Comments for EB discussion paper

NGOs

ASEAN Wound Council

Canadian Federation of Podiatric Medicine (CFPM) and Canadian Podiatric Medical Association (CPMA)

D-Foot International

Diabetes Awareness Association (DAA)

Diabetes Canada

DiabetesIndia and Research Society of Study of Diabetes (RSSDI)

Dr Dia Footcare

Feel Foot Advance Foot and Wound Care Centre (Amandeep Hospital)

Geneva Foundation for Medical Education & Research (GFMER)

Global Liver Institute and Fatty Liver Alliance

Insulin for Life USA

International Alliance of Patients' Organizations (IAPO)

International Diabetes Federation (submission supported by NCD Alliance, World Heart Federation, World Obesity) (IDF)

International Diabetes Federation (additional comment) (IDF)

International Federation of Pharmaceutical Manufacturers & Association (IFPMA)

International Pediatric Association (IPA)

International Society for Pediatric and Adolescent Diabetes (ISPAD)

International Society of Nephrology (ISN)

Intersectoral Forum to Fight NCDs in Brazil (ForumDCNTs)

Journal of Wound Care (JWC)

Juvenile Diabetes Research Foundation International, UK, Canada, Australia, Israel and the Netherlands

Life for a Child (LFAC)

Malaysian Society of Wound Care Professionals (MSWCP)

MAX Healthcare

Médecins Sans Frontières (MSF)

Nurses Specialized in Wound, Ostomy & Continence Canada (NSWOCC)

Nutrire Collective

PATH and the Coalition for Access to NCD Medicines and Products

Pediatric Endocrine Society (PES)

Scottish Diabetes Group

The Diabesties Foundation

T1International

The diaTribe Foundation

World Council of Enterostomal Therapists (WCET)

World Diabetes Foundation (WDF)

World Union of Wound Healing Societies (WUWHS)

Wound Healing Association of Southern Africa (WHASA)

WoundPedia

Wounds Canada and the Diabetic Foot Canada Committee

Academic institutions

Boston University School of Public Health, Department of Global Health

Staffordshire University

University of Toronto, Dalla Lana School of Public Health

UN

Convention Secretariat, WHO Framework Convention on Tobacco Control (WHO FCTC Secretariat)

Member states

Australia

Mexico

Norway

United States

AUSTRALIA

Consultation on *Draft recommendations to strengthen and monitor diabetes responses within national noncommunicable disease programmes, including potential targets*

September 2021

Australia thanks the WHO and academic group for their work on developing the proposed recommendations and global targets for 2030 as outlined in the Discussion Paper - *Draft recommendations to strengthen and monitor diabetes responses within national noncommunicable disease programmes, including potential targets*, in line with resolution WHA74.4 *Reducing the burden of noncommunicable diseases through strengthening prevention and control of diabetes.*

Australia recognises the escalating global burden and the significant, and often preventable, impacts diabetes has on the health and wellbeing of individuals, as outlined in the Discussion Paper.

Overall, Australia is supportive of the proposed actions for Governments, international partners and the WHO. We note that the recommended actions largely align with our domestic policy, such as the Australian National Diabetes Strategy and are consistent with the approach needed to address diabetes in Aboriginal and Torres Strait Islander peoples.

Australia supports the recommendations to further develop and strengthen surveillance and monitoring systems for diabetes and other NCD risk factors.

We also welcome the recommended actions for the WHO in supporting the development of monitoring frameworks and assisting in the development and maintenance of surveillance systems.

Global Coverage Targets

We are appreciative of the detailed technical information on the development methodology for the proposed voluntary global coverage targets for diabetes and note their alignment with the WHO Global Action Plan for the Prevention and Control of Noncommunicable Diseases, and the WHO Global Diabetes Compact. We have provided specific comments for the five targets below.

Proposed target 1: 80% of people with diabetes are diagnosed

Australia supports this target.

Note: Australia has assessed this metric using data from the Australian Bureau of Statistics (ABS) Health Measures Survey.

Proposed target 2: 80% of people with diagnosed diabetes have good control of glycaemia

Australia supports this target. However, we note that the target may not be appropriate in relation to treatment for older people with diabetes, where targets are often individualised for this cohort.

Note: As this target may not be appropriate for older people with diabetes, Australia has previously applied age restrictions to assess this metric.

Proposed target 3: 80% of people diagnosed with diabetes have good control of blood pressure

Australia supports this target.

Note: Australia has assessed this metric using data from the ABS Health Measures Survey, but used a <130/80 mmHg target rather than <140/90. Australia could assess the data using the proposed target.

Proposed target 4: 60% of people with diabetes receive statins

Australia supports this target for people with type 2 diabetes. Australian health guidelines recommend all adults with type 2 diabetes and known prior CVD (except haemorrhagic stroke) should receive the maximum tolerated dose of a statin, irrespective of their lipid levels. [1]

We understand there is some evidence that the treatment of type 1 diabetes with statins decreases CVD risk in people over 40 years old, or who have had type 1 diabetes for more than 10 years, or other CVD risk markers. However, noting that the use of statins for younger people with type 1 diabetes is not recommended, the proposed target irrespective of other risk factors may not be appropriate, and consequently may also skew the data.

Note: A linkage project is currently under development to routinely monitor this target.

Proposed target 5: 100% of people with type 1 diabetes have access to insulin and blood glucose self-monitoring

Australia supports this target.

Note: Australia has assessed this metric based on data from the National (insulin-treated) Diabetes Register.

[1] The Royal Australian College of General Practitioners. Management of type 2 diabetes: A handbook for general practice. East Melbourne, Vic: RACGP, 2020, accessed 13 September 2021, https://www.racgp.org.au/clinical-resources/clinical-guidelines/key-racgp-guidelines/view-all-racgp-guidelines/diabetes/type-2-diabetes-and-cardiovascular-risk.

Mexico Comments on the WHO Draft Recommendations to Strengthen and Monitor Diabetes Responses within National Noncommunicable Disease Programmes, including potential targets

LESSONS LEARNED

- 3. b). It is suggested to include the following text to this paragraph:

  "b) Monitoring outcomes: Improving the accuracy and availability of data on the ***incidence and*** *prevalence of diabetes, access to prevention interventions,* ***adherence to treatment, quality of*** *care and essential medicines, complications* ***and mortality*** *of diabetes is needed to evaluate the effects of diabetes policy and initiatives.* ***Efforts should be made to have a national diabetes registry to generate data on new diabetes cases and deaths.*** *WHO has initiated regular national WHO STEPwise Approach to NCD Risk Factor Surveillance (STEPS) in order to improve monitoring of NCD risk factors.1 However, these surveys do not fully capture the performance of the health system. This will require guidance and support for improving the availability and quality of data in health facilities."*

STRENGTHENING DIABETES RESPONSES

- 4. C). It is suggested to add the following recommended actions in this section:

  - Increase the early detection of diabetes on people with risk factors.
  - Promote the evaluation of cardiovascular disease risk score on people living with diabetes.

Development of recommendations to strengthen and monitor diabetes responses within national noncommunicable disease programmes, including considering the potential development of targets in this regard

Comments from Norway

We appreciate that the secretariat has recommended actions in order to strengthen the monitoring of diabetes, which we support. We also strongly support the work on setting diabetes coverage targets. With reference to the five recommended targets, we have the following comments:

- "80% of people with diabetes are diagnosed", at the same time as "100% of people with type 1 diabetes have access to insulin and blood glucose self-monitoring". This is somewhat contradictory, and we recommend amending these targets to "100% of people with type 1 diabetes are diagnosed", and "80% of people with other types of diabetes are diagnosed", additionally (or as an alternative to the first target), "100% of people **diagnosed** with type 1 diabetes have access to insulin and blood glucose self-monitoring".

- Regarding the target "100% of people with type 1 diabetes have access to insulin and blood glucose self-monitoring", we recommend to add the word **affordable.** Member state point 1.6 in the diabetes resolution, states "to ensure that national strategies for the prevention and control of noncommunicable diseases contain the necessary provisions to cover persons living with diabetes with quality essential health services and promote access to diagnostics and quality, safe, effective, affordable and essential medicines, including insulin, oral hypoglycemic agents and other diabetes-related medicines and health technologies for all people living with diabetes, in accordance with national context and priorities".

- The background paper refers to RCT evidence for "adults with diagnosed diabetes who are at least 40 years of age taking lipid-lowering medications", but the target is defined as "60% of people with diabetes receive statins.". We would therefor suggest to add the age threshold or according to national guidelines.

World Health Organization

WHO DISCUSSION PAPER
(Version dated 9 August 2021)

DRAFT RECOMMENDATIONS TO STRENGTHEN AND MONITOR DIABETES RESPONSES WITHIN NATIONAL NONCOMMUNICABLE DISEASE PROGRAMMES, INCLUDING POTENTIAL TARGETS

CHALLENGES AND OPPORTUNITIES

1. Never in the past has our knowledge been so profound and the modalities to prevent diabetes and treat all people living with diabetes so great. And yet, many people and communities in need of effective prevention, life-enhancing and live-saving treatment for diabetes do not receive them:

a) There is growing awareness and concern about the large and escalating burden of diabetes. The global age-adjusted prevalence of diabetes among adults over 18 years of age rose from 4.7% in 1980 to 8.5% in 2014.[1] Today, more than 420 million people are living with diabetes worldwide. This number is estimated to rise to 570 million by 2030 and to 700 million by 2045.[2] One in two adults with diabetes are unaware of their condition and are at great risk of debilitating complications that can be prevented through diagnosis and proper disease management.

b) The increasing prevalence of diabetes is largely caused by the increasing prevalence of obesity and concurrent physical inactivity. The prevalence of overweight and obesity among children and adolescents aged 5-19 has risen dramatically from 4% in 1975 to over 18% in 2016.[3] Only 40% of countries have an operational policy addressing overweight and obesity.[4]

c) Contrary to the other main noncommunicable diseases (NCDs) the premature mortality for diabetes has increased by 5% from 2000 to 2016.[5]

d) The global cost of diabetes for 2015 has been estimated at US$1·31 trillion or 1·8% of global gross domestic product (GDP). While the main drivers of cost are hospital inpatient and outpatient care, indirect costs accounted for 34·7% of the total burden, mostly attributable to production losses due to labour-force dropout and premature mortality.[6]

e) Twenty-seven percent of countries do not have an operational policy, strategy or action plan for diabetes, and 20% do not have it for reducing unhealthy diet and physical inactivity.

f) Limited progress has been seen for diabetes towards target 3.8 of the Sustainable Development Goals on achieving universal health coverage (UHC). The WHO UHC Monitoring Report (2019) shows that diabetes health services are conspicuous by their lack of progress as part of universal

[1] Global report on diabetes. Geneva: World Health Organization; 2016
[2] Saeedi P, Petersohn I, Salpea P, Malanda B, Karuranga S, Unwin N, Colagiuri S, Guariguata L, Motala AA, Ogurtsova K, Shaw JE, Bright D, Williams R; IDF Diabetes Atlas Committee. Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045: Results from the International Diabetes Federation Diabetes Atlas, 9th edition. Diabetes Res Clin Pract 2019;157:107843
[3] https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight
[4] Assessing national capacity for the prevention and control of noncommunicable diseases: report of the 2019 global survey. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO
[5] World health statistics 2020: monitoring health for the SDGs, sustainable development goals. Geneva: World Health Organization; 2020
[6] Bommer C, Heesemann E, Sagalova E, Manne-Goehler J, Atun R, Bärnighausen T et al. The global economic burden of diabetes in adults aged 20–79 years: a cost-of-illness study. Lancet Diabetes Endocrinol 2017; 5: 423–30

health coverage in comparison to those for communicable diseases.[1] Only two-thirds of countries report having time-bound NCD targets, which may include targets of no increase in diabetes and obesity and improved access to medicines and technologies, in line with the nine voluntary global targets of the WHO Global Monitoring Framework.

g) In general, primary health-care facilities in low-income countries do not have the basic technologies needed to diagnose and manage diabetes.[1] Essential medicines for diabetes are generally available in about 80% of facilities of the public health care sector.

h) Insulins and associated health technology products remain unaffordable in many countries particularly to patients paying out of pocket or to health systems in many LMIC that are unable to provide sustained and equitable coverage for all people with diabetes due to high prices of these products. Effective public policymaking to improve access to affordable medicines and health products requires the use of evidence from accurate analysis of sound and transparent data on prices and availability.[2][3]

i) The COVID-19 pandemic has revealed the fragility of overstretched health care systems. A WHO survey indicated that half of countries surveyed had partially or completely disrupted services for diagnosis and treatment for diabetes and diabetes-related complications. One-third of countries did not have diabetes in their emergency preparedness plans.[4]

j) Data on diabetes derived from monitoring and surveillance systems in most countries are sparse and inadequate. Only 56% of countries have recently conducted a diabetes prevalence survey. While 50% of countries, mostly high-income ones, report having diabetes registries, their predominantly hospital-based nature and limited coverage do not provide sufficient information on diabetes outcomes.[5] Less than two-thirds of low-income countries report having vital registration systems to capture information on cause of death and the reliability of the information on diabetes is doubtful. Most countries do not have a system in place to evaluate national actions or programmes.

k) Only one-third of countries report having a policy or plan for NCD research and research is among the least-funded key actions of the Global action plan for the prevention and control of noncommunicable diseases.

2. Opportunities exist to facilitate solutions to the challenges. The main opportunities are:

a) **Tracer for all NCDs**: optimal management of diabetes requires coordinated inputs from a range of health professionals, access to essential medicines and technologies and a system that supports patient empowerment. This has relevance beyond diabetes and diabetes could serve as a tracer condition for general comprehensiveness and strength of national responses to NCDs.

b) **A solid basis for scaling up**: 85% of countries report having staff dedicated to diabetes in their NCD unit/branch/department; 73% of countries report having an operational policy, strategy or action plan on diabetes, increasing from 45% in 2010. Eighty percent of countries report having operational policies or strategies for reducing unhealthy diet and physical inactivity. Eighty-four percent report having national diabetes management guidelines that are used in at least 50% of health facilities.

[1] https://www.who.int/data/monitoring-universal-health-coverage
[2] Babar ZUD, Ramzan S, El-Dahiyat F, Tachmazidis I, Adebisi A and Hasan SS. The availability, pricing, and affordability of essential diabetes medicines in 17 low-, middle-, and high-income countries. *Frontiers in pharmacology* 2019:*10:*1375.
[3] https://www.who.int/publications/i/item/9789240011878
[4] The impact of the COVID-19 pandemic on noncommunicable disease resources and services: results of a rapid assessment. Geneva: World Health Organization; 2020
[5] https://apps.who.int/iris/bitstream/handle/10665/204871/9789241565257_eng.pdf?sequence=1

c) **Improving accountability:** Setting time-bound national targets and indicators for diabetes and obesity prevention and control, complementary to existing NCD targets could stimulate accelerated implementation of existing policies and introduction of new ones.

d) **Towards universal health coverage**: the global push towards universal health coverage to achieve SDG target 3.8 is an opportunity to include diabetes prevention and control in benefit packages and address diabetes more effectively and equitably, and ensuring financial protection of the most vulnerable.

e) **A new perspective on NCDs:** The COVID-19 pandemic has disproportionately affected people with diabetes and this can provide an impetus to better integrate diabetes in pandemic and other emergency preparedness and response.

f) **Marking the 100 year anniversary of insulin** : The establishment of the Global Diabetes Compact offers an opportunity for the global diabetes community to come together to reflect on addressing barriers in accessing insulin and associated health technologies, including the promotion of convergence and harmonization of regulatory requirements for insulin and other medicines and health products for the treatment of diabetes; and assessment of the feasibility and potential value of establishing a web-based tool to share information relevant to the transparency of markets for diabetes medicines and health products.

g) **Harnessing digital technologies**: Increasing use of digital technologies could facilitate monitoring and surveillance, enhancing the capacity to assess and report on risk factors, availability and real need of essential medicines, diabetes outcomes and national responses.

h) **Promoting inclusiveness**: Participation of individuals with diabetes and their caregivers~~carers~~ provides essential expertise to positively impact policy design, and powerful narratives to raise awareness of diabetes among the public and build commitment among policymakers. The involvement and active participation of people living with diabetes in the Global Diabetes Compact provides a platform and model for their meaningful participation in decision making.

Commented [A1]: Missing from this and other discussion papers is access to digital technologies and ability to utilize (e.g., education/learning) digital tech.

Commented [A2]: Suggestion for clarity

LESSONS LEARNED

3. Lessons learned in implementing activities for the prevention, control and monitoring of diabetes include:

a) **Diabetes through a pandemic lens:** The disruption of services by the COVID-19 pandemic and particular vulnerability of people with diabetes have shown that countries need not only to restore the health care system to the level it was before. Member States need to build back better to integrate diabetes management, including diabetes complications, into primary health care and relevant health programmes and work with global financial institutions to include funding for diabetes as a critical comorbidity.[1]

b) **Monitoring outcomes:** Improving the accuracy and availability of data on the prevalence of diabetes, access to prevention interventions, care and essential medicines, and complications of diabetes is needed to evaluate the effects of diabetes policy and initiatives. WHO has initiated regular national WHO STEPwise Approach to NCD Risk Factor Surveillance

[1] Responding to non-communicable diseases during and beyond the COVID-19 pandemic. Geneva: World Health Organization and the United Nations Development Programme, 2020 (WHO/2019-nCoV/Non-communicable_diseases/Policy_brief/2020.1). Licence: CC BY-NC-SA 3.0 IGO.

(STEPS) in order to improve monitoring of NCD risk factors.[1] However, these surveys do not fully capture the performance of the health system. This will require guidance and support for improving the availability and quality of data in health facilities.

STRENGTHENING DIABETES RESPONSES

4. Recommended actions for **Member States:**

a) Strengthen national capacity, leadership, governance, multisectoral action and partnerships to accelerate country response for the prevention and control of diabetes:

- Strengthen the capacity of ministries of health to exercise a strategic leadership and coordination role in diabetes policy development that engages all stakeholders across government, civil society, people living with diabetes, and the private sector, ensuring that issues relating to the prevention and control of diabetes receive a coordinated, comprehensive and integrated response.

- Provide sufficient national budgetary allocation for diabetes prevention and control, and identify financing mechanisms to reduce out-of-pocket expenditure.

- Strengthen the design and implementation of policies for diabetes by ensuring that existing national UHC benefit packages and NCD multisectoral strategy/policy/action plans contain the necessary provisions for diabetes prevention and management.

- Consider setting national diabetes coverage targets, building on the guidance provided by WHO, to progressively cover more people with quality diabetes care, increase accountability, and periodically assess national capacity for the prevention and control of diabetes.

b) Reduce modifiable risk factors for diabetes and underlying social determinants:

- Accelerate implementation of policies and strategies to reduce risk factors for diabetes and its complications.

- Promote health literacy and strengthen involvement of people living with NCDs in clinical decision-making with a focus on health-professional-patient communication.

- Consider disproportionate diabetes burdens among subpopulations and address the underlying social determinants that expose these populations to greater risk of developing diabetes and its complications, substandard care, or lack of access to essential diabetes medicines.

c) Strengthen and orient health systems to address the prevention and control of diabetes through people-centered primary health care and universal health coverage:

- Expand the delivery of and prioritize primary health care as a cornerstone of sustainable, people-centered, community-based and integrated diabetes care.

- Set minimum standards of diabetes management across the continuum of care with a focus on primary health care, while strengthening referral systems between primary and other levels of care.

[1] https://www.who.int/teams/noncommunicable-diseases/surveillance/systems-tools/steps

- Consider adopting global coverage targets to be achieved by 2030* to stimulate early detection and improved management, and consider their adaptation to local circumstances.

- Strengthen health workforce and institutional capacity to detect early and manage diabetes, including diagnosis and management of diabetes related complications, provision of psycho-social support, promotion of self-care, and provision of palliative care and rehabilitation.

- Ensure availability and affordability of essential medicines and priority devices by bundling medicines, insulin delivery devices and blood glucose monitoring devices as part of national benefit packages.

- Ensure uninterrupted treatment of people living with diabetes in humanitarian emergencies.

- Evaluate the impact of innovative digital health solutions.

- Include PLWD in decision making processes on policies, strategies and implementation of diabetes prevention and control.

d) Promote and support national capacity for high-quality research and development for the prevention and control of diabetes

- Explore the reasons for little progress on NCD research and options to address them.

5. Recommended actions for **International Partners**, including the private sector:

a) Strengthen national capacity, leadership, governance, multisectoral action and partnerships to accelerate country response for the prevention and control of diabetes:

- Maintain visibility of diabetes on the global health and development agenda.

- Align international cooperation on diabetes with national plans concerning non-communicable diseases in order to strengthen aid effectiveness and the development impact of external resources in support of diabetes.

- Civil society to foster accountability and support countries in regular review of progress of national diabetes roadmaps toward the achievement of national diabetes targets.

b) Reduce modifiable risk factors for diabetes and underlying social determinants:

Commented [A3]: Consider whether these two activities adequately capture strategies on food insecurity

- Advocate for and support population-based policies, health promotion activities and health literacy campaigns.

- Advocate for and help implement and evaluate community-based diabetes prevention and control initiatives.

c) Strengthen and orient health systems to prevent and control of diabetes through people-centered primary health care and universal health coverage:

- Commit to support of activities that improve affordability and availability of essential medicines and basic technologies for diagnosis, management, and self-care of people with diabetes.

- Support and scale up implementation of digital health solutions based on country need assessments.

- Invite the private sector to strengthen its commitment and contribution to the prevention and management of diabetes by participating in WHO prequalification programmes for insulin and self-monitoring devices, to register and publish their contributions, including through the reporting mechanism WHO will use to register and publish these contributions, and to participate in international pooled-procurement mechanisms for diabetes medicines (once established) led by the United Nations and other intergovernmental organizations, and international financing mechanisms.

d) Promote and support national capacity for high-quality research and development for the prevention and control of diabetes

- Invest in and support national capacity for research on diabetes prevention and control relevant to the implementation of recommendations.

6. Recommended actions for **WHO**:

a) Strengthen national capacity, leadership, governance, multisectoral action and partnerships to accelerate country response for the prevention and control of diabetes

- Convene and lead partners through the Global Diabetes Compact to raise awareness, create synergies for action, and harness the collective capacity of global, regional and national actors working to improve diabetes prevention and control.

- Support country activities for including diabetes in UHC and develop recommendations for adequate, predictable, and sustained financing of diabetes prevention and control, including in resource-constrained settings, and to address the needs of disadvantaged and marginalized populations.

- Scale-up meaningful engagement of people with diabetes in the design, implementation and evaluation of programmes and services for diabetes.

b) Reduce modifiable risk factors for diabetes and underlying social determinants:

- Provide guidance on prevention of type 2 diabetes through health promotion and health literacy.

c) Strengthen and orient health systems to prevent and control of diabetes through people-centered primary health care and universal health coverage:

- Support country adaptation and implementation of WHO diabetes management guidelines.

- Develop technical and normative products to cover the whole spectrum of diabetes care and facilitate implementation of evidence-based digital solutions.

- Develop expanded coordination ~~bundled management-enhancing solutions~~ with the private sector, prequalification of insulin, pooled procurement, and harmonization of regulatory requirements.

- Develop guidance for enabling uninterrupted treatment of diabetes in humanitarian emergencies.

Commented [A4]: This language was unclear to reviewers. Please clarifying what WHO considers as components of "bundled management-enhancing solutions". "Expanded coordination" could be simpler.

- Estimate the cost of achieving the global coverage targets.

d) Promote and support national capacity for high-quality research, innovation and development for the prevention and control of diabetes

- Develop a plan for supporting national research in diabetes prevention and control.
- Support prioritization of research agenda for diabetes prevention and control and promote implementation research to assess effectiveness of individual and population-wide interventions to prevent and control diabetes and obesity.
- Support countries in developing diabetes-related research policies or plans that include community-based research and an evaluation of the impact of interventions and policies.

SETTING DIABETES COVERAGE TARGETS

7. The Secretariat, supported by an academic group, developed an approach to setting diabetes coverage targets based on which it drafted a proposal[1]. The draft proposed coverage targets were discussed at a technical consultation to seek additional expert advice on refining the methods and results. The expert consultation was held on 28-29 July 2021 and a technical paper will be submitted for publication.

8. Following this process, the Secretariat recommends that five voluntary global diabetes coverage targets be established for achieved by 2030:

- 80% of people with diabetes are diagnosed.
- 80% of people with diagnosed diabetes have good control of glycaemia.
- 80% of people with diagnosed diabetes have good control of blood pressure.
- 60% of people with diabetes receive statins.
- 100% of people with type 1 diabetes have access to insulin and blood glucose self-monitoring.

Commented [A5]: Please clarify which targets are already tracked in WHO surveys and/or have data available from many countries. These overlap with but are not the same as targets and indicators in the Global Monitoring Framework.

9. Modelling projections have demonstrated that:

- Achieving the target levels of diagnosis, treatment, and control of 3 targets (glycemia, blood pressure, and statin use) of at least 60% results in a gain in median DALY of 38 per 1000 persons over 10 years, whereas achieving a target of 80% results in a gain in median DALYs of 64 per 1000 persons over 10 years.
- In most regions, improving treatment and control without screening reduces CVD deaths by 25-35% and improving diagnosis, treatment, and control reduces the most common cause of deaths (CVD) by more than 40%.

