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ABSTRCT:

The objective of this study was to describe and compare the quality of clinical guidelines for Type 2 diabetes mellitus (T2D) from Kenya, Zimbabwe, Tanzania and Nepal. Alumni from "peoples-uni" were invited to review and evaluate T2D clinical management guidelines used in their settings. The "Appraisal of Guidelines for REsearch & Evaluation II" (AGREE II) instrument was used to evaluate the guidelines. Each guideline was randomly allocated to three assessors, who evaluated the guidelines separately and allocated scores for items on the AGREE II tool. The guidelines from Zimbabwe and Kenya scored generally better than the Tanzania and Nepal guidelines. The main areas that needed the most improvement across all the guidelines were rigour of development (41%), applicability (40%) and editorial independence (35%). There is a need to improve several aspects of T2D clinical guidelines, which is a useful starting point to improve management of these patients.

Keywords: Appraisal; Developing Countries; Diabetes mellitus; Disease Management; Guidelines

INTRODUCTION:

Diabetes and its complications have become an epidemic in the developing world. In Africa, there will be a significant impact, with a high risk of premature mortality among thousands of Africans due to diabetes [1]. Some epidemiologists predict the economic impact and death toll from diabetes will surpass that of HIV infections and AIDS in the near future [1]. A systematic review of the economic impact on household expenditures showed that in low- and middle-income countries (LMIC), 6 -11% of the total population would be impoverished if they had to purchase the lowest price generic diabetes medication [2]. This is likely an underestimate due to economic domains such as coping strategies and the exclusion of marginalized or vulnerable people who do not seek medical attention. Thus, diabetes is likely to have a significant global impact on households and impoverishment in all continents and levels of income [2].

The Diabcare Africa project spanning across six sub-Saharan African countries found that among 2352 type 2 diabetes (T2D) patients treated at specialist clinics, half the patients received standard care with only one-third achieving appropriate glycaemic control. This was attributed to access to, rather than quality of care [3]. A more recent study of T2D patients from Nigeria, Ghana and Kenya found a high burden of comorbidities, with 71% having

hypertension, 34% with hyperlipidaemia and 27% obesity; as well as complications, with 32% cataracts, 15% diabetic retinopathy, 13% nephropathy and 35% with erectile dysfunction [4]. This reinforces the urgent need for public health strategies prioritising prevention and early detection of T2D; as well as strengthening health care systems to treat diabetes and its complications.

In LMICs, the main challenges to manage T2D include inadequate financial and human resources in health systems, underdeveloped service delivery models and information systems, and a need to improve the evidence-base around clinical management [5]. The availability of quality management guidelines will help to raise the standards of care provided to T2D patients. Clinical practice guidelines are systematically developed statements to assist clinicians and patients decide on appropriate healthcare for specific clinical circumstances. This includes recommendations intended to optimise patient care informed by systematic review of available evidence and an assessment of benefits and harms of alternative care options [6,7].

In this paper, we describe and compare the quality of clinical guidelines for T2D from Kenya, Zimbabwe, Tanzania and Nepal and provide recommendations to improve this aspect of T2D management.

METHODOLOGY:

Peoples-uni (People's Open Access Education Initiative) provides postgraduate level online courses to help build public health capacity in LMICs. Graduates are invited to join an online alumni group to collaborate on research and developing public health systems in their countries [8].

Peoples-uni alumni were invited to review and evaluate T2D clinical management guidelines used in their settings. The Appraisal of Guidelines for REsearch & Evaluation II (AGREE II) instrument was used to evaluate the guidelines. This consists of a 23-item tool, with six quality-related domains, which includes scope and purpose, stakeholder involvement, rigour of development, clarity of presentation, applicability and editorial independence [9,10].

Graduates that participated in the project had facilitated online discussions, including a one-hour interactive session on the use of the AGREE II instrument. This involved pre-reading material about the AGREE II instrument prior to the session, followed by guided examples of rating each component during the session.

Each guideline was randomly allocated to three assessors, who then evaluated the guidelines separately using the online version of the AGREE II tool.

RESULTS:

Four guidelines (from Kenya, Zimbabwe, Tanzania and Nepal) were assessed [11-14]. The scores for each of the 23-items in the six domains are shown in Table 1.

