HEARTS

Technical package for cardiovascular disease management in primary health care

Access to essential medicines and technology

World Health Organization
American Heart Association | American Stroke Association
Centre for Chronic Disease Control
International Diabetes Federation
International Society of Hypertension
ISN 1960
RESOLVE TO SAVE LIVES
Pan American Health Organization
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WORLD HEART FEDERATION
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HEARTS Technical Package

More people die each year from cardiovascular diseases (CVDs) than from any other cause. Over three-quarters of heart disease and stroke-related deaths occur in low- and middle-income countries.

The HEARTS technical package provides a strategic approach to improving cardiovascular health. It comprises six modules and an implementation guide. This package supports Ministries of Health to strengthen CVD management in primary care and aligns with WHO's Package of Essential Noncommunicable Disease Interventions (WHO PEN).

HEARTS modules are intended for use by policymakers and programme managers at different levels within Ministries of Health who can influence CVD primary care delivery. Different sections of each module are aimed at different levels of the health system and different cadres of workers. All modules will require adaptation at country level.

The people who will find the modules most useful are:

- **National level – Ministry of Health NCD policymakers responsible for:**
  - developing strategies, policies and plans related to service delivery of CVD
  - setting national targets on CVD, monitoring progress and reporting.
- **Subnational level – Health/NCD programme managers responsible for:**
  - planning, training, implementing and monitoring service delivery
- **Primary care level – Facility managers and primary health care trainers responsible for:**
  - assigning tasks, organising training and ensuring the facility is running smoothly
  - collecting facility-level data on indicators of progress towards CVD targets.

Target users may vary, based on context, existing health systems and national priorities.

MODULES OF THE HEARTS TECHNICAL PACKAGE				
Module	**What does it include?**	**Who are the target users?**		
		National	**Subnational**	**Primary care**
Healthy-lifestyle counselling	Information on the four behavioural risk factors for CVD is provided. Brief interventions are described as an approach to providing counselling on risk factors and encouraging people to have healthy lifestyles.		✓	✓
Evidence-based protocols	A collection of protocols to standardize a clinical approach to the management of hypertension and diabetes.	✓	✓	✓
Access to essential medicines and technology	**Information on CVD medicine and technology procurement, quantification, distribution, management and handling of supplies at facility level.**	✓	✓	✓
Risk-based CVD management	Information on a total risk approach to the assessment and management of CVD, including country-specific risk charts.		✓	✓
Team-based care	Guidance and examples on team-based care and task shifting related to the care of CVD. Some training materials are also provided.		✓	✓
Systems for monitoring	Information on how to monitor and report on the prevention and management of CVD. Contains standardized indicators and data-collection tools.	✓	✓	✓

Introduction

Procurement and supply management activities are fundamental to consistent and reliable access to essential medicines and health products.

To reduce the impact of CVD, action needs to be taken to improve prevention, diagnosis, care and management of CVD diseases. Affordable essential medicines and technologies to manage CVD disease must be available where and when they are required.

Medicines and technologies need to be managed appropriately to ensure that the correct medicines are selected, procured in the right quantities, distributed to facilities in a timely manner, and handled and stored in a way that maintains their quality. This needs to be backed up by policies that enable sufficient quantities to be procured in order to reduce cost inefficiencies, ensure the reliability and security of the distribution system, and encourage the appropriate use of these health products.

In order to avoid stock-outs and the disruption of treatment, all related activities need to be conducted in a timely manner, with performance continually monitored, and prompt action taken in response to problems that may arise.

Additionally, medication must be dispensed correctly and used rationally by the healthcare provider and patient alike. The purpose of this guide is to explain the necessary steps.

This module focuses on access to medicines and basic equipment for CVD management, and includes:

- information on the pharmaceutical management cycle and policies
- selection of appropriate drugs and technologies
- supply-chain management, including quantification, forecasting, distribution, storage and handling
- ensuring supply and accountability
- rational use of medicines.

1 Framework and policy

Drug management requires continuous support, including policies and legislative frameworks, such as a country's national CVD programme and regulatory authority. If countries do not have a regulatory authority, the WHO List of Prequalified Medicinal Products can be consulted to ensure that quality-assured medication is being procured and utilised.

Access to essential medicines by policy makers depends on four factors:

- rational selection
- affordable prices
- sustainable financing
- reliable health systems.

Essential medicines are those medicines that satisfy the priority health care needs of the majority of a given population and are selected after consideration of their relevance to public health, their efficacy and safety, and their comparative cost-effectiveness. They are intended to be available within the context of functioning health systems and should be available at all times, in adequate amounts, appropriate dosages, with quality assurance and adequate information, and at a price that individuals and communities can afford. *(1)*

An essential medicines list (EML) gives priority status to medicines that address a country's most pressing public health programmes, and provides recommendations, based on quality and cost-effectiveness, to assist those tasked with purchasing medicines and products.

An essential medicines list, drawn up as part of the core principles of a national drug policy, helps to set priorities for all aspects of the pharmaceutical system. This is a crucial step in ensuring access to health care and in promoting rational use by health professionals and consumers. The implementation should be flexible and adaptable to address all levels of care:

- private and public sectors
- primary, secondary and tertiary levels
- in both rural and urban areas.

Political commitment is critical to ensuring a successful national drug policy and the selection of essential medicines.

Policy makers can do the following:

- Establish a consensus process to develop and use national EMLs (NEMLs). *(2)*
- Use an objective, and transparent process, in conjunction with clinical standard treatment guidelines.
- Ensure funding for medicines and products on the NEML list.
- Use the NEML list to guide policies related to access.
- Regularly review and update the NEML list against the most recent WHO Model List. www.who.int/medicines/publications/essentialmedicines/20th_EML2017_FINAL_amendedAug2017.pdf?ua=1

2 Selection of drugs

Ensuring the availability of, and access to, essential medicines and health products for the management of hypertension, diabetes and increased lipids requires government commitment, guaranteed financing, and effective supply management, including procurement and service delivery.

The Hearts Technical Package lists the essential medicines for the management of hypertension, diabetes and increased lipids. *(3)*

- thiazide or thiazide-like diuretic
- calcium channel blocker (CCB) (long acting) (amlodipine)
- angiotensin converting enzyme inhibitor (ACE-I) (long acting) and angiotensin receptor blocker (ARB)
- statin
- insulin
- metformin
- glibenclamide
- beta-blocker
- aspirin.

When medications are not on a country EML, a country can adapt the protocols to address their specific needs. It is, however, recommended that every country's NEML reflects the list of essential CVD medicines consistent with protocols in the E module of the HEARTS technical package to ensure the effective management of CVD risk.

