics in SA. Even though insulin is cheaper than other countries, it is unaffordable to the LPGW. This highlights the importance of ensuring a constant availability of insulin in the free public sector. Whilst human insulins are cheaper than newer analogue insulins and SA faces cost constraints, important variables in favour of newer insulins, such as ease-of-use, long term outcomes and value should be considered when treatment guidelines are updated. Annual POC testing should be available and offered free to all patients to detect diabetes early.

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KEYWORDS Access; affordability; availability; co-payments; point-of-care blood glucose testing; insulin; pricing; South Africa

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Introduction

About 422 million people worldwide have diabetes, the majority living in lowand middle-income countries, and 1.5 million deaths are directly attributed to diabetes each year (WHO, 2024). In South Africa, the prevalence of diabetes has rapidly increased from 4.5% in 2010 to 12.7% in 2019 (Sifunda et al., 2023). It is estimated that almost 5.5 million South Africans will have diabetes by the year 2030 (International Diabetes Federation, 2021). The International Diabetes Federation (IDF, 2020) estimates that approximately 4 million people die each year as a consequence of diabetes, and that many of these deaths could be prevented with affordable and reliable access to medicines and supplies.

According to the Department of Statistics South Africa, there has been an increase in deaths due to non-communicable diseases. Diabetes mellitus was found to be the leading underlying natural cause of death in South Africa in 2017 (Stats SA, 2018). Insulin remains a predominant life-saving medication for type 1 and type 2 diabetes mellitus (Sharma et al., 2019).

Even though the state contributes about 40% of all expenditure on health, the public sector is under pressure to deliver services to about 80% of the population. This is because most South Africans rely on the public sector to provide free healthcare (Niëns & Brouwer, 2013). This leaves the public sector overburdened and under-resourced. From the year 2017 to 2018 health spending in South Africa accounted for 33% of total provincial expenditure, which is more than the 5% recommended by the World Health Organization (WHO). Despite this high expenditure, health outcomes remain poor when compared to similar low to middle-income countries. This may be due to the inefficient use of allocated funds and inequities between the public and private sector (Ngobeni et al., 2020).

WHO has set a voluntary target of 80% availability of affordable essential medicines, including generics, to treat major non-communicable diseases, including diabetes, in countries by 2025 (Ewen et al., 2017). At the 75th World Health Assembly in 2022, WHO set 5 new global targets for diabetes, one of which was that 100% of people with type 1 diabetes should have access to affordable insulin and blood glucose self-monitoring by the year 2030. The aim is to reduce the risk of diabetes and move towards 'a world where all people who are diagnosed with diabetes have access to equitable, comprehensive, affordable and quality treatment and care' (WHO, 2022).

Although countries may have a legal obligation to make essential medicines available to those who need them at an affordable price, populations from low-income settings often have to pay out-of-pocket for the medicines that they need when they are ill, due to these medicines being unavailable at public institutions (Niëns & Brouwer, 2013). These populations may not be able to afford to purchase their own medication, and will therefore go without their medication, or cut down on other essential needs in order to pay for it (Niëns & Brouwer, 2013). Whilst the majority of South Africans rely on the public health system, over 13% choose to subscribe to a private medical aid scheme, or health insurance (Department of Health, 2020). These patients are often expected to make copayments for their medication, in addition to their monthly scheme payments. Co-payments, also called out-of-pocket (OOP) payments, are an important feature in many health care systems (Herrmann et al., 2018). They are a portion that an insured patient must pay of the actual costs for health care services including medicines.

In addition to medicines used to treat diabetes, point-of-care (POC) blood glucose testing and self-monitoring blood glucose (SMBG) systems have the potential to play an important role in the management of diabetes and in the reduction of risk of serious secondary clinical complications (Buss et al., 2019; Clarke & Foster, 2012). POC tests, or screening tests, are characterised as the ability to conduct tests at the patient's side without the need for a laboratory (Buss et al., 2019). WHO identifies affordability and 'deliverability' (access to end-users) as two of the six criteria that every POC test should have. These tests can help 'optimize treatment decision-making, avoid referrals, improve the efficiency of care and decrease costs, especially in resource-constrained settings where laboratory infrastructure is weak' (Kosack et al., 2017). They can also be used to improve patients' access to testing (Clarke & Foster, 2012).

In 2016, a group of organisations launched the #insulin4all campaign which demanded that everyone with diabetes in Africa should have access to affordable insulin and injection devices (Miller-Petrie et al., 2016, p. 54). Whilst the campaign is a much needed one, there was little research on whether 'most (South) Africans ... have the medical supplies, education and monitoring needed to use this life saving medication' (Miller-Petrie et al., 2016). Previous research in South Africa has focused on the diagnosis, prevention, burden and treatment of diabetes, but not much data is available on access and affordability of insulin and its related diagnostics in South Africa. This study therefore aimed to evaluate the availability of insulin and related diagnostics in both public and private sectors of healthcare in South Africa.

Methods

Study design

This was a quantitative, descriptive, cross-sectional study, conducted during the month of March 2023 in South Africa.

Study setting

The study was situated in South Africa. The population of South Africa is estimated to be 60,6 million by the end of June 2022. Gauteng comprises the largest share of the South African population with approximately 26.6%, followed by Kwazulu-Natal (Stats SA, 2022). The 2019 General Household Survey (GHS) indicates that approximately 72.5% of all households in South Africa use public healthcare institutions as their first point of access to healthcare services (Abrahams et al., 2022). In March 2021, the Minister of Health of South Africa reported that 84% of South Africans make use of public healthcare services, while the remaining 16% utilise private healthcare services (Abrahams et al., 2022).

