ISSN 1948-9358 (online)

World Journal of *Diabetes*

World J Diabetes 2023 July 15; 14(7): 939-1145

Published by Baishideng Publishing Group Inc

World Journal of Diabetes

Contents

Monthly Volume 14 Number 7 July 15, 2023

OPINION REVIEW

REVIEW

MINIREVIEWS

ORIGINAL ARTICLE

Basic Study

World Journal of Diabetes

Monthly Volume 14 Number 7 July 15, 2023

Contents

World Journal of Diabetes

Monthly Volume 14 Number 7 July 15, 2023

Contents

ABOUT COVER

Editorial Board Member of *World Journal of Diabetes*, Sonia Eiras, BSc, PhD, Senior Researcher, Traslational Cardiology, Health Research Institute, University Hospital of Santiago de Compostela, Santiago de Compostela 15706, Spain. sonia.eiras.penas@sergas.es

AIMS AND SCOPE

The primary aim of *World Journal of Diabetes* (*WJD*, *World J Diabetes*) is to provide scholars and readers from various fields of diabetes with a platform to publish high-quality basic and clinical research articles and communicate their research findings online.

WJD mainly publishes articles reporting research results and findings obtained in the field of diabetes and covering a wide range of topics including risk factors for diabetes, diabetes complications, experimental diabetes mellitus, type 1 diabetes mellitus, type 2 diabetes mellitus, gestational diabetes, diabetic angiopathies, diabetic cardiomyopathies, diabetic coma, diabetic ketoacidosis, diabetic nephropathies, diabetic neuropathies, Donohue syndrome, fetal macrosomia, and prediabetic state.

INDEXING/ABSTRACTING

The *WJD* is now abstracted and indexed in Science Citation Index Expanded (SCIE, also known as SciSearch®), Current Contents/Clinical Medicine, Journal Citation Reports/Science Edition, PubMed, PubMed Central, Reference Citation Analysis, China National Knowledge Infrastructure, China Science and Technology Journal Database, and Superstar Journals Database. The 2023 Edition of Journal Citation Reports® cites the 2022 impact factor (IF) for *WJD* as 4.2; IF without journal self cites: 4.1; 5-year IF: 4.5; Journal Citation Indicator: 0.69; Ranking: 51 among 145 journals in endocrinology and metabolism; and Quartile category: Q2.

RESPONSIBLE EDITORS FOR THIS ISSUE

NAME OF JOURNAL
World Journal of Diabetes

ISSN
ISSN 1948-9358 (online)

LAUNCH DATE
June 15, 2010

FREQUENCY
Monthly

PUBLICATION DATE
July 15, 2023

World Journal of Diabetes

Submit a Manuscript: https://www.f6publishing.com

World J Diabetes 2023 July 15; 14(7): 939-941

DOI: 10.4239/wjd.v14.i7.939

ISSN 1948-9358 (online)

OPINION REVIEW

Access to novel anti-diabetic agents in resource limited settings: A brief commentary

Poobalan Naidoo, Kiolan Naidoo, Sumanth Karamchand, Rory F Leisegang

Specialty type: Medical ethics

Provenance and peer review: Invited article; Externally peer reviewed.

Peer-review model: Single blind

Peer-review report's scientific quality classification

Grade A (Excellent): A
Grade B (Very good): B
Grade C (Good): 0
Grade D (Fair): 0
Grade E (Poor): 0

P-Reviewer: Ma JH, China; Shen Q, China

Received: October 13, 2022
Peer-review started: October 13, 2022
First decision: November 27, 2022
Revised: December 31, 2022
Accepted: June 13, 2023
Article in press: June 13, 2023
Published online: July 15, 2023

Poobalan Naidoo, Department of Internal Medicine, Nelson R Mandela, School of Medicine, University of Kwa-Zulu Natal, Durban 4001, Kwa-Zulu Natal, South Africa

Kiolan Naidoo, Department of Law, University of South Africa, Pretoria 3, Gauteng, South Africa

Sumanth Karamchand, Department of Cardiology, University of Stellenbosch and Tygerberg Hospital, Stellenbosch 7600, Western Cape, South Africa

Rory F Leisegang, Department of Pharmacometrics, Upsala University, Uppsala 751 04, Sweden