Addressing availability of these essential medicines within countries and at all levels of care and sectors is critically important. An analysis by Cameron and colleagues across 40 countries showed that chronic disease medicines were significantly less available than those for acute conditions, in both the public and private sectors, with this lack of availability even more evident in the public sector, as highlighted in Table 1.

Table 1: Availability of medicines for chronic and acute disease across 40 countries

Mean availability of lowest-priced generic medicines (% of facilities)		
	Chronic disease medicines	Acute disease medicines
Public	36	54
Private	55	66

Chronic Disease Medicines Acute Disease Medicines

N=2779 facilities (total of public and private outlets) across 40 countries. *(4)*

3 Selection of equipment

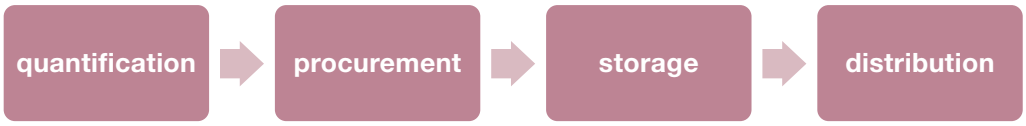
Monitoring technologies, such as glucometers and urine test strips, are excluded from most NEMLs, *(5)* and in many countries there is only limited availability. With the increasing burden of chronic diseases in LMICs, it will be important to include these essential technologies in lists of essential medical products, from national to global, if these diseases are to be managed effectively.

A simple essential list of technologies *(6)* for CVD screening and monitoring includes:

- stethoscope
- measuring tape
- weighing scale
- equipment and supplies for measuring urine albumin and ketones
- blood pressure measurement device
- equipment and supplies for measuring blood glucose and cholesterol.

4 Supply management

Figure 1: Components of a supply chain



Quantification

Quantification, comprising both forecasting and supply planning, is the process of determining the quantity of any medicine or technology to procure in a set timeframe. This includes forecasting future needs for the short-, medium-, and long term.

Effective forecasting for NCD medicines and technologies at the district and then national level starts with the number of patients currently being treated by facility for a given condition, current and anticipated burden of disease, and existing stock information. The district health management team and NCD programme coordinator should maintain estimates of the number of patients likely to come to health facilities within the district for these services (maybe based on the experiences of other health care facilities in the country).

Supply planning involves the prediction of future needs in order to ensure adequate supply, based on demand and available funding.

Information needed for supply planning includes:

- expiration dates of current available stock
- supplier details such as prices and lead times
- funding information such as source and disbursement schedule
- procurement details
- distribution details. *(7)*

Quantification can be challenging for cardiovascular diseases because of the lack of reliable and consistent data on the burden of disease and essential medical product (EMP) use. As the burden of disease grows, it will be even more challenging to develop accurate estimates.

Procurement

The national EML (NEML) list can serve as the basis for the training and education of health professionals and of public education about medicine use. It can also be the basis for public-sector procurement and distribution, and can influence practice in the private sector through education. The public sector or health insurance system cannot afford to supply or reimburse the purchase of all medicines available in the market, and may also struggle to know which products are qualified and are cost-effective. EMLs can be used to guide the procurement and supply of medicines in the public sector and by systems that reimburse medicine costs. Using the NEML as a starting point, care institutions such as district hospitals and primary health centres can develop their own list of medicines.

A cycle of procurement involves three interlinked activities:

- alignment of needs and procurement budget
- tendering and purchasing
- contract performance.

Procurement models commonly used

A model of centralized procurement usually leads to bulk purchasing and better prices.

Depending on the nature of health financing in a country, often a decentralized procurement model is used, whereby provinces, counties, districts or health facilities purchase directly from suppliers. While it does not have the benefits of bulk purchasing benefits found in centralized procurement systems, and prices can be high, it leads to more responsive procurement and supply.

Alternative procurement options are to use a UN agency (e.g. UNICEF or non-profit international procurement agents such as IDA, Mission Pharma and Crown Agents). In some regions, countries have joined pooled procurement groups, which buy collectively on behalf of member countries. (The Eastern Caribbean Pooled Purchasing, PAHO Revolving Fund and Gulf Coordination Council are notable examples.) Ultimately, countries will have to study which procurement model best serves the procurement of CVD products.

Tendering models used:

- International Competitive Bidding (ICB) and limited ICB
- National Competitive Bidding (NCB)
- direct purchase.

Pricing and market control

To allow for distribution, and health system and consumer confidence in the medicines and products distributed, it is recommended that countries facilitate the registration of quality and cost-effective EMPs. The WHO Model list of Essential Medicines can be a guide to the development of an NEML. Along with regulatory approval, an NEML is a key factor in determining procurement and hence supply and availability of EMPs at the country level as well.

The availability, price, and affordability of these EMPs are indicators of access to treatment for CVDs, so it is important to assert market control over these medicines and health products. Price is assessed as the median price ratio (MPR), which compares the local price for a product to the international reference price (IRP) for the product,

Box 1: Variations in pricing

In an analysis of affordability of cardiovascular medicines in 36 countries, mean MPR for public sector procurement of hydrochlorothiazide (HCT) was 9 times the IRP, revealing that governments in Africa procured HCT at prices, on average, 9 times that of the IRP, though this varied widely within the region. *(8)*

A diabetes-focused secondary analysis of 32 country surveys found that the median public sector MPR for glibenclamide was 1.1 times the IRP, with a range between 0.27 in Chennai, India to 17.37 times the IRP in Nigeria. *(9)* Median public-sector procurement price for metformin was below the IRP, with a median MPR of 0.72 across 21 surveys, ranging from 0.17 in Chennai, India to 8.17 times the IRP in Shandong, China. In another survey, of 36 countries, the mean MPR for public-sector procurement of glibenclamide was 2.15 times the IRP, with mean MPR the highest in the African region at 3.42 times the IRP. *(10)*

thereby demonstrating how much the procurer or end-user pays for the product as compared to the IRP.

Box 2: Case study of mark-ups

Mark-ups in price from procurement to the end-user purchase point vary widely and significantly affect affordability. An analysis of the affordability of metformin and captopril demonstrated the unaffordability of these essential medicines. In only 2 of the 25 countries surveyed did a month's course of these two medicines together cost less than a day's wage. The price in Ghana was the least affordable, with these two medicines costing 15 days' wages for a 30-day supply. *(11)*

In addition, limited public sector availability of EMPs often means that people have to purchase these at private retail stores, which, if unregulated, can lead to higher prices that make some essential products unaffordable. *(10)*

Mark-ups in price along the supply chain, from procurement to end-user purchase point, can impact affordability significantly, and wide variations in pricing reflects variations in regulation, procurement efficiency, and market conditions within countries. Governments can exercise market control in order to control these mark-ups in price to allow for greater affordability of these EMPs.

