**Session 10 – Selection of Essential Medicines**

Welcome to this session, in which you will be introduced to the Essential Medicine Concept, and the selection of medicines in relation to Rational Medicine Use. You will also learn about the role players involved in establishing an Essential Medicine List (EML) and how they function in a country. The relationship between the disease burden of a country and a health facility, the EML, Standard Treatment Guidelines (STGs) and Formularies will become apparent as you navigate this session.

**Session 10 will cover the following topics:**

1. Introduction to Essential Medicines List (EML) Concept

2. Developing an Essential Medicines List

3. Role players and tools used in an Essential Medicines List

4. Governance

5. Role of Anatomical Therapeutic Chemical (ATC) classification of medicines in the selection process

6. Structure and functioning of an Essential Medicines Programme

7. Summary

8. References and further reading

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| **Learning Outcomes**By the end of the session, you should be able to:* Describe essential medicines and standard treatment guideline concepts
* Explain the roles of the National Essential Medicines List (EML) committee in standard treatment guidelines and essential medicine lists
* Identify and apply the principles and criteria for selection of essential medicines
* Describe approaches to developing EML, formularies and standard treatment guidelines in the health setting
* Outline the importance and implementation of standard treatment guidelines in promoting rational medicine use
* Apply the principles of Evidence Based medicine, ATC classification and DDD (Defined Daily Doses) in rationalising EML and Formulary development at health facility level.
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**Readings**

Laing, R., Waning, B., Gray, A., Ford, N. & ‘t Hoen, E. (2003) 25 years of the WHO essential medicines lists: progress and challenges. *Lance*t: 361: 1723-1729

[http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(03)13375-2.pdf](http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736%2803%2913375-2.pdf)

Van den Ham, R., Bero, L., Laing, R., (2011) *Selection of Essential Medicines: World Medicines Situation 2011*. Geneva: World Health Organisation

<http://apps.who.int/medicinedocs/documents/s18770en/s18770en.pdf>

WHO (2013) *The Selection and Use of Essential Medicines: Report of the WHO Expert Committee, 2013* (including the 18th WHO Model List of Essential Medicines and the 4th WHO Model List of Essential Medicines for Children). Available at: <http://apps.who.int/iris/bitstream/10665/112729/1/WHO_TRS_985_eng.pdf?ua=1>

WHO (2013) WHO model list of Essential Medicines:18th list

[*http://www.who.int/medicines/publications/essentialmedicines/en/*](http://www.who.int/medicines/publications/essentialmedicines/en/)

WHO (2002) *The Selection of Essential Medicines – WHO Policy Perspectives on Medicines*. Available at: <http://www.who.int/medicinedocs/en/d/Js2296e/>

**1 INTRODUCTION TO THE ESSENTIAL MEDICINES LIST (EML)**

 **CONCEPT**

Essential medicines are definedas:

*“…those that satisfy the priority health-care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and the community can afford.” (WHO, 2002).*

This definition derives from 2002 and builds on the first definition in 1977 which was adopted in the Alma Ata Declaration of 1978.

What is the purpose of an “Essential Medicines List”?

An EML promotes health delivery equity and helps to set health related priorities, by promoting the use of a limited number of carefully selected medicines based on agreed clinical guidelines. The use of an EML leads to:

* a better supply of medicines
* more rational prescribing
* lower costs
* improved price competition through economies scale
* more focused training of health workers
* improved medicine information for patients and health workers
* prescribers gaining more experience with fewer drugs

By the end of 1999, 156 countries had official essential medicines lists, of which 127 had been updated in the previous five years. Most countries have national lists and some have provincial or state lists as well. National lists of essential medicines usually relate closely to national guidelines for clinical health care practice which are used for the training and supervision of health workers. No public sector or health insurance system can afford to supply or reimburse all medicines that are available on the market. Therefore, lists of essential medicines also guide the procurement and supply of medicines in the public sector, schemes that reimburse medicine costs, medicine donations, and local medicine production. Many international organizations, including UNICEF and UNHCR (UN Refugee Agency), as well as non-governmental organizations and international non-profit supply agencies, have adopted the essential medicines concept for their supply systems. Several developed countries also use the same approach e.g. Australia.

You can link to the following WHO publication, *The Selection of Essential Medicines – WHO Policy Perspectives on Medicines* at <http://www.who.int/medicinedocs/en/d/Js2296e/> for further comprehensive reading on the topic.

The essential medicines concept is considered a key facilitator of rational medicines use. WHO first produced a Model List of Essential Medicines in 1977 and it is revised every two years by the WHO Expert Committee on the Selection and Use of Essential Medicines. The WHO Model List consists of a core list and a complementary list. The core list comprises medicines required for a basic health care system and the complementary list for medicines for use in specialized health care facilities. A fairly recent addition is the Essential Medicines List for Children (EMLc) first produced in 2007.

The WHO model list is produced as a starting point for countries to draw up their own national Essential Medicines List.