10. Achieving the five voluntary global diabetes coverage targets will contribute to the achievement of SDG target 3.4 (one-third premature mortality reduction from noncommunicable diseases). The five targets are also aligned with the WHO Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013-2020[2], the UN High-Level Meeting on Prevention and Control of Noncommunicable Diseases (2018)[3] and health systems strengthening for social protection and universal health coverage, as set out in United Nations General Assembly resolution 72/81.

11. The methodology used to develop the targets is summarized in a technical paper which is available on WHO's website.

[1] Gregg E, Buckley J, Ali MK, Davies J, Flood D, Griffiths B et al. Target Setting to Reduce the Global Burden of Diabetes Mellitus by 2030: The Current Status and Scientific Rationale (unpublished data)

[2] WHO. Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013-2020. Available at: http://apps.who.int/iris/bitstream/handle/10665/94384/9789241506236_eng.pdf?sequence=1

[3] 2018 Political Declaration on NCDs. Available at : https://www.un.org/en/ga/search/view_doc.asp?symbol=A/RES/73/2

MONITORING DIABETES RESPONSES

Recommended actions to monitor the trends and determinants of diabetes and evaluate progress in their prevention and control

12. Recommended actions for **Member States:**

- Develop and strengthen surveillance and monitoring systems for diabetes and other NCD risk factors, guided by WHO NCD surveillance framework.
- Develop and strengthen monitoring systems to evaluate the treatment gap and clinical outcomes (morbidity and mortality) and health system performance (capacity and interventions) through the systematic collection of standardized routine facility-based diabetes care indicators.

13. Recommended actions for **International Partners**, including the private sector:

- Support the development and maintenance of surveillance systems and promote the use of information and communications technology.
- Invest in information systems that link various sources of information on management and outcomes.

14. Recommended actions for **WHO**:

- Continue monitoring NCD risk factor dynamics and country capacity to prevent and control NCDs, including diabetes.
- Develop a monitoring framework and tool for monitoring the performance of health care system through monitoring of processes of care and outcomes at the level of health facilities.
- Support the development and maintenance of surveillance systems and promote the use of information and communications technology.

ACTION BY THE EXECUTIVE BOARD

15. The Executive Board is invited to adopt the recommendations for Member States, international partners and WHO (paragraphs 4 to 6, and 12 to 14), as well as the five voluntary global diabetes coverage targets (paragraph 8), and recommend their endorsement at the World Health Assembly.

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Response to the 'WHO Discussion Paper: Draft recommendations to strengthen and monitor diabetes responses within national noncommunicable disease programmes, including potential targets (version August 9, 2021)'

September 17, 2021

Dear WHO Diabetes Targets Expert Consultation Group,

We read with interest the draft WHO recommendations to strengthen and monitor global responses to diabetes, including the creation of voluntary global diabetes coverage targets for 2030.[1] The document, in our view, provides a comprehensive account of the challenges due to the increasing global diabetes burden. Moreover, it is encouraging to note that over three-fourths of the member states now have a dedicated staff as well as an operational policy/strategy or action plan to scale up diabetes monitoring, control and treatment.

The establishment of the WHO Global Diabetes Compact, coinciding with the 100th anniversary since insulin discovery, offers an opportunity to not only reflect on barriers to adequate access to diabetes care but also to push towards implementing the urgent measures needed to ensure that all patients can actually get needed insulin, other essential treatments and associated devices. While we acknowledge that diabetes prevention (e.g., reduction of modifiable risk factors) is a strategy with the utmost significance, our comments focus mainly on the proposed recommendations and targets relating to diabetes diagnoses and access to treatments.

While we understand the complexities and barriers surrounding these targets, broadly, we wonder if the proposed 2030 global coverage targets could not be more aggressive, namely targeting that at least 80% of people with diabetes are diagnosed by the health system and then aiming for at least 80% of those diagnosed achieve good glycemic control. Indeed, even these more aggressive targets would still , in effect, only translate to an end result calling for good glycemic control in only about 64% (i.e. 80% of the 80%) all the people living with diabetes (diagnosed or undiagnosed). More needs to be done:

[1] WHO Discussion Paper: Draft recommendations to strengthen and monitor diabetes responses within national noncommunicable disease programmes, including potential targets. https://bit.ly/3hKe4wq

[1]. Need for improved epidemiological data:

Three of the five proposed voluntary targets are: (i). 80% of people with diabetes are diagnosed, (ii). 80% of people with diagnosed diabetes have good control of glycaemia and (iii) 80% of people with diagnosed diabetes have good control of blood pressure.

We note one challenge mentioned by the Expert Group i.e. "data on diabetes derived from monitoring and surveillance systems in most countries are sparse and inadequate." We emphasize that national governments – along with the private sector and international partners – must help develop and strengthen the mechanisms to identify their populations with diabetes.

First, we think such efforts must also capture *the distinction (i.e. the patient-mix) between Type 1 and Type 2 diabetes*, given the associated policy and treatment need implications. For instance, all people with Type 1 diabetes require insulin and continuous glucose monitoring but that is not the case for those with type 2 diabetes.

Second, to develop better understanding about the burden diabetes (and other NCDs) and their unmet needs, we need to link routine information about population demographics, health services and clinical outcomes in order to strengthen disease monitoring. However, it may not be possible anytime soon in many member states, especially in low- and middle-income countries (LMICs), due to lack of robust health insurance plan(s) and electronic medical records. Further, patients often navigate between the public and private health-care sectors with limited/no reporting frameworks. In this regard, while the efforts to establish linked-health registries or electronic medical databases may be underway; LMICs should *leverage their existing, regularly conducted household surveys to collect population data regarding the prevalence of Type 1 and 2 diabetes and the barriers/facilitators to treatment access*.[2] Leveraging existing surveys to gather complementary information about disease burden and health services has been proven beneficial in the low-income settings.[3]

Third, there is lack of country-specific data on the insulin utilization rates among the persons living with Type 1 and 2 diabetes. While one would expect all patients with Type 1 diabetes should be using insulin in quantities determined based on the individual's clinical profile, clearly not all persons with Type 2 diabetes clinically require insulin. Yet the number of person among those with Type 2 diabetes who are in fact using insulin at present, are likely to be less than those who actually require it. *Quality data on the treatment patterns and need with optimal granularity* are necessary to inform evidence-based policies and access programs to ensure adequate coverage levels.

[2] Mishra SR, Sharma A, Kaplan WA, et al. *Lancet Diabetes Endocrinol* 2016; 4: 482-3

[3] Sharma A, Kaplan WA, Satheesh G, et al. *Global Heart* 2021;16: 38. http://doi.org/10.5334/gh.927

[2]. Targeted solutions for improved treatment supply and access to treatments:

The other two of the five proposed voluntary targets are: (iv). 60% of people with diabetes receive statins. (v). 100% of people with type 1 diabetes have access to insulin and blood glucose self-monitoring.

As noted in the technical background paper, the treatment coverage among persons with diabetes depends a lot on a country's health system ability to increase the percent diagnosed and that even the 60% statin coverage target would be very ambitious for countries in Africa, South Asia and the Pacific. In this regard, the Expert Group has proposed to set "incremental country-specific targets of 10 to 20 percent point increases over 10 years." Given that access and rational use of diabetes treatments depends on continuum of care and regular disease monitoring, we *suggest that the Expert Group also include specific targets relating to improving availability of affordable diagnostic tests*.[4]

The draft recommendations note bundling of diabetes medicines, insulin delivery devices and glucose monitoring devices as part of national benefits package to improve access, but these lack specific targets. *One of the well-accepted measures for such a target is that an essential health commodity (such as insulin, other treatments, blood-glucose test strips/devices) should be available in at least 80% of all the health facilities in both public and private sectors at all times*.[5,6] The Expert Group should adopt this target and recommend that national governments and international bodies allocate adequate resources to regularly monitor how the provision of diabetes treatment and access barriers vary, across health sectors, within a country and across socio-economic strata.

To improve insulin availability and affordability, other measures proposed by the Expert Group include the use of the WHO-prequalification of insulin and pooled procurements (once established by the UN). It is well-known that three multi-national companies dominate the global insulin market, and that has implications for global security of insulin supply. We agree that national governments and insulin buyers from a global or regional pooled procurement mechanism to achieve the best value for money by encouraging monopsony, whereby a single buyer dominates a market. *However, it is not clear why the language describing the target (v) is limited only to Type 1 diabetes*, when some significant proportion of Type 2 diabetes may well end up needing insulin. *Limiting the insulin coverage target is not only clinically incorrect (selective) but also goes against the economic idea by which the proposed pooled procurement or advanced market*

[4] Pai M, Walia K, Boehme CC. *Lancet Public Health* 2019; 4: e494. doi.org/10.1016/ S2468-2667(19)30165-3
[5] Sharma A, Rorden, Ewen M, Laing R. *Journal of Pharmaceutical Policy and Practice* 2016; 9: 12 doi.org/10.1186/s40545-016-0059-5
[6] Sustainable Development Goals; Target 3.8. https://apps.who.int/iris/handle/10665/208286

commitments work (i.e. promise to purchase high volume, lower commodity price; as seen in GAVI Vaccine Alliance).[7]

Here we respectfully present a case example demonstrating why comprehensive epidemiology data and treatments procurement/supply information are important for identifying country-level unmet need and for developing targeted solutions

Study: Insulin imports fail to meet many countries' needs. *Science* 2021; 373: 494-7.[7]

Our previous in-country research shows that often insulin is not available on pharmacy shelves in low- and middle-income countries.[8,9,10] Further, only a few countries (n~20) have insulin-manufacturing capacity – meaning all the other countries would be dependent on imports for insulin. While the actual and physical availability of insulin for use by the patients depends on the myriad of in-country processes, we wondered if the many countries that cannot manufacture insulin and depend on imported insulin – are actually importing enough in the first place.

Using two sets of data – i.e. the United Nations global commodity trade data and available country-specific diabetes prevalence estimates – we calculated import-need ratios for 104 countries during 2000-2018, where annual ratio ≥ 1.0 means that a country imported enough insulin to meet enough insulin to meet the estimated need of person diagnosed with diabetes. Briefly, we found that while the gap between countries' insulin imports and the domestic need has narrowed since 2000, there still are many countries in almost all parts of the world—particularly in Africa and Asia—where insulin imports are just not enough to treat all those who need it. During years 2012 to 2018, 62 percent of study countries had a median supply-need ratio less than 1.0 – therefore, an inadequate supply – including 88.9 percent of studied countries in Asia, 87.5 percent in Africa, 46.2 percent in the Caribbean and Oceania, 37.5 percent in Eastern Europe, 28.6 percent in the Middle East, and 20.8 percent in the Americas.

We note several reasons for observed under-importation compared to estimated need, including that problem of missed patients (due to lack of diagnosis, under treatment and/or poor access). If the problem of poor epidemiological data (disease Type 1 and 2 prevalence, insulin utilization pattern versus actual need, and barriers to physical access to insulin) – also noted as a limitation in paper – insulin need, and therefore import forecasts, may continue to be artificially lowered.

[7] Sharma A, Kaplan WA. *Science* 2021; 373: 494-7. science.org/doi/abs/10.1126/science.abg4374
[8] Sharma A, Kaplan WA. *BMJ Global Health* 2016;1:e000112. dx.doi.org/10.1136/bmjgh-2016-000112
[9] Sharma A, Bhandari PM, Neupane D, *et al*. *International Health* 2018; 10: 182–190. doi:10.1093/inthealth/ihy012.
[10] Satheesh G, Unnikrishnan MK, Sharma A. *Journal of Pharmaceutical Policy and Practice* 2019; 12: 31. doi.org/10.1186/s40545-019-0190-1

On contrary, we also see (according to our calculations) that some countries, especially in the Middle East and Eastern Europe, imported higher volumes that what the estimated number of patients with diabetes would need. For that, several reasons are possible:

- First, it is possible that the actual number of patients with diabetes in those countries are higher than what the published estimates say.
- The actual need often is much higher than the conservative assumption in our calculations (i.e. only 10% persons with diabetes need insulin) – thus higher imports.
- Several studies have shown that pharmaceutical marketing plays a major role in the utilization of the type and quantity of insulin that physicians prescribe and patients use. Such phenomenon may result in higher that needed insulin imports.

This study – besides highlighting several health systems, supply and access related barriers to access – demonstrates the significance of developing quality data about treatment need, supply and access barrier to achieve the coverage and clinical outcomes goals. Unless we have better evidence on who, where and how many need treatment (insulin) and what are the health system and patient-level barriers to access, we are afraid that the policies regarding coverage decisions, financing/resource allocation, health technology procurement and delivery will remain sub-optimal.

Best regards,

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15 September 2021

Non-communicable Diseases Department
World Health Organisation
<via email: hemmingsenb@who.int>

Dear Sir or Madam,

I am writing on behalf of Staffordshire University in response to your call to comment on the development of recommendations to strengthen and monitor diabetes responses within national noncommunicable disease programmes, including potential targets.

As your report outlines, diabetes is a growing global health problem with devastating complications. We would like to see this reflected in the paper. For example, diabetic foot disease is one of the most expensive complications of diabetes leading to significant morbidity and mortality.

Our previous work[1] has clearly highlighted the limitations of currently available diabetic foot screening guidelines; which aim to identify patients at risk of foot complications, such as ulcerations and amputations, and who therefore may require mobility assistive devices. Also, there are differences between screening guideline recommendations at the national level and this contributes to the differences in national diabetic foot disease outcomes and associated burden[2]. There is also a lack of high-quality evidence on which these guidelines are based which is responsible for the current gaps between guidelines, standard clinical practice, and development of complications[3].

One of our previous work focussed on publicly available datasets to retrieve relevant information relating to physical disability as a result of diabetes. It also examined the national guidelines for screening and their relationship to global guidelines. Whilst publicly available datasets highlight and host up to date information on the global burden of diabetes, it has little or no information relating to the complications resulting from diabetes and in particular no data on amputations or mobility related assistive devices. There is a clear need for collecting structured data during screening at a primary care level. This, in addition to helping to reduce the complications of the disease, will help to understand the assistive technology needs of these patients. With latest advances in science and technology, we can effectively utilise additive manufacturing and artificial intelligence to provide individual specific interventions.

In addition, although previous reports have called for efforts to promote healthy ageing and strategies for mitigating this risk through prevention and management, there is still a lack of culturally competent screening guidelines focusing on diabetes.

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[1] Formosa C, Gatt A, Chockalingam N. A Critical Evaluation of Existing Diabetic Foot Screening Guidelines. Rev Diabet Stud. 2016 Summer-Fall;13(2-3):158-186. doi: 10.1900/RDS.2016.13.158. Epub 2016 Aug 10.
[2] Formosa C, Chockalingam N, Gatt A. Diabetes foot screening: Challenges and future strategies. Foot (Edinb). 2019 Mar;38:8-11. doi: 10.1016/j.foot.2018.10.002.
[3] Formosa C, Gatt A, Chockalingam N. Diabetes foot screening: Current practice and the future. Foot (Edinb). 2018 Mar;34:17. doi: 10.1016/j.foot.2017.11.002.

In summary, we would like you to include the following within your discussions:

(1) Requirement for universally accepted, evidence-based and culturally competent screening guidelines for diabetes and its complications.
(2) Acknowledgement of physical disability as a result of diabetes and the requirement of assistive devices and technology.

Yours Sincerely

Nachiappan Chockalingam
Professor of Clinical Biomechanics
Director, Centre for Biomechanics and Rehabilitation Technologies

UNIVERSITY OF TORONTO
DALLA LANA SCHOOL OF PUBLIC HEALTH

16th September, 2021

To: World Health Organization

RE: Advocating for Diabetic Foot Prevention and Management to be included in WHO Global Diabetes Targets to 2030

The global prevalence of diabetes is escalating at an alarming rate. The International Diabetes Federation 9th atlas describes diabetes as one of the fastest growing global health emergencies of the 21st century.[1] The IDF reported that in 2019 an estimated 463 million people have diabetes and estimates that the numbers will increase to 578 million in 2030 and 700 million by 2045.[1]

There are a multitude of diabetes-related complications, many of which are vastly debilitating, including lower limb amputations. In people with diabetes, lower limb amputations are 10-20 times more common when compared to people without diabetes.[2] Globally, it is estimated that a lower limb, or part of the lower limb, is amputated every 30 seconds due to diabetes.[1] Eighty-five percent of amputations are preceded by a foot ulcer.[3] Diabetic foot ulcers can be attributed to multiple factors including peripheral neuropathy, bony deformity of the foot, repetitive microtrauma, peripheral arterial disease, edema and callous formation.[4,5] In Canada, diabetes is the principal reason for non-traumatic lower-limb amputations.[6]

A 2017 Canadian study reported a 13% increase in diabetes-related lower limb amputations from April 1, 2006, to March 31, 2012.[7] A 2019 population-based Ontario, Canada study also found an increase in diabetes-related lower limb amputations in the past 10 years with the highest rates in Northern Regions with a higher indigenous population.[8]

Amputations have debilitation consequences on quality of life and results in increased health care costs ranging from, US $43,000 to $63,000 per case.[9] Patients who have had a diabetes-related major amputation have a 68% risk of having another one in 5 years.[10] They also have a 50% mortality rate in the 5 years after the initial amputation[10] and a 50% likelihood of going back to independent mobility.[9]

Patient education on proper foot care, along with early detection and appropriate treatment of diabetic foot ulcers may prevent up to 85 percent of amputations.[11,12] The most recent International Working Group on the Diabetic Foot (IWGDF) guidelines (2019) recommends 5 elements for foot ulcer prevention: identifying the high-risk foot, regular foot examination, foot care education, appropriate footwear and managing factors for ulceration.[13] Every person with diabetes should have at least 1 foot examination per year, and more frequently for those at a higher risk of complications.[14]

Screening for the high-risk diabetic foot, including appropriate foot care, is an integral part of the comprehensive approach to preventing and managing diabetic foot ulcers and ultimately, amputations.[11,13,14,15] Narayan et al proposed that a systematic approach to diabetic foot screening and foot care as key cost savings priorities especially for low- and middle-income countries.[16] An impactful quality improvement initiative, The Guyana Diabetes and Foot Care Project, demonstrated a 68% decrease in diabetes-related lower limb amputations.[17] The main interventions from this project included providing key opinion leader training, screening for the high-risk diabetic foot, streamlining referral pathways and provision of a cost effective offloading (plantar pressure) device.[17]

I am advocating that diabetic foot care and prevention be included in the proposed Diabetes targets to 2030.

R. Gary Sibbald
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Chair of Education Committee, World Union of Wound Healing Societies https://wuwhs2022.org/wuwhs-2022-congress
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and Foot Care Project: A Complex Quality Improvement Intervention to Decrease Diabetes-Related Major Lower Extremity Amputations and Improve Diabetes Care in a Lower-Middle-Income Country. PLoS Med 12(4): e1001814. doi:10.1371/journal.pmed.1001814

ASEAN WOUND COUNCIL

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INDONESIA
WIDASARI SRI GITARJA

16TH September 2021

Dear sir/madam,

Ref:WHO DIABETES STRATEGY 2030

Greetings and salutations from the ASEAN Wound Council which is a grouping of ten countries in South East Asia spearheading wound management especially diabetic foot management in the region.

2. Diabetes is predominant in this region and has reached epic proportions. Every twenty seconds a foot is being amputated according to the IWGDF in 2011. Since the St. Vincent declaration in Italy in 1989 we have been losing the battle.

3. Armstrong et al 1985 stated that 85% of the diabetic foot amputation can be prevented with proper prevention and foot care. Therefore, we would like to reiterate that we support all the present points in the strategy but advice that the diabetic foot in terms of prevention, management and prevention of amputation should be included. We have to measure the number of amputations and take a look at our present strategies to manage this end organ complication of diabetes mellitus.

The complications should be mentioned in the document and the strategy of the World Health Organization. I thank you from the bottom of my heart and please feel free to contact me if you need any assistance.

Thank you.

Yours Sincerely,

PROF DR HARIKRISHNA K R NAIR

Chairman, ASEAN WOUND COUNCIL

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Bianca Hemmingsen, Medical Officer
World Health Organization
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September 17, 2021

Re: World Health Organization's Diabetes Strategy to 2030

Dear Ms. Hemmingsen,

We believe that considerations of foot health should be included in the World Health Organization's voluntary global diabetes coverage targets from now to 2030.

The Canadian Federation of Podiatric Medicine (CFPM) and the Canadian Podiatric Medical Association (CPMA) are non-profit professional organizations comprising duly qualified foot care practitioners in Canada. Our clinicians are on the front-line providing care for patients that experience complications of diabetes. It is a high priority in our efforts and ongoing work to focus on diabetic foot ulcers and amputee prevention/limb preservation.

> *Across Canada, approximately 5,000 lower-limb amputations occur annually due to diabetic foot ulcers, and recent research indicates numbers are on the rise.* ***An estimated 80% of these amputations are preventable.***
>
> *About 50% of patients undergoing nontraumatic lower-limb amputations have diabetes (2). These patients have high mortality following amputation, ranging from 39% to 80% at 5 years*[1].

…2/

[1] Reiber GE: Epidemiology of Foot Ulcerations and Amputations in Diabetes, 6th ed. St. Louis, MO, Mosby,2001Google Scholar — from: Amputation and Mortality in New-Onset Diabetic Foot Ulcers Stratified by Etiology; Probal K. Moulik, MRCP, Robert Mtonga, MB2 and, Geoffrey V. Gill, MD.

Currently, it's understood that there are five core metrics worldwide that indicate optimal diabetes management (% diagnosed, Glycemic control, Blood pressure, Lipids, availability/access of medicines) but we request consideration to develop and include metrics relating to foot health.

We believe that access to universal health insurance coverage for diabetic patients is important and essential. This coverage should include promotion, prevention, treatment, rehabilitation and palliative care. As well as necessary access to medications and medical professionals.

> *As we move into the next decade, it is important that we continue to work Inter-Professionally and in addition, work with primary care practitioners to improve their ability to screen and educate patients. Indeed, improving front-line skills and competencies should be an important part of our efforts globally.*

Prevention, risk reduction and treatment need to be brought into focus. We would encourage a focus on prevention, early detection and timely initiation of treatment to improve foot health and well-being and reduce morbidity, disability and mortality of people living with diabetes. Specialist consultations are not always possible. Simple screening tools exist and could be refined/redesigned to identify complications that lead to increased morbidity and mortality. Universal screening tools (e.g. Inlow foot screening tool) can be utilized to standardize risk assessment and teach basic foot care. When patients are identified with nephropathy, retinopathy, Peripheral Vascular Disease (PVD) automatic further assessment should be performed and teaching for prevention of possible lower limb complications should commence.

We work closely and Inter-Professionally with several other health care groups, including vascular surgery, nursing, family medicine, pharmacy and organizations such as Diabetes Canada. We would bring this broad coalition to supporting and working with the WHO. And we are prepared to contribute directly to this project/initiative.

We believe the work of The WHO is important and sets the framework for jurisdictions globally. We are willing to work diligently, in concert with The International Federation of Podiatry, D-Foot International and the World Health Organization,

> We will work on ***screening tools,*** and a set of ***early warning indicators*** that can be used by clinicians on the front line to impact individual patient outcomes.

A set of Standards such as this will help 'Save Limbs and Save Lives'. We are willing to contribute to the development of these, working with our colleagues around the world and in

…3/

Canada. We are suggesting but this is an important area for consideration within the overall diabetes strategy and would like this to be given full consideration.

Joel Alleyne,
Executive Director, Canadian Podiatric Medical Association

On behalf of:

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Vijay Viswanathan, M.D, D-Foot International

D-FOOT international

September 17, 2021

Bianca Hemmingsen, Medical Officer
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Feedback on WHO consultation on a draft global strategy on draft recommendations and targets concerning the monitoring of diabetes responses within national noncommunicable disease programmes, including voluntary global diabetes coverage targets for now to 2030

As the President of D-Foot International for the biennium 2021 to 2023, I am writing to you regarding the development of recommendations and core metrics for the World Health Organization's Diabetes Strategy. Our global experts are recommending that WHO includes diabetic foot health as a core metric, including the prevention and treatment of diabetic foot ulcers and lower limb amputations.

Diabetic foot ulcers and amputations are one of the most feared and serious complications for people with diabetes. Diabetic foot ulcers are caused by underlying factors of ischemia, neuropathy and deformity and without timely access to appropriate treatment, they can quickly lead to an amputation. Every 20 second a limb is lost due to diabetes. Across globe approximately 40 to 60% lower limb amputations occur annually due to diabetic foot ulcers that did not heal properly, and recent research indicates his number is on the rise. **An estimated 80% of these amputations are preventable.**

Both the personal and societal cost of these amputations are staggering. The cost of these amputations nationally is estimated approximately over $70,000. American Podiatric Medical Association (APMA). The cost of health care for ulceration and amputation in diabetes in 2014-2015 is estimated at between £837 million and £962 million; 0.8% to 0.9% of the National Health Service (NHS) budget for England. More than 90% of expenditure was related to ulceration, and 60% was for care in community, outpatient and primary settings. Diabet Med. 2019 Aug; 36(8):995-1002.

In 2016 D Foot international was successful in collaboration with WHO and 50 items were proposed by WHO and D-Foot was part of it. "Priority Assistive Products List" Improving access to assistive technology for everyone, everywhere.