Storage

Medicines and related supplies need to be stored correctly for optimal performance. A sound storage system preserves a product's physical integrity, stability and efficacy, ensuring it reaches the patient in usable condition while minimizing waste and loss.

The appropriate storage of EMTs include the following key steps:

- Maintaining a cold chain and proper storage temperatures when required.
- Maintaining a secure storage space that can be locked and is cool, dry, well maintained and well organized to act as a pharmacy store. The storage space should be separate from the area where medicines are dispensed. If a health care facility does not have a room to use as a pharmacy store, a lockable cupboard or cabinet with shelves should serve as the "store".
- Monitoring stock levels and their entry and exit at facility level (health facility and storage facility) through storeroom recordkeeping, using tools such as stock cards. Recordkeeping will aid understanding of the flow of supplies into and out of a health care facility and will also enable staff to know:
  - what items are in stock
  - the quantity of each item in stock
  - how much stock is used on a weekly, monthly and quarterly basis
  - when and how much of each item should be reordered.
- Ensuring traceability of medicines and equipment to prevent loss.

At the national level, it is important to ensure that processes for clearing customs are not onerous and that custom duties and value added tax imposed on EMPs do not create a barrier for these essential drugs to be procured. These fees increase the end price of the products for both the national procurers and the end user, and can discourage importation of these essential medicines and technologies.

Box 3: The importance of national and county-level commitment

The Kenya Health Sector Strategic and Investment Plan (KHSSP) of July 2013 to June 2017 identifies the Kenya Package for Health (KEHP) service package for providing essential health services by level of care. Under the KEHP service package, general outpatient services for the "Management of Endocrine and Metabolic Conditions (Diabetes mellitus, Hypothyroidism, Hyperthyroidism)" are to be provided at the primary care level. *(12)*

While the sampling size was limited, survey data found little to no availability of diabetes medicines and technologies at primary level health care facilities in the public health sector. The one exception was Nyeri County, where county health care officials have chosen to promote the availability of diabetes medicines and technologies at primary-level health care facilities.

For example, for metformin, Nyeri country and Nairobi County had 100% availability, while Kisumu, Vihiga, and Homa Bay had 0% availability. For both amlodipine and blood glucose test strips Nyeri County had 100% availability and the other counties had 0% availability. These findings illustrate the impact that a commitment by county-level health officials can have on improving availability of essential medicines and technologies at primary-level health care facilities. *(12)*

Box 4: Distribution challenges

In Kyrgyzstan, one study found that insulin supplies were sufficient to meet country demand, but distribution processes were ineffective and inefficient. Distributors provided facilities with whatever insulin was available, regardless of whether or not it was the type ordered, forcing patients to switch their insulin regimens and sometimes use incorrect syringes for the type of insulin they were using. In addition, distribution only took place every three months, so facilities limited their distribution of supplies to avoid stock-outs. *(13)*

Distribution

Distribution can often be the most challenging stage of the supply chain, as it is dependent on local infrastructure. At the national level, distribution consists of transporting EMPs through the supply chain, from the arrival port and customs, to the central warehouse, the regional/ district warehouse, and onwards to the health facility or other final destination.

5 Ensuring a secure supply

Market dynamics is a set of skills and approaches used to evaluate, and thereby improve access to, products and services. It involves regular interactions that take place among key stakeholders (producers, distributors, purchasers and consumers) and are based on the effectiveness and efficiency of key attributes of market health: affordability, availability, assured quality, appropriate design, and awareness. Such an analysis might lead to inefficiencies being identified in the way the market operates, and potential interventions being devised that would ultimately lead to improved health outcomes.

Efforts to shape the market in global health care seek to support sustainable access to medicines and technologies by catalysing the development of new markets and/or improving existing ones. For essential CVD medicines and technologies, investments in market shaping may help to further catalyse access to existing products in low- and middle-income countries. The following recommendations use a market dynamics perspective to identify and address existing market shortcomings.

Improve demand visibility to ensure supply availability

Investing in routine collection of market information, and coordinating the messaging of demand expectations to members of industry (both distributors and manufacturers) early and often can help mitigate supplier risk as well as ensure consistent supply.

In the public health sector, manufacturers and distributors usually lack accurate forecasting information to effectively manage production for and sales to LMICs. Even with a number of generic CVD medicines available in the market, supply cannot be assured without better predictability of demand.

Conduct routine market analyses to improve local decision-making

Collecting broad market information can help ensure access to CVD medicines.

For instance, before procuring medicines or devices, it is a good idea to understand the supply landscape (e.g., available brands and/or models, manufacturing capacity, pricing and quality). Note that landscaping exercises can be resource intensive, particularly for individual countries to support. Therefore, before a separate process is initiated, it is worth making enquiries with global partners such as the Global HEARTS programme or UNICEF supply division, who often maintain such supply landscapes for global use.

Improved market information increases visibility throughout the supply chain, which can ensure proactive stock management at all levels of care, and enable informed decision-making for potential improvements.

For example, assessing import taxes and tariffs, the margins of local sales agents or distributors, and shipping costs may help identify pain points in the supply system for CVD medicines and technologies, as well as potential opportunities to improve the efficiency of local distribution.

An understanding of the market landscape may also help purchasing agents justify tenders as single or split awards, based on an understanding of immediate purchasing needs, minimum production requirements for manufacturers, and opportunities for price reductions.

Finally, improved market information not only serves domestic decision-making, but can also inform collaboration with a broader set of regional or global stakeholders. Well-articulated need and potential demand can contribute to global discussions to improve access to and further prioritize activities and investments for CVD medicines and technologies.

Improve confidence in the market by providing predictable financing

Making public-sector investments in longer-term financing strategies may help optimize and allocate resources most efficiently. Such investments will also establish demand expectations and improve predictability for suppliers, based on realistic budget constraints.

Limited and unpredictable financing of CVD medicines and technologies by governments can discourage suppliers from engaging in LMIC markets.

Strategically categorizing and prioritizing health technologies can help key decision-makers determine the most appropriate model for technology ownership (e.g., rent, lease, or buy), and the best strategies for sourcing maintenance (insourcing vs. outsourcing) and for contracting ongoing service.

Generate demand by increasing awareness

The generation of demand is an essential component in improving the market for essential CVD medicines and technologies. Increased incentives for healthcare providers, pharmacists and/or retail drug shop owners to screen and identify patients with symptoms, to stock the required screening tools and treatments, and to maintain affordable prices in delivery of these services will help drive awareness for the prevalence of CVD, and increase demand. In addition, awareness-raising for secondary prevention and key risk factors, adherence support services, and real-time medicines and technology alerts for patients are programmatic efforts that link closely to the effectiveness of efforts to increase demand for these services in this area.