Study population and sampling

The study population consisted of all public and private sector pharmacies/ dispensaries in South Africa, viz. all public and private sector community (retail) and hospital (institutional) pharmacies. A list of these pharmacies was obtained from the South African Pharmacy Council. The responsible pharmacists were emailed and invited to participate in the study. Of the 4496 pharmacies emailed, a total of 254 pharmacies consented to participate. This included 194 from the private sector (n = 0.76) and 61 pharmacies from the public (n = 0.24). This represented a 5.7% response rate. In terms of sample size calculation, with a 5% error, 95% confidence interval and an 80% response distribution, the sample required was 234.

Data collection

The list of insulins were extracted from the 22nd WHO EML list and those in the 2020 edition of the South African Standard Treatment Guidelines and Essential Medicines List (STG and EML), Primary Healthcare Level as recommended by the WHO/HAI study. In addition, a list of all insulins available in South Africa were obtained from the South African Health Products Regulatory Authority (SAHPRA). A total of 18 insulins were also included on the South African Medicine Price Registry (MPR), and therefore selected for the study. This included all short acting, intermediate acting and biphasic insulin as well as the rapid acting insulin glulisine (Apidra) and long acting insulin glargine (Table 1). A list of disposable insulin needles available in South Africa was studied. Five ISO 15197:2013 compliant glucometers used in South Africa, which were used by Dickson et al in their study on glucometer accuracy, were studied (Dickson et al., 2019). The blood glucose test strips (BGTS) studied were those compatible with the above glucometers. The study investigated 3 components of insulin and SMBG systems access, viz. availability, pricing and affordability. The internationally validated WHO/HAI tool was adapted to an online survey and utilised for data collection of availability and prices of insulin.

Due to the covid pandemic, access to pharmacies was restricted, and data collection could only be completed with the assistance of the responsible

Proprietary name of insulin	Active ingredient
Regular biphasic	
Actraphane HM	Insulin NPH isophane & regular human inj 100 unit/ml
Biosulin 30–70	Human insulin: 100iu/1ml
Biosulin L	Human insulin zinc: 100iu/1ml
Diabulyn 30/70	Insulin NPH isophane & regular susp cart 100 unit/ml
Humulin 30/70	Insulin NPH & regular susp pen-inj 100 unit/ml (70–30)
Insuman Comb 30/70	Human insulin and isophane 30–70 300 iu/3 ml
Regular short acting	·
Actrapid HM	Human insulin: 100iu/1ml
Biosulin R	Human insulin: 100iu/1ml
Humulin rR	Insulin regular (human) inj 100 unit/ml
Long acting glargine	
Basaglar	Insulin glargine 100iu/ml
Endulin Select	Insulin glargine 100iu/ml
Lantus	Insulin glargine 100iu/ml
Optisulin	Insulin glargine 100iu/ml
Toujeo	Insulin glargine 300iu/ml
Regular intermediate	
Protaphane HM	Insulin NPH (human) (isophane) inj 100 unit/ml
Humulin N	Insulin NPH (human) (isophane) inj 100 unit/ml
Biosulin N	Human insulin: 100iu/1ml
Insulin glulisine	
Apidra	Insulin glulisine 100iu/ml

pharmacists from each pharmacy. Detailed instructions were provided in the survey to allow for accurate reporting. Insulin was considered available if it was physically seen at the time of survey completion, not expired and was suitable for use. Different strengths of the same medicine were considered to determine overall availability as patients can use a different strength of a medication and adjust the amount taken to receive the correct dose, so availability of treatment is not compromised. The study also determined whether POC blood glucose testing was available at each of the pharmacies and the cost for a single test at private sector pharmacies. Private pharmacies were asked if free glucometers were dispensed to patients within the last 6 months and the source of these free glucometers (independent promotional campaign or provided by a sales representative) was determined.

The second component of the study was pricing. The price of insulin is the actual price paid by the patient (cash or medical aid co-payment), or the government procurement price (GPP). The final unit price of each insulin in the private sector, was determined as the selling price inclusive of 15% value added tax (VAT) and the maximum dispensing fee. The co-payments levied on insulin by both closed and restricted medical aid schemes in South Africa were also studied by examining the medical aid formularies and their co-payment conditions. The GPP were extracted from the National Department of Health's Master Health Product (MHP) list. The selling prices of glucometers, BGTS and insulin needles were obtained from the survey and from a single community pharmacy. Insulin prices were also collected from the South African MPR.

The prices of insulin from a basket of countries were also collected to allow for an international price comparison. The insulin prices in South Africa were compared to the United States of America (USA), United Kingdom (UK), Australia and selected countries from the AFRO Essential Medicines Price Indicator (EMPI). The AFRO EMPI last collected the prices of medicines from a basket of African countries in 2015, and then calculated an average price of each medicine in Africa to compare to other countries. This study used the correspondence agencies of the AFRO EMPI as a reference, and collected current African prices from Kenya, Tanzania and Ghana.

Affordability was estimated using the daily wage of the lowest-paid unskilled government worker (LPGW) by determining the number of days' wages required to purchase either the cheapest one months' supply of insulin alone (World Health Organization and Health Action International, 2008), insulin combined with 30 disposable insulin needles (Physicians, 1999; University of Michigan Health, 2020), or insulin, needles and 60 BGTS (Falk et al., 2017; Klatman et al., 2019).