There was generally a consensus for rating scores between at least two of the assessors for all domains; with two assessors (C and D) marking several domains with lower scores than their peers. The T2D guidelines from Zimbabwe and Kenya scored generally better than the Tanzania and Nepal guidelines. The main areas which needed the most improvement across all the guidelines were rigour of development (41%), applicability (40%) and editorial independence (35%). Clarity of presentation was the highest scoring domain (72.5%) on the AGREE II tool, followed by scope and purpose (58.5%). The overall total percentage scores for each domain of the AGREE II tool are shown in Table 2.

Table 1: Scores of the four T2D clinical guidelines using the AGREE II Instrument

	Origin of Guidelines:	Kenya			Zimbabwe			Tanzania			Nepal		
	Assessors (indicated by letters A-F):	A	B	C	D	E	F	A	B	D	E	F	C
Scope & Purpose	Objectives specifically described	6	6	7	1	6	7	5	6	3	3	2	1
	Health questions specifically described	7	5	4	2	6	7	5	4	3	7	7	1
	Population to apply guideline specifically described	7	5	2	3	7	7	5	5	3	6	7	3
Stakeholder Involvement	Development Group includes individuals from all relevant professional groups	7	5	6	5	7	7	4	4	2	3	2	2
	Views & preferences of target population sought	7	5	3	3	4	2	4	3	2	1	2	1
	Target users clearly defined	7	6	2	3	5	6	5	5	4	7	1	1
	Systematic methods used to search for evidence	2	5	2	1	5	6	3	3	4	7	4	3
Rigour of development	Criteria for selecting evidence clearly described	2	5	1	2	2	7	2	4	3	4	1	1
	Strengths and limitations of the body of evidence clearly described	2	2	1	2	1	5	1	4	1	7	1	2
	Methods for formulating recommendations clearly described	2	4	5	3	1	7	2	5	3	1	1	3
	Health benefits, side effects, and risks have been considered in formulating recommendations	5	6	5	3	7	7	5	6	5	7	6	5
	Explicit link between recommendations and supporting evidence	5	5	3	3	3	6	5	5	2	7	7	4
	Guideline externally reviewed by experts prior to publication	5	2	5	3	5	2	5	5	5	1	2	1
	Procedure for updating guideline provided	2	2	6	5	6	6	7	2	4	1	1	1
Clarity of presentation	Recommendations are specific and unambiguous	4	6	6	4	6	6	4	6	5	7	7	6
	Different options for management of the condition or health issue clearly presented	6	6	6	5	7	6	5	6	6	7	7	6
	Key recommendations are easily identifiable	4	6	6	4	7	7	4	6	4	7	7	5
Applicability	Guideline describes facilitators and barriers to application	4	4	2	3	7	6	3	4	3	4	2	1
	Guideline provides advice and/or tools how the recommendations can be put into practice	5	5	2	5	5	7	3	5	5	2	7	2
	Potential resource implications of applying recommendations have been considered	4	5	1	3	7	7	3	5	3	1	2	1
	Guideline presents monitoring and/or auditing criteria	1	5	1	3	5	2	1	3	3	1	6	1
Editorial Independence	Views of the funding body have not influenced the content of the guideline	5	6	3	3	3	7	4	3	4	1	7	2
	Competing interests of guideline development group members have been recorded and addressed	1	5	3	3	2	4	2	4	2	1	1	2
Overall Assessment		5	6	5	4	6	7	4	4	4	5	6	4

Table 2: Total percentage Scores for each of the domains on the AGREE II tool

	Kenya	Zimbabwe	Tanzania	Nepal	Mean
Scope and Purpose	74%	69%	56%	35%	58.5%
Stakeholder Involvement	72%	61%	44%	11%	47%
Rigour of Development	42%	51%	47%	24%	41%
Clarity of Presentation	76%	80%	69%	65%	72.5%
Applicability	38%	67%	40%	15%	40%
Editorial Independence	47%	44%	36%	13%	35%

The overall comments by the assessors for each guideline were as follows:

For Kenya: "the guidelines cover a wide area in the management of diabetes in Kenya. The technical aspects were strong. However, some information related to the guideline development process and stakeholders' involvement and scope were missing. The drafting process, methodology, criteria, use of external reviewers, recommendations and funding or conflicts of interests should have been described".

For Zimbabwe: "the guideline met the basic requirements for an internationally reputable standard. However, there needs to be further details regarding steps taken to arrive at their conclusions. There is room to review, revise and edit the contents to align with the AGREE II Plus appraisal tool".

For Tanzania: "the process of development should involve a wider range of stakeholders. Methodology, criteria, declarations of competing interests and providing clear recommendations with evidence can be improved".