6 Ensuring accountability

Maintaining good records for the steps involved in ordering, receipt, storage, inventory control and dispensation is critical to ensuring an overall accountability regarding drug supply at your health centre. This is especially important for CVD medicines and technologies, as they are expensive and at higher risk of pilferage and diversion.

Maintain all your documents and records

Apart from regularly updated stock-control cards, the following documents should be maintained and organized into files that can be easily accessed:

- daily use/dispensing register
- stock control register
- requisition/delivery form
- any other correspondence with District, Regional or Central Stores or other supply sources regarding drug supplies.

Track performance

When time permits, also try to estimate performance measurements for your health centre, such as:

- percentage of individual items ordered in each month or quarter that were delivered on time and in the full quantities requested;
- for each item, the quantity ordered/requested vs the quantity received in each month;
- the number of days when a product was not in stock in your health centre.

Discuss these metrics routinely with the Medical Officer in Charge (MOIC) of your health centre and also with the district or regional supplies officer/pharmacist.

Cycle counts

Cycle counts should be performed regularly to ensure that the quantity of medicines actually in stock matches up the quantity of a drug the health facility should have on the shelf, based on stock registers. Cycle counts can be done on randomly selected items, on items that are high cost or at higher risk of theft/diversion, or items where routine review by the MOIC reveals some discrepancies.

Conduct audits and maintain supervision

Every few months the MOIC should conduct a self-audit:

- Ensuring that drugs are properly arranged on shelves in the dispensary.
- Tallying records of receipts and cross-checking with stock-control cards.
- Tallying records from daily issues register and cross-checking with the stock-control cards/stock register.
- Recalculating at random a few of the requisition quantity figures to ensure that they are correct.
- Asking questions about the reasons for any items not being in stock.

Cold/refrigerated products

Insulin requires refrigeration to maintain stability. The MOIC should periodically review the temperature log book, which has records of temperature/refrigerator status. If it is found that a product that requires refrigeration was either out of the fridge for longer than the recommended amount of time or the refrigerator was not functioning, the product needs to be discarded. This can be discussed with the district or provincial pharmacist.

The MOIC should also ensure that adequate security measures for the drug store/dispensary are always followed: e.g. locking when staff leave for the day, vetting of substitute staff on days the main assigned person is on leave. They should also follow up regarding how to fulfil the training needs of the person responsible for drug supplies at the health facility.

Box 5: Maintenance of equipment

It is important to regularly check the devices and supplies used. For example, the appropriate maintenance of equipment is critical for accurate measurement of BP. The equipment – whether aneroid, mercury, or electronic – should be regularly inspected and validated to eliminate conditions that could cause the blood pressure measurement to give a reading that was erroneously high or low.

Likewise, glucose monitors should be regularly checked for device malfunctions. Temperature or environmental error codes on the glucose meter should alert the operator to check the test strips using control samples to verify reagent performance prior to further patient testing. Improper storage and use of urine and glucose testing, rough handling, and expired test strips are some of the most common sources of measurement error.

7 Rational medicine use and adherence

Rational use of medicines is when "patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community".

Irrational (inappropriate, improper, incorrect) use of medicines is when any of these conditions are not met.

While evidence-based treatment protocols exist to guide the rational use of medicines for the treatment of high blood pressure, diabetes, high blood cholesterol and the reduction of CVD risk, rational use can be affected by a number of factors, and influenced by health workers and patients. Given the chronic nature of these diseases, short-term changes in individual requirements affecting dosage, and long-term changes due to co-morbidities and advancement of disease mean that the rational use of medication must be regularly assessed.

There are several tools to promote the rational use of medicines in health facilities:

- **Clinical guidelines:** The HEARTS Technical Package's *Evidence-based protocols* module provide clear guidance on treatment regimens for high blood pressure, diabetes, high blood cholesterol and various levels of risk and co-morbidities. These resources can be used to establish treatment protocols for CVD, if national protocols do not exist.
- **Essential Medicines List:** The essential medicines and technologies lists in this module are harmonized with WHO Model List of Essential Medicines and evidence-based recommendations for CVD management. An NEML and a national EMP list will provide a core selection of medicines and products for procurement and ordering.
- **Health worker education:** Training can be offered through HEARTS training modules or local programmes so that staff continuously update their knowledge base and practice.
- **Use of independent information on medicines:** Use reliable sources of information, such as WHO's technical guides and national guidelines, to guide practice.
- **Public education about medicines and technologies:** Patient education is essential in order to achieve long-term rational use of medications. The role of clinical pharmacists in counselling and monitoring a person while dispensing their medication to them is invaluable in terms of making sure the medication has the maximum effect. Educate the public about good generic medications, which it is perfectly acceptable to use.

To support rational use, the dispenser is responsible for following protocol and for maintaining attention to detail in each step of the dispensing process, as described earlier in this section. Errors and problems in dispensing can occur, so it is important to keep these in mind when reviewing dispensing practices, and identify ways of preventing or resolving these issues.

Potential problems include the following (this list is not exhaustive):

- wrong interpretation of the prescription (or diagnosis)
- retrieval of the wrong drug from stock
- wrong dosages
- inadequate packaging/labelling of proprietary drugs
- inaccurate counting
- inadequate or absent labelling
- no knowledge of proper drug compliance
- poor patient understanding of the disease and its effect on their body
- insufficient time to talk with patients about their medication
- inability to communicate with patients about the treatment regimen.

Bulk dispensing should also be considered as a way of improving adherence in stable patients. This requires further investigation into your current dispensing system and ability to handle bulk dispensing.

It is important to note the additional requirements for proper storage, monitoring and patient education regarding insulin. Devising a system to distinguish between medication packages that are similar in appearance can help avert mistakes.

Rational use is influenced by availability, affordability, financial constraints, patients' sociocultural backgrounds, co-morbidities, age, sex, drug allergies, personal preferences, and health beliefs such as "if I don't have symptoms I am not sick". It is important for the dispenser to be aware of these factors and be prepared to address rational use with patients, using an appropriately sensitive approach.

Pharmacovigilance

Pharmacovigilance is the science and activity relating to the detection, assessment, understanding and prevention of adverse effects or any other possible medicine-related problems. Pharmacovigilance aims to:

- improve patient care and safety in relation to the use of medicines and all medical interventions;
- improve public health and safety in relation to the use of medicines;
- detect problems related to the use of medicines and communicate findings in a timely way;
- contribute to the assessment of benefit, harm, effectiveness, and risk of medicines, leading to the prevention of harm and maximization of benefit;
- encourage the safe, rational and more effective (including cost-effective) use of medicines;
- promote understanding, education, and clinical training in pharmacovigilance and its effective communication to the public. *(14)*

Box 6: Adverse Drug Event (ADE)

The Adverse Drug Event Prevention Study Group reported that the odds ratio of a severe ADE in relation to cardiovascular medication was 2.4 times that of other medications.