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Rue de la loi, 42, 1040
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D-FOOT international

By continuing to collaborate, we making diabetic foot health a priority within the new WHO Diabetes Strategy, your committee will be elevating this serious issue, which will help to make it a priority in health-care systems across the world.

Thank you for your consideration of this important issue.

Sincerely,

Dr. Vijay Viswanathan

The President

president@d-foot.org

About:

D-Foot International is a registered international non-profit association under Belgian law promoting the global profile of diabetic foot prevention and care through awareness, guidance, education, research and professional development.

The purpose of DFI is to be the leading, authoritative global organization to create awareness of and improve diabetic foot management and facilitate prevention worldwide.

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DAA

DIABETES AWARENESS ASSOCIATION

Prepared By:

Willis Kalitera

BACKGROUND INFORMATION

In most developing countries and Malawi being one of them, it has been noted that Non communicable diseases (NCD) are the major causes of death and diabetes is one of the major disease claiming lives every day with each one of us being affected by it either directly or indirectly. This serious problem exists across the globe with a lot of people dying due to lack of knowledge about the disease. It has been noted that a serious problem exists where 4 out of 5 people die due to diabetes without knowing what really killed them even though information is available. Many country also at the moment do not have any NCD prevention and health promotion programs or NCD surveillance, monitoring and evaluation on diabetes available .People do not have the understanding of exactly how deadly the disease is.

For instance according to the research conducted by the World Health Organization (STEP WISE SURVEY) it has showed that 94.4% of the infected Malawians can survive if provided with the information because only 6% of the affected take up the initiative to know what they are suffering from. The research also showed that the levels of people suffering from diabetes are higher of those from the rural areas compared to those from the urban area .The results showed that 9.2% of the people in the rural areas are suffering from diabetes and 7.4% in the urban areas this is due to the lack of awareness programs in the country.

According to the research it was also noted that there are three main risk factors which have triggered diabetes in the country. It shows that the country has a high level of alcohol drinking both in the urban and rural areas and is higher with men as compared to women. The other risk factor which has shot up the diabetes level is physical inactivity. It shows that Malawians are typically lazy when it comes to exercising which has also lead to the other risk factor obesity. The country does not have any action plan on these risk factors yet to date.

Diabetes is claiming a lot of lives globally because of lack of **awareness**. **Strategies** therefore need to be created with the intention of helping in **sensitization** about diabetes across the countries by carrying out awareness campaigns across the globe and in addition to this creating an NCD prevention and health promotion programs or NCD surveillance, monitoring and evaluation on diabetes. The global mission is to make every person aware of the dangers diabetes posses to them. The vision is to reduce the deaths caused by this disease by at least 94.4% through our aims and objectives. The goals are to reduce deaths.

RECOMMENDATIONS

The coming up of strategies to fight diabetes is a new concept and can or should be capitalised in a viable way to reduce the number of deaths globally. The strategies should focus on informing, educating and counseling people especially those from the low income areas the dangers of diabetes and in addition intend to create an NCD prevention and health promotion programs or NCD surveillance, monitoring and evaluation on diabetes. It is expected that through these programs it will be possible to have a direct and positive effect on the fight against diabetes. The strategies should mainly utilise volunteers, who have been affected by diabetes and others who are already are fighting the disease. The volunteers will be community leaders, nurses and people who are already suffering from diabetes. Each volunteer is expected to contribute at least 4 to 5 days a month for the cause.

OBJECTIVES AND GOALS

There are three major goals of the Diabetes project and there exists specific objectives within each of the projected goals.

Goal 1

-

To reduce the number of deaths related to diabetes.

Objectives

1.1 To inform everyone with the relevant information regarding diabetes.

1.2 To assist the people in learning how to apply Diabetes information in helping themselves to live healthy.

1.3 To teach people how to evaluate changes in their health.

Goal 2

To reduce the number of cases related to Gestational diabetes.

Objectives

2.1; to reduce the number of child related deaths globally.

2.2; to work hand in hand with pregnant women to avoid premature Births cases related to diabetes.

Goal 3

To create an NCD prevention and health promotion programs or NCD surveillance, monitoring and evaluation on diabetes available

Objective

3.1 To monitor the gradual changes in diabetes in the countries every year.

TASKS

- Provide knowledge of types of diabetes
- Provide awareness of type 1 and 2
- Provide awareness of children with diabetes
- Life Stages of diabetes
- Living a life with diabetes
- Food, diet, exercise
- Self-health monitoring
- Treatment and support

CLIENTELE

There are two different beneficiaries for this program.

The first and primary beneficiary is everyone and this group is represented in the project goals 1 and 3.

The second and secondary beneficiaries are the pregnant women represented in the project goal 2

Both clienteles are important and essential components of this project as it is expected that significant learning will take place for and through both clienteles.

STRATEGY

The primary methods for achieving the goals and objectives of the project will be:

1: DIABETIES CLINICS

For all the goals and objectives of this project to be achieved, first there will be need to create Diabetes centers across the globe. This will be the focal point for all Diabetes operations. Clinics will then be established within the office premises where by people will come for free testing as well as counseling.

Having a clinic at Diabetic premises will help reduce the stress at government diabetes clinic which is usually there only once a week for instance in most low income countries like Malawi. Doctors and nurses will be responsible for the management of this clinic.

Apart from dealing with patient, the clinic will also be responsible for providing relevant information about diabetes to the public.

2: Awareness raising workshops with the communities

Diabetic communities should be created whereby they shall be trained to help in sensitization in their respective area.

The committees should comprise of 15-20 members depending on size who will work on voluntary basis. Each community is to be expected to make at least 90 meetings each year.it is expected that in all these 90 meetings it will be essential to have regular information workshops explaining the status of the project and its activities. The communities will encourage awareness raising forums to sensitize the community about the causes, consequences, the

dangers of diabetes. The communities will also help highlight project objectives and its importance.

To ensure communities participation for a sustained period of time, it is intend to setup specific workshops addressing project issues which will include all segments of the community including women, religious leaders and other development partners working in the area including government institutions.

In additional this strategy can be implemented in public orientation in religious places like churches, holidays where public gathering is held. Sensitization in these gathering will involve a clear description of the programs, the existing problems, what role each person can play, how to sustain project outcomes. Sensitizing and raising the levels of awareness of the community will help to promote local level participation and participatory approach.

Communities will participate in identifying causes, assessing their resources, annual action plan preparation and regular assessment of progresses or monitoring on a regular basis.

At local level, monitoring of project progresses can become a powerful force for participatory development approach which is fully compatible with the spirit of the project design. In particular, it provides an opportunity for communities to participate more fully in tracking physical and socio-economic progresses of the project to propose course corrections; communities to sensitize and internalize the current resource degradation and poverty prevalence.

Raising awareness through communities can contribute to easy community involvement in that it helps people formulate their interests, knowledge and understanding as being a precondition for real participation of the community in the project implementation. Public participation processes are an important means of raising awareness.

Their involvement in the project management (problem identification & prioritization, resource assessment, annual action plan implementation, monitoring) and decision-making is a means of transmitting knowledge and values.

They provide opportunities for dialogue, mutual learning, and ownership. It will help increasing communities' commitment and participation beyond enhanced knowledge and skills, and as such may be described as an empowerment process.

We believe that through Sensitizing and raising the levels of awareness with communities it will help to promote local level participation and participatory approach.

Community mobilization will involves building the capacity of members of the community to enable them identify the problems and to take actions to solve them. Mobilizing and organizing the community ensures that they truly understand the causes of the specific problems and actively participate in the course of implementation to reverse the situation.

Therefore, building the capacity of various stakeholders will be crucial to achieve the set objectives of the program through enhancing their awareness level, attitudinal and behavioral change.

Special focus on capacitating community leaders like chiefs into mobilizing and convincing their constituencies is one important approach of enhancing the awareness levels of the community at large. This could be widely disseminated through training of the volunteers which is a kind of ToT so that they can train their constituencies.

The training modules which should be developed will take into account their level of understanding and educational level will be well designed, that is, both technical matters as well as conceptual issues that could help them easily understand and mobilize the community through awareness -raising.

Moreover, awareness raising activity should be included as one part of project activity in the Community Annual Action Plan for continuous refreshing of the community on latest issues including lessons from the previous years or seasons.

Leaders like chiefs, traditional authorities, and religious leaders play an important role in the flow of information within a community and thus, we intend to use them appropriately to greatly impact the overall success of the village committee.

In particular, leaders influence the community, help pass the message to others have the power/authority to change things, can encourage "ownership" of initiative throughout the community. Therefore, it is important to capacitate and keep these people well informed on the issues to demonstrate to communities their exemplary behavior and action.

Lastly to support community interactive monitoring and results assessment, appropriate M&E Instruments will be prepared for different levels such as Community Planning Process, community Action Plan preparation process, Activity Identification & Plan Description, Activity Implementation Completion and Quality Assurance of implemented activities will be introduced and continuous capacity development activity and exercise has to be made at different levels.

These instruments will be intended to enhance communities' interactive involvement in the project problem identification, planning, results assessment, quality assurance of activities done and suggest solutions by their own initiative. We believe though the formation of the communities we can achieve our goal number 1 and 3.

3: NATIONAL WIDE SURVEYS AND SENSITISATION CAMPAIGNS

nationwide survey will be carried out during in a chosen time interval on which NCD prevention and health promotion programs or NCD surveillance, monitoring and evaluation on diabetes will be made.

This will enable us to fulfill our number 3 project goal which is the creation of NCD prevention and health promotion programs or NCD surveillance, monitoring and evaluation on diabetes. By having nationwide survey, it will help to establish the current number of people affected by diabetes in the country, those in danger of being infected. With the data collected from the survey, we will also be able to determine the number of people who have died within the last 5years of that year. The survey will also help establish the consumption level of sugar per household, level of exercise and diet of every family.

Furthermore the survey will act as a milestone for the sensitization process. A nationwide sensitization campaign will follow the after a nationwide survey. This is where people will be provided with adequate information about diabetes, proper diet and important of exercise. This will be done through distribution of pamphlets, door to door campaigns, and distribution of t-shirts.

It's essential for the project to also host radio, television programs on the nation public radio stations to help spread the message. This will help us in achieving our number one and third goals which are to reduce the number of deaths related to diabetes and To create an NCD prevention and health promotion programs or NCD surveillance, monitoring and evaluation on diabetes respectively

So basically the nationwide survey will help DAA in the following:

- A measuring tool and a basis on which NCD prevention and health promotion programs or NCD surveillance, monitoring and evaluation on diabetes will be made.
- Give current statistics/data on how bad the situation is globally
- Will act as a milestone for the nationwide sensitization campaigns

4: Experience sharing/exposure visits; Seeing is believing

This can be done in different ways

After the community workshop has been held, a community member will make visits to the other communities or the project office where lessons could be conducted.

This will be at the beginning of the project where project results have not yet matured. Later, such experience sharing will be done among the communities who presented report in that particular year.

This will initially work as cross check of the report with actual achievement on the field so that others will learn from such experiences.

Exposure visits within and outside the project, in the Region and outside could also be made to gain good lessons and broaden knowledge and skills.

5: MEDIA

The media is the most powerful tool of communication. It helps a lot in informing the public about realities of life. It helps in promoting the right things in society. The media is the mouthpiece of almost social issues affecting our societies.

The use of print media, electronic media as well as social media in carrying out its work cannot be overlooked.

Printed materials such as newspapers, posters and leaflets are commonly used methods for sensitizing communities when doing awareness campaigns. As it is in this case, it is possible to promote the project through leaflets, local newspapers, magazines and different posters with key messages that will be easily understood by the targeted audience.

As in most developing countries, literate levels is pegged at around 70 percent, there will be need to design pictorial posters that can be understood without so much difficulty for people who cannot read nor write especially in the rural communities.

Disseminate messages through the use of billboards is an easy and cost-effective method of attracting the attention of a broad section of people. Specific messages can be conveyed through the use of slogans and pictures displaying diabetic information used to alert community members.

These could be displayed in specific intervention sites showing the contrasts of the before and after intervention pictures on the billboard set up at the intervention site or like a sign post erected at the center with provocative slogans. A relevant quote can be helpful to build community efforts. A well chosen slogan can draw the communities' attention to key messages.

This technique could potentially be used to convey conservation-oriented messages, but the amount of information that can be included is very limited, and messages need to be easily understood by the community. The message could be chosen through discussion with the community or community team members.

Another method is the use of radio and video products. These products will include short documentaries for both radio and television, comedies and averts which will be shown to the communities during public gatherings like in health centers, communities and other major occasions.

The content will be from the project through contrasting areas managed well and degraded areas or good experiences from other similar circumstances.

Engaging the support of the local media in raising awareness considerably broadens the impact. It is quite possible to use it as an awareness raising tool. Most people at the community level rarely read printed materials, they prefer more listening to entertaining radio and television programs. This could be done through sponsoring the program to broadcast diabetes issues once per week or more based on the resource availability. The programs should be articulated carefully considering the target audience.

Awareness messages are most effective when they adopt the language best understood by the target audience. Even if it is going to be broadcasted in venacular technical wordings and expressions should consider whether it is correctly understood by the rural communities. The contents of the radio and television program should be well designed in a modular form in a sequential manner. The project area communities should know the exact time and date when these programs are being broadcasted. Such program will have broader impact even outside of the project areas.

Another strategy not to be overlooked is the use of social media in its activities. This will be through its websites, its official Facebook pages and other means of social media. Through social media, this will be able to reach out to many people worldwide and give people a platform where they can discuss several issues concerning diabetes.

All these modes of communication can also be used during focus discussions on different occasions. But in the case of printed materials, as the majority of the communities are not illiterate, an arrangement could be made, may be through local interpreters so that some can read the message and the whole community discuss on it.

6: Popular Personalities

Personalities known in the area, such as religious leaders, traditional leaders, elders who know the area and people in their earlier times can convince and sensitize communities for the rehabilitation. This could be done during public gatherings such as Sundays after church ceremony, different holidays and occasions to alert the communities.

Inviting such personalities to become involved in public awareness campaigns could be an effective means of promoting project activities. A primary advantage of this technique is that it can reach easily to a wide and varied audience and can convince the communities in their own way of communication with no cost.

7: School programs

In order to reach more youth in the country projects should to intends to visit at least all government and private secondary schools across the country.

This campaign will ensure that the youth are well informed about the dangers of diabetes. Raising the awareness of youths in the community has an important multiplier effect as they can pass on information to their own parents, neighbors and the society at large.

Involving young people in awareness-raising allows them to share in a dynamic vision of their communities and the training they receive or skills they acquire while carrying out activities can serve them in the future. As tomorrow's parents and community leaders, young people can be powerful agents for social change.

8: Commemoration OF WORLD DIABETIES DAY

As one way of bringing diabetic people together more effort should be made towards world Diabetes day. For instance holding a yearly sports day where people will participate in various types of sports and also will help realize the value of physical fitness.

9: capacitating

Finally, to achieve our goal number two that is reduce the number of child related deaths in the country, our nurses will be conducting sensitization meetings with pregnant women in different hospitals and outreach clinics across the globe during post-natal checkups and antenatal checkups. Nurses will educate pregnant women and mid-wives on the dangers on gestational diabetes and how it can be prevented.

10: Certificate of Recognition or Awareness Award & Incentives

Organizing awards ceremony on annual basis for individuals or groups of people who have done remarkable work and contributed effectively in raising the awareness level of the community with regards to the project issue creates a learning event among the community.

This is a kind of giving recognition for their contribution in sensitizing and making the community aware of project related issues. This award could be simple like provision of certificates, hand tools and the like.

As said above, the award could be for individuals who played key role in mobilizing and sensitizing the community leaders, administrations which the selection criteria could be developed in a transparent way where community representatives participated in setting the criteria.

The certificate could simply be written like "in recognition of your outstanding contribution in helping promote awareness ". This could be made at the commemoration of the project to attract the attention of the community. Received prizes should be assessed in subsequent years, regardless of their intention to participate to keep the momentum alive.

Bianca Hemmingsen
Medical Officer
World Health Organization
Avenue Appia 20
1211
Geneva 27

Via email to hemmingsenb@who.int

September 16, 2021

Dear Ms. Hemmingsen:

Diabetes Canada greatly appreciates the opportunity to comment on the World Health Organization's draft recommendations to strengthen and monitor diabetes responses within national noncommunicable disease programmes, including proposed diabetes coverage targets.

Diabetes Canada is the registered national charitable organization that is making the invisible epidemic of diabetes visible and urgent. Diabetes Canada partners with Canadians to End Diabetes through providing resources for health care professionals on best practices to care for people with diabetes; advocacy to governments, schools and workplaces; and funding world-leading Canadian research to improve treatments and find a cure.

We have reviewed the draft diabetes targets and the background paper and commend the World Health Organization on this work. We are very supportive of the approach overall and the targets.

We note that it is important in many cases to differentiate between types of diabetes. For example, it is not sufficient just to diagnose someone with diabetes, but, because treatment approaches and disease progression can differ so much, it is also essential to record which type of diabetes they have in any national registry or database. The Background and Discussion papers rarely differentiate between the types of diabetes and should be encouraged to do so.

Diabetes Canada recognizes that the global targets proposed (e.g. A1c < 8%) are likely appropriate on a global scale, though they are higher than Diabetes Canada's Clinical Practice Guidelines recommend.

Again, Diabetes Canada commends the World Health Organization on this important work. We look forward to supporting the implementation of these targets in any way.

Sincerely,

Laura Syron
President and CEO
Diabetes Canada

Attn: Bianca Hemmingsen
World Health Organization
Non-communicable Disease Program

September 13th, 2021

Dear Dr. Hemmingsen,

Re: Draft diabetes targets-amendment of target to include 100% diagnosis of **type 1 diabetes**

Thank you for the opportunity to provide input and inform the World Health Organization's (WHO) current consultation process around the recommendations to strengthen and monitor diabetes response within national communicable disease programmes, including voluntary global diabetes coverage targets for 2030 (the Targets). We commend the WHO for undertaking this activity.

Diabetes care India is the NGO that supports individuals living with type 1 diabetes. This letter is sent by **Dr. Banshi Saboo** the founder and the Chairman of Diacare-Diabetes and Hormone Clinic in Ahmedabad, Gujarat, India. The other organizations that supports type 1 activities in India are DiabetesIndia and Research Society of Study of Diabetes In India (RSSDI). Dr. Saboo is currently the President of RSSDI and secretary for DiabetesIndia.

We are pleased to note that the draft Targets clearly include that 100% of people with type 1 diabetes should have access to insulin and blood glucose self-monitoring, and are strongly supportive of its retention unchanged. In the forthcoming publication on global burden of type 1 diabetes mellitus[1] states, nearly a third of the global burden of type 1 diabetes on the unstable access to insulin and lack of blood glucose monitoring equipment. This target will encourage a significant shift in the baseline of treatment and management of type 1 diabetes in India and other low and middle income countries too. The organization like Changing Diabetes in Children and Life for a Child supports people living with type 1 diabetes in India, however it has its own limitations. India is in need of such organizations that can support T1Ds.

[1] Ogle, Graham et al. Global Burden of Type 1 diabetes Mellitus: a Modelling Study. Unpublished, 2021

We have significant concerns, however, with the wordings of the first target, which states “80% of people with diabetes are diagnosed”. This would endorse a 20% mortality rate at onset in type 1 diabetes, which is the consequence of non-diagnosed or misdiagnosed.

The rate of non-diagnosis or death at onset for type 1 diabetes is the under recognized problem globally. This is witnessed in the same publication mention above that, one in ten incidents cases of all type 1 diabetes globally result in death at onset. This further contributes to approximately one-third of the total disease burden of time 1 diabetes, in reference to life years lost.

Hence our collective suggestion is to revise the first draft WHO target as below,

From: “80% of people with diabetes are diagnosed”

To: “80% of people with type 2 diabetes and 100% of people with type 1 diabetes are diagnosed”

As an organization dealing with type 1 diabetes we help deliver the aims of the Global Diabetes Compact. We remain encouraged by the scope of this collaborative efforts and are committed to ensuring better outcomes for all people living with T1D in India

I am available at banshisaboo@hotmail.com, if you need more information.

Yours Sincerely,
Dr. Banshi Saboo

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TO WHOMSOVER IT MAY CONCERN

DATE: 17-09-2021

SUB: Feedback for including diabetic foot care in WHO Diabetes Strategy

Respected Sir/Madam,

1. Dr Dia Footcare is an India-based private organisation working with and treating diabetic foot care patients since 5 years now. In a country like India, diabetes is like an epidemic with 82 million diabetic people recorded in 2017 and 151 million estimated in 2045. India is 2nd highest in reporting diabetic cases globally.

2. People with diabetic foot ulcers have a 20x risk of amputations. 20-95% of world-wide lower extremity amputations are diabetes related. After 5 years of amputation, 50% are reported dead or need to have a 2nd amputation.

3. With effective policies for early screening of diabetic foot issues, it will be possible to detect neuropathy and Peripheral vascular diseases at early stages. This can reduce the incidence of foot ulcers and ultimately lower extremity amputation.

4. Development of low cost screening tools and preventive products can also be useful in early detection and prevention of diabetic foot issues at early stages.

5. We would like to solicit your support for this effort to include diabetic foot care/prevention of ulcers and amputations as part of their targets for core developmental metrics. This can have a great impact for persons with diabetes over the next 5-10 years.

AMANDEEP HOSPITAL & CLINICS

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International Scientific Panel (WUWHS 2022)
Executive Board Member (Indian Podiatry Association)

Ministry Health and Family Welfare of India (2016) has adopted few guidelines from international consensus, yet proper diabetic foot screening is not consistently carried out in diabetic foot clinics despite existing evidence to support this practice. There is no defined preventive & referral pathway for patients at risk of foot complication in the foot clinics. To fulfil these challenges, there is a need on urgent bases of Diabetic foot care to prevent diabetic foot complications and amputations.

To obtain good outcomes for patients, DFU's requires a multidisciplinary team (MDT) approach (Vazdanpanati, 2015). Recent evidences show that the longer the delay before being seen by MDT, the worse the prognosis is for foot ulcers. Local patients often delay seeing doctor and ignore symptoms so late presentation (Strom, 2017).

I work with a team of endocrinologist, orthopaedic, vascular surgeon and general practitioners. We are increasingly seeing patients with DFU's in advance stages which is due to lack of awareness in the patients and health care practitioners (HCP). Patients come to us in an advanced stage of diabetic foot complication due to lack of early identification, prevention and management as there are no proper guidelines for diabetic foot management in India. Early risk assessment via the diabetic foot care pathway is crucial in minimising diabetic foot complications like gangrene and amputation. A pan-India survey on the burden of diabetes has shown that Chandigarh (13.6 %) is on course to becoming the country's diabetes capital, while Punjab (9.8 %) is a close second (Anjana et al., 2017). In Southern Punjab region, we see high prevalence of diabetic foot patients (Kotru, 2015).

In OPD clinic there is a lack of annual diabetic foot checks. Sometimes there is a failure to make timely prevention and referral to other professionals. There is need for all HCP's to treat patients early in that window of clinical presentation between the time a patient presents with

neuropathy but before an ulcer develops. It is well recognised internationally that all active diabetic foot problems should be referred on urgent bases to the MDT.

In India proper diabetic foot guidelines are lacking, at some places adapted guidelines are used for the diabetic foot assessment, prevention, management and treatment (Ministry Health and Family Welfare of India, 2016). There is also need of national and international protocols to improve patient outcome and prevent serious complications like gangrene or limb amputations. HCP's in India often fail to adequately assess patients and make appropriate or timely referrals because of the lack of awareness and skills. Thus, there is an urgency to implement foot care practice using current evidences to improve quality of life of the patients, their families and financial burden in the health service.

OUTCOMES

- ✓ A uniform diabetic foot care tool would make effective treatment and monitoring of patients easier
- ✓ Prevent delayed referral of patients 'at risk' of foot complications.
- ✓ As per International guidelines on the diabetic foot we need to pay far more attention on examination to identify high risk patients.
- ✓ Early prevention by use of appropriate pressure redistribution can help patients to prevent diabetic foot ulcers.
- ✓ It will encourage best practice using up-to-date evidences.
- ✓ Help in timely Identification of patients at low, medium and high risk of diabetic foot.
- ✓ Cost effective and economical treatments.
- ✓ Help to reduce recurrence rate of ulcers in diabetic patients.
- ✓ High level of patient satisfaction and improves adherence.
- ✓ Technical competency of foot care specialist.
- ✓ Reduction of cost in the local healthcare systems and ultimately national healthcare expenditure.
- ✓ In clinical settings the concept of limb salvage and quality care to the patients will add on to the services.
- ✓ Help to raise awareness among local diabetic population.
- ✓ Help to educate patients and others.

So, there is an need to include diabetic foot care / prevention of ulcers and amputation as a part of current targets for core development metrics. This can have a great impact for persons with diabetes over next 5 to 10 years.