For Nepal: "the guideline focused more on the technical and management aspects. The rationale, target group, use of guidelines, process involved, methods used, evidence and applicability were not described".

DISCUSSION:

There was some variability in the quality of T2D clinical guidelines between four LMICs (Kenya, Zimbabwe, Tanzania and Nepal), which may have implications on the management of T2D in these countries. The main areas for improvement were in terms of rigour of development, applicability and editorial independence, which was consistent with three other systematic reviews.

A systematic review of 17 T2D management guidelines found variation in quality when assessed using the AGREE II tool, with the highest scoring domain as clarity of presentation and the lowest being applicability (37%) and rigour of development (43%) [15]. These findings were similar for paediatric T2D guidelines with clarity of presentation being the highest scoring domain (72%) and rigour of development (45%) and editorial independence (45%) being the lowest scoring domains on the AGREE II tool [16]. A systematic review of 98 T2D guidelines from China also identified a need for improvement, particularly rigour of development (19.1%), applicability (18.1%) and editorial independence (0%) [17]. These aspects can be improved by using the AGREE II tool as a basis for developing guidelines to ensure the different domains are covered.

Limited involvement of patients was also identified, with these guidelines mainly focusing on the perspective of clinicians. A cross-sectional survey of 4071 hypertensive and

diabetic patients from Thailand found that despite a policy initiative to improve primary care using a Chronic Care Model, it did not necessarily satisfy the patient's perception on quality of chronic care [18]. Thus, their perspective as the main end-user and care recipient should be sought to improve outcomes.

Their opinions would also be valuable to ensure applicability to their settings and identifying barriers to implementation. A systematic review of T2D patients from sub-Saharan Africa found that patients rarely checked their glucose levels, had inadequate physical activity, were only moderately compliant to diet and medications and had poor knowledge regarding diabetes related complications [19]. These aspects all need to be improved on and should be considered in guideline development, as self-management is essential to reduce complications of T2D.

CONCLUSION:

Overall, the impact of diabetes is significant in sub-Saharan Africa, with unique challenges such as limited funding for non-communicable diseases, limited studies or guidelines specific to the population, limited access to medications, and inequity between rural and urban, as well as public and private sector health care [20].

Quality guidelines are a useful starting point to improve management of T2D patients.

However, there is a need to improve several aspects of T2D clinical guidelines, particularly rigour of development, applicability and editorial independence.

Limitations:

The study assessed only the main national guidelines identified and/or used by the co-author from the respective country. Other guidelines related to T2D management, such as hospital or clinic specific guidelines from these countries were not evaluated.

Conflict of Interest:

The authors have no conflicts of interest to declare.

REFERENCES:

1. Azevedo M, Alla S. Diabetes in sub-Saharan Africa: Kenya, Mali, Mozambique, Nigeria, South Africa and Zambia. Int J Diabetes Dev Ctries 2008;28(4):101-108.
2. Jaspers L, Colpani V, Chaker L, van der Lee SJ, Muka T, Imo D, Mendis S, Chowdhury R, Bramer WM, Falla A, Pazoki R, Franco OH. The global impact of non-communicable diseases on households and improverishment: a systematic review. Eur J Epidemiol 2015;30(3):163-88.
3. Sobngwi E, Ndour-Mbaye M, Boateng KA, Ramaiya KL, Njenga EW, Diop SN,

Mbanya JC, Ohwovoriole AE. Type 2 diabetes control and complications in specialised diabetes care centres of six sub-Saharan African countries: the Diabcare Africa study. Diab Res Clin Pract 2012;95(1):30-36.

4. Ekoru K, Doumatey A, Bentley AR, Chen G, Zhou J, Shriner D, Fasanmade O, Okafor G, Eghan Jr B, Agyenim-Boateng K, Adeleye J, Balogun W, Amoah A, Acheampong J, Johnson T, Oli J, Adebamowo C, Collins F, Dunston G, Adeyemo A, Rotimi C. Type 2 diabetes complications and comorbidity in Sub-Saharan Africans. EClinicalMedicine 2019;16:30-41.

5. Ali MK, Rabadan-Diehl C, Flanigan J, Blanchard C, Venkat Narayan KM, Engelgau M. Systems and capacity to address noncommunicable diseases in low- and middle-income countries. Sci Transl Med 2013;5(181):181cm4

6. Widyahening IS, Wangge G, van der Graaf Y, van der Heijden GJM. Adapting clinical guidelines in low-resources countries: a study on the guideline on the management and prevention of type 2 diabetes mellitus in Indonesia. J Eval Clin Pract 2017;23(1):121-27.