Data analysis

Data validation and analysis was performed using Microsoft Excel.

Availability

Availability was reported as the percentage of pharmacies in which each item was found. The percentage availability of each group of items (short acting, intermediate, biphasic rapid and long acting insulin, glucometers, BGTS, needles and POC testing) in pharmacies of each sector, as well as the percentage of overall total availability of each group across all sectors was calculated. The following ranges were used for describing the extent of availability of study components:

- Absent (0% of pharmacies): not found in any pharmacy surveyed
- Very low (< 30% of pharmacies): very difficult to find
- Low (30–49% of pharmacies): somewhat difficult to find
- Fairly high (50–80% of pharmacies): available in many pharmacies
- Very high (>80% of pharmacies): good availability (Gong et al., 2018)

Pricing

The actual prices paid and the government procurement prices (GPP) were compared to the national insulin prices from the Australia Pharmaceutical Benefit Scheme (PBS), together with the United Kingdom's British National Formulary (BNF), the United States' (US) Center for Medicare & Medicaid Services (CMS) and 3 of the countries included in the AFRO EMPI (Kenya, Tanzania and Ghana). To compare these international prices, all prices were converted to the US dollar on the last day of data collection. Whilst some international price databases present prices as cost price, others include service fees and tax and others include all fees including dispensing fees. Therefore, prices were compared like for like, depending on what data was made available.

Affordability

Affordability was estimated using the daily wage of the LPGW and determined as the national minimum wage from the Department of Employment and Labour. The daily wage of the LPGW was used to determine the number of days' wages required to purchase the cheapest:

- 1. 10 ml, 100 IU/ml of Insulin (short acting, intermediate, and biphasic)
- 2. 60 test strips
- 3. 30 disposable insulin needles.
- 4. 10 ml of 100 IU/ml of Insulin, 60 test strips and 30 disposable insulin needles combined.

The online survey was open for completion over 6 weeks, beginning on the 1st of March 2023. During this time, all other data was collected. All data collected and captured manually was double checked to ensure accuracy, and to avoid transfer errors.

Results

The results were separated into insulin results followed by related diagnostics.

Insulin

Overall availability of insulin

Nine respondents (6.08%) had no insulin available in their pharmacies. The insulin Apidra (glulisine) had the highest availability by province and by type of facility.

Availability of insulin by province

In KwaZulu-Natal (KZN), the public sector primary care facilities showed 50% availability of at least 1 type of insulin in each group, with the exception of Apidra, which had a 75% availability (Supplemental Table S1). If public sector dispensaries keep only one type of each group of insulin at any

given time (due to tender agreements), then the total availability of at least one insulin in each group is 75%, with the exception of long acting insulin glargine at 100%. Public sector hospitals have a 100% availability of at least 1 type of insulin in each group except for long acting glargine (0%).

Private hospital pharmacies of KZN had no stock of regular intermediate, regular short acting insulin or Apidra. KZN public primary care facilities at rural level had 100% availability of Actrapid, Actraphane and Protaphane and Apidra. No other insulins were available in this sector. In the KZN private sector community pharmacies, the insulins with the highest availabilities were all long acting insulin glargine, ranging from 55.17% for Basaglar and 82.76% for Optisulin. Actrapid, Actraphane and Protaphane were all below 50% available. Apidra was available in many pharmacies (72.41%).

In Gauteng, the response from the public sector was poor, but there seemed to be availability of only regular short acting insulin, regular basic insulin, and rapid acting glulisine (Supplemental Table S2). In the Gauteng private sector hospital pharmacies, long acting insulin glargine, regular intermediate and regular short-acting insulin had a 100% availability.

The Western Cape (WC) public sector dispensaries had a 100% availability of one insulin from each group of insulins recommended as first line treatment for diabetic patients on insulin (Supplemental Table S3). These insulins were Actrapid, Actraphane and Protaphane. In the WC private sector community pharmacies, Actrapid had a very low availability (8.33%), and the other 2 had a 50% (Protaphane) and 58.3% (Actraphane) availability. Whilst the public sector showed a 11–22% availability of some long acting glargine insulins, the private sector showed a good to fairly high availability of these insulins. Optisulin had 91.67% availability. The high availability of glargine in public dispensaries of KZN is inconsistent with public sector dispensaries across all provinces, and also in KZN public hospital pharmacies, in which glargine had low availability.

Availability of insulin by type of facility

The most commonly stocked regular biphasic insulin in the public sector, Actraphane, had a 76.47% availability which is considered high. Similarly, the most commonly stocked regular short acting insulin (Actrapid) had 64.71% availability, long acting glargine was 29.41% and rapid acting glulisine, Apidra, was 52.94%. This translates to a fairly high availability of insulin in the public sector dispensaries, with the exception of long acting insulin glargine which had low availability (see Table 2). Public sector hospitals showed a very high availability of over 80% for Actrapid, Actraphane and Protaphane. It must be noted that most public sector pharmacies had stock of only one type of insulin in each insulin group. Insulin glargine had low availability in the public hospital sector (8.7%), and Apidra had a 26.09% availability. The two most kept regular biphasic insulins in private sector retail pharmacies had a fairly high availability (56.44% Actraphane and 55.45% Humulin 30/70). Interestingly, regular short acting insulin was limited in its availability, whilst long acting insulin glargine was available in most pharmacies, unlike in the public sector. Apidra, the rapid acting insulin, showed overall higher availability in the private sector (70.3% in community pharmacies).