You can read more about the historical development of WHO essential medicines in the Lancet article by Laing *et al*, (2003). [http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(03)13375-2.pdf](http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736%2803%2913375-2.pdf)

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| ***Activity 1: Identifying main principles of the WHO Model List****The process for updating the WHO Model List has evolved over time and the principles adopted are relevant for development of national essential medicines lists and local formularies.**Read the WHO Model List in Van den Ham R, Bero L, Laing R, (2011). Selection of Essential Medicines in The World Medicines Situation 2011. Pages 3-5 Geneva: World Health Organisation.*[*http://apps.who.int/medicinedocs/documents/s18770en/s18770en.pdf*](http://apps.who.int/medicinedocs/documents/s18770en/s18770en.pdf)*Jot down the main principles mentioned and think about whether these principles are being practiced in your country and/or local setting.*  |

**Feedback**

Key principles:

* Evidence-based decision making
* Cost effectiveness of treatments
* Transparency of information and evaluations
* Full disclosure of conflicts of interest
* Fixed-dose combinations

**2 DEVELOPING AN ESSENTIAL MEDICINES LIST**

The process by which medicines are selected is critical. An essential medicines list which is imposed from above will not reflect the needs of the users or be accepted by them. The WHO essential Medicine List is a good starting point and as many countries have adopted it and refined it accordingly. It is therefore very important that the process be consultative and transparent, that the selection criteria be explicit, that the selection of the medicines be linked to evidence-based standard clinical guidelines, that the clinical guidelines and the list be divided into levels of care, and that both are regularly reviewed and updated. A review of the clinical guidelines and the list should be carried out at least every second year, and their use and the impact should be monitored.

Below is a diagram illustrating the relationship between common health problems, the best clinical guidelines, the list of essential medicines, training, financing, and supply - leading to rational medicines use aimed at standardising and improving patient care by adherence to the EML/STGs.


**Fig. 1: Roles of clinical guidelines and EML/Formularies in treatment of common diseases and complaints**

At a national level, a standing committee should be appointed to give technical advice. This committee may include people from different fields, such as medicine, nursing, pharmacology, pharmacy, public health, consumer affairs and health workers at grass-roots level. Formal and informal consultations may be organized with interested parties, including representatives of professional bodies, pharmaceutical manufacturers, consumer organizations and the government budget and finance group. However, the final medicines selection by the committee members should be carried out independently.

An important principle that needs to be accepted by the committee is that not all evidence is equally strong. For example, the result of a systematic review of clinical trials carries more weight than the result of an observational study without controls, and much more than personal experiences of individual experts. The strength of the evidence defines the strength of the recommendation.

**2.1 Selection of medicines**

The selection of essential medicines is a two-step process. Market approval of a pharmaceutical product is decided on and governed by individual countries regulatory bodies. It is granted on the basis of efficacy, safety and quality, and rarely on the basis of a comparison with other products already on the market, or cost. This regulatory decision defines the availability of a medicine in the country. Inter-product comparisons are driven by decisions around comparison between various medicine products, and on considerations of value for money.

A list of essential medicines is best developed for individual countries based on disease burden and for different levels of care, and on the basis of standard clinical guidelines for common diseases and complaints that can and should be diagnosed and treated at that level.



**Fig.2. The essential medicines target: the national or institutional list of essential medicines is a subset of registered medicines, divided by level of care**

**2.2 Selection criteria**

Selection decisions are recommended based on many different factors, such as the pattern of prevalent diseases, treatment facilities, the training and experience of available personnel, financial resources, and genetic, demographic and environmental factors. The following criteria are used by the WHO Expert Committee on the Selection and Use of Essential Medicines:

• Only medicines for which sound and adequate evidence of **efficacy and safety** in a variety of settings is available should be selected.

• Relative **cost-effectiveness** is a major consideration for choosing medicines within the same therapeutic category. In comparisons between medicines, the total cost of the treatment - not only the unit cost of the medicine - must be considered, and be compared with its efficacy.

• In some cases, the choice may also be influenced by other factors such as **pharmacokinetic properties** or by local considerations such as the availability of facilities for manufacture or storage.

• Each medicine selected must be **available** in a form in which adequate quality, including bioavailability, can be ensured; its stability under the anticipated conditions of storage and use must be determined.

• Most essential medicines should be formulated as **single compounds**. Fixed dose combination products are selected only when the combination has a proven advantage in therapeutic effect, safety, adherence or in decreasing the emergence of drug resistance in malaria, tuberculosis and HIV/AIDS.

