Access to insulin: a comparison between low- and middle-income countries and the United Kingdom

Insulin was discovered 100 years ago but, sadly, across the globe there are significant inequities in access to this life-saving medicine.

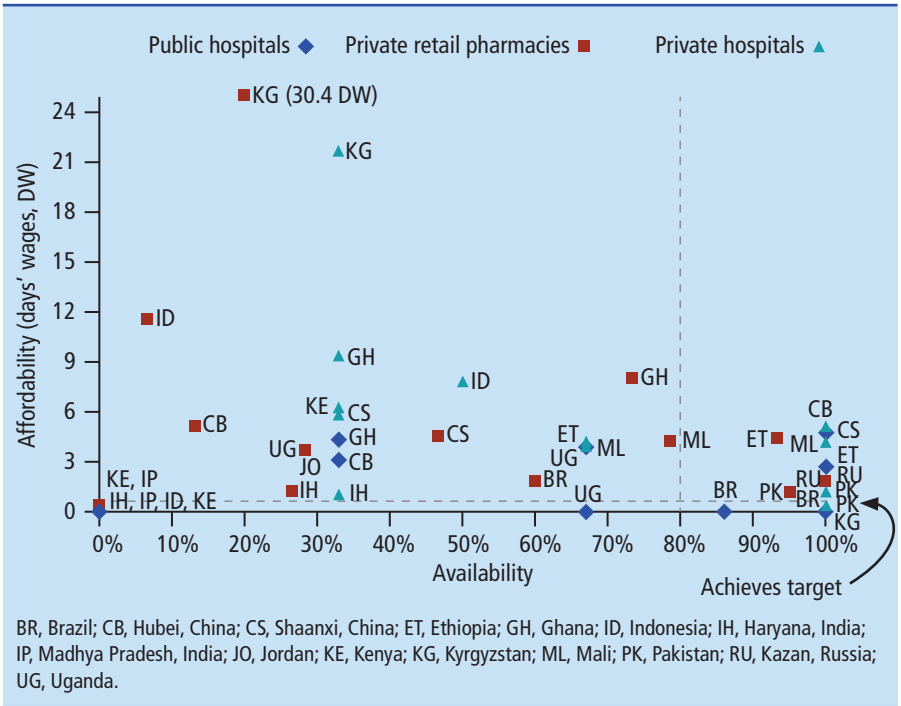
Here, the authors investigate such inequities, the challenges of available and affordable insulin, its delivery systems and blood glucose monitoring. Challenges not only include costs but also the lack of expertise in managing diabetes care.

Now is the time for those in the diabetes community to come together to address the global issue of access to insulin for all.

Introduction

In 1925 RD Lawrence, one of the co-founders of what is now Diabetes UK, stated 'Now modern discoveries, particularly insulin, have completely changed the outlook. There is no reason why a diabetic should not, if he can be taught to do so, lead a long normal life.'[1] While this is true in the United Kingdom (UK), with the National Health Service providing insulin free-of-charge to both people with type 1 diabetes and type 2 diabetes who need insulin, there are significant inequities in access to this life-saving medicine across the globe.

The main barriers to accessing insulin can be summarised by looking at its availability and affordability. Availability is simply whether or not the insulin is in stock in a facility. Affordability relates to whether or not the insulin can be purchased given the financial means of the individual. Although ideal diabetes care may not reach all people living with diabetes in the UK,[2] insulin access is considered to be very good.[3] This contrasts to the situation in many low- and middle-income countries (LMIC).



BR, Brazil; CB, Hubei, China; CS, Shaanxi, China; ET, Ethiopia; GH, Ghana; ID, Indonesia; IH, Haryana, India; IP, Madhya Pradesh, India; JO, Jordan; KE, Kenya; KG, Kyrgyzstan; ML, Mali; PK, Pakistan; RU, Kazan, Russia; UG, Uganda.