Corresponding author: Poobalan Naidoo, BPharm, MBChB, MMedSc (Pharmacology), DipHIVMan (CMSA), Medical Registrar and Academic Research, Doctor, Department of Internal Medicine, Nelson R Mandela, School of Medicine, University of Kwa-Zulu Natal, Sydney Road, Umbilo, Durban 4001, Kwa-Zulu Natal, South Africa.
poobalan1naidoo@yahoo.com

Abstract

The prevalence of diabetes mellitus is increasing in resource limited settings. Simultaneously, there has been an increase in the number of novel therapies for the management of diabetes mellitus. However, use of novel antidiabetic therapies is limited because of major market access challenges in resource limited settings. Niching products to those patients with the highest absolute risk for major adverse cardiovascular outcomes, and thus most likely to benefit from the therapy, are less likely to have negative budget impact for funders. To improve access, and reduce morbidity and mortality, requires alignment amongst key stakeholders including patient advocacy groups, health care professional councils, national departments of health, the pharmaceutical industry, treasury and finance departments.

Key Words: Type 2 diabetes mellitus; Novel anti-diabetic agents; Resource limited settings; Access

Core Tip: The manuscript addresses the problem of access to novel anti-diabetic agents in resource limited settings. Niching therapies for use in those with highest major adverse cardiovascular risk, may limit budget impact for funders. To improve access, and reduce morbidity and mortality, requires alignment amongst key stakeholders including patient advocacy groups, health care professional councils, national departments of health, the pharmaceutical industry, treasury and finance departments.

Citation: Naidoo P, Naidoo K, Karamchand S, Leisegang RF. Access to novel anti-diabetic agents in resource limited settings: A brief commentary. *World J Diabetes* 2023; 14(7): 939-941
URL: https://www.wjgnet.com/1948-9358/full/v14/i7/939.htm
DOI: https://dx.doi.org/10.4239/wjd.v14.i7.939

INTRODUCTION

Type 2 diabetes mellitus (T2DM) is increasing rapidly in resource limited settings[1]. This is likely to be multifactorial in aetiology including urbanisation, sedentary lifestyle and an increase of screening[2]. The diabetes epidemic has been paralleled by a rapid increase in the number of new therapies to manage type 2 diabetes[3]. These therapies include sodium - glucose transporter 2 inhibitors (SGLT2i), dipeptidyl peptidase-4 inhibitors and glucagon-like-peptide-1 receptor agonists (GLP-1 RAs). The American Diabetes Association and European Association for the Study of Diabetes 2022 consensus report of the management of hyperglycaemia in T2DM recommend an SGLT2i or GLP-1 RA with demonstrated cardiovascular benefit as initial therapy for individuals with T2DM with or at high risk for atherosclerotic cardiovascular disease, heart failure, and/or chronic kidney disease[4].

Unfortunately, in resource limited settings, treating clinicians and patients living with T2DM, have limited access to these therapies due to cost and access constraints. The situation was compounded by the coronavirus disease 2019 pandemic that consumed financial and human resources, that would otherwise have been used for non-communicable diseases such as diabetes.

The irony is that resource limited settings partake in clinical trials programs that test the safety, efficacy and tolerability of novel therapies. Although these countries partaking in the clinical trial programs, patients in these resource limited settings have constrained access to these interventions regardless of regulatory approval. Post-trial access and care are virtually non-existent in these settings[5]. In the absence of a robust post-trial access program, this places a substantial burden on the patient who contributes to the scientific body of evidence supporting a drug's approval but is unable to obtain treatment benefit beyond a predefined, finite period[6].

A major challenge is how to make novel therapies available to patients in resource limited settings. From a clinical perspective, a viable argument is for relevant authorities to facilitate product access for patients at the highest risk and most likely to benefit from therapies. This will niche these novel agents and thus minimise the number of patients on these therapies. For example, SGLT2is can be used in patients with congestive cardiac failure and with diabetes mellitus thus optimising glycaemic control while also reducing hospitalising for heart failure and subsequently reducing healthcare resource utilisation. This would be more cost effect than rolling out these therapies to all patients with diabetes, which is not financially sustainable in developing countries.