Other criteria used for the selection of essential medicines, some of them linked to those mentioned above, include:

* Needs – meets health care needs of the majority of the population
* Affordability for patients
* Effectiveness - proven over time in the real world
* Substantial safety and risk benefit ratio
* Quality – for example ensured regulatory bodies such as the Medical Control Councils in South Africa
* Evidence based decision-making – sufficient proven scientific data available regarding effectiveness and safety
* Implications for practice – viable and implementable in particular context

***Reflection***

*Think about priorities in selection criteria for essential medicines. Which of the criteria listed above do you think are the most important? If possible, discuss with a colleague or fellow student. There are obviously no correct or wrong answers, but it is interesting to see how different people have different views.*

The WHO has created a model “List of Essential Medicines” which serves as a guide for the development of national and institutional essential medicine lists. It is updated and revised every two years by the WHO Expert Committee on Selection substances. You can find this at

[*http://www.who.int/medicines/publications/essentialmedicines/en/*](http://www.who.int/medicines/publications/essentialmedicines/en/)

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| ***Activity 2: Drawing up an Essential Medicines List****Read the scenario below, and draw up a list of 10 medicines based on this scenario. Refer to the WHO (2013) model List of Essential Medicines mentioned above to guide you.* *You will then share your lists and any comments or questions you have about the process of drawing up an EML through the online Discussion Forum:* Scenario: You have been tasked to manage the emergency pharmaceutical supply system for an NGO that has opened a refugee camp in Southern Ethiopia where the current political instability and warfare has forced thousands of people into refugee camps. There is a limited budget and your director has instructed you to choose only 10 medicines that you can purchase*.* *Note: You may need to first prioritise the disease burden in order to make your final list of 10 medicines.* |

You probably realised, in considering the scenario in Activity 2, that medicine selection is not a simple process. Various widely accepted criteria are considered in essential medicine selection, such as:

* disease prevalence
* evidence on efficacy
* safety
* comparative cost-effectiveness

This information set needs to be interpreted by various highly skilled role players such as clinical pharmacists and clinical pharmacologists, epidemiologists, health economists and medical practitioners once any changes to the EML are required. The selection process is driven by good sound evidence. Evidence Based Medicine (EBM) assumes rigorous methodological approaches to assess published data used to make decisions, including development and refinement of essential medicines lists. Session 8 introduced you to Evidence Based Medicine). Remember that there are many factors that may influence the quality of the results of medicine trials that get published, for example there may be a negative influence when a medicine trial is funded by the company, or data is manipulated.

**3 ROLE PLAYERS AND TOOLS USED IN ESSENTIAL MEDICINES LIST**

As we mentioned above, a number of role players are involved in the process of selecting essential medicines for the health needs of a patient group or population, and there is a range of tools available to them to assist in their tasks. Below is a list of some of the role players and possible tools.

Role players include:

* Role players include: Prescribers of the essential medicines
* Supply chain managers (procurement) of the essential medicines
* Dispenser (pharmacist or nurse) of essential medicines
* Academic clinical pharmacologists with expertise in Evidence Based Medicine
* National health governance and finance (budget) team
* Health facility managers
* Heath care workers
* Pharmaceutical and Therapeutics Committee (PTC)

Available tools include:

* Standard Treatment Guidelines (STGs)
* Formularies and Essential Medicines

One of the key role players (PTC’s) and one of the key tools (STG’s) are described in more detail in the following sections.

**Figure 3: The Pharmaceutical Framework explaining where “Selection” fits into the Drug Supply Management Cycle**

The pharmaceutical framework in Figure 3 illustrates the four keys pharmaceutical management functions - selection, procurement, distribution and use and the main roles at different levels within the country health system.

Selection of medicines occurs primarily at a national level with the development of standard treatment guidelines and the essential medicine list, and then at lower levels, provincial, district or facility level these may be refined or narrowed to a tailored formulary for provincial, district or facility use. These will be developed with input by local practitioners and take into account local circumstances such as burden or disease, level of care and availability of human and financial resources. A critical aspect to ensure rational use of resources is to align medicines selection and procurement.

**3.1 The Pharmaceutical and Therapeutics Committee (PTC)**

The Pharmaceutical and Therapeutics Committee (PTC) is responsible for numerous important pharmaceutical management functions. The committee is responsible for establishing a formulary (sometimes known as a code list) for the province, district or facility. The PTC also identifies and corrects medicine use problems, manages adverse drug reactions, manages allocated budgets and authorisation of specialised treatment options for specific patient.

The PTC is an important role player in the Essential Medicine Programme in many countries, probably including your own, although it may be called by other names e.g. ‘Drug and Therapeutics Committee’ (DTC). The PTC will be discussed in detail in the next session (Session 11). Briefly, the role of the PTC covers a wide range of functions, including:

* Providing advice on all aspects of medicines supply management
* Evaluating and implementing medicines policies
* Evaluating and selecting medicines for the formulary list for the facility
* Developing motivations for changes to, and implementing STGs
* Investigating medicine use and identifying usage problems
* Conducting interventions to improve medicine use
* Reviewing quality of medicine use – adverse drug reactions and medicine error review
* Communicating policy and decision making re medicines, budgets, restrictions, shortages etc. to all health practitioners
* Managing the facility medicines budget
* Review of motivations for specialist medicines for individual patients
	1. **The Standards Treatment Guidelines (STGs)**

The aim of this section is to help you understand the importance of a Standard Treatment Guideline in promoting rational use of medicines in health facilities. It should also enable you to explain the procedure you would follow to ensure the implementation of a guideline in your hospital or clinic.