An error at any step of the dispensing process, poor patient adherence to medication, and adverse drug events (ADEs) can negatively impact the efficacy and safety of a treatment regimen. Good pharmacovigilance requires adhering to good dispensing practices *(14)*, as described in this section, namely:

- Assessing patient adherence to medication.
  - Provide patient education and/or referral as needed to establish and maintain proper adherence.
- Ensuring patients (and/or families/caregivers) are aware of possible adverse reactions to prescribed medications, and explaining what to do in the event of an adverse reaction.
  - Provide additional education as required. Refer patients to care for management of adverse reactions as needed. Document any relevant adverse reactions.
- Being alert to and advising patients on potential drug–drug or food–drug interactions. Additionally, being aware that comorbidities or acute illness (e.g., infection) can alter blood pressure or blood glucose and may require adjustment to treatment regimens.
  - Provide education on signs and symptoms of ADEs commonly caused by drug–drug or food–drug interactions and refer to care as needed.

Note: Attention to food–drug ADEs is especially important for people with diabetes requiring insulin injections. Assess patient understanding of the interactions between diet, dosage, and timing (time between insulin dose and food intake). Assess the patient's food security and provide additional education as necessary and appropriate.

Record each patient's medication history, including complementary therapies and current medications (obtained both at your facility and elsewhere) to enable identification of potential drug–drug interactions or duplication of medications.

If a potential drug–drug interaction or duplication is identified, contact the patient's prescribing physician or refer the patient to care to re-evaluate the current medication regimen and prevent an ADR.

Aids such as posters, patient education materials, interview guidelines and materials for taking medication histories can support facility uptake and implementation of good pharmacovigilance efforts.

Annex A: Ordering supplies

Ensuring that a health facility is adequately stocked with medicines and health technologies to serve CVD patient needs must be balanced with preventing the overstocking of medicines that could expire before they are used. Over time, it will be essential to establish new data systems and automated decision-making to ensure that quantities ordered are "in sync" with a patient's clinical stage and other information obtained from patient registers and electronic records. This section of the facility guide provides a step-by-step approach for such facilities to decide when to order and how much to order.

Step 1: Compile a list of essential medicines and technologies relevant to the HEARTS package

Compile a list of medicines supplied by the central/district agency in charge of medicines supply. Quantities cannot be calculated until you know which products are to be ordered.

Here is the list of medicines and products recommended as part of the HEARTS package:

- thiazide or thiazide-like diuretic
- calcium channel blocker (CCB) (long acting) (amlodipine)
- beta-blocker
- angiotensin converting enzyme (ACE) inhibitor (long acting) and angiotensin receptor blocker (ARB)
- statin
- insulin
- metformin
- glibenclamide
- aspirin.

Obtain a copy of the National Essential Medicines List (NEML) and the supply catalogue of the supply agency (central or regional store, or other supplier) from which your health facility orders its stock. Using the list in Table 1, develop a detailed list of products, including the following information.

- product generic name, or INN
- dosage form (tablet, dispersible tablet, test strip)
- strength or concentration
- basic units (tablet, pack)
- pack sizes available/to be stocked.

Treatment protocols and comorbidities for many of the conditions are such that they create strong interdependencies between the items on this list. For example, patients with hypertension and CKD will often be treated concomitantly with a thiazide-like diuretic or CCB; and an ACE inhibitor or ARB. Furthermore, if a tender process is used it would be important to obtain (as far as possible) the same medication (e.g. same CCB) to ensure that practitioners and patients can identify the medication easily.

Non-availability of any one of the three of four single drugs required by a hypertensive patient with, say, a comorbidity of diabetes or CKD, has consequences for the health outcomes, sometimes serious ones. Similarly, non-availability of complementary products such as glucometer strips can put an entire treatment programme in jeopardy.

In some cases, two, three or four medicines may be combined in one tablet, known as a fixed-dose combination (FDC), which eases this problem. But the availability and use of FDCs for most CVDs is currently very limited for a variety of reasons, including availability of these products, trial and research data, and the nature of customization in therapy required for each patient.

Step 2: Determine how often your health care facility receives deliveries

If your source of supply (central/regional store, district hospital, other source) routinely delivers supplies to your health facility, then how often do they deliver: monthly / 3-monthly?

If someone from your health facility travels to the regional/district to obtain supplies, how often do they go to collect supplies? weekly / monthly / every 2 months / every 3 months?

The delivery or collection of supplies may not be regular, but somewhat ad-hoc. Capture the most likely interval. Also, keep in mind the shortest and the longest interval between two resupplies. We will use this to determine safety stock later.

In most cases a **monthly** delivery or collection schedule is recommended, as it achieves a good balance between not having to order too far into the future and not making too frequent collection/delivery trips.

The reorder factor is a number that will help you calculate how much of each item you need to order. It includes the requirement to hold enough stock to cover demand up to your next reordering, and an additional buffer to protect against higher and anticipated demand or delays in delivery/pickup.

Box 7: Drawing down from framework contracts

In some countries, large health facilities can purchase some products directly from the suppliers under a framework contract. This establishes the product specifications, prices and delivery terms.

If your facility has such an option, consult with the department that has created the framework contract and confirm to your supplier your draw-down quantity accordingly.

This could be particularly useful for maintaining supplies of essential medicines and technologies on the national EML that are not in stock at the regional/central store. CVD medicines may require such an approach during the preliminary stages of the programme.

The following reorder factors are recommended (supply interval (month) x 2) for most primary-level health care facilities.

Box 8: Reorder factor

The reorder factor is 2 if supplies are delivered once a month (1 x 2 = 2)

The reorder factor is 6 if supplies are delivered every 3 months (3 x 2 = 6)

The reorder factor is 12 if supplies are delivered every 6 months (6 x 2 = 12)

Step 3: If you are starting to offer new NCD services, estimate the quantity of medicines needed to start CVD services at your facility.

Effective forecasting for CVD medicines and technologies starts with the number of current patients on treatment for a given condition and projected patients to be enrolled. If your facility is starting to offer CVD services, quantities of CVD medications are determined by the recommended treatment guidelines for the agreed initial number of patients likely to come to your health care facility to start hypertension, diabetes, services. Consult your district health management team to obtain details of estimates they may have conducted of the number of patients likely to attend. These quantities may have been based on experiences from other health care facilities in your country. If you are interested in learning more about how such estimation is carried out, see Annex B.