Pricing of insulin

The selling prices obtained from the community pharmacy and/or MPR (Medicine Price Registry, 2021) were used for most price comparisons. The cheapest insulin selling price recorded at the community retail pharmacy visited was Actraphane 10 ml, at USD 21.3 for 10 ml. This insulin is a regular biphasic insulin. The most expensive insulin was Basaglar, a long acting glargine insulin, which sold at USD 33.4.

The GPP of insulin were much lower than the price at which insulin was sold to private community pharmacies. The GPP for Actrapid, Actraphane and Protaphane was USD 1.89 for 10 ml. The wholesale prices obtained from the private community pharmacy order system, indicated a selling price of Actraphane at USD 17.9. Prices were similar for Actrapid and Protaphane. The GPP for these insulins are therefore 10.59% of the wholesale

Product	PuSHP Pu		PuSPO	iPC PSHP		,	PSCP		Total respondents
	percent	n	percent	n	percent	n	percent n		n
None of the above	0.00%	0	11.76%	2	0.00%	0	6.93%	7	9
Actraphane HM	28.57%	2	76.47%	13	91.30%	21	56.44%	57	93
Actrapid HM	14.29%	1	64.71%	11	86.96%	20	12.87%	13	45
Apidra–	42.86%	3	52.94%	9	26.09%	6	70.30%	71	89
Basaglar–	42.86%	3	11.76%	2	0.00%	0	49.50%	50	55
Biosulin 30–70	0.00%	0	5.88%	1	4.35%	1	7.92%	8	10
Biosulin L	0.00%	0	0.00%	0	0.00%	0	1.98%	2	2
Biosulin N	0.00%	0	0.00%	0	0.00%	0	4.95%	5	5
Biosulin R	0.00%	0	5.88%	1	0.00%	0	1.98%	2	3
Diabulyn 30/70	0.00%	0	0.00%	0	0.00%	0	1.98%	2	2
Endulin Select	0.00%	0	0.00%	0	0.00%	0	0.00%	0	0
Humulin 30/70	42.86%	3	35.29%	6	26.09%	6	55.45%	56	71
Humulin N	28.57%	2	29.41%	5	17.39%	4	44.55%	45	56
Humulin R	28.57%	2	29.41%	5	26.09%	6	23.76%	24	37
Insuman Comb 30/70	0.00%	0	0.00%	0	4.35%	1	3.96%	4	5
Lantus	57.14%	4	29.41%	5	8.70%	2	65.35%	66	77
Optisulin	42.86%	3	29.41%	5	0.00%	0	77.23%	78	86
Protophane HM	28.57%	2	64.71%	11	86.96%	20	40.59%	41	74
Toujeo	28.57%	2	11.76%	2	0.00%	0	58.42%	59	63
Other (please specify)	42.86%	3	17.65%	3	0.00%	0	23.76%	24	30
Number of respondents	7		17		23		101		148

Table 2. Insulin availability in pharmacies in South Africa.

Notes: PuSHP: Public Sector Hospital Pharmacy; PuSPC: Public Sector Primary Care; PSHP: Private Sector Hospital Pharmacy; PSCP: Private Sector Community Pharmacy;

price in the private sector. Apidra's GPP was 3.43% of the private wholesale price, and Optisulin was 7.42%.

International price comparison of insulins

Insulin prices were compared to a basket of countries to allow for an international comparison (Table 3). The UK's selling price was compared to South Africa's, and it was found that UK prices are on average USD3.97 more than South African private sector prices (SEP excluding VAT) for all insulin groups. The average African government prices of Actrapid and Actraphane were on average USD2.31 more than South Africa's GPP. The prices of regular human insulin (short, biphasic and intermediate acting) were between USD85 and USD155 more in the US than private sector prices in South Africa (SEP including VAT). The cost of long acting insulin glargine (Lantus) was USD301.89 in the USA. Australia was the only country which was cheaper than South Africa's private sector by an average of USD7.05, when comparing selling prices including VAT and dispensing fees.

Co-payment of insulin

At least one type of insulin from each insulin group was covered in full without a co-payment required in each of the medical aid formularies studied (Table 4). This is required by law, as diabetes is a prescribed minimum benefit (PMB) and every medical aid is obligated to offer cover for its treatment in full to all of its members. A few of the insulins had a

	SA SEP		SA SEP		SA MPR			
Type of insulin	(incl VAT)	US CMS	(excl VAT)	UK BNF	unit price*	Australia PBS	SA GPP	African countries
Regular Biphasic	20.81	174.93	11.15	18.82	27.79	19	1.89	4.19
Regular Short Acting	18.39	131.2	15.63	18.82	24.37	19	1.89	4.21
Long Acting Glargine	34.17	336.06	27.39	34.7	39.55	34.76	n/a	
Regular Intermediate	20.81	106.4	17.69	18.82	27.45	19		
Insulin Glulisine	n/a		18.65	19.2	30.4	22.54		
Average	23.55	187.15	18.1	22.07	29.91	22.86	1.89	4.20

Table 3. International price comparisons in USD.