A STG is a systematically developed, evidence based statement designed to assist health practitioners to make decisions about appropriate health care for specific clinical circumstances.

The purpose of a Standard Treatment Guideline (STG) is to ensure that equitable and appropriate health care practices are carried out for the entire population in a specific health catchment area. The STG’s incorporate the EML and non-pharmaceutical treatments specific to a country and/or a specific population. Unfortunately however, evidence suggests that an approved formulary or essential medicines list does not prevent ineffective, unsafe, or wasteful prescribing.

What, then, is the benefit of using STGs? These are some of them:

* They represent one approach to promoting therapeutic effectiveness and efficient prescribing.
* They offer consistency and treatment efficiency for the patient.
* For the health provider there is a framework within which to provide health care that is based on expert opinion, current standards of care and best evidence from literature.
* The STGs allow managers of health care facilities and the regional, provincial or district managers to calculate exact quantities of medicines required to ensure a continuous supply of medicines.

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| ***Reflect:****Can you think of other possible benefits to add to the list above?*  |

NB: It is important to note that *failure to prescribe according to guidelines is considered irrational use of medicines*

STGs are a valuable resource in the management of pharmaceutical therapy as:

* Treatment of diseases may have many different approaches.
* Many practitioners will not remember the best method of treatment.
* Applying the most effective treatment benefits both the patient and the health care system.

STGs have existed for as long as the art of healing has existed. Traditional healers developed their standard sets of cures and passed them from generation to generation. Doctors, nurses, pharmacists, community health workers, and other health care providers learn about *all* of the treatments that *could* be used, instead of focusing on the *best* treatment that *should* be used. Standard treatment guidelines are used at different points of the therapeutic process. They may be used to diagnose, decide on treatment and pharmaceutical supply, and assist with adherence to the prescribed treatment. Their use will more likely lead to the desired clinical outcome.

STGs list the preferred pharmaceutical and non-pharmaceutical treatments for common health problems experienced by people in a specific health system. Each pharmaceutical treatment should include for each health problem the name, dosage form, strength, average dose (paediatric and adult), number of doses per day, and number of days of treatment. Other information on diagnosis and advice to the patient may also be included. STGs should consider non-pharmaceutical treatments. Reassurance, for example, might be the proper standard treatment for a child who is shorter than other children of his or her age, but who shows a normal growth curve, shows no signs of malnutrition or chronic disease, and has shorter than average parents.

Health problems, including specific diagnoses (e.g., malaria), symptoms (e.g., headache), and preventive health services (e.g., immunizations or prenatal vitamin and mineral supplements) may also be included in the guidelines. STGs are currently used around the world in 1st and 3rd world countries e.g. in parts of the United States, Europe, Latin America, Asia, Africa, and the Western Pacific. Thus, essential pharmaceutical programs are finding that the development of standard treatments is necessary for therapeutically effective and economically efficient use of medicines.

Although the advantages to using STGs are many, some disadvantages have also been encountered. We will now look at some of these advantages and disadvantages.

**3.3 Advantages and disadvantages of STG’s**

*Advantages*

The use of STGs can benefit health care providers, health care officials, supply management personnel, and patients in the following ways.

Health care providers

* Provides standardized guidance to all practitioners
* Encourages high quality care by directing practitioners to the most appropriate medicines for specific conditions
* Encourages the best quality of care since patients are receiving optimal therapy
* Utilizes only formulary or essential medicines, so the health care system needs to provide only the medicines in the STGs
* Provides valuable assistance to all practitioners, especially to those with lower level skills
* Enables providers to concentrate on making the correct diagnosis because treatment options will be provided for them

Health care officials

* Provides a basis for evaluating quality of care provided by the health care

professionals

* Provides the most effective therapy in terms of quality
* Provides a system for controlling cost by using funds more efficiently
* Provides information for practitioners to give to patients concerning the institution’s standards of care
* Can be a vehicle for integrating special programs (e.g. vaccination drives, diarrhea disease control, acute respiratory infection (ARI), tuberculosis control, malaria) at the primary health care facilities using a single set of guidelines

Supply Management

* Utilizes only formulary or essential medicines, therefore the health care system needs to provide only medicines in the STGs
* Provides information for forecasting and ordering (because medicines and quantities for common diseases will be known)
* Provides information for purchase of pre-packaged medicines

Patients

* Patients receive optimal pharmaceutical therapy
* Enables consistent and predictable treatment from all levels of providers and at all locations within the health care system tus meeting budget limits
* Allows for improved availability of medicines because of more consistent use and ordering
* Helps provide improved outcomes because patients are receiving the best treatment regimens available

*Disadvantages*

STGs have some drawbacks as well, including the following:

* Inaccurate or incomplete guidelines will provide the wrong information for providers and therefore do more harm than good.
* Guidelines may not be based on the most reliable information.
	+ Developing and updating guidelines is difficult and time-consuming and must be done on a regular schedule or they will become obsolete very quickly.
* Guidelines can provide a false sense of security; that is, health providers will limit their evaluation of a particular patient as soon as it fits into a particular standard treatment.

