

Concept Note

Regional Assessment of Availability and Access to Essential Medicines for Cardiometabolic Conditions (Hypertension and diabetes), Including Insulin in the African Region

1. Background and Justification:

Cardiometabolic conditions, including diabetes, hypertension, cardiovascular disease, and metabolic syndrome, have reached epidemic proportions in the African Region, contributing significantly to the burden of disease and mortality. According to the World Health Organization (WHO), non-communicable diseases, including cardiovascular diseases and diabetes, account for approximately 37% of all deaths in Africa.¹ Hypertension and diabetes, in particular, has become a major health concern in the Region.

Hypertension is the most prevalent risk factor for cardiovascular disease in the Region. Despite cost-effective lifestyle and medical interventions that could control hypertension and prevent death and disability, the African region still bears a very high disease prevalence, with poor rates of detection, treatment, and control. In 2019; there were 106M adults living with hypertension, but only 12% of them have their BP under control, leaving about 87M people at increased risk of strokes and heart attacks. Globally, around 21% of adults aged over 30 years have hypertension under control, and 42% are taking medication for the condition. Hypertension is a major risk factor for stroke and heart attack—the cardiovascular diseases responsible for most deaths due to chronic illnesses in the African region.²

IN the African Region in 2019, the International Diabetes Federation (IDF) estimates that there were 19.3 million adults living with diabetes and this number is projected to rise to 47 million by 2045³.

Access to essential medicines, and diagnostics including insulin for hypertension and diabetes, is critical for effective management and control of these conditions. However, significant barriers including limited healthcare infrastructure, inadequate supply chain

¹ World Health Organization (WHO). Noncommunicable diseases: Key facts. Retrieved from: <https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases>.

² WHO . A global brief on hypertension. http://www.who.int/cardiovascular_diseases/publications/global_brief_hypertension/en/. Accessed 8/10/20

³ International Diabetes Federation (IDF). IDF Diabetes Atlas, 9th edition. 2019. Retrieved from: https://diabetesatlas.org/upload/resources/material/20200302_133351_IDFATLAS9e-final-web.pdf

systems, high medication costs, regulatory challenges, and healthcare professional capacity gaps, contribute to the suboptimal availability and affordability of essential medicines ^{4,5} in the African Region.

Conducting a regional assessment of the availability and access to essential medicines, diagnostics, and technologies for cardiometabolic conditions, including insulin for type 1 diabetes, is crucial to fully understand the extent of the problem and develop targeted interventions. This assessment will provide valuable insights into the specific challenges faced by countries in the African Region and guide the development of evidence-based strategies to improve availability, affordability, and equitable access to essential medicines.

By addressing these barriers, we can enhance disease management, reduce complications, and ultimately improve health outcomes and the quality of life for individuals with cardiometabolic conditions in the African Region.

2. Objectives:

- To assess the current availability and accessibility of essential medicines for cardiometabolic conditions, including insulin, in the African Region.
- To identify key barriers and challenges that hinder the availability and accessibility of these essential medicines.
- To provide evidence-based recommendations to improve the availability and access to essential medicines, including insulin, for effective management of cardiometabolic conditions.
- To advocate for policy changes and interventions that enhance the procurement, distribution, and affordability of essential medicines for cardiometabolic conditions.
- To support capacity-building initiatives for healthcare professionals on the appropriate use and administration of essential medicines for cardiometabolic conditions, including insulin for type 1 diabetes.

3. Activities and Implementation Plan:

3.1. Assessment:

Conduct a comprehensive regional assessment to evaluate the availability and access to essential medicines for cardiometabolic conditions. The assessment should include data collection on medicine availability, affordability, distribution, and regulatory frameworks (1). The assessment should cover the following medicines and technologies:

⁴ World Health Organization (WHO). Access to medicines: Making market forces serve the poor. Retrieved from: <https://www.who.int/whr/2008/en/>

⁵ The Lancet Commission on Essential Medicines Policies. Essential Medicines for Universal Health Coverage. Retrieved from: <https://www.thelancet.com/commissions/essential-medicines>.