Notes: SA GPP: Government Procurement Price (R. o. S. A. Department of Health, 2021); Australia PBS: Pharmaceutical Benefit Scheme (Commonwealth of Australia, 2023); UK BNF: United Kingdom British National Formulary (Business Services Authority, 2023); US CMS: United States Center for Medicare and Medicaid Services (US Centers for MMS, 2023). African countries: Average price from Ghana (NHIS, 2023), Kenya (Code for Africa, 2017) and Tanzania (OpenAfrica, 2019). SEP: Single Exit Price by manufacturer including value added tax (VAT) 15%. Unit Price = selling price inclusive of Value added Tax (15%) and maximum dispensing fees. Prices taken are cheapest SEP for each insulin (pen vs cartridge) at maximum unit price. *SEP and Unit Prices taken from the South African Medicine Price Registry (Medicine Price Registry, 2021).

ITEM	Open Scheme 1	Closed Scheme 1	Open Scheme 2	Open Scheme 3	Closed Scheme 2
Insulin:	Selicine 1	Scheme i	Serience 2	Seneme 5	Seneme 2
Regular Biphasic					
Actraphane HM (10 ml vial)	х	Х	Х	1	х
Humulin 30/70 (10 ml vial)	x	X	\checkmark	7 53.01	X
· · · · · · · · · · · · · · · · · · ·	^ ✓	Ĵ	<i>,</i>	55.01 ✓	, ,
Diabulyn 30/70 (3 ml)	✓ Discontinue	•	~	~	~
Biosulin 30–70 (3 ml cartridge)	Discontinue				
Biosulin L (3 ml cartridge)					
Insuman Comb 30/70 (3 ml cartdridge)	Discontinue	20			
Regular Short Acting	D:	1			
Actrapid HM (ge) (10 ml vial)	Discontinue		,	,	
Biosulin R (3 ml cartridge)	Х	√			<i>✓</i>
Humulin R (10 ml vial)	Х	Х	~	✓	Х
Long Acting Glargine					
Lantus (10 ml vial)	Х	Х	Х	Х	Х
Toujeo (1.5 ml pen)	Х	Х	Х	Х	Х
Optisulin (3 ml) cart 5's	✓	1	1	1	1
Basaglar (3 ml cartridge)	Х	1	1	1	1
Endulin Select (3 ml)	Discontinue	ed			
Regular Intermediate					
Protaphane HM (10 ml vial)	Х	Х	Х	1	Х
Humulin N (10 ml vial)	Х	Х	1	37.53	Х
Biosulin N (3 ml cartridge)	Х	1	Х	1	1
Insulin Glulisine					
Apidra (3 ml)	1	1	1		1
GLUCOMETER:					
Contour Plus	х	1	Х	х	1
Accu-Chek Active	х	1	Х	х	1
Glucocheck classic	х	1	Х	х	1
One Touch select plus flex	х	1	Х	х	1
Freestyle Optium Neo	х	1	Х	х	1
TEST STRIPS 50s					
Contour Plus	х	1	1	6.21	1
Accu-Chek Active	х	1	1	х	1
Glucocheck classic	1	1	1	х	1
One Touch select plus flex	1	1	1	х	1
Freestyle Optium Neo	х	1	1	х	1
NEEDLES X100S					
BD Ultrafine	discontinue	bd			
Insupen	X	X	1	х	х
Novofine	, V	Ĵ	1	60.6	Î,
Novofine Plus	x	1	1	X	1
Novofine Twist	discontinue	•	-	~	•

Table 4. Medical aid cover of insulin and related diagnostics.

Notes: ' \checkmark ': item on formulary; 'x': item not on formulary; amounts for Open Scheme 3 in ZAR, to indicate the difference in single exit price (SEP) and MMAP, charged as co-payment.

maximum medical aid price (MMAP) which allows medical schemes to elect to pay only a specified maximum price for off-patent products that have generic equivalents (Council for Medical Schemes, 2020; Medicine Price Registry, 2021). All the MMAPs were within the MPR recommended price range (incl VAT and fees)(Medicine Price Registry, 2021). If a selected pharmacy charges more than the MMAP, the member is charged for the excess amount, in the form of a co-payment. If an insulin is not on the medical

aid formulary but is still clinically appropriate, a co-payment is charged. This amount varies from 20% to 40% of the selling price. The co-payments can be deducted from the member's medical savings account (MSA) if it is active, and not depleted for the year. If there is no MSA, or the MSA is depleted, the patient will pay cash. If the member goes to a non-designated service provider, a co-payment will also be charged. This co-payment ranges from 20% to 40% depending on the scheme. Patients must obtain prior chronic medication authorisation, before qualifying for full cover. In addition to the insulins listed on the WHO/HAI list and STG, most medical aids also cover insulin aspart (Novorapid, Fiasp), lispro (Humalog) and detemir (Levemir).

Related diagnostics

Availability of diagnostics

Of the 38 public facilities, the highest availability of the listed glucometers in the public sector was Accu-Chek (26.32%) (see Table 5). Most public sector facilities (60.53%) indicated the availability of the Viva-Chek glucometer which was not mentioned in the list. The availability of the corresponding BGTS for these glucometers was 60.61% for Viva-Chek and 36.36% for Accu-Chek. This suggests that public sector facilities had enough availability of the glucometer and its corresponding test strips. Novofine needles were the most stocked insulin needles and were available in many facilities (76.42%).