**3.4 Implementing Standard Treatment Guidelines**

One of the challenges of making STGs work in a health care system is to get buy in from healthcare practitioners. All practitioners must be educated in the use and importance of the guidelines. Correct marketing of the guidelines will be crucial.

The following are important elements for planning to implement Standard Treatment Guidelines:

* Legislated health policy adoption relating to STGs in the country
* Complete buy in and political will by top health officials
* Accurate easy to use printed reference materials
* Official launch with electronic cover
* In-depth initial training of health care practitioners
* Reinforcement training by using actual cases from practice
* Ongoing monitoring and audit
* Effective supervision

Printed reference materials may include manuals, posters, and training materials. Depending on the number of treatments involved, printed references may be in the form of wall charts, pocket handbooks, or larger shelf-size reference books. Pocket-sized books can also include information about individual medicines or other reference data. The contents of pocket manuals can be organized in summary tables, in diagnostic and treatment decision trees or flowcharts, or simply in written text.

An official launch is important. The Minister of Health, the leaders of professional bodies, and leading clinicians should present the new guidelines at a public forum. Ideally, the presentation should be covered by the press and broadcast media and attended by representatives of health worker associations. Initial training is also important. Ideally, standard treatments guidelines should be introduced during formal pre-service training for doctors and other health care providers. Use of the standard treatment guidelines and the reference manual or wall chart early in training develops good habits for later clinical practice

One of the problems introducing STGs is that practitioners may not appreciate how the treatments were prepared and at first may not trust the treatments. Most important, if the standard treatments differ substantially from current practice (e.g., fewer injections or fewer antibiotics than currently prescribed), these differences should be identified and discussed. Participants should be strongly encouraged to accept the standard treatments, perhaps even by signing a written agreement.

Especially for health care providers already in practice, reinforcement training during the first 6 to 12 months after the initial training can play an important role in reemphasizing the importance of following standard treatments and can allow the PTC to respond to questions that have arisen from attempts to apply the treatments.

Finally, the monitoring system and supervisory efforts should focus on the priority health problems and standard treatments for these problems. Routine reports that focus on high-priority problems such as diarrheal disease and ARI can also include information on treating these problems and, of great importance, on adequacy of supply of the few medicines needed for these conditions. Using medicine use evaluations (MUEs) can be helpful in monitoring and ensuring compliance with the STGs.

**3.5 Developing Formularies**

Formularies are derived from National EML’s, and are managed by the PTC’s. EMLs, formularies and treatment guidelines are inter-dependent and must be developed in a systematic way. They must, first and foremost, be driven by the health needs of the population being served. For example it is no good putting anti-malarials on the local hospital formulary if malaria never occurs in your region. However, it may be available on the EML for your country if it is needed for other regions.

Another important factor to consider is the level of care at which certain medicines are available. For example, it is not helpful to have a medicine used only in the intensive care unit (ICU) available at Primary Health Care clinics where there is no expertise or instrumentation to facilitate its safe use.

For each medicine listed in the formulary there will be information on use, dosage, adverse effects, contra-indications and warnings, supplemented by guidance on selecting the right medicine for a range of conditions.

The diagram below shows the minimum type of information that is included into a formulary. Remember the formulary is very specific to your facility but is always driven by the core structures reflected in the diagram below.

**Fig 4 - Three categories of information required to develop a formulary**

**3.6 Critical review of the Essential Medicines List**

The Essential Medicines List must be seen as a dynamic list of medicines that have to justify their position on the list.

The reading below gives an example of an EML review, from the 19th meeting of the WHO Expert Committee on the Selection and Use of Essential Medicines, which took place in Geneva, Switzerland, in 2013. The purpose of the meeting was to review and update the 17th WHO Model List of Essential Medicines (EML) and the 3rd WHO Model List of Essential Medicines for Children (EMLc). The Expert Committee evaluated the scientific evidence on the comparative effectiveness, safety and cost–effectiveness of medicines to update the EML and the EMLc.

The Expert Committee considered 52 applications and 15 reviews and made the following changes:

* approved the addition of 17 new medicines to the EML (10 to the core list and seven to the complementary list
* approved the deletion of one medicine from the EML
* approved new indications for three medicines already listed on the EML;
* approved the addition of a new dosage form or strength for four medicines already on the EML
* approved the moving of two medicines from the complementary list to the core list, and one from the core list to the complementary list
* rejected nine applications for the addition of medicines to the EML and deferred a decision in the case of a further two applications
* approved two medicines for neonatal care.