Box 9: Why medicines should be ordered more frequently

Often, increased transport costs (delivery model) or the time spent in travelling and waiting to collect supplies is used to justify infrequent deliveries or pickups. This increases the need for stock at the health facility and increases the risks of stock-outs, as it is harder to anticipate demand for a few months into the future than for the next 15 days or month.

CVD medicines and technologies should be ordered as frequently as possible. During a programme scale-up or at the start of a new programme, past consumption is often a poor predictor of future months' demand. Ordering enough stock to cover 2 to 3 months based on past consumption or an uncertain forecast would make stock-outs more likely. If drugs are not always available in the early days of the programme, patients may lose confidence and will be discouraged from continuing their care and ensuring proper adherence to their treatment.

Remember to plan for a small supply of buffer stock in case there are delays in deliveries. Also, make sure you consult with the district/provincial health management team and NCD programme coordinator for guidelines on determining initial stock levels.

Box 10: Simple method for calculating the initial supplies for patients with diabetes

The Taylor Clinic will start hypertension services for an initial number of **50 patients next month.**

Forty of them will be treated with amlodipine. They have recently been started on amlodipine (5 mg PO) at other facilities, but will be transferred to your facility. The remaining 10 patients have a contraindication to amlodipine and will be treated with lisinopril (20 mg PO).

Step 1: For the planned 50 patients the diabetes medications for one month's treatment will be:

40 patients: Amlodipine tabs:
40 x 1 (tabs/day) x 30 (days treatment) = **1,200 tabs**

10 patients: Lisinopril tabs: 10 x 1 (tabs/day) x 30 (days treatment) = **300 tabs**

Step 2: Check the unit sizes carefully for each medicine.

Amlodipine comes in boxes of 84 tabs. For the required 1,200 tabs, you need:
1,200 ÷ 84 = 14.3 **~15 boxes**
(As you cannot order less than a whole box, always round up to the nearest unit size.)

Lisinopril comes in boxes of 100 tabs. For the required 300 tabs, you need:
300 ÷ 100 = **3 boxes.**

Step 3: Calculate the amount to order for the first month. If you receive supplies once a month, the first time you order you will need to order for approximately 2 months. If you receive supplies every 3 months you will have to order for 6 months.

If the Taylor clinic receives supplies every month, the initial order of medicines will be:

	expected consumption	x reorder factor	= quantity to be ordered
Amlodipine	15	x 2	= **30** boxes
Lisinopril	3	x 2	= **6** boxes

Remember that after the initial few weeks of treatment, the patient dose and strength will be titrated to achieve the target levels of blood glucose, blood pressure and lipid control. Take this into account when ordering for supplies beyond the first month.

Step 4: Transition to a more routine requisitioning model

After the initial month of ordering supplies, the ordering system needs to stabilize to a more routine reordering system, based on past consumption.

Box 11: Top-up system of replenishment

Where demand is not seasonal and a treatment programme has reached equilibrium stage, a top-up system can be used. Once the initial maximum stock levels are determined, based on average monthly consumption, there is no need for health facility staff to reorder. Each month the stock that is used is replenished by a delivery vehicle, accompanied by a pharmacy technician or a staff trained in restocking.

Variants of this model also exist where the pharmacy technician (or staff trained in restocking) determine the quantity to be replenished, based on more sophisticated replenishment algorithms using decision-support technology tools.

In a typical system, when stock of an item falls below a set minimum desired level, sufficient units of that item are ordered/requisitioned to raise the stock level to the maximum desired level. Typically, the reorder points and minimum stock levels for your health facility should be set up by a trained logistician. In estimating the re-order level, they will consider factors such as monthly drug consumption, as estimated earlier; ordering frequency (monthly, quarterly); time lag between placing orders and receiving the orders; and uncertainties in forecasted demand or reliability of delivery lead time.

A Projected monthly consumption (as determined in Box 10 above, Step 1)
B Lead-time + review period = say 1 month
C Safety stock (to be determined by logistician, use 1 month of supply when no other estimate available)
D Current stock-on hand (from stock-control card or stock register)

Quantity to be ordered = **(A x B) + C – D**

After the first 6 months of starting CVD services, as the system stabilizes, past monthly consumption should be collated with data obtained from *stock-control cards* and *stock register*. At this stage, monthly consumption also becomes a good way to approximate the relative ratio of patients with a condition and how they will be put on different products/dose/strength.

Compare the average monthly consumption with the estimates created using population and prevalence data (see above). Collaborate with the MOIC to assess large deviations between the average monthly consumption (obtained from stock-cards) and the estimated monthly consumption (obtained from prevalence data).

Over time, the right quantity to order will be based on estimates of average past consumption, adjusted for any patients expected to be enrolled based on subjective knowledge. See Annex B for details on forecasting method for monthly consumption.

Apart from its use in estimating the quantity to order, it is important to consider the average consumption rate as a guide-post for assessing stock-out and expiration risks. Pay close attention to the stock of items with a low average monthly consumption rate. Some CVD medicines are likely to be slow movers and it is important to ensure they are not overstocked and their stock is rotated quickly.

Quantification methods for single-use products such as laboratory reagents and consumables

Consistent availability of laboratory reagents and consumables is a critical component of a facility's ability to manage CVD risk. The quantification process detailed above for medicines can be applied to laboratory supplies. However there are a few additional factor to consider.

Box 12: Definition of terms *(15)*

Reagents: Reagents are defined as compounds such as sulphuric acid, hydrochloric acid, sodium hydroxide, etc. that are used in a chemical reaction to detect, measure, examine, or produce other substances. Reagents vary widely in cost, stability, cold-chain requirements, availability, and associated hazards. Reagents can either be chemical or biological. The reagents used in a particular laboratory are determined by which tests the laboratory performs, the equipment used, and the standard operating procedures in place.