POC blood glucose diagnostic testing is free at public sector facilities however only 31.25% of respondents in the public sector indicated that they offered blood glucose testing at the pharmacy. In the private sector, respondents indicated a fairly high availability of at least one of the glucometers listed (56% Contour Plus, 61% Accu-Chek), and POC testing was offered in 69.66% of private hospital and retail pharmacies combined. 74.7% of private community pharmacies indicated the availability of POC blood glucose testing.

Pricing of diagnostics

The survey prices of glucometers in the private sector varied greatly. The most kept glucometer was Accu-Chek Active. The selling price for this glucometer varied from USD 5.7 to 21.4. The strips for Accu-Chek ranged from USD 8.7 to 11.1. Most of the pharmacies who gave free glucometers (60%), were provided these metres for free by pharmaceutical sales representatives (82%). The cost of insulin needles also varied greatly. 71% of respondents indicated selling 30 Novofine needles at more than USD 4.9. The selling price at the private community pharmacy for Novofine was USD 16.9 for 100 needles, or USD 5.06 for 30 needles. The cheapest selling price for BGTS for the Accu-Chek glucometer according to the survey was 10.3 USD

	None of the	Accu-Chek	Freestyle Optium	Glucocheck	One Touch Select Plus	Contour		Total
	above	active	Neo	Classic	Flex	Plus	Other	Respondents
PuSPC	6.67%	33.33%	13.33%	13.33%	6.67%	20.00%	46.67%	15
	1	5	2	2	1	ſ	7	
PuSHP	4.35%	21.74%	13.04%	0.00%	4.35%	0.00%	69.57%	23
	-	5	£	0	1	0	16	
Public Sector	5.26%	26.32%	13.16%	5.26%	5.26%	7.89%	60.53%	38
Overall	2	10	5	2	2	£	23	
PSHP	57.14%	14.29%	14.29%	0.00%	0.00%	0.00%	28.57%	7
	4	-	-	0	0	0	7	
PSCP	10.75%	64.52%	8.60%	31.18%	27.96%	60.22%	26.88%	93
	10	60	8	29	26	56	25	
Private Sector	14.00%	61.00%	9.00%	29.00%	26.00%	56.00%	27.00%	100
Overall	14	61	6	29	26	56	27	
Total	16	71	14	31	28	59	50	138

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for 60 test strips (USD 8.6 for a box of 50). The selling price for 60 strips according to the MPR is USD 14.1.

POC testing was free in public sector facilities. Most private pharmacies (43.90%) charged over USD 2.7 for a POC test, and 21.95% charged between USD 1.2 to 1.6 a test. Amongst the 3 largest provinces, Gauteng was the only province in which some private pharmacies (18.18%) offered free POC blood glucose testing, however, Gauteng also had the highest percentage of private pharmacies (54.55%) offering the test at USD 2.7 or more. All private pharmacies in the Western Cape and KZN charged a nominal fee for testing. In the Western Cape most pharmacies (60%) charged a lower rate (between USD 0.6 and 1.1) than the other 2 provinces.

Co-payment of diagnostics

Health assessment tests (including POC testing) are offered annually by most medical schemes. The use of BGTS, syringes and needles are subject to clinical review by medical schemes before being authorised. Glucometers are covered by most medical schemes, at a capped amount, once every 3 or 4 years. For example, one of the closed medical schemes studied pays R1399 once every four years (Polmed Medical Aid, 2022).

Affordability of diagnostics

The minimum wage of the LPGW in South Africa is USD 1.4 per hour (USD 11.2 per day) (Department of Employment and Labour, 2023). With 61% of private sector pharmacies charging USD 1.6 or more for a single POC blood glucose test, it would cost South African workers who earn a national minimum wage on average more than one hour of work to pay for the test. It would cost just over a day's wage of the LPGW to pay for 60 BGTS for the most commonly available glucometer (Accu-Chek) and almost half a day's wages to pay for insulin needles (at more than USD 4.9 for 30) (Table 5). An insulin patient who is on insulin and testing their blood sugar twice a day will pay a minimum of USD 40.4 (3 days' wages of an LPGW) per month for insulin and glucose self-monitoring in the private sector (see Table 6).

Discussion

Babar et al. (2019) found that in the 17 countries of varied incomes studied, the total mean availability of insulin was only 36.21% (Babar et al., 2019). These findings are supported by Kasonde et al, who also determined that medicines for non-communicable diseases (NCDs) were significantly less available than infectious disease medicines in their study in Bangladesh (Kasonde et al., 2019). Unlike those studies, the results in this study have shown that there was a fairly high availability of regular short acting, biphasic and intermediate insulin in the South African public sector, whilst the long

ltem	Cheapest insulin in each group	Cost of insulin (10 ml)	Number of days' wages required to purchase 10 ml insulin**	Combined monthly cost of insulin + BGTS + needles*	Number of days' wages** required to purchase combination (total cost divided by daily wage)
Regular Short Acting	Humulin R	396.71	1.95	744.74	3.66
Regular Intermediate Acting	Protaphane	402.91	1.98	750.94	3.69
Regular Biphasic	Actraphane	387.45	1.90	735.48	3.61
Insulin Glulisine	Apidra	460.91	2.27	808.94	3.97
Long Acting (Glargine)	Basaglar	606.64	2.98	954.67	4.69

Table 6. Affordability of insulin in South Africa for the LPGW.

*Most available BGTS (Accu-Chek at ZAR255.95 for 60) + Cheapest needles (Novofine 30G AT ZAR92.08 for 30) = ZAR348.03

**The minimum wage for LPGW in South Africa is ZAR25.42 per hour (<u>ZAR203.36</u> per day). Number of days' wages = cost/daily wage.