In our experience, requests for controlled access to novel drugs, with real world data collection to inform future clinical decisions, have not been successful. The prevailing perspective of focusing on short term drug costing of SGLT2is and not the future healthcare resource utilisation savings through reduced hospitalisations for heart failure, delayed progression of chronic kidney disease and reduction in mortality, requires a paradigm shift and political willingness to address medium and long-term costs and not just short-term expenditure.

An innovative approach is needed to ensure equity of access to novel treatments within a resource limited setting. As patient advocates, we feel that clinicians are best equipped to lead the process to enable access. Merely submitting drug access applications *via* existing systems without engagement on the core challenges at hand is frustrating and often futile. How do we as busy clinicians advocate for access? Perhaps the first step is a collective approach. We suggest engaging with relevant stakeholders to define the current challenges and outline potential solutions. This can be done at a national workshop during a diabetes congress. Alignment amongst key stakeholders including patient advocacy groups, health care professional councils, national departments of health, patient advocacy groups, the pharmaceutical industry, treasury and finance departments is needed in order to improve treatment access with the ultimate intention of improving patient outcomes.

CONCLUSION

In times of economic challenges, it may be necessary to invest funds in urgent related treatment. Furthermore, sourcing drugs from markets that are cost conscious may be an option.

Ultimately, after wide consultation and workshops, laws, acts and regulations will be required to protect the interests of patients and ensure access to novel antidiabetic therapies.

FOOTNOTES

Author contributions: All authors contributed equally to this manuscript.

Conflict-of-interest statement: All the authors report no relevant conflicts of interest for this article.

Country/Territory of origin: South Africa

ORCID number: Poobalan Naidoo 0000-0002-5950-1585; Kiolan Naidoo 0000-0002-5435-8345; Sumanth Karamchand 0000-0003-4435-6685; Rory F Leisegang 0000-0003-0810-4771.

Corresponding Author's Membership in Professional Societies: Health Professional Council of South Africa, MP0718602.

S-Editor: Gong ZM
L-Editor: A
P-Editor: Chen YX

REFERENCES

1 **Misra A**, Gopalan H, Jayawardena R, Hills AP, Soares M, Reza-Albarrán AA, Ramaiya KL. Diabetes in developing countries. *J Diabetes* 2019; **11**: 522-539 [PMID: 30864190 DOI: 10.1111/1753-0407.12913]

2 **Wu Y**, Ding Y, Tanaka Y, Zhang W. Risk factors contributing to type 2 diabetes and recent advances in the treatment and prevention. *Int J Med Sci* 2014; **11**: 1185-1200 [PMID: 25249787 DOI: 10.7150/ijms.10001]

3 **Yu J**, Lee SH, Kim MK. Recent Updates to Clinical Practice Guidelines for Diabetes Mellitus. *Endocrinol Metab (Seoul)* 2022; **37**: 26-37 [PMID: 35255599 DOI: 10.3803/EnM.2022.105]

4 **Davies MJ**, Aroda VR, Collins BS, Gabbay RA, Green J, Maruthur NM, Rosas SE, Del Prato S, Mathieu C, Mingrone G, Rossing P, Tankova T, Tsapas A, Buse JB. Management of Hyperglycemia in Type 2 Diabetes, 2022. A Consensus Report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care* 2022; **45**: 2753-2786 [PMID: 36148880 DOI: 10.2337/dci22-0034]

5 **Usharani P**, Naqvi SM. Post-trial access. *Perspect Clin Res* 2013; **4**: 58-60 [PMID: 23533984 DOI: 10.4103/2229-3485.106391]

6 **Naidoo P**, Rambiritch V, Webb D, Leisegang RF, Cotton MF, Etheredge HR. Mechanisms for sustainable post-trial access: A perspective. *S Afr J Bioethics Law* 2021; **14**: 77-78 [DOI: 10.7196/SAJBL.2021.v14i3.782]

Published by **Baishideng Publishing Group Inc**
7041 Koll Center Parkway, Suite 160, Pleasanton, CA 94566, USA
Telephone: +1-925-3991568
E-mail: bpgoffice@wjgnet.com
Help Desk: https://www.f6publishing.com/helpdesk
https://www.wjgnet.com