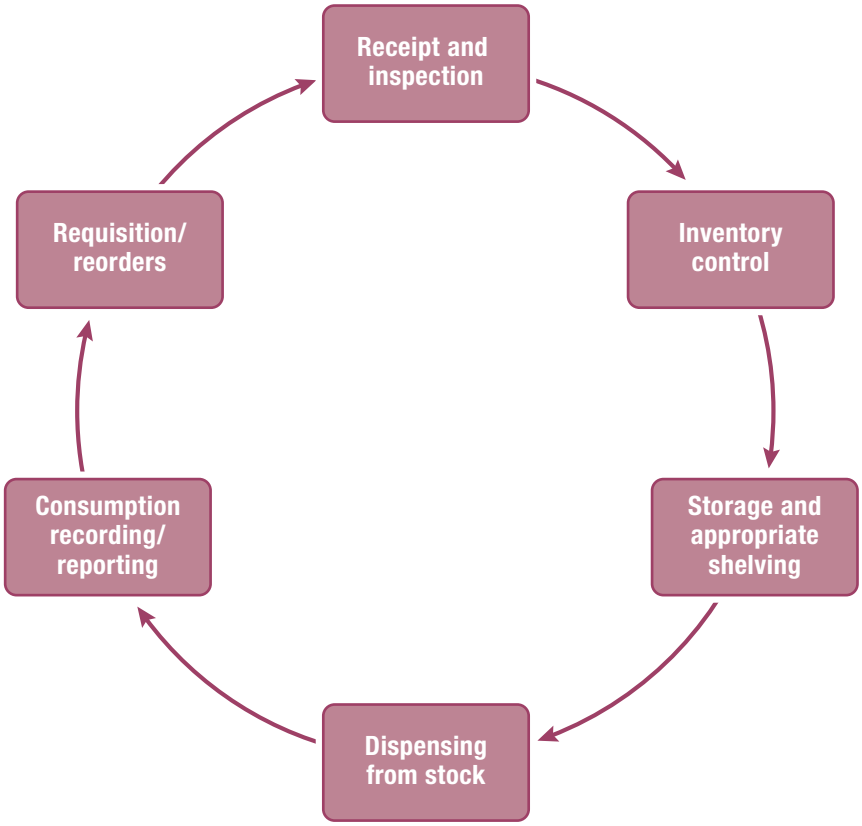
Consumables: You can define consumables for logistics purposes as items that are used once while performing a test and are not reused. Consumables can include test-specific items, such as microscope slides and cover slips. Other consumables cut across all testing services and are classified as general laboratory consumables, such as bleach, pipette tips, and gloves.

Some consumables are not used in the laboratory, but they are necessary to carry out testing and, therefore, you should include them in the quantification. For example, a vacutainer needle is required to draw blood; it is used once and discarded. If the needle is not available, the specimen cannot be collected and no test can be carried out, and so it should be included when forecasting for testing needs. After blood is drawn for laboratory testing, it is placed in a specific container for preservation and storage, then it is sent to the laboratory. The testing protocols in the laboratory will determine what type of container and preservative you should use. Include these commodities in the forecast.

Key factors to consider in determining need:

- Testing protocols are specific for each test and for each laboratory.
- Some tests can be purchased as a pre-packaged kit, with all the reagents and consumables needed for a specific test.
- Some testing equipment requires proprietary reagents and consumables; this is a closed system. In open systems, the equipment is compatible with a larger variety of standard reagents and consumables available from a variety of sources.
- Consumption rates will vary by reagent. Some reagents may be used very frequently and for multiple tests, while use of others may be quite infrequent.
- Shelf life varies greatly between reagents.
- Ensure that a designated member of the laboratory staff is responsible for or directly involved in the quantification and ordering process for laboratory reagents and consumables.

Figure 2: The receipt-to-reorder cycle



Annex B: Estimating number of patients and treatment demand

It is good practice to develop as accurate an estimate as possible of the number of patients coming to a health facility for each condition. Such estimation is best carried out by the District Health Management Team. This Annex is intended to provide details of the data that feed into such estimates and typical methods used.

Factors that influence the number of patients for each condition are:

- the profile of the population your health facility serves
- disease pattern by age.

First, a preliminary assessment is conducted to establish what forms of data are available, and how recent and accurate these data are.

Useful ways to obtain such data are:

Health Management Information System (HMIS)

This collects data about patients, the reasons for their visit to health facilities and the services provided. In addition to health facility utilization data reported through the HMIS, there are often programme monitoring reports, which also capture such data at the facility level.

Morbidity data from surveys

Prevalence or incidence of each disease/condition, such as diabetes, can be obtained from surveillance or research study surveys done for a variety of reasons by national or local governments, foreign donors, or others These may contain data from which it is possible to estimate national incidence or prevalence, usually expressed as episodes per 1,000 or 100,000 population.

Demographic data includes information about the population, such as the number of patients accessing the public sector compared with the private sector, population growth and demographic trends. Demographic data are collected through surveys and censuses. For example, Demographic and Health Surveys (DHS) are conducted every five years.

For some NCD conditions and risk factors, the WHO STEPwise approach to Surveillance (STEPS) *(16)* and DHS surveys *(17)*, which have added NCDs, with measurements of fasting blood glucose and blood pressure can be a useful source.

Some districts have a demographic surveillance system that provides verbal autopsy and other specific data which can be used when other sources of information are not available or reliable. If nothing else works, a programme has to be started by relying on qualitative/subjective estimates by clinicians.

An initial survey (Table 2) is carried out to assess which of these data elements are available.

Table 2: Status of data sources

Data Source	Data element	Most recent date	Accuracy and completeness of reporting
HMIS	Number of treatment episodes for a given condition		
Prevalence survey	Percentage of population (stratified by age or other demographic) with disease/ condition		
Facility-level surveys	Facility catchment population		

Table 3: Places to look for data regarding population and disease prevalence

Data required	Where to find it	What to watch out for
Total population in health-facility catchment area	National census	Survey data may be outdated; limited subnational data available
Population stratified by age group	National census	Age breakdown may not be available for the groups needed or for the targeted population
Disease incidence	STEPS Survey, DHS	Data may be outdated; limited sub-national data
Number of cases treated by each type of health facility	HMIS reports	May be unreliable because of poor or incomplete reporting by health facilities.
STGs	Ministry of Health	Guidelines may propose different medicines for the same condition; STG is not always used by health providers

Estimating population-level need

Use the most recent STEPS survey (or other relevant survey or research data) from your country. Find the most recent population data from your district (See Table above for sources) or the catchment population for your health facility, with age breakdowns that match STEPS and with figures for men and women. List the population 18–29 years, 30–49 years, and 50–69 years. Important points to consider:

- It is better to use national data rather than a limited sample from participating districts only (due to small size). However, choose either the rural or urban estimates, depending on the characteristics of your health facility or what is most representative of your district.
- Use the detailed results with age breakdowns rather than the combined age category of 18 to 69 in the simplified fact sheets.
- Use the fasting blood glucose threshold for diabetes, not prediabetes.

Calculate approximate population-level need (**N**) by multiplying facility catchment population or district population figure for (men + women) x disease or risk factor percentage. An example of how to use STEPS to calculate **N** is presented below:

Table 4: Table for calculating population-level need

(1) List district population or health facility catchment population				(2) STEPS results in percent-- choose rural or urban (3) Calculate approximate number in district by multiplying district population figure for (men+women) times percent (except cervical cancer screening – women only)									
	Men	Women	Both	SBP ≥140 and/or DBP ≥ 90mmHG, excluding those on medication for raised BP	N	SBP ≥140 and/or DBP ≥ 90 mmHg or currently on medication for raised blood pressure	N	Raised fasting blood glucose >7 mmol	N	Diagnosed with diabetes, on medi-cation	N	Raised blood glucose OR currently on medication for diabetes	N
18–29 years				%		%		%		%			
30–49 years				%		%		%		%			
50–69 years				%		%		%		%			
50–69 years				%		%		%		%			

Translating population-level need into health-facility demand

The STEPS survey data can help estimate the total population-level need as well as the current treatment rate for hypertension and diabetes. Knowing the current treatment gap is useful in estimating how many of those at risk will come to the facility to seek diagnosis and treatment.