Hypertension Management:

- a) Blood Pressure Lowering Drugs:
 - ACE Inhibitors (Angiotensin-Converting-Enzyme Inhibitors): Lisinopril, Ramipril, Perindopril
 - Angiotensin Receptor Blockers: Losartan
 - Calcium Channel Blockers (CCB): Amlodipine (5 mg / 10 mg)
 - Diuretics (Thiazide-like): Hydrochlorothiazide, Chlorthalidone, or Indapamide SR

- b) Antiplatelets:
 - *Aspirin*

- c) Statins:
 - Atorvastatin
- d) Monitoring equipment
 - BP Machine (Validated Digital BP Monitors)

Diabetes Management:

- a. Medications:
 - Metformin
 - Sulfonylurea (e.g., Gliclazide)
 - Human Insulin

- b. Monitoring Equipment:
 - Glycometer
 - Strips
 - Fasting Plasma Glucose (FPG)
 - Haemoglobin A1c

3.2. Challenges:

Identify the key barriers and challenges to the availability and accessibility of essential medicines, including factors related to procurement, supply chain management, pricing, regulation, and healthcare infrastructure.

3.3. Data Analysis and report drafting:

Analyze the collected data and develop evidence-based recommendations to address the identified barriers and improve the availability and access to essential medicines for cardiometabolic conditions. An update version of the WHO Medmon tool will be used for data collection.

3.4. Advocate for policy changes and interventions at the regional and national levels:

Organize regional meeting to disseminate findings from the evaluation with stakeholders. The regional meeting will facilitate a comprehensive understanding among participants of the barriers and challenges identified in the assessment that hinder the availability and accessibility of essential medicines.

The evidence-based recommendations generated from the assessment will be discussed and presented, focusing on strategies to improve the availability and access to essential medicines, particularly insulin for type 1 diabetes, for effective management of cardiometabolic conditions.

The meeting will serve as a platform to advocate for policy changes and interventions aimed at enhancing the procurement, distribution, and affordability of essential medicines for cardiometabolic conditions across the African Region.

3.5. Capacity building:

Support capacity-building initiatives for healthcare professionals on the appropriate use and administration of essential medicines for cardiometabolic conditions, including training on insulin administration for type 1 diabetes.

3.6. Monitor and evaluation.

Monitor the impact of the implemented interventions, making necessary adjustments based on the findings.

4. Methodology

The main methodology for this project will be the WHO/HAI methodology to generate reliable information of the price, availability, and affordability of selected essential. This methodology can be adapted, and list of assessed medicines and tools can be reviewed.

In Summary, the **WHO/HAI (World Health Organization/Health Action International) methodology** is a comprehensive and standardized approach used to assess the price, availability, affordability, and price components of medicines in different settings, particularly in low- and middle-income countries. This methodology has been widely adopted to provide reliable and comparable data across countries. Below is an overview of the key components of the WHO/HAI methodology:

4.1. Selection of Medicines

Medicines selected for the survey should include:

- **Core medicines:** These are essential medicines commonly used to treat major health issues in the country (e.g., for hypertension, diabetes, infectious diseases).
- **Supplementary medicines:** These are country-specific medicines that are important for the local disease burden.

Medicines should be classified based on:

- **Originator brand** (patented or branded medicines)
- **Lowest-priced generic** (cheapest available alternative)

4.2. Survey Design

The survey typically involves collecting data from:

- **Public sector:** Government-run facilities such as hospitals and pharmacies.
- **Private sector:** Privately operated pharmacies and drugstores.
- **Other sectors:** Faith-based organizations or non-governmental organizations, if applicable.

Sampling Approach:

- Select facilities randomly or systematically based on location and representativeness.
- Include a **minimum of 30 medicine outlets** from each sector in different regions (urban, rural, and peri-urban areas).

4.3. Price Measurement

Medicine prices are measured and compared using:

- **Median Price Ratio (MPR):** A measure of how much higher or lower the price of a medicine is compared to an international reference price (IRP). This helps to determine if medicines are overpriced in local markets. The IRP is often sourced from sources like the **International Drug Price Indicator Guide**.