Intersectoral Forum to Fight NCDs in Brazil - ForumDCNTs' Recommendations to the World Health Organization (WHO) to Strengthen and Monitor Diabetes Responses within National Noncommunicable Disease Programmes, including Voluntary Global Diabetes Coverage Targets for 2030

The ForumDCNTs, since 2017, unites organizations from the different sectors dedicated to policies and programs on NCDs prevention and care. It was planned from its conception to assist the country in achieving the SDG 3.4 through SDG 17 (additional details here). Nowadays, over a hundred organizations from the public, private and not-for-profit/civil society sector join efforts in the key alliance for partnerships to fight NCDs that is the ForumDCNTs. It is worth mentioning that since 2019 PAHO and WHO have also joined the ForumDCNTs in several opportunities. Regarding the web-based consultation for Member States, UN organizations, and non-State actors on a draft global strategy for the prevention and management of obesity over the life course, including potential targets (WHO Discussion Paper dated 16 August) that WHO is convening from 16 August to 17 September 2021, the ForumDCNTs, the institutions that comprise it - especially the ones co-signing below - share the following comments and recommendations.

Diabetes mellitus (DM) is listed among the most relevant NCDs due to its global high prevalence, morbimortality, and also social stigma, impairing people living with diabetes (PLWD)'s quality of life and causing a huge burden on the entire society. We compliment the authors for the expressed recommendation to include PLWD in the decision processes of healthcare policies and programs, as the ForumDCNTs has also been advocating in line with GCM-WHO, WHO/UHC2030, and NCD Alliance. The division of policies in core, considerable and basic ones is another positive aspect, as it assists in guiding national policies according to each country's health determinants. As the ForumDCNTs emphasizes, multisectoral strategies for diabetes prevention and care are also present in the text.

Regarding the targets, we are pleased to see them clearly expressed to be globally shared and agreed, encouraging an international effort to halt the lack of access to quality care in several countries. At the same time, we understand that some adjustments should be made. Starting from the first target, we agree with and support the recommendations submitted by the Life for a Child (LFAC) and the Juvenile Diabetes and Research Foundation (JDRF), where they (and we) express significant concerns with the first target where "80% of people with diabetes are diagnosed". While this would be a defensible target for type 2 and gestational diabetes, for type 1, this would mean a 20% mortality rate at its onset. Therefore, for type 1 diabetes, we suggest changing the target to "100% of people with type 1 diabetes are diagnosed". As we have additional recommendations below, we suggest that if WHO opts for keeping the targets table concise, to split it into one table for type 1 and another for type 2 targets.

With reference to the second target in the table, HbA1c levels, we admit that achieving the DCCT's and UKPDS's recommendations of HbA1c below 7%, to reduce the risks of chronic complications, is hard and not recommended to certain groups of PLWD. At the same time, it is the target in several national and international guidelines, including the WHO's HEARTS-D

for the majority of PLWD. Our main concern is a high HbA1c level in children, who are expected to live decades with diabetes. Thus, we suggest including, at least in the text of the document, additional recommendations of HbA1c below 7%, and more than 70% of the Time in Range (70-180 mg/dL), whenever possible and to groups who would benefit from a more stringent management. A lower HbA1c target for some groups would reduce or postpone the development of complications that severely decrease life quality and increase treatment costs dramatically. In order to achieve those goals and reduce the risks of hypoglycemia, especially for insulin users, children with type 1 diabetes and pregnant women with diabetes, the use of glucose sensor/continuous glucose monitoring would also be recommended, whenever possible. A warning note should be added explaining that HbA1c <8.0-8.5% would be acceptable among those who are over 65 years old and present multiple coexisting chronic illnesses, cognitive impairment, functional dependence, frailty, risk of hypoglycaemia and/or of cardiovascular outcomes.

It is very encouraging to see among the targets one on hypertension and another on dyslipidemia management, both important actions towards secondary and tertiary prevention. In our experience measuring HbA1c, cholesterol and renal function for diagnosis, monitoring and therapeutic adjustments may be very challenging. One solution we tested, found cost-effective and suggest to be added to the document is the use of Point-of-Care equipment in primary health care facilities.

The fifth target, on medicine availability and access, is well structured for type 1 diabetes, to whom we suggest ideally comprehensive care. Meanwhile, we wondered why access to type 2 medicines and supplies were not mentioned. Would this be another aspect to justify splitting the table in one for type 1 and another for type 2? While type 1 is an aggressive condition that requires fast and close management, it comprises around 10% of total diabetes cases around the world. Thus, the availability of medicines present in the WHO Essential Medicine List - such as Metformin, Gliclazide and SGLT2 inhibitors - for 100% of individuals with type 2 diabetes, as well as insulin and test strips whenever prescribed, should also be among the key targets.

The burden of diabetes is highlighted in the document. A reduction of 50% in the incidence of end-stage renal disease (ESRD) and amputations are considered, together with mortality. We would suggest the addition of diabetic retinopathy (DR) and diabetic peripheral neuropathy (DPN) in this group of recommendations. DR is developed closely with ESRD and can be prevented with glucose management, and early treatment may prevent vision loss. Its development would severely reduce the quality of life of people affected by this chronic complication. Point-of-Care equipment and digital health services make diagnosis, monitoring, screening for DR and ESRD easier and more accessible, as recent reviews suggest. In line with D-FOOT's feedback, knowing that 50% of PLWD have DPN and most of them do not have symptoms, and that DPN is the main permissive factor for diabetic foot ulcers (DFU), which precedes 85% of amputations, we suggest to include recommendations regarding this complication in the text. It is unfortunately common that most PLWD neither have experienced a basic foot examination to identify the at-risk foot of ulcers and amputations, nor have they received proper education on how to self-care. Thus, screening and setting targets for the different microvascular complications will favor the achievement of diabetes goals by 2030, as each one of them play a role as a marker or risk factor for the others.

About digital health services, we recommend more extensive and detailed guidance on its development for diabetes care. The COVID-19 pandemic unveiled the need for contingency plans to continue diabetes and other NCDs care during global crises. Telemedicine was an

effective alternative and is now seen as permanent. However, we believe that it still lacks regulation and standardization. Additionally, we would recommend encouraging the use of WHO's PEN and HEARTS packages and their apps (pen's and hearts').

Gestational diabetes (GDM) is left aside with the argument that there is no consensus about its diagnosis. We would suggest, though, that while this consensus is not reached, GDM should be considered a risk factor for type 2 diabetes and cardiovascular disease, still a neglected condition among women. Thus, as people with obesity and family history of diabetes, women who presented GDM should be screened for T2D. In this case at least until two months after labor. Keeping higher risk populations unscreened reduces the chances of achieving the targets defined in this document and of the SDG 3.4.

It was noticed that diabetes education (DE) was not mentioned in any part of the document. Since insulin discovery in 1921, Dr. Elliott Joslin stated that diabetes education is not a mere part of the treatment, but the treatment itself. With proper DE, PLWD can manage their condition with autonomy, making better decisions to keep healthy, take their medications and manage their blood glucose, blood pressure and cholesterol levels. When empowered, they can also become peer leaders, advocates, and change makers, able to benefit their community and the entire society. Thus, it is an intervention that pays off and we are afraid that without DE the targets will not be achieved. In order to educate PLWD, their family members and the entire communities, health care professionals also need to be trained and, this way, master the curriculum and the education methods. Therefore, we understand that DE needs to be quoted as crucial to achieve the targets, including diabetes prevention, control, treatment adherence and quality of life.

The FórumDCNTs reinforces that the multisectoral participation and partnerships for the development of these recommendations are quintessential, strengthening the decisions and their potential to achieve the desired targets and goals.

We cordially acknowledge WHO's attention and the opportunity for this contribution, and put ourselves at its disposal to assist in global and regional recommendations, as well as to collaborate for their implementation in Brazil and abroad.

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To,

17 September 2021

The WHO Diabetes Program

WHO Diabetes Strategies 2030

Dear Dr Hemmings,

This is to respond to the WHO call on Recommendations to strengthen and monitor diabetes responses within national noncommunicable disease programmes (who.int).

Management of diabetes include foot ulcer and lower limb amputations as a result of neuropathy and ischemia, which require timely, safe surgical care. Assessments using WHO tools have shown huge gaps in offering basic (includes wound debridement) and comprehensive (includes amputation) in timely surgical services to prevent death and disability in several low- and middle- income countries [1,2].

Global efforts on diabetes require an integrated approach to support education, research and policy advocacy for investments in infrastructure and health workforce skills in resource constrained environments for prevention, treatment and rehabilitation of this growing public health burden.

This is to request you to please consider in the WHO strategies 2030 targets the addition of diabetic foot ulcers and preventable lower limb amputations as a result of ischemia in meeting the SDGs.

Thanking you for the opportunity to contribute from our Geneva Foundation for Medical Education & Research.

Best wishes

Dr Meena Nathan Cherian MBBS, MD (Anaesthesia)
(Former WHO Lead Emergency and Essential Surgical Care Program, Geneva, Switzerland).
Director Global Health New Challenges: online courses GFMER.
Geneva Foundation for Medical Education & Research (GFMER), Switzerland. www.gfmer.ch/surgery
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September 17, 2021

WHO Headquarters in Geneva
Avenue Appia 20
1211 Geneva
Switzerland

VIA Electronic Delivery

RE: Recommendations to strengthen and monitor diabetes responses within national noncommunicable disease programmes, including voluntary global diabetes coverage targets for 2030

To Whom It May Concern,

As advocacy organizations, and individual patient advocates committed to improving the lives of all people impacted by prediabetes, diabetes, and liver disease, we appreciate the opportunity to submit comments to the World Health Organization's (WHO) recommendations to strengthen and monitor diabetes responses within national noncommunicable disease programmes. We welcome the WHO's interest in developing a broad vision for accelerating research into the causes, prevention, and treatment of noncommunicable disease. We also thank the WHO for its transparency.

With this in mind, we depend on the WHO's leadership and partnership to move the field forward and shift the conversation on liver health. This is why we urge the WHO to consider the strong link between type 2 diabetes (T2D) and chronic liver disease, especially nonalcoholic fatty liver disease (NAFLD) and nonalcoholic steatohepatitis (NASH). Especially when considering how to strengthen diabetes responses, set diabetes coverage targets, and monitor diabetes responses, it is of utmost importance that the WHO highlight, research, and address the risks for patients with T2D of NAFLD and NASH.

The Risks For Patients With T2D of NAFLD and NASH

It is common for patients to have NAFLD, or its more severe form, NASH, and diabetes. For individuals with T2D, the prevalence of NAFLD affects 70% of adults in the U.S. with an estimated 30% having NASH and about 20% having liver fibrosis.[1] [2] [3] [4] In a large study in India, 56.5% of patients overall with T2D between the ages of 25 and 84 had NAFLD; in the northern Indian states alone, NAFLD was prevalent in 72.4%.[5] [6] Notably, researchers in Romania examined patients with T2D who were mostly Caucasian and older and found that having a higher body mass index (obesity) increases the risk of developing severe steatosis and fibrosis.[7]

On top of this is the impact of NAFLD and NASH as a risk factor for T2D. NAFLD is associated with a two- to three-fold increased risk of developing T2D; this risk may be even higher in patients with more severe liver disease.[8] Patients with diabetes are also at high risk of disease progression from NAFLD to NASH.[9] T2D and diabetes risk are closely associated with the severity of NAFLD, progression to NASH, advanced fibrosis, and the development of

hepatocellular carcinoma (HCC)[10] [11], independent of liver enzymes[12].

Conclusion

It is of the utmost importance that patients with T2D are aware of their increased risk for liver disease to avoid progressing to a potentially life-threatening diagnosis such as hepatocellular carcinoma, the most common type of liver cancer. Patients with both T2D and NASH have a higher risk of liver-related and non-liver related illness and premature death than those without liver disease.[13] Liver cancer is the second deadliest cancer worldwide, in large part due to a lack of knowledge among the most at-risk populations concerning their risk.

In his February 2020 article *Time to Include Nonalcoholic Steatohepatitis in the Management of Patients With Type 2 Diabetes*, Dr. Ken Cusi, a leading expert on NASH and diabetes, directly makes the case for patients with diabetes to be screened for NAFLD/NASH. He shares, "The above results call on endocrinologists to view NASH as a frequent and serious complication of T2D and to be proactive in the early identification of patients at risk for liver fibrosis."

It is also important to consider the impact of patients with NAFLD/NASH and diabetes on current clinical care pathways, and the value of using certain diagnostic tools, like shear wave elastography (SWE), to streamline primary care based clinical care pathways. For example, in Canada, research shows the value of targeting patients with T2D for NAFLD, due to their twofold higher risk of needing referral to hepatology, to streamline specialist referral of patients with NAFLD at risk for advanced liver fibrosis.[14]

With this understanding, we respectfully urge the WHO to strengthen the diabetes response recommendations to acknowledge the direct connection between liver diseases such as NAFLD/NASH and diabetes. The recommendations must highlight the value of early interventions in addressing NAFLD/NASH, and how to improve clinical care pathways, along with examining multiple outcomes at once, including the intrinsic link NASH shares with obesity and diabetes. We also stress for the WHO to expand upon its NAFLD/NASH and diabetes research dissemination and awareness strategies to better address these rising life-threatening chronic liver diseases.

If you have any questions, please don't hesitate to reach out to Global Liver Institute's Policy Director, Andrew Scott, at ascott@globalliver.org or 831-246-1586.

Sincerely,

Global Liver Institute

Fatty Liver Alliance

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Bianca Hemmingsen
World Health Organization
Noncommunicable Disease Program

September 16, 2021

Dear Dr. Hemmingsen,

Re: Draft diabetes targets

To begin, that you for allowing the community the opportunity to provide feedback for the World Health Organization's (WHO) efforts in seeking recommendations that would strengthen diabetes monitoring as part of their national noncommunicable disease programs. More specifically, identifying attainable diabetes related targets for 2030.

I submit this letter on behalf of an organization I founded eight years ago and currently serve as President, Insulin for Life USA (IFL-USA; www.iflusa.org).

By way of brief background, both myself and this volunteer organization provide services to international causes directly related to improving diabetes care in the developing world. Specifically, we provide free, life-saving diabetes management supplies, including insulin, to individuals of all ages with limited access to these resources. At last count, these efforts had reached over 9,000 individuals in 17 developing countries. We have over these many years partnered with multiple organizations for this cause including committees organized by The Lancet, Life for a Child, IDF, WHO, ACCISS, the Boston Declaration, and The Leona M. and Harry B. Helmsley Charitable Trust, to name just a few. Our organization has also dedicated time and resources to understanding the thermostability of insulin, a notion of major significance to living environments in the developing world.

It has often been said that lack of access to insulin is the major cause of death in the developing world. This may be true but, my personal belief is that poor diagnostics and care are equally if not more contributory to morbidity and mortality. Far too often, due to logistical, geographic, educational, or financial reasons, cases of type 1 diabetes are without question underdiagnosed and misunderstood. One of the major voids in seeing both better disease management and reduced mortality is a lack of an effective "plan". Your proposed efforts, by identifying targets that can be both communicated and applied, have the potential to see that goal achieved.

However, I believe the currently proposed targets should be modified (i.e., raised upwards) in order for a maximum effect to be seen. Specifically, current language ("*80%*

of people with diabetes are diagnosed") should be modified to ("*80% of people with type 2 diabetes and 100% of those with type 1 diabetes"*).

Again, thanks to the WHO for trying to make a difference in the lives of those who suffer from diabetes.

Best wishes,

Mark Atkinson, PhD
President, Insulin for Life USA

American Diabetes Association Eminent
Scholar for Diabetes Research
Jeffrey Keene Family Professor
Departments of Pathology and Pediatrics
The University of Florida

International Alliance of Patients' Organizations
A global voice for patients

September 14th, 2021

Attn:

Dr. Bianca Hemmingsen
World Health Organization
Noncommunicable Disease Program

Sub: Improving Health Outcomes of People with Diabetes Mellitus: Target Setting to Reduce the Global Burden of Diabetes Mellitus by 2030

Dear Dr. Hemmingsen,

Thank you for the opportunity to provide input and inform the World Health Organization's (WHO) current consultation process around the recommendations to strengthen and monitor diabetes responses within national noncommunicable disease programmes, including voluntary global diabetes coverage targets for 2030 (the Targets). We commend the WHO for undertaking this activity.

IAPO is the only cross disease patient organisation bringing the voice of patients across the world for various thematic areas including access to care and patient safety. We have reviewed the consultation document and have the following comments to offer for review and inclusion.

EB 150/Annex 2

Challenges and Opportunities 1. J

IAPO has conducted research on collecting data with a mixed methodology which includes 1) systematic peer-reviewed database search; 2) unstructured searches of local or real-world data; and 3) expert opinion. Our work in LMICs and LICs has revealed that collecting and analysing clean data is difficult, leading to challenges in estimating disease burden and designing appropriate programmatic responses. We offer this methodology for data collection and evidence generation. https://doi.org/10.2147/JHL.S288966 and are happy to discuss this further. Our organizations and constituents are significantly invested in the outcomes of the WHO's diabetes-related activities, including the establishment of Targets.

We also feel that patient journey mapping is of utmost importance to achieve optimal outcomes. In a highly fragmented healthcare system, patient journeys can help understand if the clinical protocols and health systems are offering the right response as per the needs of the patient. https://doi.org/10.1007/s12325-020-01519-3. Understanding the patient journey for NCDs from the patients' perspective can help healthcare systems in these settings evolve their NCD care models to address the unmet needs of patients, enhance patient participation in their management, and progress towards better outcomes and quality of life

6d- Promote and support national capacity for high-quality research, innovation and development for the prevention and control of diabetes.

We strongly recommend that the patient voice should not only be included in policy development but also contribute to research as expert patients are able to provide experience and data that can provide immense value to develop and implement the research agenda. Research investments should be need based derived from insights gathered from patients with lived experience. National research bodies should include a patient voice representative of people living with diabetes.

Voluntary diabetes targets section 8

IAPO applauds the ambitious targets set by WHO to be achieved by 2030. We have the following comments to the targets

Include the terminology in 80% of people with diabetes are diagnosed to **80% of people with all kinds of diabetes including gestational, LADA, MODY to be diagnosed.**

Addition of one more target- 100% of people on insulin are provided an enabling environment to live a stigma free life with dignity

Please do not hesitate to contact Dr Ratna Devi on ratna.devi@dakshamahealth.org should you need more information or assistance.

Yours sincerely

Dr Ratna Devi

Chair, Board of trustees
International Alliance of Patient Organisations (IAPO)
www.iapo.org.uk
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International Diabetes Federation

WHO discussion paper: draft recommendations to strengthen and monitor diabetes responses

The International Diabetes Federation (IDF) thanks the World Health Organization (WHO) for the discussion paper on draft recommendations to strengthen and monitor diabetes responses, and for the opportunity to comment through the online consultation with civil society.

IDF believes this is a very detailed and promising document, and particularly welcomes the WHO Secretariat recommendation of establishing five voluntary global diabetes coverage targets to be achieved by 2030. IDF would like to make the following comments to the document:

STRENGTHENING DIABETES RESPONSES

Recommended action for Member States A) on strengthening national capacity, leadership, governance, multisectoral action and partnerships to accelerate country response for the prevention and control of diabetes

Non-governmental organisations should be explicitly mentioned among the stakeholders to be engaged by Ministries of Health, since they have a central role in the diabetes response.

Recommended action for WHO D) on promoting and support national capacity for high-quality research, innovation and development for the prevention and control of diabetes

The recommended action should not oversee the role of research and innovation in diabetes monitoring, diagnosis and screening. IDF requests to rephrase the action as follows: "*promoting and support national capacity for high-quality research, innovation and development for the prevention, screening, diagnosis, monitoring and control*".

SETTING DIABETES COVERAGE TARGETS

We must ensure that, by 2030, 100% of people living with type 1 diabetes are diagnosed. IDF requests the first target is rephrased as follows: "*80% of people living with type 2 diabetes and 100% of people living with type 1 diabetes are diagnosed*".

MONITORING DIABETES RESPONSES

Recommended actions for Member States

The establishment and maintenance of national diabetes registries by Member States should be explicitly mentioned among the recommended actions.

IDF looks forward to continue its fruitful collaboration with WHO in the years to come, to strengthen diabetes responses and improve the lives of people living with diabetes and those at risk.

This IDF submission is supported by:

NCD Alliance · World Heart Federation · World Obesity

International Diabetes Federation

Avenue Herrmann-Debroux, 54
B-1160 Brussels – Belgium
www.idf.org

17th September 2021

Dear Bianca,

Thank you for the opportunity to provide additional comment on the global diabetes coverage targets. WHO and the expert consultation group are to be congratulated for the comprehensive and considered work.

The proposed 5 targets address important areas which can be expected to improve global diabetes outcomes and they represent a manageable number of targets for monitoring and reporting progress. The target of 100% of people with type 1 diabetes having access to insulin and blood glucose self-monitoring is particularly appropriate in this centenary year of the discovery of therapeutic insulin.

Target 1 - 80% of people with diabetes are diagnosed.

While this is an acceptable target for the adult population it is not acceptable for only 80% of children and young people with type 1 diabetes to be diagnosed. It would be unfortunate if countries interpreted this 80% target as acceptable for young people with type 1 diabetes.

It seems that the development of this target is based on population studies which are invariably carried out in people aged 18 and older (eg WHO STEPS).

It is often concluded that there are no undiagnosed type 1 diabetes in young people because they will all have died without diagnosis and insulin. However, there is a time period of 6-12 months before reaching the fulminant stage of type 1 diabetes which provides a window of opportunity for diagnosis provided that health care workers are aware of the condition and its early manifestations.

These considerations could be addressed by:

1. Rewording the target to "80% of adults with diabetes are diagnosed"

2. In addition the document could specifically make mention that every effort should be made to diagnose 100% of children and young adults with type 1 diabetes.

Another previously suggested option is to change the target to include 100% type 1 diabetes diagnosed in children and young adults but this would require future population-based surveys including children and adolescents under 18 years of age.

Regards

Stephen Colagiuri

IDF Vce President

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17 September 2021

IFPMA's contribution to the web-based consultation on WHO Draft Recommendations to Strengthen and Monitor Diabetes Responses Within National NCD Programmes, Including Potential Targets (9 August to 17 September 2021)

Statement

IFPMA and its members welcome the opportunity to comment on the draft WHO *Recommendations to strengthen and monitor diabetes responses within national noncommunicable disease programmes, including voluntary global diabetes coverage targets for 2030*. We appreciate the multi-stakeholder consultative process on targets as part of a broader dialogue on improving peoples' access to diabetes prevention and quality care.

In March 2021, IFPMA provided WHO with a comprehensive response on the 31 proposed "industry commitments" that were developed by WHO for the WHO Private Sector Dialogue in February 2021. In so doing, IPPMA outlined areas which we felt merited the greatest prioritisation, those which required further explanation, and those which appeared to be duplicative with other existing efforts. Based on our collective experience, we strongly believe that **focusing on a limited number of well-defined activities** will help achieve the highest and greatest impact for people living with (or at high risk of developing) diabetes ("PLWD"). In Spring 2021, we proactively shared with WHO four key areas for industry contributions which we are confident that, in being rightfully co-created between WHO, the private sector and other stakeholders, will make the greatest difference for PLWD. These areas are:

1. Supply chain and co-packaging solutions
2. Aggregated supply and demand mechanisms
3. Regulatory advances (including prequalification and thermostability)
4. Digital health innovations

IFPMA has engaged in activities related to the four areas above that we believe will positively impact PLWDs. Our intention has been to complement the discussions being held with WHO and other stakeholders on concrete ways forward, and as far as possible to contribute towards the objectives of the Global Diabetes Compact. The following summarises what has been done in these four areas:

- **Supply chain and packaging solutions**
  - Through its membership in the NCD Coalition, IFPMA provided seed funding and consulting support to the "Diabetes CarePak" initiative led by PATH and the Coalition for Access to Medicines and Products, which is assessing ways to build a human-centric package of diabetes products and services that will provide patients and healthcare professionals with the support they need at the point of care. We are very encouraged

that early pilot programs in Kenya are already providing useful "on the ground" insights from the perspectives of PLWDs and healthcare professionals.
    - IFPMA also convened a virtual workshop with key global health stakeholders in July 2021 that are either currently engaged in/ looking to develop work that tackles supply chain barriers to diabetes care in LMICs.

- **Aggregated supply and demand**
    - IFPMA convened a virtual workshop with key global health stakeholders in global health in July 2021 that are either currently engaged in/ looking to develop work that tackles aggregated demand and supply mechanisms to address barriers to quality diabetes care currently being experienced particularly in LMICs.

- **Regulatory**
    - WHO articulated in bilateral discussions that the two sub-areas of greatest interest concerned heat stability of insulin and securing commitment of companies to the PQ scheme for human insulin that was established by WHO in November 2019. Some IFPMA member companies are continuing to pursue conversations with WHO on PQ registration and we have also spoken with biosimilar companies to understand their assessments of potential opportunities and hurdles to joining this scheme.
    - On thermostability, IFPMA also provided resources to Chatham House in October 2020 to hold a virtual roundtable to discuss ways forward on improving guidance to HCPs on the use of insulin in humanitarian settings based on evidence available on the thermostability of insulin; our understanding is that WHO would move this conversation forward by engaging with regulatory authorities (SRAs) which appear to have a critical role in tackling this issue.

- **Digital health**
    - IFPMA has continued to explore areas to build solutions in - e.g., with the Digital Connected Care Coalition (DCCC) on diabetes and digital health solutions and brokering conversations between Roche and *Be Healthy Be Mobile* to leverage existing technical content validated by WHO within Roche-developed apps for T2 diabetes.
    - IFPMA also sponsored an op-ed on the promise of digital health innovations for PLWD in *Foresight Global Health*, published on 23 August 2021.