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| **Reading:** The Selection and Use of Essential Medicines; Report of the WHO Expert Committee, 2013 (including the 18th WHO Model List of Essential Medicines and the 4th WHO Model List of Essential Medicines for Children ). Available at: <http://apps.who.int/iris/bitstream/10665/112729/1/WHO_TRS_985_eng.pdf?ua=1>  |

The WHO Expert Committee provides information and guidance on what needs to be included with an application for inclusion, change or deletion of a medicine in the WHO Model List of Essential Medicines. Refer to these documents: [Additional Information for Application](https://ikamva.uwc.ac.za/access/content/group/99ac25fa-5408-4509-b50d-dd37af52422f/RMU%20Course%20Resources%202015/Session%2010%20Selection%20of%20Essential%20Medicines/Additional%20Information%20for_%20Application%20for%20WHO%20Model%20EML.pdf)  and the [Application Form](https://ikamva.uwc.ac.za/access/content/group/99ac25fa-5408-4509-b50d-dd37af52422f/RMU%20Course%20Resources%202015/Session%2010%20Selection%20of%20Essential%20Medicines/Application%20Form%202013_%20meeting.pdf).

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| ***Activity 3: Making Changes to the medicines list in your facility****After completing the reading above, identify the potential changes or recommendations that you think would be useful to make to the Formulary or EML used in your health facility or hospital.* *Think about how you would motivate and facilitate the process required to make changes to your formulary.* *Complete a motivation for an application, using the list of headings given in the document from the 19th Expert Committee on the Selection and Use of Essential Medicines.* *Submit your application via File Sharing. You will get feedback and an opportunity to discuss these in the Discussion Forum (see the Study Schedule for dates). This activity will prepare you for Assignment 2.* |

**4 GOVERNANCE**

Pharmaceuticals are the second largest cost driver in the health sector. Consequently there is always intense financial interest from pharmaceutical companies who can put extreme pressure on the selection decision makers.

The following two governance-related factors need to be taken into account in relation to members of an Essential Medicines List committee:

* **Declaration of Interest -** It is important to obtain “declaration of interests” from the decision makers so that an individual's secondary interests, (e.g. personal, financial) do not interfere with or influence judgments regarding the individual's primary interests (e.g. patient welfare, education, research integrity).
* **Confidentiality -** Breaches in confidentiality will put the selection and procurement process at increased risk. In terms of leaked information the risk broadly translates into:
* Loss of credibility
* Decisions are made externally based on draft material
* Reluctance of members to participate in the process and/ or loss of momentum of the review
* Negative impacts upon procurement process of the government
* Potential increased cost factors

**5 THE ROLE OF ANATOMICAL THERAPEUTIC CHEMICAL (ATC)**

 **CLASSIFICATION OF MEDICINES IN THE SELECTION PROCESS**

The use of the selected medicines at various levels within a healthcare system from procurement to actual prescribing and issue requires unique but consistent identifiers.

The **Anatomical Therapeutic Chemical (ATC) classification system** is one such tool. The system has been used since the early 1970s in drug utilization studies where it has been demonstrated to be suitable for national and international comparisons of drug utilization, for the evaluation of long term trends in drug use, for assessing the impact of certain events on drug use and for providing denominator data in investigations of drug safety.

The ATC system also includes **Defined Daily Dose (DDD)** for many drugs. It is a measure of medicine consumption based on the usual daily dose for a given medicine assuming an average maintenance dose per day of a medicine given for its main indication in an adult. By applying DDD it allows for comparison between different medicines especially if they have “different” therapeutic outcomes within a specific class.

You were introduced to these classification systems in Session 2: Identifying Medicines Use Problems.

**5.1 Anatomical Therapeutic Chemical (ATC) classification system**

The ATC classification system is a coding system that allows for classification of active ingredients of medicines according to:

* Organ or system on which they act
* Therapeutic, pharmacological properties and
* Chemical properties

ATC codes are includes in some international drug catalogues (e.g. Martindale, European Drug Index) and in several national drug catalogues. It is important to emphasise that the ATC classification does not necessarily reflect the recommended therapeutic use in all respects and that allocation to different ATC groups does not mean a difference in therapeutic effectiveness as allocation to the same ATC group does not indicate therapeutic equivalence

Some medicines have multiple therapeutic uses e.g. Aspirin (acetylsalicylic acid) when used for local oral use is A01AD05. Aspirin (acetylsalicylic acid) when used as a platelet inhibitor isB01AC06 or Aspirin (acetylsalicylic acid) when used as an analgesic and antipyretic is N02BA01

**5.2 Defined Daily Dose (DDD) Classification**

The ATC system also includes DDD for many drugs. You would have covered this in Session 2. It is a measure of medicine consumption based on the usual daily dose for a given medicine assuming an average maintenance dose per day of a medicine given for its main indication in an adult. By applying DDD it allows for comparison between different medicines especially if they have “different” therapeutic outcomes within a specific class.

This type of information allows health care officials to establish and extrapolate consumption trends. For example with antibiotics, 5 DDDs/inhabitant/year indicates that the consumption is equivalent to the treatment of every inhabitant with a 5 days course during a certain year.