Prices taken as SEP plus maximum dispensing price.

acting insulin, glargine, (which is the only long acting insulin on the EML) was difficult to find in most provinces. The high availability of insulins (with the exception of glargine) and glucometers with their corresponding BGTS in the public sector therefore suggest good accessibility of insulin and related diagnostics in South Africa, as most South Africans rely on the public sector for healthcare.

Long acting insulin

The study highlighted the disparities in the types of insulin available in the public sector compared to the private sector. Long acting insulin had a significantly higher availability in the private sector than in the public sector. Public sector facilities across the country all have very high availability of 3 insulins: Actrapid, Actraphane and Protaphane.

Until 2019, The WHO Model List of Essential Medicines included only rapid and intermediate acting insulin (WHO, 2019). However, in 2021, the WHO EML list was updated to include long-acting insulin analogues. Glargine was the only long acting insulin added to the South African EML, and is reserved for use as a second line treatment for uncontrolled Type 2 diabetes in the STG (NDOH SA, 2020).

Laing et al studied the WHO EML over 25 years and acknowledge that differences exist between the WHO EML and national EMLs since countries face varying challenges relating to costs, drug effectiveness, morbidity patterns, and rationality of prescribing (Laing et al., 2003). Beran et al. (2018)

discuss that even though better, expensive analogue insulins have been developed, less effective interventions can be justified if they are more affordable (Beran et al., 2018). Glargine costs 4.69 days of an LPGW's wage for a month's supply (Table 5). It also costs the government 49.73% more than regular insulin. The GPP prices of insulin in South Africa were a fraction of the cost at between 3.43% and 10.59% of the private sector prices. Beran et al. (2018) explain that the almost exclusive use of these public sector insulins could be because they are more affordable, and is probably also the reason for the use of Viva-Chek glucometers and BGTS. Some facilities kept Humulin N, R and 30/70. It is unclear whether these insulins were kept when the other 3 were out of stock, or whether a similar pricing tender agreement was reached for these insulins in the public sector, as the tender could not be found.

POC and SMBG testing

POC testing plays an important role in the management of diabetes and should be offered at all pharmacies. This is however not the case in South Africa, with only one-third of public pharmacies offering free testing, and two-thirds of private pharmacies offering testing at varied costs. Patients can be screened to assess the need for this test, but the test should nevertheless be available to all patients if warranted. As with POC testing, DC Klonoff (2007) stated that the high cost of SMBG is a significant barrier preventing its routine use (Klonoff, 2007). Klatman et al. (2019) identified high costs as one of the main factors influencing the use of SMBG in countries such as Ghana and India and noted that SMBG supplies are frequently more expensive than insulin (Klatman et al., 2019). Whilst BGTS in South Africa is cheaper than the cost of insulin per month and cost approximately a days' wage, many South Africans, being unemployed or earning below the minimum wage, would still consider a days' wage for a monitoring system to be unaffordable.

Co-payments

Medical aid co-payment affects only a minority of South Africans who subscribe to private medical aids. For these patients, at least one type of insulin from each insulin group was covered in full without a co-payment required. However, unlike most South Africans, whose choice of insulin is limited to whatever the government offers in the public sector, private healthcare users have a wider variety of insulins choose from. Patients who choose to use more advanced and/or more expensive insulins may have to pay a co-payment, but this can be avoided by having a discussion with the prescribing doctor to determine which insulins and related diagnostic devices are covered by the relevant medical aid.

Overall affordability

Overall, insulin prices in South Africa were cheaper than all of the other countries studied, except Australia. An insulin patient who falls under the LPGW category, and is on insulin and testing their blood sugar twice a day will pay over 3 days' wages for a combination of the cheapest insulin, 30 needles and 60 BGTS. This would be unaffordable. Unlike ARVs or most other medicines, insulin is a biological product and thus creating an exact copy (biosimilar) is more difficult than creating a copy of a chemical entity (Perrin et al., 2017). Even though insulin manufacturers have begun marketing their own 'generic' and, significantly cheaper versions of their products, these are relatively new to the market (Fralick & Kesselheim, 2019).

Limitations

In an article discussing the ethical implications and challenges of remote data collection for public health research in a COVID-19 era, Hensen et al. (2021) state that exceptions for online surveys can be made for surveys planned with specific target groups, such as members of an established association of professionals (Hensen et al., 2021). Hensen et al argue that whilst challenges to eliminate bias are present, 'potential risks need to be weighed against benefits and the ethical imperative to continue with research to generate the evidence of benefit to public health' (Hensen et al., 2021). Data on physical stock availability relied on the online survey. Surveys were emailed to the responsible pharmacist to ensure responsible reporting. Detailed instructions were provided in the survey to allow for accurate reporting, and participants were encouraged to contact the study researchers with any queries. Other data (pricing/co-payments etc.) was collected from the survey and from available datasets.

Private community pharmacies add a flexible dispensing price (capped at a maximum amount) to the medicines selling price and so prices in survey responses varied greatly. For this reason, the selling prices obtained from the community pharmacy and/or MPR were used for most price comparisons.

Availability of each item was determined on the day the survey was completed and might not be indicative of the average availability over time. Mollentze (2011) suggested that parts of South Africa may experience 'supplychain challenges' which could result in erratic supply of stock (Mollentze, 2011). According to Section 27, which is an online public interest law organisation focused on achieving access to healthcare for all South Africans, access to medicines can only be assured if a sustainable supply of affordable medicines can be guaranteed – that is, a regular, ongoing supply of affordable medicines (Section27, 2019). Therefore, stock availability should be assessed over a longer period of time for a more accurate representation.