Global Reporting

We have noted that WHO aims to work on a potential new **reporting and registry mechanism**, building on a call made in the 2021 World Health Assembly resolution on diabetes. While our industry continues to report on its various access programs and other initiatives (e.g., through the Access to Medicines Index, the UN Global Compact, the Access Accelerated Open Platform, the Access Observatory and company-specific reports, amongst others), we believe that at present the objectives and value-adds of such a tool do not make a clear and present contribution towards improving the lives of PLWDs. However, we note a potential need to fill a gap in reporting by the biosimilar and medical devices and diagnostic industries, which are currently not included in existing international reporting mechanisms.

Over the years our industry has learned lessons from local partner/stakeholders reports and company surveys regarding access reporting and measurement frameworks. These include the following:

- Systemic weak data infrastructure in LMICs poses a major challenge to data collection

- Data collection and reporting is burdensome (in terms of time, resources and personnel) for local implementing partners of companies (usually civil society organisations that have finite resources) as well as global companies
- Some reporting platforms have contained many questions requiring too much detail
- Repetition across multiple platforms further increases the burden

We believe these criteria are critical for getting broad participation by many companies, including small and medium-sized enterprises identified by WHO as potential key contributors. We therefore strongly recommend that we address these challenges when WHO is considering any new measurement/reporting framework, especially as WHO is aiming for participation beyond the innovative biopharmaceutical industry. We should avoid creating an additional burden for local, resource-constrained partners, but should rather:

- Prioritize user-friendliness, ease of use and efficiency as critical principles when designing any new M&E framework
- Leverage existing reporting mechanisms and data sources
- Focus on high quality reporting by focusing on flagship programs and identifying "must-have" vs. "nice to have" metrics by clearly defining from the outset: What is the measurement gap that WHO would like to fill? What does success look like for WHO? For instance, how will collected data contribute to the proposed targets?
- Provide capability building for data collectors
- Link reporting to new global diabetes targets, so that all key stakeholders – *beyond* the private sector - are held accountable to doing what they can to improve lives of PLWDs.

Global Targets

IFPMA is optimistic that **global targets for diabetes** can help drive alignment and focus on meaningful local actions that are required to have a significant "on the ground" impact for PLWDs. We are hopeful that targets will motivate all stakeholders, particularly member states, to accelerate investments and actions that are urgently required to improve the lives of PLWDs. We believe that it will be imperative to emphasize the linkages between the new global targets and the new global reporting framework/mechanism that the WHO is planning to roll out.

Considering WHO's proposed targets, we have questions regarding target #5, namely "100% of people with type 1 diabetes have access to insulin and blood glucose self-monitoring". This objective, while laudable, would appear to be unrealistic given the complexity of the conditions and the multiple and intertwined elements impeding access to quality diabetes care. We are not aware of any other global health target that reaches 100% -- this could, in our view, demotivate rather than motivate governments and key actors to step up efforts. In addition, we question the absence of any target on access to insulin and blood glucose self-monitoring for people with type 2 diabetes. Our industry would also appreciate more information on the rationale behind the targets related to cardiovascular disease: high blood pressure and cholesterol. Finally, we regret to not have any target related to prevention, particularly for type 2 diabetes - for instance public health measures to reduce the risk of developing diabetes, such as nutrition or physical activity actions.

IFPMA and its members appreciate the breaking down of recommendations by sector. Our industry remains committed to engaging in constructive discussions between WHO, diverse industry sectors and civil society stakeholders to co-create and implement impactful solutions for improving the lives of people living with (or at high risk of developing) diabetes. WHO, governments and other stakeholders need to increase their collaborative efforts to deliver on the objectives stated in the Global Diabetes Compact, and need to step up and do their essential parts. These include:

- Providing increased financing for diabetes prevention and quality care

- Enacting fit-for-purpose regulatory approval frameworks and prescribing policies to ensure appropriate products are available to patients at the point of care
- Building properly equipped and managed supply chain infrastructures
- Providing healthcare professionals with the right tools & training
- Empowering people with the quality information they need to prevent or manage their disease

We believe that global targets for diabetes should be precise, based on data, and should be possible to measure with quality data (a challenge in many LMICs), with clear linkages to plans to improve patient care, build health system capacity and increase resources/investments to improve the lives of PLWD. Leveraging current best practices regarding "SMART" objectives, diabetes targets should be "SMART" – Specific, Measurable, Ambitious but achievable, Realistic/relevant and Time-bound.

Comments on recommended actions for Member States

- We applaud the inclusion of these recommended actions for Member States, and recommend that these be reflected into WHO global targets for diabetes and translated into ''SMART" objectives as outlined above.
- How do these factor into global reporting mechanisms, and global targets, to improve the lives of PLWD?

Comments on recommended actions for International Partners, including the private sector

- See comments above.

Comments on recommended actions for WHO

- We applaud the inclusion of these recommended actions for WHO, and recommend that these be reflected into WHO global targets for diabetes and translated into ''SMART"objectives as outlined above.
- IFPMA and its members encourage the WHO to proactively collaborate with every sector to design the solutions that would help achieving the Global Diabetes Compact objectives.
- How do these factor into global reporting mechanisms, and global targets, to improve the lives of PLWD?

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IPA Recommendation on WHO Discussion Paper
Draft Recommendations to Strengthen and Monitor Diabetes Responses within National Non-Communicable Disease Programmes, including Potential Targets

Recommended Actions for Member States

- Diabetes is a major health problem in children. IPA urges WHO to specifically address diabetes in children in the recommended actions for member states as Type 1 and Type 2 Diabetes occurs in children as well.
- IPA recommends all member states to establish national registries specifically for Type 1 and Type 2 Diabetes in children.
- IPA recommends that the recommended actions for member states must address the disruptions to Type 1 and Type 2 Diabetes in children responses due to the COVID-19 pandemic.
- Access to insulin and laboratory examinations are still limited, especially in low- and middle-income countries. IPA urges member states to place Type 1 and Type 2 Diabetes in children as a national priority and guarantee the access to insulin and laboratory examinations in their respective countries.
- The care of Type 1 and Type 2 Diabetes in children require an interdisciplinary diabetes care team, which includes mental health specialists as youth with diabetes are more likely to develop depression, anxiety, psychological distress, and eating disorders. IPA recommends the WHO to specify the “minimum standards of diabetes management” (Recommendation 4c) to include the interdisciplinary diabetes care team.
- The management of Type 1 and Type 2 Diabetes in children should involve nutritional management and physical activity. IPA recommends the WHO to specify this as part of the recommended actions of member states to control diabetes.
- IPA endorses strengthening the involvement of young people living with NCDs in clinical decision-making, with a focus on health-professional-patient communication. IPA also supports including young people living with NCDs in decision making processes on policies, strategies and implementation of diabetes prevention and control.

International Pediatric Association

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- Children with Type 1 and Type 2 Diabetes must have equal rights and opportunities as the general population. IPA recommends WHO to specify this as part of the recommended actions to member states.
- IPA recommends that young people living with NCDs are engaged in monitoring systems to evaluate the treatment gap through communication technology that is available to them.
- IPA recommends that the WHO recommend policies for member states to make products correlated with diabetes tax-free.

Recommended Actions for International Partners, including the Private Sector

- Diabetes is a major health problem in children. IPA urges WHO to specifically address diabetes in children in the recommended actions for international partners, including the private sector.
- IPA urges WHO to recommend industries and companies providing products correlated in Type 1 and Type 2 Diabetes globally to lower the price of products associated with the treatment of Type 1 and Type 2 Diabetes and encourage the availability of such products in countries globally, especially low- and middle-income countries.

Recommended Actions for WHO

Diabetes is a major health problem in children. IPA urges WHO to specifically address diabetes in children in the recommended actions for WHO. IPA urges WHO to act on the inequality in the care of children with diabetes globally.

Setting Diabetes Coverage Targets

IPA recommends WHO to include targets that specifically address Type 1 and Type 2 diabetes in children.

International Pediatric Association

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IPA: working for Every Child, Every Age, Everywhere

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September 2021

Via email: hemmingsenb@who.int

Dear Ms Hemmingsen,

Re: Draft Diabetes targets

Thank you for the current opportunity to provide input to the World Health Organization's (WHO) current consultation process around the recommendations to strengthen and monitor diabetes responses within national non communicable disease programmes, including voluntary global diabetes coverage targets for 2030 (the Targets).

As a unique scientific society with a focus on children , adolescents and young adults with all forms of diabetes, we're very grateful for this initiative of WHO, considering the high death toll of this condition. Although type 1 diabetes will be most frequent in the pediatric population, type 2 diabetes incidence in youth is increasing and needs to be considered as well.

Working closely together with our international partners such as JDRF and LFAC we fully endorse their comments and would like to re inforce these:

1. *Target 1 Diagnosis of Type 1 Diabetes*

From "80% of people with diabetes are diagnosed"
To: "80% of people with type 2 diabetes and
100% of people with type 1 diabetes are diagnosed"

Non-diagnosis / 'death at onset' of type 1 diabetes globally is a significant and under-recognized problem.
Organizations such as Life for a Child, Changing Diabetes in Children, Santé Diabète, Insulin for Life, Action for Diabetes and others have provided more insight in this.
As mentioned as well by LFAC, a reduction in Diabetic KetoAcidosis at onset to < 35% may be a proxy marker for this target and we would be happy to discuss this further.

2. *Target 2 Glycemic Control Target 80% HbA1c <8.0%*

Specify: 80% of people with type 1 diabetes mellitus and 80 % of the persons with type 2 diabetes have a good metabolic control HbA1c<8.0% (64mmol/mol)

According to our Clinical Practice Consensus Guidelines[1], the target of HbA1c in children with diabetes should be 7.0% based on the relationship with chronic complications and death. It has been demonstrated and implemented by the UK to strive for an even lower HbA1c (NICE guidelines <6.5%) based on the relationship between target setting and outcome.[2]

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Taking into account the current metabolic outcome in children, adolescents , and young adults with type 1 diabetes in many countries (including high income countries)[3] , the proposed target 80 % with an acceptable metabolic control and HbA1c < 8.0% is endorsed.

3. *Target 5 100% of people with Type 1 diabetes have access to insulin and blood glucose self monitoring.*

   Please add 100% of people with Type 1 diabetes have access to insulin, blood glucose self monitoring ***and diabetes education.***

Type 1 diabetes mellitus requests a 24/7 management. Insulin alone, will rarely prevent the chronic complications and we're very grateful for the inclusion of blood glucose self monitoring.
Based on the complexity of the condition and certainly in the pediatric age group (growth, pubertal development etc) , it may be important to consider mentioning **diabetes education** to ensure best use of the drug to improve long term outcome. Or is this considered to be included in the choice of the words *blood glucose self monitoring?*

We thank you once again for this initiative in this year, characterized by the discovery of insulin a 100 years ago **and** the frustration of lack of access to insulin and diabetes care worldwide.

Kind regards

Carine de Beaufort — Jamie Wood

President ISPAD — Secretary General ISPAD

[1] ISPAD CPCG DiMeglio et al. Pediatric Diabetes .2018; 19 (Suppl. 27): 105–114.

[2] Swift et al . Pediatric Diabetes 2009; 11(4):271-8

WHO web-based consultation on recommendations to strengthen and monitor diabetes responses within national NCD programmes, including potential targets

The International Society of Nephrology (ISN) welcomes the opportunity to provide feedback on the *WHO Discussion Paper: Draft recommendations to strengthen and monitor diabetes responses within national noncommunicable disease programmes, including potential targets* and on the document *Improving Health Outcomes of People with Diabetes Mellitus: Target Setting to Reduce the Global Burden of Diabetes Mellitus by 2030*

Circulatory diseases are the world's number one cause of disability and mortality. Chronic kidney disease affects 752 million individuals worldwide and over 850 million people are estimated to have some form of kidney disease[1]. In 2016, the global burden of chronic kidney disease expressed in Disability-Adjusted Life Years (DALYs) amounted to over 60 million years and in over 49 million of Years of Life Lost (YLLs)[2].

Approximately 500 million people live with diabetes worldwide. The number of people living with diabetes has tripled over the last 20 years[3]. Diabetes-related mortality is on the rise in low, middle and high-income countries. Since 2000, the number of diabetes-related deaths has increased by 70% and, between 2000 and 2016, the probability of dying prematurely (30-70 years) from diabetes increased by 5%[4]. the risks of cardiovascular diseases and additional comorbidities will increase further. Efforts to prevent and control diabetes can have a positive impact in protecting kidney health, since adults living with the condition are [5], , in up to 40% of cases, eventually suffer kidney failure5[6], with dire consequences for both patients' health and health systems.

The close relationship between diabetes and kidney disease is evident by the fact that they are currently reported as one category by the Global Burden of Disease Study. Indeed, an impaired fasting glucose accounted for 58% of the age-standardized rate of chronic kidney disease DALYs in 2017[7].

The Global Burden of Disease study[8] (GBD) estimated that:

- In 2017, 1.2 million people died directly from chronic kidney disease, an increase of 34% since 2007.

[1] https://www.kidney-international.org/article/S0085-2538(19)30786-0/pdf
[2] Driving Sustainable Action for Circulatory Health. White Paper for Circulatory Health. https://www.world-heart-federation.org/wp-content/uploads/2018/11/White-Paper-for-Circulatory-Health.pdf
[3] IDF Diabetes Atlas. Ninth edition 2019.
[4] WHO: The top 10 leading causes of death. 9 December 2020. https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death
[5] Driving Sustainable Action for Circulatory Health. White Paper for Circulatory Health. https://www.world-heart-federation.org/wp-content/uploads/2018/11/White-Paper-for-Circulatory-Health.pdf
[6] https://www.kidney.org/atoz/content/diabetes
[7] https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(18)32335-3.pdf
[8] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5388903/

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- One third of these deaths were attributed to diabetic kidney disease, which increased by 23% and 41% for type 1 and type 2 diabetes since 2007.

In addition,

- There are around 3 million people with end-stage kidney failure currently living on dialysis or with a kidney transplant[9].
- At least as many people are estimated to die annually in lower-resource settings because they lack access to these therapies.
- Diabetes is the leading cause of end-stage kidney failure globally and, therefore, likely leads to many more deaths in these regions than is currently reported.

With regard to health systems, kidney disease is associated with a tremendous economic burden as high-income countries typically spend more than 2–3% of their annual health-care budget on the treatment of end-stage kidney failure, even though those receiving such treatment represent under 0.03% of the total population[10]. Prevention of kidney disease progression is key to save lives and reduce costs. Indeed, screening for kidney disease (case finding) has been shown to be cost-effective in high-risk populations, especially in those with diabetes[11].

As has been made painfully clear during the COVID-19 pandemic, patients with chronic illness, and especially those undergoing dialysis or living with a kidney transplant, are at the highest risk for severe illness and death[12].

Given the significant burden in terms of human life and suffering as well as economics and the strong causal relationship between diabetes and kidney failure, we encourage WHO Member States to increase the capacity of health systems to detect, diagnose and manage diabetes; integrate diabetes care into existing programs; scale-up health promotion efforts to prevent diabetes, particularly among young people; and provide patients suffering from diabetes with holistic care, which includes reducing the risk of chronic kidney disease, cardiovascular disease, strikes, peripheral vascular disease, infections and complications, and being able to access healthy affordable food.

Finally, regarding *Table 1: Domains, risk tiers, and potential metrics initially considered for the Diabetes Compact* of the document *Improving Health Outcomes of People with Diabetes Mellitus: Target Setting to Reduce the Global Burden of Diabetes Mellitus by 2030*, the ISN would suggest adding to the 'processes of care' column 'prescriptions for SGLT2i' or 'medications that help reduce cardiovascular risk' in this population. It may also be useful to separate into clinical vs. behavioural interventions/processes of care. Furthermore, the ISN would suggest adding a column with strategies on how to identify those who belong to the high risk group, so to better target education/counselling/structured support.

[9] https://pubmed.ncbi.nlm.nih.gov/25777665/
[10] https://www.who.int/bulletin/volumes/96/6/17-206441/en/
[11] https://pubmed.ncbi.nlm.nih.gov/24529536/
[12] https://www.kidney-international.org/article/S0085-2538(21)00177-0/fulltext?dgcid=raven_jbs_aip_email

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About 25% of patients with diabetes develop a foot ulcer (Singh et al, 2005). Prevalence of foot ulceration varies internationally, ranging from about 1% in studies from some European countries and North America, to more than 11% in some African nations. People with diabetes are 23 times more likely to have a leg, foot or toe amputation than those without diabetes (National Wound Care Strategy Programme (NWCSP), 2021). Meanwhile, diabetic foot ulceration is associated with a high risk of infection, healing complications and mortality.

The health economic burden of diabetic foot ulcers is huge. In the UK, it is estimated that the cost of diabetic ulceration and amputation in 2014-15 was between £837 million and £962 million (Kerr et al, 2019). In the US, it was estimated that the cost of managing a diabetic foot ulcer ranges from US$993 to US$17,519 (1994–2000) and that of an amputations between US$16,488 and US$66,215 (1998 currency) (Raghav et al, 2018). The costs will be higher in countries with a higher incidence of ulceration.

Much focus in recent years has been on treatment, but clearly there is a need for emphasis on prevention, both of occurrence and complications. This involves raising awareness among non-diabetes specialists of the signs and symptoms of diabetic foot ulceration, with knowledge of when to refer to the multidisciplinary foot care team. Good initial management, followed by early referral to the right specialists can reduce the risk of complications and thus preventing patient morbidity and mortality, saving health service resources and avoiding devastating psychosocial effects for patients and their families.

There is a clear need for consistent guidance and a clinical framework for the assessment and management of the diabetic foot ulcer. In the UK, the National Wound Care Strategy Programme (NWCSP), a government-led initiative, is leading the way with its pathway on the care of the lower limb. However, we need to go further than national guidance, with a global approach that can reach countries where the incidence of diabetic foot ulceration is higher. JWC therefore proposes that the prevention and care of diabetic foot ulcers should be included in the WHO recommendations for strengthening and monitoring diabetes responses within national communicable disease programmes. This will help prevent considerable morbidity and mortality.

Kerr M, Barron E, Chadwick P et al. The cost of diabetic foot ulcers and amputations to National Health Service in England. Diabetes Med. 2019; 36(8): 995–1002
National Wound Care Strategy Programme. Lower Limb. Recommendations for lower limb ulcers. https://tinyurl.com/68ffax5s
Raghav A, Khan ZA, Labala RK et al. Financial burden of diabetic foot ulcers to world: a progressive topic to discuss always. Ther Adv Endocrinol Metab 2018; 9(1): 29-31
Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. Jama. 2005 Jan 12;293(2):217-28.

Attn: Bianca Hemmingsen
World Health Organization
Noncommunicable Disease Program

6th September 2021

Via email: hemmingsenb@who.int

Dear Dr Hemmingsen

Re: Draft diabetes targets – amendment of target to include 100% diagnosis of type 1 diabetes

Thank you for the opportunity to provide input and inform the World Health Organization's (WHO) current consultation process around the recommendations to strengthen and monitor diabetes responses within national noncommunicable disease programmes, including voluntary global diabetes coverage targets for 2030 (the Targets). We commend the WHO for undertaking this activity.

JDRF is the leading charitable supporter of type 1 diabetes (T1D) research and progress around the world. This letter is sent by the CEOs of JDRF International in the US, JDRF Canada, JDRF UK, JDRF Australia, JDRF Netherlands, and JDRF Israel. Our organizations and constituents are significantly invested in the outcomes of the WHO's diabetes-related activities, including the establishment of Targets.

We support 100% access to insulin and blood glucose self-monitoring

We are particularly pleased to note that the draft Targets explicitly include that 100% of people with T1D should have access to insulin and blood glucose self-monitoring and are strongly supportive of the retention of this Target unchanged. Recent estimates in a forthcoming paper on the Global Burden of Type 1 Diabetes Mellitus[1] attribute **nearly a third of the global burden of T1D to unstable access to insulin and lack of blood glucose monitoring equipment.** This target will encourage a significant shift in the baseline of care and management of T1D for low- and middle-income countries and will drive vital improvements.

We propose a goal of achieving 100% diagnosis of T1D

We have significant concerns, however, with the wording of the first Target, namely that "80% of people with diabetes are diagnosed". This would, in effect, endorse a 20% mortality rate at onset of T1D.

The number of deaths annually due to non-diagnosis of T1D globally is a significant and under-recognized problem. It occurs where there is a high prevalence of conditions with similar symptoms to T1D and low access to blood glucose testing facilities. Its consequence is typically death within 6-12 months of onset, particularly in children. The same study cited above includes a novel analysis estimating that, in 2021, more than one in ten incident cases of all T1D globally results in death without diagnosis. In some countries, this figure may be as high as 8 in 10. This mortality contributes **to a further one-third of the total disease burden of T1D, in terms of life years lost**. In those terms, non-diagnosis

[1] Ogle, Graham et al. Global Burden of Type 1 Diabetes Mellitus: a Modelling Study. Unpublished, 2021.

of T1D is a **more significant problem in its own right than lack of access to insulin**, and is equivalent in scale to the problems caused by lack of access to insulin and blood glucose self-monitoring combined.

Currently, most HICs have a close to 100% diagnosis rates for T1D. While non-diagnosis and mortality rates remain high in LICs, proven program models[2] have shown that it is possible to rapidly and cost-effectively improve diagnosis rates and reduce mortality. Something close to a 100% diagnosis rate for T1D, particularly in pediatric populations, is an attainable goal for all WHO member countries.

It may initially be challenging to measure and monitor progress towards reducing the number of deaths due to non-diagnosis each year, but this is not a sufficient reason to avoid setting a clear aspiration to save the lives of the millions of children that could otherwise be lost in the coming decades. Instead, we propose that the WHO recommend a three-point plan:

1. Expand systematic screening and testing for T1D in clinical settings, particularly pediatric settings (like the Mali model cited above) in more locations in more countries. This will both save lives and enable better quantification of historical rates of non-diagnosis (ie. if new cases per year in a given region are doubled through intervention, then it is reasonable to estimate that at least half of new cases were missed prior to intervention)
2. Regularly survey health care professionals and patients to estimate non-diagnosis rates in their region. The accuracy of this "wisdom of crowds" polling data can then be calibrated using the hard data collected in point one, like an election polling company that compares its polls against results on election day and becomes more accurate over time
3. In the meantime, proxies from well-functioning diagnostic systems could be used – such as DKA at onset – as an objective measure of diagnostic performance and as a further correlate for the hard data collected under point one

Greater attention to this challenge as enabled by a revised WHO Target would encourage investment in proven and cost-effective interventions that support and educate clinicians and equip them with blood glucose tests, dramatically reducing non-diagnosis and saving the lives of potentially millions of children over the coming decades.

Hence our collective suggestion is to revise the first draft WHO target as below:

From: **"80% of people with diabetes are diagnosed"**

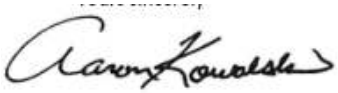
To: **"80% of people with type 2 diabetes and 100% of people with type 1 diabetes are diagnosed"**

JDRF looks forward to working with the WHO to progress these ambitious targets and help deliver the aims of the Global Diabetes Compact. We remain encouraged by the unprecedented scale and scope of this collaborative effort and are committed to ensuring better outcomes for all people living with T1D across the world.

2 Ogle et al. Rapid increases in observed incidence and prevalence of Type 1 diabetes in children and youth in Mali, 2007-2016. Pediatr Diabetes 2021 Jun;22(4):545-551. doi: 10.1111/pedi.13191. Epub 2021 Feb 22.

Please do not hesitate to contact Mike Wilson at mwilson@jdrf.org.au should you need more information or assistance.

Yours sincerely



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September 17, 2021

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Dear Dr. Hemmingsen,

Re: Life for a Child feedback – Draft recommendations to strengthen and monitor diabetes responses within national noncommunicable disease programmes, including potential targets

Life for a Child (www.lifeforachild.org) congratulates the World Health Organization for developing targets to strengthen and monitor diabetes responses within national noncommunicable disease programmes, including potential targets, for consideration by EB150 and WHA75. Indeed, Life for a Child has been particularly encouraged in 2021 to see the WHO working to ensure that all people who are diagnosed with diabetes have access to equitable, comprehensive, affordable and quality treatment and care. We believe this is particularly important for the millions of people living with Type 1 Diabetes in low-resourced settings.

Life for a Child understands that the bulk of people living with diabetes have Type 2 Diabetes and that most of the population living with both Type 1 and Type 2 Diabetes are adults. However, we note that the targets and supporting documents that the World Health Organization have established in their otherwise excellent **draft recommendations do not specifically mention** Type 1 Diabetes in children and youth, in whom Type 1 is a rapidly fatal disease if they cannot access to accurate and timely diagnoses, and then appropriate treatment and care. Type 1 Diabetes has peak onset in childhood and adolescence, and when these young people (and those diagnosed as adults) access the above-mentioned components of care, they can expect to live long, safe, healthy, and productive lives.