Note when there is a known discrepancy between the prescribed daily dose (PDD) and the DDD, it is important to take this into account when interpreting drug consumption figures. In addition, caution should be taken in situations where the recommended dosage differs from one indication to another (e.g. antipsychotics), in severe versus mild disease (e.g. antibiotics) and where PDDs may differ from one population to another (e.g., according to sex, age, ethnicity or geographic location). Finally, it should be taken into consideration that some prescribed medications are not dispensed, and the patient does not always take all the medications which are dispensed.

**5.3 Application of ATC/DDD Systems**

The main purpose of the ATC/DDD system is as a tool for presenting medicine utilization statistics with the aim of improving medicines use.

The ATC/DDD system can be used for collection of medicines utilization statistics in a variety of settings and from a variety of sources, including those listed below: (see Sessions 5 for more on Medicine Utilisation Studies):

* Medicine usage data from national, regional or district level.
* Dispensing data either comprehensive or sampled.
* Collection of demographic information on the patients, and information on dose, duration of treatment and co-prescribing
* Information on indications, and outcomes such as hospitalisation, use of specific medical services, or adverse drug reactions.
* Patient encounter based data, potentially providing accurate information on Prescribed Daily Doses, patient demographics, duration of therapy, co-prescribing, indications, morbidity and co-morbidity, and sometimes outcomes.
* Patient survey data.  Collection of data at the patient level can provide information about actual drug consumption and takes into account compliance in filling prescriptions and taking medications as prescribed.  It can also provide qualitative information about perceptions, beliefs, and attitudes to the use of medicines.
* Health Facility data.  Data on medication use at all the above levels is often available in health care settings such as hospitals and health centres at regional, district, or village level.

Use of the ATC/DDD system allows standardisation of medicine groupings and a stable medicines utilization metric to enable comparisons of medicine use between countries, regions, and other health care settings, and to examine trends in medicine use over time and in different settings.

Medicine consumption figures should preferably be presented as numbers of DDDs/1000 inhabitants/day or, when in-hospital medicine use is considered, as DDDs per 100 bed days.

Prescription data is presented in DDD/1000 inhabitants/day and may provide a rough estimate of the proportion of the population within a defined area treated daily with certain medicines.  For example, the figure 10 DDDs/1000 inhabitants/day indicates that 1% of the population on average gets a certain treatment daily.

**5.4 Improving medicines use**

Collecting and publishing medicine utilization statistics allow for profiling of medicine consumption patterns in a setting or country allowing for benchmarking. In turn it allows for feedback within health services to individual health facilities, groups of health care providers, or individual health providers. The statistics also allow for identification of possible over-use, under-use or misuse of individual medicines or therapeutic groups.

**5.5 Medicine Safety Assessment**

Estimates of frequency trends in spontaneously reported cases of suspected adverse reactions for certain population groups may be linked to trends in medicine consumption, using the ATC/DDD system.  Use of the DDD/1000 inhabitants/day as a medicine utilization metric as the denominator, where frequency of adverse reactions is the numerator, allows trends in the frequency of adverse reaction reports to be examined against trends in medicine utilization.  For comparisons between medicines, validation by PDDs would be necessary.

The WHO Collaborating Centre for International Drug Monitoring ([Uppsala Monitoring Centre](http://www.who-umc.org/)), Sweden, was set up in 1978 and receives spontaneous reports of suspected adverse reactions from national centres around the world. As of July 2015, 122 countries have joined the WHO Programme for International Drug Monitoring, and in addition 28 'associate members' are awaiting full membership while compatibility between the national and international reporting formats is being established.

Information on all medicinal products appearing in these reports is stored in a medicines register, linked to the reports database.  All single and multiple ingredient preparations are given an ATC code at the substance level, which allows flexible searches comprising different medicine categories or groups of medicines.

This information is useful to countries as they prepare or review standard treatment guidelines and essential medicines lists. Find out more about WHO Programme for International Drug Monitoring at the Uppsala Monitoring Centre by clicking on this link:

<http://www.who-umc.org/DynPage.aspx?id=98080&mn1=7347&mn2=7252&mn3=7322&mn4=7324>

**5.6 Medicine costs, pricing and reimbursement and cost-containment**

Medicine utilization data has a central role in the quality of care cycle and ATC and DDD methodologies can be helpful in following and comparing trends in cost, but need to be used with caution, as the DDD is intended as a technical medicine use metric.

 **6 THE STRUCTURE AND FUNCTIONING OF COUNTRIES’ ESSENTIAL MEDICINES PROGRAMMES**

A country’s national EML is a government-approved selective list of medicines that guides the cost-effectiveness and effectiveness of production, procurement and supply in the public sector. Nearly all developing countries (95%) have a published national EML, many of which have been updated in the past five years. The WHO Model EML serves as a guide for the development of national and institutional EMLs; however the final list takes into consideration regional factors such as patterns of prevalent diseases; availability of medicines, treatment facilities and personnel; affordability; and genetic, demographic, and, environmental factors. Regular updating of the national list ensures continuing relevance to the current health scenario in the country.