Formula for MPR:

$$\text{MPR} = \frac{\text{Local price}}{\text{International reference price}}$$

- **Procurement price:** The price at which the public sector purchases medicines.
- **Patient price:** The price that patients pay out-of-pocket at public or private sector outlets.

4.4. Availability Measurement

Availability is measured as the percentage of outlets where a particular medicine is found on the day of data collection.

4.5. Affordability Measurement

Affordability is assessed by calculating the number of **days' wages** required by the lowest-paid unskilled government worker to purchase a standard treatment regimen for common conditions (e.g., hypertension or diabetes).

4.6. Price Components

This part of the methodology tracks the supply chain to understand where price markups occur. It identifies and calculates the contributions of various elements along the supply chain to the final price of a medicine.

- **Manufacturer's price:** The base price of the medicine from the manufacturer.
- **Add-ons:** Includes costs added at each stage of the supply chain, such as:
 - Import tariffs and taxes
 - Distributor mark-ups
 - Wholesaler mark-ups
 - Retailer mark-ups
 - Other handling and transportation costs

Data is collected from government and private sector records on the various stages of the supply chain to calculate price mark-ups at each level.

4.7. Data Collection and Analysis Tools

- The WHO/HAI methodology uses a **structured data collection form** and an **Excel-based analysis tool** to input and analyze the collected data.
- Data are collected by trained personnel from selected pharmacies or facilities.
- Data is analyzed to generate:
 - **Median Price Ratio (MPR)**
 - **Availability percentage**
 - **Affordability measures**
 - **Breakdown of price components** along the supply chain.

4.8. Results Interpretation

- **Price:** An MPR >1 suggests that the medicine is priced above the international reference price, indicating potential overpricing.
- **Availability:** Availability of medicines below 50% suggests significant gaps in access to essential medicines.
- **Affordability:** If more than 1 day's wage is required to afford treatment, it indicates poor affordability and a potential barrier to access.
- **Price Components:** Identifying key points where price mark-ups occur helps highlight inefficiencies in the supply chain and opportunities for cost reduction.

4.9. Reporting and Recommendations

The findings of the survey are compiled in a comprehensive report, including:

- **Summary of price and availability data**
- **Affordability analysis**
- **Price components breakdown**
- **Recommendations** for improving medicine access, lowering prices, and addressing affordability issues through policy interventions such as price controls, reducing mark-ups, or tax exemptions.

5. Timelines:

Date	Activity
Q3 2024	Recruitment of the research institution
Q3 2024	Finalize the methodology and development of assessment tool
Q4 2024	Data collection
Q4 2024	Data analysis
Q1 2024	Report drafting
Q1 2024	Report edition, translation, and printing
Q2 2024	Establishment of a dashboard to highlight availability of diabetes services and products in DHIS2
Q3 2024	Organize regional meeting to disseminate finding from the evaluation with stakeholders

6. Expected Outcomes:

- Comprehensive assessment of the availability and access to essential medicines for cardiometabolic conditions, including insulin for type 1 diabetes, in the African Region.
- Identification of key barriers and challenges and evidence-based recommendations to improve availability and access to essential medicines.

Smart and interactive dashboard on availability of essential medicines for Cardiometabolic conditions in Africa.

- Policy changes and interventions implemented to enhance procurement, distribution, and affordability of essential medicines.
- Enhanced capacity of healthcare professionals on the appropriate use and administration of essential medicines, including insulin for type 1 diabetes.

7. Conclusion:

By conducting a regional assessment and implementing evidence-based interventions, this project aims to improve the availability and access to essential medicines for cardiometabolic conditions, including insulin for type 1 diabetes, in the African region.

8. Roles & Responsibilities

To execute and accomplish a finalized document for local implementation and publication the roles of WHO and WDF are:

- **WHO AFRO**
 - Development of data collection tools and recruitment of consultant to collect data.

- Technical and administrative oversight on the data collection, collation, analysis and report writing.
 - Convening of regional meeting to disseminate the findings of the assessment.
 - Support implementation in member countries through regional/country including the establishment of a dashboard to highlight availability of diabetes services and products in DHIS2.
- **Partners (WDF & RTSL)**
- Provide funding to execute the project.
 - Provide technical support when needed.