We therefore would like to raise three areas to be considered for integration within the draft recommendations referenced above:

1) Diagnosis of Type 1 Diabetes re: Target 1 - "80% of people with diabetes are diagnosed"

Life for a Child has been stating for some years[1] that we believe the most common global cause of death in Type 1 Diabetes is lack of diagnosis, with these deaths occurring in less-resourced countries. There are increasing data supporting this premise[1,2,3], and the background work that has gone into the soon-to-be-released first version of the T1D Index has greatly strengthened information in this area. The proposed target of 80% of people with diabetes being clinically diagnosed is adequate for Type 2 Diabetes, but not for Type 1 Diabetes, where the absence of a diagnosis means a quick death. The desirable target in Type 1 diabetes is 100%.

As this "known unknown" is difficult to measure until time has passed and incidence has risen with improved case recognition, it is not easy to ascribe a measurable target to this number. However, *a proxy target* could be the rate of Diabetes Ketoacidosis (DKA) at diagnosis. This rate of this fatal acute complication of Type 1 Diabetes is generally 20-30% in High-income countries, but this can be around 80% in some Lower-income countries[4]. Even in some high-income countries it is currently over 40%[5]. Life for a Child believes a target of <35% is reasonable, and if the World Health Organization and Working Group were interested in exploring a proxy target, we would be happy to discuss further and assist efforts. Life for a Child works closely with the International Society of Pediatric and Adolescent Diabetes (ISPAD) and they are also supportive of this approach.

We are also aware that JDRF is making a similar submission on this topic and has proposed methods of estimating the Type 1 Diabetes diagnosis rate, and endorse these suggestions should the WHO decide to explore them.

2) **Glycaemic Control re: Target 2 - "80% of people with diabetes have good control of glycaemia"**
   Life for a Child agrees with Draft recommendations target of 80% of people with diabetes have an HbA1c level of <8%. This is also a reasonable target for Type 1 diabetes. We note that the global target, as defined by ISPAD, is <7.0% for well-resourced settings and <7.5% for lower-resourced settings, but 80%+ <8.0% is still a reasonable global target (and not yet achieved in many high-income countries such as Australia and USA). Our concern is that the target is written "for total diagnosed diabetes". This would permit achieving of this target for the whole group (and it is easier in Type 2 given the wide variability in stage of disease), and therefore Type 1 could miss out. We therefore suggest that this target be stated for both Type 1 and Type 2 diabetes. Then individual countries, if they wished, could have tighter targets.

3) **Education re: Target 5 "100% of people with Type 1 diabetes have access to insulin and blood glucose self-monitoring"**
   Life for a Child is delighted to see that the draft recommendation targets include glucose monitoring supplies. Safe and efficacious use of both glucose monitoring supplies *and* insulin requires appropriate and encouraging diabetes education of the young person living with Type 1 Diabetes and their families. Life for a Child strongly believes that education and access to skilled health professionals (preferably in multidisciplinary teams) are just as critical as consumables, and without education of patients/families and health professionals they will die just as quickly, or go on to develop early and devastating complications. It is very difficult to define a measurable target for diabetes education, but we believe strongly that the importance of education needs to be mentioned in the Draft recommendations.

Thank you for considering our comments. I will be pleased to discuss them further if you wish.
Yours sincerely,

Dr Graham Ogle *on behalf of the Life for a Child Steering Committee*
Life for a Child
Diabetes NSW & ACT
26 Arundel St., Glebe 2037
Australia
grahamo@diabetesnsw.com.au

1. Ogle et al. The IDF Life for a Child Program Index of diabetes care for children and youth. Pediatr Diabetes 2016: 17: 374–384.
2. Marshall et al. Prevalence and incidence of clinically recognized cases of Type 1 diabetes in children and adolescents in Rwanda, Africa. Diabet Med. 2015;32:1186-1192.
3. Sandy, Besançon et al. Rapid increases in observed incidence and prevalence of Type 1 diabetes in children and youth in Mali, 2007–2016. Pediatric Diabetes 2021;2021:1-7.
4. Usher-Smith et al. Variation between countries in the frequency of diabetic ketoacidosis at first presentation of type 1 diabetes in children: a systematic review. Diabetologia. 2012;55:2878-2894.
5. Cherubini et al. Temporal trends in diabetic ketoacidosis at diagnosis of paediatric type 1 diabetes between 2006 and 2016: results from 13 countries in three continents. Diabetologia 2020 Aug;63:1530-1541.

Malaysian Society of Wound Care Professionals
(0624-11-WKL)
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53000, Kuala Lumpur.
Email : hari@mswcp.org
Website: www.mswcp.org

To Mr. Hemmings
World Health Organisation.

16th September 2021

Dear Mr. Hemmings,

WHO DIABETES STRATEGY 2030

With reference to the abovementioned I would like to suggest on behalf of the Malaysian Society of Wound Care Professionals that diabetic foot care/prevention of ulcers and amputations should be included as part of the WHO targets for core developmental metrics.

2. This can have a great impact for persons with diabetes over the next 5-10 years. End organ damage and complications such as diabetic foot complications have to addressed in this comprehensive strategy. We would be more than delighted to help you in any way possible as this is a huge problem. The incidence of diabetes mellitus in Malaysia is 20% of the population above the age of 18 years old and the amputation rates are alarming even in developed countries let alone the poor and middle income countries.

We hope your goodself will see the need to address these important points as save lives, save feet is crucial at this period and upt to 2030. Thank you for your support .

Thank you.

Yours sincerely,

(PROF. DR. HARIKRISHNA K. R. NAIR S.I.S KMN)
Chairman, Wounds Malaysia
President, Malaysia Society of Wound Care Professionals (MSWCP)

WOUND HEALING WITH PASSION

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MAX Healthcare

In India proper diabetic foot guidelines are lacking, at some places adapted guidelines are used for the diabetic foot assessment, prevention, management and treatment (Ministry Health and Family Welfare of India, 2016). There is also need of national and international protocols to improve patient outcome and prevent serious complications like gangrene or limb amputations. HCP's in India often fail to adequately assess patients and make appropriate or timely referrals because of the lack of awareness and skills. Thus, there is an urgency to implement foot care practice using current evidences to improve quality of life of the patients, their families and financial burden in the health service.

OUTCOMES

- ✓ A uniform diabetic foot care tool would make effective treatment and monitoring of patients easier
- ✓ Prevent delayed referral of patients 'at risk' of foot complications.
- ✓ As per International guidelines on the diabetic foot we need to pay far more attention on examination to identify high risk patients.
- ✓ Early prevention by use of appropriate pressure redistribution can help patients to prevent diabetic foot ulcers.
- ✓ It will encourage best practice using up-to-date evidences.
- ✓ Help in timely Identification of patients at low, medium and high risk of diabetic foot.
- ✓ Cost effective and economical treatments.
- ✓ Help to reduce recurrence rate of ulcers in diabetic patients.
- ✓ High level of patient satisfaction and improves adherence.
- ✓ Technical competency of foot care specialist.
- ✓ Reduction of cost in the local healthcare systems and ultimately national healthcare expenditure.
- ✓ In clinical settings the concept of limb salvage and quality care to the patients will add on to the services.
- ✓ Help to raise awareness among local diabetic population.
- ✓ Help to educate patients and others.

So, there is an need to include diabetic foot care / prevention of ulcers and amputation as a part of current targets for core development metrics. This can have a great impact for persons with diabetes over next 5 to 10 years.

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(CIN: U45400DL2008PTC176962)

MAX Healthcare

Dr Bharat Kotru
Podiatrist & Wound care specialist
Department of Podiatry & Advanced Wound Care (Max Hospital)
Feel Foot Advance Foot And wound Care Centre (Amandeep Hospital)
M.Sc Clinical Skin Integrity & Wound Management (Hertfordshire UK)
Faculty IIWCC (University of Toronto)
Faculty, Project TAAC, South Africa
Scientific & Clinical Advisor of Dr.Diafoot Care
International Scientific Panel (WUWHS 2022)
Excutive Board Member (Indian Podiatry Association)

Ministry Health and Family Welfare of India (2016) has adopted few guidelines from international consensus, yet proper diabetic foot screening is not consistently carried out in diabetic foot clinics despite existing evidence to support this practice. There is no defined preventive & referral pathway for patients at risk of foot complication in the foot clinics. To fulfil these challenges, there is a need on urgent bases of Diabetic foot care to prevent diabetic foot complications and amputations.

To obtain good outcomes for patients, DFU's requires a multidisciplinary team (MDT) approach (Vazdanpanati, 2015). Recent evidences show that the longer the delay before being seen by MDT, the worse the prognosis is for foot ulcers. Local patients often delay seeing doctor and ignore symptoms so late presentation (Strom, 2017).

I work with a team of endocrinologist, orthopaedic, vascular surgeon and general practitioners. We are increasingly seeing patients with DFU's in advance stages which is due to lack of awareness in the patients and health care practitioners (HCP). Patients come to us in an advanced stage of diabetic foot complication due to lack of early identification, prevention and management as there are no proper guidelines for diabetic foot management in India. Early risk assessment via the diabetic foot care pathway is crucial in minimising diabetic foot complications like gangrene and amputation. A pan-India survey on the burden of diabetes has shown that Chandigarh (13.6 %) is on course to becoming the country's diabetes capital, while Punjab (9.8 %) is a close second (Anjana et al., 2017). In Southern Punjab region, we see high prevalence of diabetic foot patients (Kotru, 2015).

In OPD clinic there is a lack of annual diabetic foot checks. Sometimes there is a failure to make timely prevention and referral to other professionals. There is need for all HCP's to treat patients early in that window of clinical presentation between the time a patient presents with neuropathy but before an ulcer develops. It is well recognised internationally that all active diabetic foot problems should be referred on urgent bases to the MDT.

Medecins Sans Frontieres (MSF) Response To WHO Global Diabetes Targets

15 Sept 2021

MSF welcomes the WHO initiative to set global targets for the diagnosis and management of diabetes, including goals for the control of hypertension in this population.

Global targets should drive action at national level, be translatable to the workforces implementing the actions and speak to those living with diabetes who advocate for improved access to care.

We would like to raise the following points for consideration:

Disaggregate indicators to reflect the cascade of care for type 1 diabetes. Although the 5th indicator, currently labelled medicine availability, singles out access to insulin and glucose test strips for type 1 diabetes, the indicators overall should be disaggregated to reflect the cascade of care for people living with type 1 diabetes.

Type 1 diabetes presents in a much younger population and with distinct symptoms. In many settings, awareness of these symptoms is poor amongst healthcare workers, leading to missed diagnoses, and fatal consequences. Specific investment is needed in the training of healthcare workers in the management of type 1 diabetes. Understanding each step of the cascade will be essential to drive funding, training and advocacy to ensure people with type 1 diabetes access the specific care they need. Without disaggregated indicators, type 1 diabetes will remain a neglected disease amongst the millions with type 2.

Reflect linkage to (access to) treatment. The 95-95-95 indicators for HIV reflect proportions of all people living with HIV who are aware of their status, those aware of status on treatment and those on treatment who are controlled. These steps are important for understanding the gaps at programme level.

The proposed indicators for diabetes communicate the proportion diagnosed and controlled, and indicator 5 singles out access to insulin for type 1 diabetes. We recommend another indicator that specifically reflects linkage to treatment for all people living with diabetes. Access to any form of treatment, be that oral hypoglycaemics or insulin, is not a given.

By only stating control rates, this does not communicate whether people have not accessed treatment, or they are accessing treatment but have not yet achieved control. This is a very important distinction to make for global advocacy on access to diabetes treatment both for oral medications and insulin.

Reflect the need for insulin in those living with type 2 diabetes. If there is to be a specific indicator reflecting access to insulin (although we suggest disaggregation and to replace

indicator 5 with the addition of a cascade step reflecting access to treatment) we suggest this reflects all those (type 1 and 2) in need of insulin and glucose monitoring devices.

Do not limit monitoring to the availability of glucose strips. Indicator "Medicines availability" currently includes glucose test strips. If kept it should be reworded to "availability of glucose monitoring". Newer devices for glucose monitoring are entering the market and may be used in innovative ways to achieve improved control. Specifying glucose strips in this indicator is too restrictive.

Consider removal of treated with statins as a separate target, for now. Before this is set as a global target, there should be further priority analysis at country level. The priority should be first to increase access to medications for glycaemic and blood pressure control. Inclusion of this target at this point, may deter from these primary goals.

Furthermore, WHO HEARTS-D package recommends statins as below. Therefore, the denominator of this indicator, if included, needs to reflect those with type 2 diabetes and the age consideration.

"Statins are recommended for all people with type 2 diabetes 40 years old or older, but only if this does not negatively impact access to glucose-lowering and blood pressure lowering medication."

Consistency of targets to drive change. Although each target has been benchmarked through analysis of the current coverage data, having this range of targets set for each indicator may confuse messaging. We would suggest aligning the targets for diagnosis, access to treatment, glycaemic and hypertension control.

NSWOCC

Nurses Specialized in Wound, Ostomy & Continence Canada

66 Leopolds Drive, Ottawa, Ontario, K1V 7E3

www.nswoc.ca • office@nswoc.ca

September 15, 2021

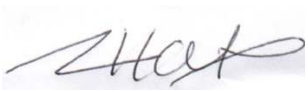
To whom it may concern,

Nurses Specialized in Wound, Ostomy and Continence Canada (NSWOCC), a national registered charity, is an association representing advanced practice nurses caring for individuals living with wound, ostomy and continence related issues. NSWOCs are advanced clinicians, researchers, managers and patient advocates. The NSWOCC would like to applaud the World Health Organization (WHO) for developing recommendations to strengthen and monitor diabetes, including exploring the prevalence of diabetes, estimates on glycaemic control, blood pressure control, management of hyperlipidemia and access to medications such as insulin. We do however, have concerns related to the omission of the prevention, assessment, and management of diabetic foot ulcers.

Diabetes-related complications include microvascular diseases (for example, retinopathy, blindness, nephropathy, and kidney failure) and macrovascular diseases (coronary heart disease, stroke, peripheral vascular disease, and lower-extremity amputation).[1] It has been well documented that diabetic foot ulcers are one of the most serious and costly complications of diabetes.[1],[2] In the Canadian population, individuals with diabetes have a 25% lifetime risk of developing a foot ulcer, with an annual incidence of 2%. While amputation is the most preventable complication of diabetic foot disease, it is preceded by foot ulceration in greater than 85% of major amputations. Foot complications can also be seen as indicators of other complications related to diabetes. [3] A 2015 project in Guyana, reported that through a collaborative approach to care and a directed effort to identify those at risk and implementation of a dedicated prevention plan, the prevalence of diabetic foot ulcers can be greatly decreased. [4]Supporting the concept that an interprofessional approach to DFU management is critical given the etiological complexity involved. [2]

Given the high prevalence and associated risk for lower leg amputation, the NSWOCC strongly encourages the WHO to include recommendations pertaining to a collaborative approach to the prevention, assessment, and management of diabetic foot ulcers. This action is essential to improving the outcomes of individual's suffering from diabetic ulcers and to reduce the risk of amputation.

With best regards,



Nevart Hotakorzian, RN, BScN, NSWOC - NSWOCC President

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[1] International Diabetes Federation. Clinical Practice Recommendation on the Diabetic Foot: A guide for health care professionals : International Diabetes Federation, 2017.

[2] Somayaji R, Elliott JA, Persaud R, Lim M, Goodman L, Sibbald RG (2017) The impact of team based Interprofessional comprehensive assessments on the diagnosis and management of diabetic foot ulcers: A retrospective cohort study. PLoS ONE 12(9): e0185251. https://doi.org/10.1371/journal.pone.0185251

[3] Hopkins RB, Burke N, Harlock J, Jegathisawaran J, Goeree R. Economic burden of illness associated with diabetic foot ulcers in Canada. BMC Health Serv Res. 2015 Jan 22;15:13. doi: 10.1186/s12913-015-0687-5. PMID: 25608648; PMCID: PMC4307900.

[4] Lowe J, Sibbald RG, Taha NY, Lebovic G,,Martin C, Bhoj I, et al. (2015) The Guyana Diabetes, and Foot Care Project: A Complex Quality improvement Intervention to Decrease Diabetes- Related Major Lower Extremity Amputations and Improve Diabetes Care in a Lower-Middle-Income Country. PLoS Med 12(4): e1001814. doi:10.1371/journal.pmed.1001814

Dear Committee Members,
I am writing on behalf of a collective of anthropologists working to understand what drives food, chronic illness, and particularly diabetes. I have listed our names as a collective below the seven concerns and/or considerations we have with the report.

We collective observe that:
1. Focusing on treatment alone overlooks how crucial upstream factors are for curbing diabetes.

2. Conceptualizations of prevention are incomplete without attention to complications that in many parts of the world have come to be normal ways of living with diabetes. In part this is because the technology considered essential to appropriately monitoring diabetes - glucometers - are not universally available. To focus on prevention at the expense of complications leaves a gap in knowledge as people may associate diabetes with diet and exercise, but not the variegated ways it shapes everyday experiences with sickness.

3. Ways of conceptualizing food, hunger, and eating (diets) are incomplete. The increasing prevalence of diabetes is largely caused by the structure and systemic political disregard for the lives of poor, Brown and Black people who make up a large majority of cases of diabetes worldwide. Recognizing the systemic barriers to "good food" and cultural dynamics that shape what people eat and why are crucial.

4. The crucial role of mental health and well being is completely overlooked in this report.

5. Rarely does diabetes, especially type 2, exist alone; diabetes becomes syndemic in many contexts because of its close connection to the HPA-axis and other pathways of inflammation. Recognizing how crucial mental health care is for diabetes care is fundamental for keeping people with insulin resistance healthy and well.

6. It is impossible to completely overlook politics when thinking about how to care for people with diabetes and curb the out-of-control epidemics around the world. Doing so emphasizes that diabetes is solely a medical or biological problem. Diabetes instead reflects much broader aspects of society--it emphasizes the complex dynamics of changing economies, cultures, foods, and relationships. Looking only at medical responses will continue to perpetuate poor health related to diabetes and other cardiometabolic problems of the heart, blood, and kidneys.

7. Tackling corporate responsibility in the food produced and marketed around the world is fundamentally a job of the World Health Organization. Without mentioning corporate responsibility and the failure of global food production to promote good health, the WHO fails to address a crucial tenet of global diabetes. Moreover, considering the innovative and important work on health taxes currently undergoing at the Alliance for Health Policy and Health Systems Research at the WHO, it is unconscionable that a report on diabetes would overlook this necessary step.

The Nutrire Collective includes: Diana Burnett; Megan A. Carney; Lauren Carruth; Sarah Chard; Maggie Dickinson: Diana Burnett, Megan A. Carney, Lauren Carruth, Sarah Chard, Maggie Dickinson, Alyshia Galvez, Hanna Garth, Jessica Hardin, Adele Hite, Heather Howard, Lenore Manderson, Emily Mendenhall, Abril Saldana-Tejeda, Dana Simmons, Natali Valdez, Emily Vasquez, Megan Warin, Emily Yates-Doerr

Dear Bianca,
On behalf of PATH and the Coalition for Access to NCD Medicines and Products, we wanted to thank you for the opportunity to review the draft recommendations and diabetes targets. Kindly see our consolidated feedback below.
After reviewing the feedback, please let us know of any questions.
Many thanks,
Molly

Feedback on Draft Diabetes Targets

- We would recommend the target 80% of people with diabetes are diagnosed be refined with an addition including "……**in advance of the onset of complications"**
- We were pleased to see the inclusion of specific targets relevant to treatment of the three factors leading to complications – glycemia, blood pressure and lipids
- We were pleased to see the inclusion of blood glucose monitoring along with insulin but we **recommend that you also include syringes**
- We would suggest an additional target be added to the list: "100% of primary health care facilities provide diagnosis, monitoring and treatment of glycaemia, blood pressure and lipids along with insulin and blood glucose monitoring for diabetes."
- We support the linkage to the other targets found in the; SDG 3.4, Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013-20202, the UN High-Level Meeting on Prevention and Control of Noncommunicable Diseases (2018)3 and health systems strengthening for social protection and universal health coverage, as set out in United Nations General Assembly resolution 72/81. but **recommend they also include reference to additional WHO documents and tools relevant to operationalizing and achieving the proposed targets** including the 2020 WHO PEN guideline at https://www.who.int/publications/i/item/who-package-of-essential-noncommunicable-(pen)-disease-interventions-for-primary-health-care and PEN flow sheets to provide guidance .

Feedback on Draft Recommendations

- We were pleased to see the reference to private sector responsibilities in point 5 C, (bullet 3), of the discussion paper: ''Invite the private sector to strengthen its commitment and contribution to the prevention and management of diabetes by participating in WHO prequalification programmes for insulin and self-monitoring devices, to register and publish their contributions, including through the reporting mechanism WHO will use to register and publish these contributions, and to participate in international pooled-procurement mechanisms for diabetes medicines (once established) led by the United Nations and other intergovernmental organizations, and international financing mechanisms.'' However, we would recommend that WHO make reference to the broader commitments ("31 Asks"), as the current wording limits the contributions to PQ and pooled procurement. We would also suggest that a line could be added after ''including through the reporting mechanism WHO will use to register and publish these contributions, and existing mechanisms to measure private sector action such as the Access to Medicine Index.''
- It would be useful to see concrete suggestions in the recommendations to member states within the "Strengthen capacity..." section, regarding how this should be done. Perhaps the approach might be to recommend research into the existing installed capacity and identify those approaches/instruments that could be developed to strengthen the capacity.
- We would recommend including supply chains under the research agenda.
- We were pleased to see the recommendation for international partners re "bundling" and would recommend that partners support member states in this collaborative effort rather than independently, as the recommendation seems to suggest.
- We would suggest including a recommendation for mobilizing resources needed in LMIC to carry out these recommendations.

- We applaud the inclusion of a multisectoral approach to achieving these targets particularly PLwD, governments, private sector entities, civil society, etc….as represented in the coalition for access…. And the Global Diabetes compact. We believe the success of moving towards stated targets is only possible contributions across all sectors.

Molly Guy
Senior Program Officer, Noncommunicable Diseases

PEDIATRIC ENDOCRINE SOCIETY

6728 Old McLean Village Drive • McLean • VA • 22101 • 703-556-9222 • www.pedsendo.org

Bianca Hemmingsen, MD, PhD
Medical Officer
Noncommunicable Disease Program
World Health Organization
Via email: hemmingsenb@who.int

16 September 2021

Re: Draft diabetes targets – amendment of target to specify 100% diagnosis of type 1 diabetes

Dear Dr. Hemmingsen,

We appreciate the opportunity to contribute feedback to the World Health Organization's (WHO) draft recommendations to strengthen and monitor diabetes responses within national noncommunicable disease programmes, including targets ((WHO Discussion Paper dated 9 August 2021).

The Pediatric Endocrine Society (PES) is the professional organization for this specialty in the United States and Canada with a mission to advance and promote the endocrine health and well-being of children and adolescents. PES has ongoing liaisons and partnerships with pediatric endocrinology organizations around the world.

We commend WHO's diabetes efforts as it is a disease with an increasing impact on health worldwide. We are particularly pleased to note that the draft targets explicitly state that 100% of people with type 1 diabetes should have access to insulin *and* blood glucose self-monitoring. We would support unchanged retention of this target in the strongest terms. In type 1 diabetes, insulin is lifesaving, and the ability to provide appropriate dosing requires blood glucose monitoring. This target will encourage a significant shift in the treatment and management of type 1 diabetes for low- and middle-income countries and will drive vital improvements in health outcomes.

We would, however, recommend a clarification of the first target that "80% of people with diabetes are diagnosed." We understand that in many settings, this is already a challenging goal. With respect to type 1, in which insulin is absolutely required for survival, a goal of 80% diagnosis targets the other 20% of people with type 1 diabetes for mortality. The rate of non-diagnosis, or 'death at onset,' for type 1 diabetes is a significant and under-recognized problem globally. An estimated **one in ten incident cases of type 1 diabetes globally result in death at onset*** (i.e. without diagnosis, or with misdiagnosis). This constitutes **approximately one-third of the total disease burden** of type 1 diabetes in terms of life years lost. Greater attention to this challenge as enabled by a revised WHO Target would encourage

investment in proven and successful interventions such as those by Life for a Child, Changing Diabetes in Children, Santé Diabète, Insulin for Life, Action for Diabetes and others, dramatically reducing non-diagnosis / death at onset.

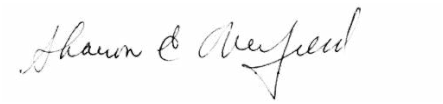
We therefore recommend a revision of the first target in the draft recommendations

From: **"80% of people with diabetes are diagnosed"**

To: **"80% of people with diabetes (and 100% of people with type 1 diabetes) are diagnosed"**

We at PES look forward to working with the WHO to advance these ambitious goals and deliver the aims of the Global Diabetes Compact. Please do not hesitate to contact Maureen Thompson at Maureen@degnon.org if we may be of further assistance.

Kindest regards,



Sharon Oberfield, MD

PES President

Reference:

*Ogle, Graham et al. Global Burden of Type 1 Diabetes Mellitus: a Modelling Study. Unpublished, 2021.