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| --- |
| ***Reflection****Before we look in more detail at a specific example of a national EML programme, think about your own knowledge and experience of Essential Medicines selection in your country and/or facility.* *Are you aware of the structures and people involved?**Do you know about the processes followed and whether these are evidence based?* *Are you familiar with the development of medicine selection over time?* |

**6.1 The South African Experience**

So how does the concept of the rational medicine selection process actually contextualise the process of medicine selection in a country? We will look at the example of South Africa.

The national Essential Medicines Programme was established in South Africa in accordance with the National Drug Policy. The aims of this policy are:

* To ensure the availability and accessibility of medicines to treat the most common conditions -essential medicines.
* To promote the rational use of medicines and still achieve optimum therapeutic outcome

Below is a diagram of the South African Essential Medicines Programme model which illustrates how the process of medicines selection takes place and who is involved.

**Fig. 6: The South African EML model**

Source: Jugathpal, J. (2015) Introduction to the Essential Drugs Programme. National Dept. of Health, South Africa

The National Essential Medicines List Committee (NEMLC), illustrated in Fig.7 below, is a key part of the Essential Drug Programme Unit shown in Fig.6. It consists of a chair (Chief Director, Sector-wide Procurement); a secretariat (Essential Medicines Programme at the NDoH) and members (representatives from provinces, expert groups, departmental programmes and technical content experts – e.g. health economists). The committee reviews and approves (or not) proposed amendments to the EML, and implements changes and policy. They are also responsible for evaluation of the programme.

**Fig. 7: Expert review committees in NEMLC**

Source: Jugathpal, J. (2015) Introduction to the Essential Drugs Programme. National Dept. of Health, South Africa

 South Africa’s Department of Health published its first EML for Primary Health Care (PHC) in 1998, after the appointment by government of a National Essential Drugs List Committee in 1995. The committee includes pharmacists, general practitioners, medical specialists, pharmacologists and public health experts.

As in other countries, the South African National EML is used as the basis for formularies developed and monitored in provinces, districts and facilities by the relevant PTC’s. The initial medicine list is drawn up based on the WHO guidelines and on the most prevalent conditions at the primary care level in the country. The draft list is then widely circulated for comments, standard treatment guidelines are prepared and an EML is derived.

Whereas the WHO Model List of Essential Medicines is only updated every 2 years, the South African system involves a continuous series of updates. As soon as an STG/EML set is completed, the planning process for its revision commences.

The following pictures and boxes show what has been produced in South Africa with regard to selection of essential medicines, and how the essential medicines lists and the various selection committees which have a voice in their creation (from hospital to national ) exist in a dynamic relationship.

* National Essential Medicines List Committee (NEMLC) is appointed by Minister of Health
* Mandated to develop and review National EML and STGs for 3 levels of healthcare
	+ Primary Healthcare level
	+ Secondary Hospital Level
	+ Tertiary and quaternary Level



In SA Provincial PTCs are represented on the NEMLC and are responsible for the communication of decisions made by NEMLC to district and institutional PTCs

During the review of the STGs and EML, PTCs submit motivations for amendments to the STGs and EML to the NEMLC.

PTCs should promote the use and implementation of the STGs and EML.

As you have seen, the medicines selection process in South Africa has matured since the introduction of the essential medicines concept in 1996, with input and involvement from stakeholders growing over time.

In every health system, there is resistance to selection and guideline decisions, often seen as limiting clinicians’ judgment or choice. Effective communication of processes and policy is therefore essential for improving the functioning of the EDP, for example through the establishment of functional Pharmacy and Therapeutics Committees in districts and hospitals, and through the use of appropriate information and communications technologies, such as the mobile apps and web sites.

**7 SESSION SUMMARY**

Essential medicines are meant to satisfy the health care needs of the majority of the population of a country. There are many different medicines and formulations available worldwide to choose from. Model Essential Medicines Lists (EML) for adults and children have been generated and are updated regularly by the WHO and can form the backbone of a country’s individualised EML. The essential medicines list must be selected on very specific criteria including; country disease burden, proven efficacy and safety, scientific data that endorses use in specific populations including PK/PD information, reliable regular availability, favourable cost-benefit ratio, if at all possible be manufactured locally and identifiable via the INN (International Non-Proprietary Nomenclature).

Selection of the medicines on the EML for a country needs to be done in wide consultation with relevant stakeholders to ensure that the correct medicines are included and ongoing uptake. The list can and should be adapted for the different levels of care facilities. A Formulary, which is a medicine centred tool, as opposed to the STGs which are disease specific treatment plans, should also be constructed to meet individual facility needs that are managed via the facility PTC (Discussed in detail in Session 11). An open and transparent system of regular updating of the EML as well as the Formulary should be undertaken to ensure alignment with international trends in treatment and the health needs of the country or locality. Any motivations for changes on the EML or Formulary need to be accompanied by well-constructed motivations that are supported by reviewed “Evidenced Based” quality literature.

**8 REFERENCES AND FURTHER READING**

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