7. Liu Y, Zhang Y, Wang S, Liu L, Che G, Niu J, Ma Y. Quality of pediatric clinical practice guidelines. BMC Pediatrics 2021;21:223.

8. Heller RF, Machingura PI, Musa BM, Sengupta P, Myles P. Mobilising the alumni of a Master of Public Health degree to build research and development capacity in low- and middle-income settings: The Peoples-uni. Health Res Policy Sys 2015'13:71.

9. Brouwers MC, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, Fervers B, Graham ID, Grimshaw J, Hanna SE, Littlejohns P, Makarski J, Zitzelsberger L. AGREE II: Advancing guideline development, reporting and evaluation in healthcare. CMAJ 2010;182:E839-42.

10. AGREE Next Steps Consortium. Appraisal of guidelines for research & evaluation II (AGREE II) instrument. The AGREE II Instrument. Canada: AGREE Next Steps Consortium. 2017. www.agreetrust.org/wp-content/uploads/2017/12/AGREE-II-Users-Manual-and-23-item-Instrument-2009-Update-2017.pdf

11. Ministry of Public Health and Sanitation. National clinical guidelines for management of diabetes mellitus. First Edition. Republic of Kenya: Ministry of Public Health and Sanitation; July 2010. www.worlddiabetesfoundation.org/sites/default/files/WDF09436%20National%20Clinical%20Guidelines%20for%20Management%20of%20Diabetes%20Melitus%20-%20Complete.pdf

12. The National Medicine and Therapeutics Policy Advisory Committee (NMTPAC). EDLIZ 2015. 7th Essential medicines list and standard treatment guidelines for Zimbabwe. Republic of Zimbabwe: Ministry of Health & Child Care. 2015 . https://extranet.who.int/ncdccs/Data/ZWE_D1_7th%20edition%20EDLIZ%202015%20_%20Final%20Version%20with%20Signatures.docx

13. Ministry of Health and Social Welfare. Chronic non communicable diseases. Cardiovascular disease, Type 2 diabetes, cancer and COPD in adults. Case management desk guide. United Republic of Tanzania: Ministry of Health and Social Welfare. Updated 2013 Dec. www.worlddiabetesfoundation.org/sites/default/files/NCD%20Desk%20Guide%20Tanzania.pdf

14. Shrestha D, Shrestha P, Sharma S, Bhattarai J, Shrestha H, Pradhan A, Shakya A. National consensus statement on the management of Type 2 diabetes mellitus in Nepal. J Diab Endocrinol Assoc Nepal 2019;3(1):38-57.

15. Lam WMJ, AL-Khalifah R, Florez ID, Curz-Lopes L, Sekercioglu MF, Couban R, Fu R, Cherney DZI, Sekercioglu N. Management of type 2 diabetes using non-insulin glucose-lowering therapies: a

critical appraisal of clinical practice guidelines with the AGREE II instrument. Diab Med 2020;37(4):636-47.

16. Bhatt M, Nahari A, Wang PW, Kearsley E, Falzone N, Chen S, Fu E, Jeyakumar Y, Zukowski J, Banfield L, Thabane L, Samaan MC. The quality of clinical practice guidelines for management of pediatric type 2 diabetes mellitus: a systematic review using the AGREE II instrument. Syst Rev 2018;7:193.

17. Gao Y, Wang J, Luo X, Song X, Liu L, Ke L, Liao Z, Wang D, Mu Y, Chen Y, Estill JAM. Quality appraisal of clinical practice guidelines for diabetes mellitus published in China between 2007 and 2017 using the AGREE II instrument. BMJ Open 2019;9:e022392.

18. Aekplakorn W, Suriyawongpaisal P, Srithamrongsawadi S, Kaewkamjonchai P. Assessing a national policy on strengthening chronic care in primary care settings of a middle-income country using patients' perspectives. BMC Health Serv Res 2021;21(1):223

19. Stephani V, Opoku D, Beran D. Self-management of diabetes in Sub-Saharan Africa: a systematic review. BMC Public Health 2018;18:1148.

20. Pastakia SD, Pekny CR, Manyara SM, Fischer L. Diabetes in sub-Saharan Africa – from policy to practice to progress: targeting the existing gaps for future care for diabetes. Diabetes Metab Syndr Obes 2017;10:247-63.