Prof Brian Kennon
Consultant Diabetologist
National Lead for Diabetes Scotland
Queen Elizabeth University Hospital
1345 Govan Road, Glasgow, UK
G51 4TF

16th Sept 2021

Attn: Bianca Hemmingsen
World Health Organization Noncommunicable Disease Program
Via email: hemmingsenb@who.int

Dear Ms Hemmingsen,

RE: Consultation on Draft diabetes targets

I am writing as national lead for diabetes in Scotland and chair of the Scottish Diabetes Group. I would firstly like to thank you for the opportunity to provide input into the World Health Organization's (WHO) current consultation process around the recommendations to strengthen and monitor diabetes responses within national noncommunicable disease programmes, including voluntary global diabetes coverage targets for 2030. I feel that this is a welcome development and helps support a lot of the work that is underway nationally and internationally to drive improvements in diabetes care and outcomes.

We are fortunate in Scotland to have a national population wide diabetes specific IT resource, in SCI-diabetes, that is fully integrated into other NHS systems. We have been using our data to develop a 'diabetes dashboard' and 'diabetes quality index scores' to drive improvement initiatives. As such the WHO focusing on diabetes targets will undoubtedly help support this work. This will also help complement the recent publication of our revised Diabetes Improvement Plan which outlines the Scottish Governments commitments to improve diabetes care and outcomes within Scotland (Diabetes care - Diabetes improvement plan: commitments - 2021 to 2026 - gov.scot (www.gov.scot).

In relation to the proposed WHO diabetes target "**80% of people with diabetes are diagnosed**" then I feel there would be merit in differentiating between type 1 and type 2 diabetes and would support the notion that the target for type 1 diabetes should be 100%. Recent evidence from Scotland has shown that deaths under the age of 50 can be partly related to avoidable diabetic ketoacidosis (DKA) and as such having a more stringent target for type 1 diabetes would seem appropriate (Time trends in deaths before age 50 years in people with type 1 diabetes: a nationwide analysis from Scotland 2004-2017 - PubMed (nih.gov). Again this would support many of the international efforts at DKA prevention both at diagnosis and for those with pre-existing type 1 diabetes.

I appreciate setting clear and concise worldwide targets is challenging but I wonder if the '**60% of people with diabetes receive statins'** should include either an age specific cut off i.e. >40 years old or use 10 year CV risk. In which case the % could be justifiably higher but it would ensure that younger people who are less likely to benefit, but may still be at risk of adverse events related to statin use, are not included in this target.

The Scottish Diabetes Group and the wider Scottish diabetes community welcome the WHO desire to drive improvements in the care and outcomes of individuals with diabetes and would be happy to support ongoing initiatives to help realise there targets. Please do not hesitate to contact me on brian.kennon@ggc.scot.nhs.uk should you wish ongoing involvement/support from the Scottish Diabetes Group.

Yours sincerely

Brian Kennon
National Lead for Diabetes, Scotland
Chair Scottish Diabetes Group

Re: WHO DRAFT RECOMMENDATIONS TO STRENGTHEN AND MONITOR DIABETES RESPONSES WITHIN NATIONAL NONCOMMUNICABLE DISEASE PROGRAMMES, INCLUDING POTENTIAL TARGETS

The WHO Draft Recommendations present clear and compelling data to support a strengthened, triaged response to improve diabetes diagnosis, care, and insulin and medication access worldwide. We appreciate your consideration of our comment, which was produced collaboratively by the T1International staff team and our advocacy volunteers around the world. We have included the names of those who have officially indicated their support beneath our comment, which is organized by section and presented below.

Overarching feedback:

- **DIABETES TYPE DELINEATION:** Overall, the background, metrics, and recommended targets would benefit by having type 1 diabetes broken out from other forms of diabetes, as the cause, treatments, and challenges of type 1 diabetes are often distinct from other types, even while they may be related.
- **PATIENTS AS EXPERTS:** While we acknowledge and appreciate the effort to include patient engagement, we see this not as satisfying the concept of 'inclusion,' but rather as satisfying a basic necessity of informed policy and, as such, suggest that it be its own recommended action. Patients are experts on diabetes, whose input is essential to achieving improvements in health outcomes.
- **EQUITY & INCLUSION:** An effort at inclusion must center those who have been historically excluded (for example individuals of racial and ethnic minorities in any given nation or region, poor people, LGBTQ+ people, people living with diabetes (PLWD) and other comorbidities, complications, and/or disabilities). Relatedly, meaningful patient engagement must include adequate financial compensation for these individuals who are offering their time, energy, and expertise.
    - Access for PLWD to healthcare should be culturally competent and consider community contexts to accommodate varying ethnic, religious, and regional practices.
    - Within many nations there are small pockets of cities, providences, and neighborhoods whose culture and social norms differ greatly from the nation as a whole. These areas are mostly occupied by historically excluded (marginalized) individuals. It is important to equip the healthcare institution within these areas with tools that will produce better management and prevention for these populations.
    - Education and services should be made available in indigenous languages.
    - Access to health care for PLWD should be decentralized, that is to say that hospitals, clinics, medical units, and healthcare professionals should be available not only in large cities or capitals, but also and especially in rural, marginalized areas.
- **QUALITY OF LIFE AND MENTAL HEALTH:** More specific acknowledgement and attention to quality of life metrics and the mental health toll of diabetes, both for patients and their caregivers/support systems, and the treatment approaches necessary to address patients' and their caregivers'/support systems' psychological needs, is warranted throughout.

  EDUCATION (add section):
    - Diabetes care should include prioritization of growing the workforce capacity to include sufficient health professionals who are trained and updated in diabetes care and follow-up.

- Diabetes Educators should be prioritized in health care teams treating people with diabetes as key agents in diabetes prevention, education, follow-up and feedback.
- Diabetes prevention and awareness should be included in school programs teaching daily healthy choices and actions that fit an overall healthy lifestyle.

Specific feedback:

1a. Provide background statistics that distinguish between type 1 and other forms of diabetes. While a unified prioritization of all forms of diabetes is warranted, understanding how lack of symptomatology awareness and delayed diagnosis differs for people with type 1 versus other forms of diabetes is essential. Since type 1 diabetes is typically more imminently deadly than other, non-insulin dependent forms of the condition, its distinct prioritization ensures the survival and health of those impacted.

1g. Clarify whether the statistic related to essential medicine availability in primary care facilities applies evenly to all forms of diabetes (i.e. whether essential medicines for the management of type 1 diabetes are also available in 80% of primary care facilities, or whether this information pertains mainly to essential medicines for type 2 diabetes and other non-autoimmune forms of the condition.

2h. This section needs an expanded definition of inclusiveness. Including PLWD in the decision-making process is a basic essential, but it does not satisfy the principle of inclusiveness. Inclusiveness speaks to actively seeking participation from individuals who have been historically excluded (individuals of racial and ethnic minorities in any given nation or region, individuals living in LMIC and humanitarian crises, individuals in rural or other underserved regions). Furthermore, inclusiveness means compensating these individuals, for whom devoting time and energy comes at a greater cost than it might for those with more resources, for their time and contributions.

- Suggest adding an item before this titled, "**'Centering Patient Input:' Patients are experts in diabetes and their input and feedback is essential to creating an informed strategy that will meaningfully improve the physical, mental, and emotional health of PLWD worldwide."** This would then be followed with the item speaking specifically to efforts to engage those who have been most marginalized within the patient population.
- Research investigation and proposal teams should always include PLWD as compensated members.

4a., In the metric, **"Strengthen national capacity, leadership, governance, multisectoral action and partnerships to accelerate country response for the prevention and control of diabetes..."** the word 'management,' rather than 'control,' will help clarify whether this is speaking to controlling the acceleration of diabetes in the population or controlling blood sugar itself. Furthermore, the word control can have negative connotations for the patient community, as it implies that achieving more stable and normalized blood glucose is attainable, when in reality that is rarely the case within the constraints of available diabetes treatment. 'Management' more accurately represents realistic goal-setting for PLWD, and this reframe is supportive to the emotional and mental health of this patient population.

4a., Addition to Bullet 2 - …"including but not limited to industry taking the lead on lowering list price to an affordable cost to governments."

4a., Bullet 3 - This recommendation would benefit by being broken out by type 1 and type 2 diabetes. To be meaningful, this bullet should indicate a minimum level of care related to the supplies (including type of insulin and number of test strips daily) that a health care system will ensure access to for people living with type 1 diabetes and others who are insulin dependent.

4b., Bullet 1, Add:

- "Concerted action should be taken by ministries of health and other health care bodies to oversee traditional medicine doctors who are delivering diabetes care and to limit the influence of uncertified traditional healers and practitioners." This will greatly reduce potentially dangerous myths around diabetes and its treatment.
- "Consider and address the mental and emotional burden on people with diabetes related to financial distress due to excessive pricing of insulin and other diabetes supplies, as well as complete lack of access. Additionally, consider and address, through health systems changes and lowered list prices by pharmaceutical companies, the distress this causes in regards to greater risks of complications due to substandard diabetes management."

4c., Add:

- Universal Health Coverage should include analogue insulins, glucometers, test strips, syringes or pen needles, oral medications, laboratories (HbA1c, lipid profile, urine exam, kidney exam, eyes exam, feet exam), subsidized diabetes technology, and diabetes education for PLWD and their support systems, as well as attention from nutrition and mental health professionals. All these should follow previously established guidelines that are defined for each type of diabetes.
- Ensure psychological treatment for PLWD, alongside proper and continuous diabetes education at diagnosis and beyond, in order to prevent and/or treat mental health complications related to daily diabetes management such as depression, distress, disordered eating, diabetes burnout and anxiety disorders.
- Strengthen health workforce and institutional capacity for early detection and management of diabetes, including provision of psychosocial support, promotion of self-care, and provision of palliative care and rehabilitation.
- Enforce proper education in type 1 diabetes symptoms and value of early diagnosis in order to prevent DKA and early death in this population.
- **Add to 4c., final bullet -** "Include PLWD in decision making processes on policies, strategies and implementation of diabetes prevention and control…" addition: "Include PLWD in decision making processes on policies, strategies and implementation of diabetes prevention and control **and compensate them appropriately."**

5a., Final bullet - This section does not speak directly to any recommendations or guidelines for industry partners. Consider adding: "Industry partners are asked to commit to reducing the list price of each form of insulin by at least 50% by the year 2030."

6a., Final bullet - "Scale-up meaningful engagement, **including adequate financial compensation,** of people with diabetes in the design, implementation and evaluation of programmes and services for diabetes."

6c., Final bullet - "Estimate the cost of achieving the global coverage targets."
Please clarify, is this cost based on production or based on manufacturer mark-up? Or both? Ideally, the cost of achieving these targets would be estimated and presented separately using both the cost of production for insulin and test strips, as well as list price. Additionally, it is important to define the cost of human vs. analogue insulin and for health care systems to strive to provide the best quality (analogue) insulins for patients worldwide.

SETTING DIABETES COVERAGE TARGETS
8., Bullet 1, suggesting: 80% of people are diagnosed with diabetes across all types; 100% of individuals with type 1 diabetes are diagnosed.

8., Bullet 2: Is 'good' defined by ADA/ISPAD guidelines of <7.0% HbA1c? If so, it would be helpful if this bullet delineated how evaluation of good management will be achieved (bi-annual HbA1c tests for all patients?). Otherwise, it would be good to specify that this is 80% of those who are able to have their glycemic control regularly evaluated.

- Here it would be appropriate to include a comprehensive definition of 'good diabetes control' that includes psychological measures of well-being and quality of life. For example: diabetes distress, experiences of stigma and acceptance, fear of hypoglycemia and long-term complications, and other measures of mental health impacts.

8., Bullet 5: It is admirable that the WHO has set its target for insulin access and blood glucose monitoring for people with type 1 diabetes at 100%. This target provides additional support for the need to set the target for diagnosis at 100% for those with type 1 diabetes. If the target for diagnosis of type 1 diabetes is not 100%, then it will be impossible to achieve access to insulin and blood glucose self-monitoring for 100% of this population, because up to 20% may be dying ahead of diagnosis.

13. These recommendations provide no meaningful asks for the private sector. We suggest:

- Full disclosure statements related to the pharmaceutical industry (such as the Tobacco and Arms declaration used for WHO meetings) to be used at all high-level meetings and partnerships.
- Pharmaceutical industry to provide fully transparent profit information related to insulin and other essential diabetes medications, including cost of production, list price and profit margin, and any other relevant information.

14. These recommendations should aim to include at least 50% patient representation (compensated) in all meetings, forums, committees, working groups, etc.

We welcome any of your questions and thank you again for your consideration.

Katherine J. Souris,
Global Advocacy Consultant
T1International

Elizabeth Pfiester,
Founder & Executive Director
T1International

Signed on behalf of the T1International team and its Advocacy Volunteers around the world, including:

1. Lejla Druskic, Bosnia and Herzegovina
2. Daniela Rojas Jiménez, Costa Rica
3. Liam Robertson, England
4. Adrianna Maciejczyk, France
5. Katarina Braune, Germany
6. Konstantina Taki, Greece
7. Pramita Jasuja, India
8. Mridula Kapil Bhargava, India
9. Qadeera rasti Baghban, India
10. Cyrine Farhat, Lebanon
11. Angélica Gabriela Luna Rodríguez Bueno, México/USA
12. Sobia Aziz Siddiqui, Pakistan
13. Pilar Gómez, Panamá
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*Consent to publish names and countries publicly was obtained for all.

THE DIABESTIES FOUNDATION

Attn: Bianca Hemmingsen
World Health Organization
Noncommunicable Disease Program

September 13th, 2021

Via email: hemmingsenb@who.int

Dear Dr. Hemmingsen,

Re: Draft diabetes targets – amendment of target to include 100% diagnosis of type 1 diabetes

At the onset, we would like to thank the WHO for taking Diabetes as a central focus point and work with organisations and governments across the globe to pay more attention to outcomes. We also want to thank you for the opportunity to provide our inputs for the work on global diabetes targets.

The Diabesties Foundation is a not-for-profit organisation in India working with a mission and vision to make those with Type 1 Diabetes feel heard, understood, supported and celebrated. In India, we face **unique challenges** that make living with Type 1 Diabetes, slightly more challenging. Right from **disturbing myths and taboos**, to **false promises** of cures, from **misdiagnosis** to lack of access to insulin - we have witnessed heartbreaking stories of people living with this condition. We **do not** have a 360 degree Type 1 Diabetes support system in our country, as our health sector is already overburdened - people with T1D often have to figure out the technicalities about their condition by themselves and failing to do so, sometimes results in unfavourable situations. We aim to bridge that gap with our list of projects and activities. Our projects are divided into three over arching banners: Advocacy and Access I Education I Support. They cater to every stakeholder in diabetes management: from health care professionals, people living with diabetes, caregivers and family members.

As an organisation working primarily in India on Type 1 Diabetes, we are keenly invested in the T1D focused targets in the upcoming document.

We are pleased to note that the draft Targets explicitly include that 100% of people with Type 1 Diabetes should have access to insulin and blood glucose self-monitoring. Recent estimates including those in a soon-to-be-published paper on the Global Burden of Type 1 Diabetes Mellitus place nearly a third of the global burden of type 1 diabetes on unstable access to insulin and lack of blood glucose monitoring equipment. **In India, the situation is grim to the extent that there is no data to project exact number of T1D cases in the country owing to lack of blood glucose monitoring. The 100% target will encourage a significant shift in the baseline of treatment and management of type 1 diabetes for low- and middle-income countries and will drive vital improvements across care and management.**

Our concerns as a patient-driven organization pertain to the wording of the first Target, namely that “80% of people with diabetes are diagnosed”. This would, in effect, endorse a 20% mortality rate for death at onset in Type 1 Diabetes, which is the consequence of non-diagnosis and also lifetime disability which results from delayed diagnosis of T1D (loss of limb, dwarfism, cognitive disabilities, loss of or impaired vision etc). The additional expenses of a disability resulting from delayed diagnosis of T1D would impose a financial burden on the patient as well as healthcare systems.

Our collective suggestion is to revise the first draft WHO target as below:

From: "80% of people with diabetes are diagnosed”

To: “80% of people with type 2 diabetes and 100% of people with type 1 diabetes are diagnosed”

307, Next to Riverside School, Near ARMY CSD Depot
Airport Road, Ahmedabad 380004
+91 9726322017
foundation@d1abesties.com

THE DIABESTIES FOUNDATION

The Diabesties Foundation looks forward to working with the WHO in any capacity to further care for those living with Type 1 Diabetes in India and around the world.

Thanking you in anticipation,

Jazz Sethi

Founder / Director

The Diabesties Foundation

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foundation@d1abesties.com

THE diaTribe FOUNDATION

Attn: Bianca Hemmingsen
World Health Organization
Noncommunicable Disease Program

September 13, 2021

Via email: hemmingsenb@who.int

Dear Dr. Hemmingsen,

Thank you for the opportunity to provide input to the World Health Organization's (WHO) consultation process regarding recommendations to strengthen diabetes responses within national noncommunicable disease programs, including voluntary global diabetes coverage targets for 2030 (the "Targets"). We commend the WHO for undertaking this activity.

The diaTribe Foundation is a leading supporter of diabetes education and progress. Our organization and constituents are significantly invested in the outcomes of the WHO's diabetes-related activities, including the establishment of the Targets.

We wish to bring to your attention our significant concerns with the wording of the first Target, namely that "80% of people with diabetes are diagnosed." This would, in effect, endorse a 20% mortality rate for death at onset in type 1 diabetes, which is the consequence of non-diagnosis.

The rate of non-diagnosis / 'death at onset' for type 1 diabetes globally is a significant and under-recognized problem. Research suggests that one in ten incident cases of all type 1 diabetes globally result in death at onset (i.e. without diagnosis, or with misdiagnosis).

A revised WHO Target would encourage investment in proven and successful interventions such as those by Life for a Child, Changing Diabetes in Children, Santé Diabète, Insulin for Life, Action for Diabetes and others, all of which dramatically reduce non-diagnosis / death at onset.

Our suggestion is to revise the first draft WHO Target as below:

From: **"80% of people with diabetes are diagnosed"**

To: **"80% of people with type 2 diabetes and 100% of people with type 1 diabetes are diagnosed"**

The diaTribe Foundation looks forward to working to deliver the aims of the Global Diabetes Compact. Please do not hesitate to contact me at jim.carroll@diatribe.org should you need more information or assistance.

Very truly yours,

Jim Carroll
CEO, The diaTribe Foundation

World Council of Enterostomal Therapists® (WCET®)

(Registered Charity 1057749) www.wcetn.org

A world of expert professional nursing care for people with ostomy, wound or continence needs. ™

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14 September 2021

Dear World Health Organization:

The World Council of Enterostomal Therapists® (WCET®) is a professional association of nurses in over 65 countries who care for patients with ostomy, wounds, or continence care needs. We are writing in response to the WHO recommendations for improving health outcomes of people with Diabetes mellitus; Target setting to reduce the Global Burden of Diabetes Mellitus by 2030.

WCET® urges WHO to include foot care, prevention and treatment of foot ulcers and prevention of lower limb amputations as an essential target component. Previous studies have documented the 5-year mortality rate for persons with DM who had a non-traumatic lower limb amputation. Fifty percent were dead in five years which is worst then the five-year survival rate for breast or prostate cancer. (Armstrong 2007) Early identification of DM foot complications including Charcot Foot has long supported international initiatives to address the importance of the insulin being affordable for all persons so that avoidable deaths from the complications of diabetes mellitus can be mitigated. During our 2016 biennial Congress in Cape Town South Africa, the WCET® supported the Cape Town Declarations including saving lives and saving limbs.

As a multicultural association, WCET® has published important evidence in our peer reviewed professional CINHAL indexed journal which is currently published in five languages, English, Chinese, French, Portuguese and Spanish. Relevant articles include teaching how persons in resource limited countries can use fishing line to make monofilaments to assess for diabetic neuropathy (Ayello 2012)) as well as teaching the use of a 60 second screening tool (Ostrow, 2010) in conjunction with an interprofessional specially trained team can reduce amputations by 68% and save health care system costs.

It is our hope that WHO will include diabetic foot care including prevention of ulcers and amputations as part of your targets for core developmental metrics for diabetes. Please let us know how WCET® can assist.

Sincerely,

WCET® President 2020-2022 **WCET® President Elect 2020-2022**

Armstrong DG, Wrobel J, Robbins JM. Guest editorial: Are diabetes-related wounds and amputations worse than cancer? Int Wound J2007; 4:286-7.

Ostrow B, Woo KY, Sibbald RG. The Guyana diabetic foot project: reducing amputations and improving diabetes care. in Guyana. WCET Journal. 2010;30 (4):28–32.

Ayello EA, Sibbald RG, Ostrow B, Smart H. Teaching healthcare professionals in resource challenged countries to construct monofilaments for the purpose of diabetic foot screening. © WCET. 2012; 32(4):14-32.

Saving Diabetic Feet in Africa:
Cape Town Declaration of Action 2016

International Interprofessional Wound Care Course (IIWCC)

Saving Limbs Saves Lives

Diabetes is the major cause for lower limb amputations in the world. Africa has the highest percentage of undiagnosed diabetes worldwide. Persons with diabetes in Africa also have the lowest chance of high risk diabetic foot screening. Undetected diabetic foot complications, including preventable loss of limbs and lives[2], are due to the lack of gold standard care.

We, the combined voices of WoundPedia, International Interprofessional Wound Care Course, World Council of Enterostomal Therapists, the Pan-African Diabetic Foot Study Group, Santé Diabète, T1International[3], Wound Healing Association of Southern Africa, and the International Interprofessional Wound Care Group gathered together in Cape Town, South Africa, call for the implementation of evidence informed interprofessional diabetic foot care.

We endorse and recommend the 5 S's and VIPS of diabetic foot care for all of Africa. This is an extraordinary challenge and achievable goal with millions of lives at stake.

We call for all to endorse this declaration.

Prevention

Systemic blood glucose control
Screening for undiagnosed diabetes must be increased. Insulin must be provided for all (#insulin4all) who need it. Ministries of Health must prioritize diabetes care.

Screening for the high risk foot
Education and application of foot screens e.g. Simplified 60 Second Screening Tool

Smoking cessation

Shoes and socks
Foot wear and pressure offloading devices must be made available to people with high risk feet so ulcers are prevented

Skin temperature
Monitoring skin temperature should be available at diabetes centers to facilitate early deep inflammation and infection

Treatment

Vascular supply
For quick assessment of adequate blood supply to heal assess foot pulses

Infection
Early diagnoses and treatment of surface critical colonization (treat topically) or deep and surrounding infection (treat systemically)

Plantar pressure redistribution
Plantar pressure redistribution devices (e.g. deep toed shoes and orthotics) are required with loss of protective sensation. Callus indicates pressure, blisters indicate friction and/or shear Regular callus removal is needed for healing

Sharp or surgical debridement
On a regular basis when needed to accelerate healing provided there is adequate blood supply to heal and the cause has been corrected

1 International Diabetes Federation, World Diabetes Atlas, 7th Ed. 2015. www.diabetesatlas.org

2 Abbas ZG, Archibald LK. Challenges for management of the diabetic foot in Africa: doing more with less. Int Wound J. 2007

3 T1International. #Insulin4all. www.t1international.com

4 Woodbury MG, Sibbald RG, Ostrow B, Persaud R, Lowe JM. Tool for Rapid & Easy Identification of High Risk Diabetic Foot: Validation & Clinical Pilot of the Simplified 60 Second Diabetic Foot Screening Tool. PLoS One.

Insulin Access for Africa:
Cape Town Declaration of Action 2016

#insulin4all

People with diabetes are dying in Africa because they cannot afford or access insulin. This is despite nearly 100 years having passed since the discovery of insulin by University of Toronto researchers, who all wished for universal access.[1] Most Africans also do not have the medical supplies, education and monitoring needed to use this life saving medication.

One in two people who need insulin cannot afford it.[2] Over the next decade, many of the over 22 million Africans living with diabetes today will die predictable and avoidable deaths without insulin treatment. [3]

We, the combined voices of WoundPedia, International Interprofessional Wound Care Course, World Council of Enterostomal Therapists, the Pan-African Diabetic Foot Study Group, Santé Diabète, T1International, Wound Healing Association of Southern Africa, and the International Interprofessional Wound Care Group gathered together in Cape Town, South Africa and resolved that we cannot accept that diabetes has now surpassed malaria, tuberculous and HIV/AIDS as a leading cause of adult death in Africa.[4]

We want everyone with diabetes in Africa to have access to affordable insulin and injection devices.

We demand #insulin4all. [5]

We call for the World Health Organisation to announce a goal of universal access to insulin treatment. We launch this plea in the same spirit as the 2002 Cape Town Declaration of Action for HIV/AIDS access that has saved millions of lives.[6] Our task force and international allies will hold governments, international agencies, donors, the pharmaceutical industry and the private sector accountable for universal access to insulin in Africa.

This is an immense challenge with millions of lives at stake. This is an achievable goal. We call for everyone to endorse this declaration.

1 Rosenfeld L. Insulin: discovery and controversy. Clin Chem. 2002. www.clinchem.org/content/48/12/2270.full

2 Beran D, Ewen M, Laing R. Constraints and challenges in access to insulin: a global perspective. Lancet Diabetes Endocrinol. 2016;4(3):275-85.