Figure 1. Combined availability and affordability of NPH human insulin in 13 low-income and middle-income countries by sector. (Reproduced with permission from: Ewen M, *et al. BMJ Global Health* 2019;4:e001410)[6]

Availability and affordability of insulin

Data collected by the World Health Organization (WHO) in 2016–2019 from 24 countries on four continents found the availability of human and analogue insulin in health facilities was 61% and 13%, respectively.[4] Within a country, there can be differences in insulin availability at different levels of the health system, and in different areas and sectors. For example, in Peru mean availability of NPH (intermediate-acting) insulin in tertiary and secondary hospitals was 100% and 61%, respectively.[5] In the capital Lima, NPH availability was 86% whereas in La Libertad region (in the north of the country) it was only 14%. For Peruvians who cannot access insulin in the public sector, their chances of purchasing in the private sector is low as mean availability was less than 11%.[5]

Prices of insulin are highly variable depending on the type of insulin purchased and the sector from which it is purchased. A 2016 study in 13 LMICs showed 10ml of 100IU/ml human insulin cost people from $US 1.95 to $US 32.63 in public sector facilities, with a median price of $US 9.36.[6] Prices for analogue insulins were higher, ranging from $US 18.96 to $US 118.29, with a median price of $US 29.39. Based on these median prices and an affordability threshold of one month's treatment costing no more than one day's wage of the lowest paid unskilled government worker, four days' wages for human insulin and seven days' wages for analogue

insulin are needed to purchase 10ml insulin, which makes treatment unaffordable in these LMICs.[6]

Insulin needs to be both available and affordable to ensure appropriate diabetes care. With these two criteria in mind, the WHO Global Action Plan for the Prevention and Control of NCDs 2013–2020 (GAP) has set a voluntary target of '80% availability of affordable essential medicines, including generics, to treat major non-communicable diseases (NCDs), in the public and private sectors of countries by 2025'.[7] Many LMICs fail to reach this target. Across 13 LMICs for NPH insulin, only Brazil (public sector and private hospitals), Pakistan (public sector) and Kyrgyzstan (public sector) met the target, with insulin provided free-of-charge in the public sector.[6] (Figure 1.)

Issues impacting access to insulin

Global and national factors impact the affordability of insulin. Globally, over 90% of the insulin market is dominated by three multi-national pharmaceutical companies (Eli Lilly, Novo Nordisk and Sanofi).[8] Limited competition impacts insulin prices, and hence affordability, for governments and for individuals. There are several independent insulin biosimilar manufacturing companies, in India, China and elsewhere, but their global market share is small. In the UK, the three multi-national companies cover the market; 58.5% Novo Nordisk, 30.2% Sanofi and 11.4% Lilly (by volume).[9] A mixed picture is seen in LMICs: e.g. in Peru, of the human insulins found in facilities, 100% (public sector) and 62% (private pharmacies) were made by biosimilar insulin manufacturers.[5] A different situation was found in Mali where, across the public and private sector facilities, 90% of all insulins found were made by Novo Nordisk.[6] A study of insulin trade flows, from 2004 to 2013, found 62 countries (28%) purchased insulin from only one source country.[10]

Regulatory issues are also impacting insulin access. Clinical trials of biosimilar insulins are no longer required by the European Medicines Agency or the US Food and Drug Administration when certain conditions are met.[11,12] However, in many LMICs clinical trials are required which increases the cost of investment and impacts market entry and prices. Additional challenges in LMICs can include the lack of regulatory pathways for insulin, including biosimilars, and the poor technical capacity of national medicine regulatory authorities to evaluate application dossiers.[13,14] The inclusion of human insulin in WHO's Prequalification Programme is a positive step in assisting LMICs in the regulation of insulin products.[15]

Good government procurement requires adequate financing, reliable estimation of need, effective procurement practices (including selection), and efficient supply systems. Without these, insulin may not be available in facilities when needed, nor at an affordable price for the government or individual. Price transparency is important to aid efficient procurement of insulin by governments. While the UK government publishes their insulin prices, many other governments do not. Insulin manufacturers are unwilling to disclose actual selling prices. Surveys in LMICs show government procurement prices of insulin are highly variable. In 2016, across 13 LMICs, they ranged from approximately $US 2–25 for human insulins and $US 22–106 for analogues (for 10ml 100IU/ml) depending on the country, insulin type and presentation.[6] By contrast, UK Drug Tariff prices in April 2021 ranged from approximately $US 17–22 for human insulin and $US 19–43 for analogues (for 10ml 100IU/ml).[16] While most of the LMIC governments were paying less than the UK Drug Tariff price for human insulin, those buying analogues were paying up to twice that of the UK price despite their lower economic level. Where prices are higher and budgets are fixed, less insulin can be procured than needed resulting in fewer people being treated. The government procurement price also matters as it is the base price from which people get charged when forced to pay out-of-pocket in public sector facilities.