The availability of stock in private pharmacies at the specific time of data collection is affected by other factors. One of these is the ease of utilising wholesale orders systems. Most private pharmacies use an electronic pharmaceutical procurement system such as Orderwise (Muse Technology, 2016). The system combines all the individual wholesaler programmes in the South African market to allow a pharmacy to compare prices and select the cheapest option. Once a product is ordered, delivery of the product is usually within 24 h, and so private pharmacies can choose not to keep stock on hand, but rather order on demand (Muse Technology, 2016). Medicines that require refrigeration are also not allowed to be returned to the wholesaler if excess stock is ordered and unused. The current load shedding crisis in South Africa, in which power is switched off in rotating parts of the power grid of each province, for a few hours each day (ranging from 2 to 10 h) also makes the storage of refrigerated insulin difficult (Laher et al., 2019). As such, the order-on-demand system would be an attractive alternative to prevent poor storage conditions. Researchers should investigate in detail how these factors affect availability of medications requiring refrigeration in the private sector, and the affect of these factors on accessibility to the patient.

The WHO/HAI tool uses the wage of the LPGW to calculate the affordability of medicines. Mendis et al. (2007) and Chow et al. (2018) note a substantial proportion of the population in some lower to middle income countries earn less than the wages of the LPGW, which would mean that even treatments that seem to be affordable are out-of-reach of a large number of people (Chow et al., 2018; Mendis et al., 2007). The LPGW in South Africa should receive a minimum wage of ZAR25.42 per hour (ZAR203.36 OR USD11.18 per day), but a publication by the Department of Employment and Labour in 2020 states that 43.5% of workers reported earnings below the minimum wage (Department of Employment and Labour, 2021). Surveying household incomes might give a more accurate understanding of affordability within a country, however, a comparison to the LPGW is easy to apply and to understand as people in any country can easily position themselves relative to the LPGW (Niëns et al., 2012).

For international price comparisons, the AFRO EMPI notes that 'direct comparison of prices between suppliers for a given product may be unrealistic because of the varying units of presentation and terms and services offered by different suppliers. Similarly, units of presentation for some of the products in countries are not specified and vary; therefore direct comparison of prices is not always possible and realistic'. Whilst some international price databases present prices as cost price, others included service fees and/or tax and/or dispensing fees. Therefore, the study compared prices which were similar, depending on what data was made available by each country.

Recommendations

This study confirms a good overall availability of insulin and its related diagnostics in the country. It is unclear what the POC blood glucose testing policy is in public institutions and whether testing is offered to all patients when it is available. It is also unknown whether patients on BGTS are limited in the quantity they receive. Together with the above, the quality of care and provision of health education offered to diabetic patients in the public sector must be studied.

Diabetic patients should be studied to determine whether each patients' specific treatment regimen (insulin type, delivery device and corresponding needles or syringes, BGTS for specific glucometer) is available, and the personal cost of this regimen should be compared to each patient's income, to determine affordability. It must also be noted that diabetic patients usually have comorbidities, and so require not only diabetic treatment, but also treatment for other conditions. This affects affordability of treatment, as combined treatments may make treatment unaffordable. Households may also have more than one family member on chronic medicine treatment, and so affordability will be better ascertained by comparing total household incomes to total household medicine expenses.

Future studies also need to ascertain availability over a few months at both public and wholesale pharmacies, for a better understanding of availability over a longer period of time.

Conclusion

The results of this study show that overall, there is a good availability of insulin and related diagnostics in South Africa. There is a disparity in the types of insulins more available in the public vs private sector, such as long-acting insulin being more available in the private sector. Even though the prices of insulin are cheaper in comparison to most of the other countries studied, the LPGW will still find it unaffordable. POC testing, whilst available, is most often not free in the private sector. This could deter patients from choosing to test their blood sugar. In the public sector, POC testing, whilst available, is not offered to all patients. At least one type of insulin from each insulin group was covered in full by every medical aid without a copayment required. Private healthcare users have a wider variety of insulins to choose from and are not limited to those on the EDL. These insulins may be more expensive and require a co-payment.

Annual POC blood glucose testing should be available and offered to all public and private patients free of charge. At the next review of diabetes management guidelines by healthcare stakeholders, policymakers should consider offering rebates for POC blood glucose testing in private

pharmacies, to allow for increased early detection of diabetes. Whilst the older human insulins are much cheaper than newer analogue insulins, and South Africa faces many cost constraints, other important variables in favour of including newer insulins, such as ease of use; long term outcomes, and value, amongst other factors should be considered when the STG is updated. Lastly, the study highlights the importance of ensuring the constant availability of insulin in the public sector to ensure constant access to this life-saving medication for the majority of South Africans, who rely on the public sector for treatment. Therefore, availability over a lengthier period of time should be studied to confirm the findings of this study.

Ethics approval and consent to participate

The study received ethics approval from the University of Kwa-Zulu Natal Biomedical Research Ethics Committee, approved 9 September 2022. BREC Ref No: BE541/17. Informed consent was received from all participants.

Disclosure statement

No potential conflict of interest was reported by the author(s).

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Data availability statement

Data supporting the results are reported in the article and can be requested from the authors.

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