3 International Diabetes Federation, World Diabetes Atlas, 7th Ed. 2015. www.diabetesatlas.org

4 Besançon S, Doré. M, Salignon .P In Africa, diabetes and cardiovascular diseases kill more than AIDS. Time to take action. 2016. Ideas for development the official blog of the French Development Agency. http://ideas4development.org/en/in-africa-diabetes-and-cardiovascular-diseases-kill-more-than-aids-time-to-take-action/

5 T1International. #Insulin4all. www.t1international.com

6 Treatment Action Collation. Pan-Africa HIV/AIDS Treatment Access Movement: Declaration of Action. 2002. www.tac.org.za/community/node/2480

WORLD DIABETES FOUNDATION

Krogshøjvej 30
2880 Bagsværd
Denmark
www.worlddiabetesfoundation.org

World Health Organization
Av. Appia 20
1211 Geneva
Switzerland

Att.
Division for UHC/Communicable and Noncommunicable Diseases

September 2021

Recommendations to strengthen and monitor diabetes responses within national non-communicable disease programmes, including voluntary global diabetes coverage targets for 2030 – feedback from World Diabetes Foundation as part of web based consultation

_____

With reference to World Health Assembly resolution WHA74.4. and to WHO Discussion Paper of 9 August 2021 and the technical background paper.

World Diabetes Foundation (WDF) is grateful for the opportunity to take part in the web based consultation undertaken by the WHO as part of the process to develop recommendations to strengthen and monitor diabetes responses within national noncommunicable disease programmes, including potential targets, for consideration by EB150 and WHA75, and hence for the opportunity to submit feedback to the Discussion Paper.

WDF wishes to provide feedback as follows:

1. WDF as philanthropic foundation has supported diabetes responses in low- and middle income countries (LMICs) for the past 20 years and since the 2011 First UN High-level Meeting on NCD Prevention and Control and the launch of the WHO Global Action Plan for the Prevention and Control of NCDs in 2013 WDF's support has increasingly been part of and contributed to the implementation of national NCD programmes as operated by ministries of health and other key stakeholders.

2. While some progress has been achieved over the past decade, including the fact that 85% of countries report having staff dedicated to diabetes in their Ministry of Health NCD unit/branch/department as stated in the Discussion Paper, and that 73% of countries report having an action plan on diabetes, the response to the diabetes burden and as part of integrated health care services remains insufficient when it comes to actual implementation and provision of diabetes screening, diagnosis and treatment at nationwide scale, in particular in LMICs and in particular at primary health care level.

3. While as the Discussion Paper states opportunities do exist to facilitate solutions to the challenge posed by the rising burden of diabetes, viable implementation across LMICs of these solutions will not be possible without considerable resource mobilisation from various sources and through differentiated mechanisms, some known and others still to be developed.

4. WDF commends and supports the recommendation outlined to set voluntary global targets for diabetes coverage, to be achieved by 2030, an aspiration substantiated by the launch of the Global Diabetes Compact which catalyses integration and convergence as mandatory principles, principles more important than ever in the decade of action towards universal health coverage.

5. Accordingly, in LMIC contexts integration should mean the advancement of integrated health care services whereby diabetes and other NCDs become institutionalised at all levels of care with particular focus at primary level, and whereby convergence should mean the persistent and progressive alignment of domestic resource allocation into a balanced health system reform, and, the obligation of commitment from the international health and development community towards such balanced health system reform.

6. In this perspective, the set of recommended actions for Member States, International Partners, and the WHO, as outlined in the Discussion Paper -although perhaps not new in content- brings forward instrumental guidance and clarity in terms of stratification and the derived opportunity to focus.

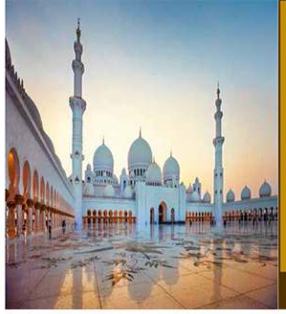
7. More precisely, the Discussion Paper articulates the financing imperative whereby Member States are recommended to 'provide sufficient national budgetary allocation for diabetes prevention and control, and identify financing mechanisms to reduce out-of-pocket expenditure', and whereby International Partners are recommended to 'align international cooperation on diabetes with national plans concerning non-communicable diseases in order to strengthen aid effectiveness and the development impact of external resources in support of diabetes [prevention and control]', and, whereby the WHO is recommended to 'convene and lead partners through the Global Diabetes Compact to raise awareness, create synergies for action, and harness collective capacity of global, regional and national actors working to improved diabetes prevention and control'.

8. WDF commits firmly to such configuration of the financing agenda as connected to prevention and control of diabetes and other NCDs and hence observes that the advancement of such agenda and derived action at global, regional and national levels is a prerequisite to any meaningful endorsement of global voluntary diabetes coverage targets and the translation or adaptation of such targets by Member States.

9. Concretely, WDF commits to a continued support towards the Global Diabetes Compact and to scale up investments into diabetes responses in LMIC contexts as unfolding within national non-communicable disease programmes, in order to support countries achieve diabetes treatment targets, and appeals to the WHO for the accelerated engagement of stakeholders and with particular emphasis to the areas related to resource mobilisation in its broadest interpretation, and hence, to the overall convergence of efforts across the global health and development community in order to spearhead the SDG3 ideal and the progress towards universal health coverage.

10. Furthermore, WDF adheres to the recommended actions for International Partners as detailed in the Discussion Paper with particular emphasis on the visibility of diabetes in the global health and development agenda, on the critical role of civil society, and, on the recommendation to support and scale up implementation of digital health solutions and to invest in information systems that link various sources of information on diabetes management and outcomes.

_____



September 16, 2021

Dear Sir,

It is with great appreciation that I, in my capacity as President of the **World Union of Wound Healing Societies (WUWHS),** take the opportunity to write you this letter with regards to the 2030 Diabetes strategy envisioned by the World Health Organization (WHO).

WUWHS is a global organization that is focused on improving patient care for those with wounds, or at risk of developing wounds. We encourage global cooperation in wound healing clinical practice, education, research, and delivery of wound care and have more than 50 wound care societies across the world as part of this endeavor. WUWHS also represents more than 90% of all practicing wound care specialists in the world.

The prevalence of diabetes for all age-groups worldwide was predicted to be 2.8% in 2000 and is estimated to reach 4.4% in 2030. The total number of people with diabetes is anticipated to rise from 171 million as it was in 2000, to at least 366 million by 2030.[1] This data provides a serious quantification of the rising public global health burden that diabetes is posing for the future.

To reduce end-organ damage as a result of Diabetes, the 2030 strategy as planned by WHO, is very much a step in the right direction. Often, when a foot problem or ulcer is diagnosed, it is associated with previously undiagnosed diabetes or presence of undisclosed sensory neuroathy.[2] Due to the distal nature thereof, the foot of the person with Diabetes is at high risk for breakdown either due to vascular supply insufficiency, infection risk, pressure from ill-fitting shoes, sensory neuropathy, or various combinations of these[3]. WUWHS therefore strongly advocate for the inclusion of a focused diabetic foot protection and management strategy to be part of the 2030 initiatives.

WUWHS strongly recommended the following:

- Adaptation of the 60 second diabetic foot screening tool[4] to be used as risk assessment for people with diabetes. This will help in the finding at risk feet in time;
- Easy access to educational tools with regards to control of diabetes, diabetic foot self-care strategies and prevention of foot complications by early intervention;
- Integrated treatment protocols that can be adapted to different care settings to treat and manage diabetes related foot complications that include ulcerations (neuropathic, ischemic, neuro-ischemic), bone deficiencies and distal limb losses;
- Strategies and plans to optimize high risk foot off-loading interventions.

Not only will this be a comprehensive pro-active approach to find those persons with a foot at risk for breakdown earlier, but will subsequently help management to limit foot, ankle, and lower limb losses as a result of irreversible tissue and bone damage.

Thank you for your attention to our letter to include the “Diabetic foot” as an additional item in the development of the WHO 2030 Diabetes strategy.

Kind Regards

Mrs. Gulnaz Tariq

President WUWHS

References:

1. International Diabetes Federation. Clinical Practice Recommendation on the Diabetic Foot: A guide for health care professionals: International Diabetes Federation, 2017.

2. Gavan NA, Veresiu IA, Vinik EJ, Vinik AI, Florea B, Bondor CI. Delay between Onset of Symptoms and Seeking Physician Intervention Increases Risk of Diabetic Foot Complications: Results of a Cross-Sectional Population-Based Survey. *J Diabetes Res.* 2016; 2016:1567405.

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Wound Healing Association of Southern Africa

13 September 2021

To: The World Health Organization

RE: Global Diabetes Strategy and the inclusion of Diabetic foot Surveillance as a target for core development metrics

We as the Wound Healing Association of Southern Africa (WHASA) would like to solicit our support for the inclusion of **Diabetic Foot Surveillance as a target for core development metrics.**

South Africa faces an epidemic of chronic non-communicable diseases (NCDs), yet national surveillance is limited due to the lack of data. Data from the South African National Health and Nutrition Examination Survey done in 2017 revealed that among individuals with diabetes in South Africa, a total of 45.4% were unscreened, 14.7% were screened but undiagnosed, 2.3% were diagnosed but untreated, 18.1% were treated but uncontrolled, and 19.4% were treated and controlled, suggesting that 80.6% of the diabetic population had an unmet need for care. Combining this data with the fact that at least 25% of people with diabetes will develop a foot ulcer which accounts for 20% of hospital admissions and about 60% of amputations the inclusion of foot surveillance as a target for diabetic care is vital (Stokes et al., 2017; Mutyambizi et al., 2019).

The single biggest risk factor for foot damage is neuropathy which affects up to 50% of Diabetics. Regular check-ups and improved surveillance could reduce the risk of complications such as amputations and mortality as well as improve quality of life (Armstrong et al., 2016).

We advocate interdisciplinary care, frequent check-ups by skilled clinicians every 3-6 months with improved patient and care giver education on daily foot care. If the foot of persons with Diabetes can be an active component in the WHO 2030 strategy, it will enable national involvement in various countries in our Southern African region. That addition from WHO has the potential to lead to national level expansions in diabetic foot prevalence, incidence, and outcome evidence generation, while simultaneously protecting limbs.

Yours in service

Febe Bruwer
President of the Wound Healing Association of Southern Africa

Febebruwer@gmail.com
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16th September, 2021

To: World Health Organization

RE: Advocating for Diabetic Foot Prevention and Management to be included in WHO Global Diabetes Targets to 2030

WoundPedia is a not for profit established after the World Union of Wound Healing Societies meeting in Toronto in 2008. This meeting was chaired by Professor Gary Sibbald and Co Chaired by 2 nurses - Dr. Elizabeth E. Ayello from New York and Heather Orsted from Western Canada. WoundPedia is the host of the International Interprofessional Wound Care Course established in 1999 and accredited by the University of Toronto to train key opinion leaders in Wound Care including prevention and management of diabetic foot ulcers. There have been over 40 courses (8-12 months each) around the world. The course is conducted annually in Canada and elsewhere in the world including Iran, Saudi Arabia, South Africa (5 courses with Stellenbosch University), and The United States (New York University). We have trained over 2,000 key opinion leaders around the world including over 100 from over 12 countries in Africa and almost 500 with 9 batches from West Asia coordinated by nurse Gulnaz Tariq the current president and meeting Chair of the World Union of Wound Healing Societies. Nurses Hiske Smart is the African Course Coordinator, Laurie Goodman the Toronto based Course Coordinator for Canada and Dr. Elizabeth E. Ayello president of World Council of Enterostomal Therapists the US Course Coordinator and international liaison.
WoundPedia has also provided international outreach:

- Guyana South America - to assist Dr. Brian Ostrow with development of a simplified 60 second screening tool that was also validated along with a 68% reduction in lower limb amputations with skills training, 15 IIWCC graduates and an interprofessional team center of excellence for diabetic foot care
- Abu Dhabi - a hub for wound care excellence through the IIWCC course that currently has 118 students, link nurses with the wound care team under Gulnaz Tariq and a venue for the World Union of Wound Healing Societies meeting March 1-5, 2022
- Diabetic Foot Ulcer Clinic in Ethiopia at Black Lion Hospital under the direction of Dr. Helen Yifter (Endocrinologist)
- WoundPedia Manilla, Basic and Intermediate courses in Manila, Philippines was founded in 2013 by nurse Dr. Elizabeth E. Ayello (Course Co-Director), now resulting in an agreement between the University of the Philippines, Philippines Air Force and WoundPedia, with recent logistical coordination by nurse Paula Aromin (Philippines Air Force) since 2019

To enhance chronic wound care expertise even further, WoundPedia has an agreement with the Ontario Canada, Ministry of Health to pioneer virtual situational learning with a project ECHO (Extension for Community Healthcare Outcomes) by modelling interprofessional care and skills virtually for improved diabetic foot ulcer prevention and management to prevent lower limb amputations among other chronic wound complex problems.

Diabetic foot ulcers are the most common and costly complication for persons with diabetes. The Narayan principles for diabetes management have labelled screening for the high-risk foot as a mechanism to both be able to improve patient outcomes and is cost saving to the healthcare system,

along with HbA1c that is currently one of your targets. The foot screening rates in Western Countries is approximately 50-75% and an obtainable target would be 80-90%.
In addition, 85% of amputations start with a foot ulcer and 80% of diabetic lower leg amputations start with a foot ulcer. In addition, 80% of the lower leg amputations in persons with diabetes are preventable. Realistically if we could cut this number in half and prevent 50% of the current number, we may have an attainable goal for 2030.
The rest of this submission includes a chart of key literature, a summary of the current state of diabetic foot ulcer concerns and some recommendations. We look forward to future collaboration and improvement of the lives of persons with diabetes.

Facts from Key Literature: From: Zhang Y, Lazzarini PA, McPhail SM, van Netten JJ, Armstrong DG and Pacella, RE. Global Disability Burdens of Diabetes-Related Lower-Extremity complications in 1990 and 2016. Diabetes Care. 2020; 43:964-74. (And other references listed below)

DRLEC = Diabetes Related Lower Extremity Complication
PWD = People with Diabetes
DF = Diabetic Foot

451 million had diabetes in 2017 (1 in 11 adults)	Cho NH, Shaw JE, Karuranga S, et al. IDF Diabetes Atlas: global estimates of diabetes prevalence for 2017 and projections for 2045. Diabetes Res Clin Practice 2018; 138:271-81.
693 million will have diabetes by 2045 (1 in 10 adults)	"
PWD are at high risk of developing complications (cardiovascular, kidney, eye & lower extremity complications)	Harding JL, Pavkov ME, Magliano DJ, Shaw JE, Gregg EW. Global trends in diabetes complications: a review of current evidence. Diabetologia 2019; 62:3-16. Gregg EW, Sattar N, Ali MK. The changing face of diabetes complications. Lancet Diabetes Endocrinol. 2016; 4:537-47
Most disabling lower-extremity (LE) complications are: Peripheral neuropathy, foot ulceration & amputation.	Boulton AJ, Vieikyte L, Ragnarson-Tennvall G, Apelqvist J. The global burden of diabetic foot disease. Lancet. 2005; 366:1719-24. Armstrong DG, Bouton AJM, Bus SA. Diabetic foot ulcers and their recurrence. N Engl J Med. 2017; 376:2367-75.
The first DRLEC is neuropathy.	
It is estimated that 50% of PWD have neuropathy.	Pop-Busui R, Boulton AJ, Feldman EL, et al. Diabetic neuropathy: a position statement by the American Diabetes Association. Diabetes Care 2017; 40:136-54. Lavery LA, Armstrong DG, Wunderlich RP, Tredwell J, Boulton AJ. Diabetic foot syndrome: evaluating the prevalence and incidence of foot pathology in Mexican Americans and non-Hispanic whites from a diabetes disease management cohort. Diabetes Care 2003; 26:1435-38.

Up to 34% will develop a foot ulcer in their lifetime	Armstrong DG, Bouton AJM, Bus SA. Diabetic foot ulcers and their recurrence. N Engl J Med. 2017; 376:2367-75.
Around 50% of the foot ulcers will become infected	Lavery LA, Armstrong DG, Wunderlich RP, Mohler MJ, Wendel CS, Lipsky BA. Risk Factors for foot infections in individuals with diabetes. Diabetes Care 2006;29:1288-93. Holman N, Young B, Stephens H, Jeffcoate W. Members of the National Foot Care Audit Steering Group. Pilot study to assess measures to be used in the prospective audit of the management f foot ulcer in people with diabetes. Diabeti Med 2015; 32:78-84. Pickwell K, Siersma V, Kars M, et al. Predictors of lower-extremity amputation in patients with an infected diabetic foot ulcer. Diabetes Care 2015; 38:852-57.
DRLECs account for up to 80% of global lower-extremity amputations	Akrepnek GH, Mills JL Sr. Lavery LA, Armstrong DG. Health care service and outcomes among an estimated 6.7 million ambulatory care diabetic foot cases in the US Diabetes Care. 207; 40:936-42 Lazzarini PA, Hurn SE, Kuys SS, et al. The siltent overall burden of foot disease in a representative hospitalized population. Int Wound J. 2017; 14:716-728. Kerr M, Barron E, ChadwiskP, et al. The cost of diabetic foot ulcers and amputations to the National Health Service in England. Diabet Med. 2019; 36:995-1002.
DRLEC result in significant quality of life and cause considerable global disability burden	Boulton AJ, Vieikyte L, Ragnarson-Tennvall G, Apelqvist J. The global burden of diabetic foot disease. Lancet. 2005; 366:1719-24. Khunkaew S, Fernandez R, Sim J. Health-related quality of life among adults living with diabetic foot ulcers: a meta-analysis. Qual Life Res. 2019; 28:1413-27.
87% of diabetes-related deaths occur in low- and middle-income countries. Only 35% of diabetes-related health expenditure is spent there.	IDF Diabetes Atlas 9th edition 2019
4 out of every 5 adults with undiagnosed diabetes live in low and middle-income countries	IDF Diabetes Atlas 9th edition 2019
Foot complications of diabetes and peripheral artery disease respond poorly to pharmacotherapy and amputation-prevention efforts remain disjointed (Ontario).	Hussain MA, Al-Omran M, Salata K, et al. A call for integrated foot care and amputation prevention pathways for patients with diabetes and peripheral arterial disease across Canada. Can J Public Health 2019; 110:253-5.

Individuals with stage 4 or 5 chronic kidney disease are fivefold more likely to develop DFU than pre-dialysis patients, while dialysis is independently associated with DFU	McIntosh C, MacGilchrist C (2018) The association between declining kidney function and diabetic foot disease. The Diabetic Foot Journal 21(2): Diabetes on the Net, June 18, 2018.
Many countries have independently conducted research and clearly demonstrated the benefit of DF teams/education and the impact on up to a 72% reduction of incidence for DF ulcers and amputations (Italy, Netherlands, Finland, Italy, Lithuania, United Kingdom, Asia, India, Australia, USA, Canada, Guyana).	Rogers LC, Andros G, Caporusso J, et al. Toe and Flow: Essential components and structure of the amputation prevention team. Journal of Vascular Surgery. 2010; 52:23S-27S.
Interprofessional care teams for DFU management are associated with improved diagnostic acumen, wound healing outcomes that can translate to cost savings.	Somayaji R, Elliott JA, Persaud R, Lim M, Goodman L, Sibbald RG (2017) The impact of team based interprofessional comprehensive assessments on the diagnosis and management of diabetic foot ulcers: A retrospective cohort study. PLOS ONE 12(9): e0185251. https://doi.org/ 10.1371/journal.pone.0185251

The negative impact of diabetes related complications on individuals with diabetes is staggering and specifically relates to quality of life and mortality. Data has been collected both regionally, nationally and internationally for decades with little translation to tangible action to reduce these complications in their tracks. Opportunities to make changes for this unique population are certainly present, evident and relatively uncharted to date from a global perspective.

Research findings have repeatedly demonstrated that interprofessional teams have an enormous impact on preventing amputations. Interprofessional teams may be as simple as a nurse, physician and foot specialist. On the other hand, more complex teams may include a full complement of interprofessional mentors (nutritionist, vascular surgeon, endocrinologist, physiotherapy, diabetic educator and others). For small teams, it has been emphasised that having access to a diverse extended interprofessional team may be beneficial for the complex cases. Virtual patient assessments, medicine and health teaching rapidly proliferated with the recent COVID-19 pandemic. Improved amputation reduction has been reported as high as 72% with a team approach for diabetes care management. There are feasible opportunities that could be applied to diabetic foot assessment, glycemic controls, and lower limb amputation reduction.

<u>Recommendations:</u>

1. All people with diabetes have the right to a comprehensive high-risk foot assessment, along with appropriate interventions to correct abnormal findings
2. Support for interprofessional teams to optimize diabetic foot management (small to large – as able by the region/locale)
3. Reduce the rates (%) for diabetes related lower limb and digit amputation

This document is endorsed by the following distinguished international leaders in wound care, including diabetic foot prevention and management:

Dr. Gary Sibbald, BSc, MD, M.Ed, D.Sci (Hons), FRCPC (Med) (Derm), FAAD, MAPWCA, JM
Professor of Medicine and Public Health, UofT
Course Director of International Interprofessional Wound Care Course (IIWCC) and Masters of Science Community Health MScCH (Prevention and Wound Care), Dalla Lana School of Public Health,
Co-Editor in Chief Advances in Skin & Wound Care Investigator, Institute for Better Health, Trillium Health Partners
Lead, Project ECHO Ontario Skin and Wound Care
Chair of Education Committee, World Union of Wound Healing Societies

☑ Gulnaz Tariq, RN, BSN, PG Dip (Pak)
Director of Nursing, Wound Care and Surgical Unit, Sheikh Khalifa Medical City
IIWCC-UAE Course Coordinator, United Arab Emirates
President, World Union of Wound Healing Societies

☑ Hiske Smart, RN, BSN, RM, MA, PG Dip(Pak)
Nurse Coordinator of Wound Healing, Bahrain
IIWCC-ZA Course Coordinator, South Africa
Former President, Wound Healing Association of South Africa

☑ Elizabeth Ayello, PhD, MS, BSN, ETN, RN, CWON, MAPWCA, FAAN
Co-Editor-in-Chief, Advances in Skin & Wound Care
Executive Editor Emeritus, WCET Journal
President, 2018-2022 WCET World Council of Enterostomal Therapists
Faculty Emeritus, Excelsior College, School of Nursing, NY, USA
Course Coordinator IIWCC, NYU, New York, Faculty in IIWCC Canada, Iran, South Africa & UAE
President, Ayello, Harris & Associates, Inc
Senior Advisor, Hartford Institute for Geriatric Nursing, New York, USA

☑ Brian Ostrow, MD, FRCS(C)
Project Lead, Guyana Diabetes and Foot Ulcer TEam
Adjunct Assistant Professor
University of Toronto

☑ Laurie Goodman, RN, BA, MHScN
Course Coordinator & Co-Director, IIWCC Canada
Advanced Practice Nurse & Wound Care Educator WoundPedia
President, Laurie Goodman Consulting Inc.

☑ Helen Yifter, MD
Assistant Professor of Medicine, Addis Ababa University
Endocrinologist and Internist College Health Sciences

☑ Paula Benilda C Aromin
Captain, Nurse Corps,
Armed Forces of the Philippines
Registered Nurse, MPM-HG (Candidate)
IIWCC-Canada 2019

September 17, 2021

Bianca Hemmingsen, Medical Officer
World Health Organization
hemmingsenb@who.int

Re: World Health Organization's Diabetes Strategy to 2030

Dear Ms. Hemmingsen,

On behalf of the Wounds Canada and the Diabetic Foot Canada Committee, I am writing to you regarding the development of recommendations and core metrics for the World Health Organization's Diabetes Strategy. Our group of specialists and researchers are in alignment with D Foot International's position and strongly recommend that WHO includes diabetic foot health as a core metric, including the prevention and treatment of diabetic foot ulcers and lower limb amputations.

Diabetic foot ulcers and amputations are one of the most feared and serious complications for people with diabetes. Diabetic foot ulcers are caused by underlying factors of ischemia, neuropathy and deformity and without timely access to appropriate treatment, they can quickly lead to an amputation. Across Canada, approximately 5,000 lower limb amputations occur annually due to diabetic foot ulcers that did not heal properly, and recent research indicates his number is on the rise. **An estimated 80% of these amputations are preventable.**

Both the personal and societal cost of these amputations are staggering. The cost of these amputations nationally is estimated approximately at 3.5 billion annually in health care costs. A person who received appropriate treatment is estimated to spend 5 days in emergency rooms, hospitals and clinics, whereas someone who has an amputation spends an estimated 86 days in these settings.

Why is this happening? In Canada, there is no comprehensive system of support or strategy in any of the country's provinces to treat these wounds, and preventative treatment is lacking. Unfortunately, the severity of the issue is not well understood in our health-care system. However, in recent years, there have been some efforts to address this issue. For example, in 2017 Ontario provided funding for offloading devices to help treat diabetic foot ulcer. In 2017 Alberta introduced diabetic foot care pathways.

By making diabetic foot health a priority within the new WHO Diabetes Strategy, your committee will be elevating this serious issue, which will help to make it a priority in health-care systems across the world, including Canada.

Thank you for your consideration of this important issue.

Sincerely,

M. Botros

Mariam Botros

CEO Wounds Canada

About:

Wounds Canada is an NGO, dedicated to advancing the prevention and management of wounds for all Canadians

The Diabetic Foot Canada Committee is a National network dedicated to advancing the prevention and management of Wounds across Canada

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