Attention needs to be given to the supply chain. Various charges, many in the form of mark-ups, can be added to the government procurement price in the public sector and the manufacturer's selling price in the private sector. These additional charges can substantially increase the price people have to pay for insulin. Case studies in six LMICs found mark-ups on insulin ranging from 8.7% to 565.8% depending on the country, sector and region within the country. The proportion of the final price attributed to the manufacturer's selling price varied from 15.0% to 92.0%.[17] A key issue is that many LMICs do not regulate mark-ups in the supply chain nor control medicine prices.

The organisation of care in a country impacts the prescribing of insulin. Unlike the UK, in many LMICs access to insulin and diabetes care is only possible in tertiary and secondary level hospitals (which can require long journeys, unpaid days off work and high transportation costs). In addition, in many LMICs only specialists are permitted to prescribe insulin. At the primary health care level, there is often a lack of experience and expertise in managing diabetes care, gaps in knowledge on insulin use, and even a fear of prescribing insulin itself.[18]

Some LMICs do not have standard treatment guidelines for type 1 diabetes management or type 2 diabetes management that requires treatment with insulin. Where such guidelines do exist, ongoing training of health care providers (clinicians, nurses, etc) on the use of the guidelines and other aspects of diabetes care may not be implemented and/or evaluated.

Further obstacles to optimising insulin use in LMICs include the lack of public awareness of diabetes as a condition and its care. Such awareness can help to remove the stigma of insulin use. Importantly, people

living with diabetes in LMICs are rarely empowered to self-manage their insulin use and other aspects of care.

Not only insulin

Although insulin is essential to guarantee the survival of people with type 1 diabetes and for better management of many people with type 2 diabetes, insulin alone is not enough. It is vital that obstacles to the supply of insulin delivery devices and blood glucose monitoring tools are overcome. Insulin syringes, or other delivery devices, are essential for insulin therapy and are often not available and affordable.[19] Availability and affordability of diagnostic tests in health care facilities, and blood glucose meters and strips for self-monitoring of blood glucose are poor in many LMICs.[19,20] A 2019 survey of facilities in Tanzania found that while blood glucose meters and strips had good availability in the public and mission sectors, insulin syringes had only 50% availability.[21] As well, the price of test strips exceeded the price of human insulin, making therapy even more unaffordable for those paying out-of-pocket.[21] The situation is compounded in people with comorbidities requiring additional medicines and treatment as this adds to the overall financial and social burden on the individual and their family.

Conclusion

One hundred years after Banting and Best's gift of insulin to the world, access remains problematic as seen when comparing the situation in the UK with that in LMICs. The UK NHS provides insulin free-of-charge to individuals; however, in England over £1 billion was spent in 2018/19 on medicines to treat diabetes so the cost to society cannot be overlooked.[22] Government provision of free insulin is enviable to people in LMICs who are forced to pay out-of-pocket. Lack of access to affordable insulin remains a key impediment to successful diabetes treatment and results in needless complications and premature deaths.[23]

KEY POINTS

- Lack of access to affordable and available insulin remains a key impediment to successful diabetes treatment and results in needless complications and premature deaths
- Although ideal diabetes care may not reach all people living with diabetes in the UK, insulin access is considered to be very good. This contrasts to the situation in many low- and middle-income countries
- Based on these median prices and an affordability threshold of one month's treatment costing no more than one day's wage, in many LMICs the lowest paid unskilled government worker must pay four days' wages for human insulin and seven days' wages for analogue insulin
- Governments must commit to improving the situation so that everyone, everywhere who needs insulin can access it

As stated by Dr Tedros, Director-General of the WHO, at the recent launch of the Global Diabetes Compact: 'It is a failure of society and the global community that people who need insulin should encounter financial hardship to buy it or go without it and risk their life'.[24]

Therefore, governments must commit to improving the situation so that everyone, everywhere who needs insulin can access it. Further, they need to regularly monitor the availability, prices and affordability of insulin, insulin syringes and other delivery devices, and blood glucose testing devices. The findings need to be made public, so everyone can track progress in ensuring equitable access to life-saving insulin.

Others also have an important role, including civil society to ensure the voice of the people most affected stay at the forefront, and to hold governments and others accountable to their commitments. WHO must fully address access to insulin issues, delivery devices and blood glucose monitoring tools in the Global Diabetes Compact.[25] The private sector must also commit, including implementing equitable access strategies (including pricing). 2021 marks the commemoration of the discovery of insulin. It also marks an opportunity for the diabetes community to come together to address the global issue of access to insulin for all.

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Declaration of interests

There are no conflicts of interest declared.

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