Let us call F our estimate of the percentage of those in the catchment population with a condition requiring treatment who will seek care at the health facility or district. A good starting estimate for F is the percentage of the catchment population that visits the health facility for any health/treatment episode in each month.

Use **N** x **F** as an estimate of the number of patients with a condition who will visit the health facility.

At the end of the first few months of having started NCD services, revisit the calculation of **F** and update it, based on actual patient visits observed in the previous 6 months.

For each condition (e.g. diabetes, hypertension), use the standard treatment guidelines to determine the number of units of each item required by a patient in a month. Record monthly need estimates for each item on the list.

For most CVD health conditions, there is more than one treatment option on the EML. In order to determine the quantity of each drug required, consider the agreed upon protocol for the standard or average treatment for each health condition. Make a calculation of the frequency with which each product will be used for a given condition.

If there is an ideal treatment and a standard treatment guideline, then it should be assumed 100% of the time. In most cases, assumptions have to be made on the basis of empirical data from retrospective studies, expert opinion or anecdotal data.

Seek advice from your district or provincial team to estimate these figures. More detailed data on the distribution of patients between different treatment options will improve the accuracy of the forecasted order quantities.

When a programme has been ongoing for 3 to 6 months, and a sufficient number of patients are on treatment, the percentage of patients receiving each drug/specific product will approximate to a steady state. Data on consumption of products for all patients currently on treatment (just initiating, new and on-treatment for > 3 months) can then be used to estimate overall requirements.

Annex C: Forecasting future consumption

The choice of the right method to estimate your health facility's expected monthly consumption depends on the type of data available and its accuracy. Inaccurate or incomplete reporting of stock and consumption data continues to be a major challenge.

Consumption method – uses past consumption of individual medicines or products (adjusted for stock-outs and projected changes in use) to project future need. When there are significant shortages/stock-outs, or medicines are not dispensed as per treatment guidelines, this method may significantly underestimate or overestimate need. The consumption-based approach has the potential to perpetuate the problems of the past into the future. Also, for new products and programmes there is no data on past consumption.

Morbidity method – estimates the need for specific medicines or products, based on disease incidence (using surveillance and demographic data), expected number of health care facility attendances (using service delivery data), and standard treatment patterns for the disease (STGs). Morbidity-based quantification is a complex and time-consuming method. Usually, several assumptions have to be made. In many countries, obtaining prevalence/incidence data by region is quite challenging. This method also assumes standard dispensing protocols.

Proxy consumption method – uses data on disease incidence, medicine consumption or use, and/or pharmaceutical expenditures from other geographic or product contexts to extrapolate the consumption or use rate to the target programme and product, considering population coverage or the service level needed, such as taking Denmark's consumption data to estimate needs in South African health facilities. Proxy consumption is the most likely to yield accurate projections when used to extrapolate from one set of facilities to another set that serves the same type of population in the same type of geographic and climatic environment. If the data from another country is used, the results will be only a rough estimate of need.

Even when target and standard facilities are closely matched, quantification estimates are only approximate, because it is a big leap to assume that disease incidence, utilization patterns, and prescribing habits will be essentially the same in both settings. Still, this method may be the best alternative in the absence of suitable data required for the other two methods. The proxy consumption method is also useful for cross-checking projections made with other methods.

Table 5: Comparison of forecasting methods

Method	Strengths	Limitations
Consumption database	Most reliable if product has been used and is in mature stage of demand, there have been no large shortages or stock-outs.	Does not work when starting a new treatment programme. Any non-adherence to Standard Treatment Guidelines, under or overuse, gets carried forward.
Morbidity based	Estimating needs in new programmes. Estimating true underlying need.	Prevalence/morbidity not available or very outdated. Standard treatment guidelines are not followed.
Proxy consumption	Estimating needs in new programmes/products when there is no consumption data and morbidity estimates are not reliable.	Requires finding analogous products or best-case geographies. Analogues are always questionable in terms of how well they compare.

Annex D: Essential laboratory investigations and tools

Table 6: Essential products and investigations

Essential technologies/lab investigations	Tools
stethoscope blood pressure measurement device* measuring tape weighing machine (scale) glucometer blood glucose test strips urine albumin test strips urine ketones test strips	BMI chart
Add, when resources permit:	
blood cholesterol assay lipid profile serum creatinine assay serum potassium haemoglobin a1c urine microalbuminuria test strips	

*Validated blood pressure measurement devices with digital readings are preferable.

Annex E: NCD technology

Table 7: NCD technology specifications, storage and prescribing information *(18)*

Technology	Single use or multiple use	Storage conditions Complimentary parts	Specification[a]	Operation/ additional information[b]
Stethoscope	Multiple	Clean, dry, room temperature	The Y tube is treated rubber with large diameter of 10 mm. Arms with spring treated to give lasting spring and maximum reliability and comfort. Removable ear-pieces. Easy to dismantle to clean and disinfect.	
Sphygmomanometer (manual blood pressure measurement device)	Multiple	Clean, dry, room temperature Standard cuff (25cm x 12 cm Alternative cuff (36 cm x 12 cm)	Inflatable rubber cuff surrounded by durable, flexible cover that can be easily fastened around upper arm. Aneroid pressure gauge displaying cuff pressure. Pumping bulb and valve allowing adjustment up and down for cuff pressure. Pressure gauge to allow reading of pressure to 2 mmHg accuracy. Maximum pressure to be at least 300 mmHg.	For facilities with non-physician health workers, a validated blood pressure measurement device with digital reading is preferable for accurate measurement of blood pressure.
Measurement tape	Multiple	Clean, dry, room temperature	Tape measure made of non-stretchable material, preferably fibreglass but not cloth or steel. The preferred tape is one that is self-retracting, with locking capability, which can accurately measure circumference in millimetres.	
Manual weighing machine	Multiple	Clean, dry, room tempreature	Analogue scale, capacity up to 200 kg, graduation weight 100 g. Reading on both sides, robust lever system, height-adjustable rod. Height rod range 60–200 cm with 1 mm graduations. Anti-slip platform. Adjustable zero point. Weighing units: kg and/or lb. Transport castors.	Calibration should be tested by certified test weights. See manufacturer's instructions for recalibration as required.

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