**Pharmaceuticals and Therapeutics Committees (PTC’s) and Rational Medicine Use (RMU)**

Welcome to this session, in which you will be introduced to the role of Pharmaceuticals and Therapeutics Committees (PTC’s) - also known as Drug and Therapeutic Committees (DTC’s) - and how they are positioned to ensure that Rational Medicine Use (RMU) occurs in health facilities, as well as at provincial and district levels. In Sessions 7 – 10 you studied strategies and tools for addressing the problem of irrational medicines use. The PTC’s are another very important and potentially effective means of working towards RMU.

In this session you will find out more about the purpose and functions of the PTC’s and how they are optimally structured and established.

You will be required to work through the notes and complete a number of activities, and are invited to view a video of an interview about experiences of PTC’s. We also recommend that you refer to the clear and useful guide by Management Sciences for Health (MSH) on drug and therapeutic committees (see reading list below). This publication offers practical, detailed information on critical aspects of the PTC’s functions.

**Session Content**

This session will cover the following topics:

1. Importance of PTC’s for RMU in the health system

2. Goals and objectives of PTC’s

3. Roles of PTC’s

4. Functions of a PTC

5. PTC structure and organisation

6. Governance in PTC’s

7. Guidelines for establishing a PTC

8. Sub-committees of the PTC

9. Assessment of PTC performance and impact

10. Session summary

11. References and further reading

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| **Learning Outcomes**  By the end of the session, you should be able to:   * Understand and describe the different roles of the PTC, its structure and organization and its relationship to other hospital committees. * Understand the different functions of a PTC including: * advisory responsibilities * development of various policies and procedures * formulary development and management * identification and investigation of medicine use problems * promotion of strategies to improve medicine use and patient safety. * Discuss the importance of the PTC in promoting rational use of medicines, especially antimicrobial use. |

**Readings**

Gauteng Provincial PTC. (2013). Guidelines for Implementation of Pharmaceutical and Therapeutics Committees in Gauteng Province. <http://apps.who.int/medicinedocs/documents/s21654en/s21654en.pdf>

Management Sciences for Health (2003) Drug and therapeutics committees: a practical guide. MSH/WHO.

<http://apps.who.int/medicinedocs/en/d/Js4882e/>

**1 IMPORTANCE OF PTC’S FOR RMU IN THE HEALTH SYSTEM**

We know that the use of “essential medicines” is the most cost effective way of saving lives and improving health in any population. RMU occurs when patients receive medications timeously, appropriate to their health needs, in the correct doses, for an adequate period of time at the lowest cost to the patient as well as the community.

In order to promote RMU we need to have fully functional effective PTC’s in place at a national, provincial and district level. Countries that have a National Drug Policy (NDP) create a policy “avenue” that details the standards for, the structure of, and the roles and functions of such a body as a PTC. In other words there must be a policy framework in place for PTC to carry out their mandate to support health care delivery to provide equitable access to safe, effective, cost-effective and affordable medicines and health care to all citizens of a country.

Pharmaceutical expenditure accounts for 30 to 40 percent of many countries’ healthcare budgets and much of that money is wasted because of irrational use and inefficiencies in procurement of medicines. In addition, governments, healthcare institutions and organizations face overuse of antibiotics, increasing antimicrobial resistance, increasing adverse drug reactions (ADRs), and considerably high costs associated with pharmaceutical use. For these reasons PTCs can provide the leadership and structure to select appropriate medicines for the formulary, identify medicine use problems, promote rational use of medicines, and help reduce pharmaceutical costs.

**Reading**

Read pages 95 – 103 of the MSH publication, for more information about promoting RMU through PTC’s.

<http://apps.who.int/medicinedocs/en/d/Js4882e/>

*Why do you think there is a need for PTCs?*

*Now consider this question, bearing in mind your own setting:*

**Feedback**

The overall value of PTC’s are not easily measured, however wide consensus is that a functional PTC provides significant benefits to the health system, including:

* Selection of effective, safe, high-quality, and cost-effective pharmaceuticals for the Formulary;
* Identification of medicine use problems that can lead to improved medicine use, including antimicrobial use;
* Improved medicine use, including antimicrobial use;
* Improved quality of patient care and health outcomes;
* Management of antimicrobial resistance;
* Increased staff and patient knowledge;
* Decreased ADRs and medication errors with improved management;
* Improved medicine procurement and inventory management;
* Management and control of pharmaceutical expenditures through better management.

**2 GOALS AND OBJECTIVES OF PTC’S**

The goal of a PTC is to ensure that patients are provided with the best possible cost effective and quality of care through determining what medicines will be available, at what cost, and how they will be used. In order to achieve this goal a PTC will have the following objectives:

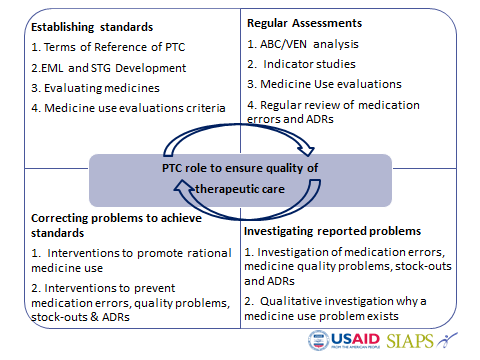
1. to develop and implement an efficient and cost-effective formulary system which includes consistent standard treatment protocols,
2. to develop a formulary list and formulary manual to ensure that only efficacious, safe, cost-effective and good quality medicines are used
3. to ensure the best possible patient safety through monitoring, evaluating and thereby preventing, as far as possible, adverse drug reactions (ADRs) and medication errors
4. to develop and implement interventions to improve medicine use by prescribers, dispensers and patients; this will require the investigation and monitoring of medicine use.

**3 ROLES OF A PTC**

The PTC’s overarching role is to be a forum that a number of health practitioners and managers can use to optimize health care, and thus the rational use of medicines, by evaluating the clinical use of pharmaceuticals, developing the policies for managing medicine use and administration, and managing the formulary system. The National, Provincial and Regional PTC’s have broad responsibilities in determining what medicines will be available and at what cost, however it is the district or hospital level PTC’s that mainly control how they will actually be used to ensure optimal patient management and patient safety.

One of the most crucial roles of PTC’s is to optimize rational use of medicines by evaluating the clinical use of pharmaceuticals, developing the policies for managing medicine use and administration, and managing the formulary system. The committee has broad responsibilities in determining what medicines will be available, at what cost, and how they will be used.

The figure below shows clearly that the PTC’s role is to ensure quality therapeutic care and this can be achieved through various interrelated activities.

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**Fig. 1: Role of the PTC in the medicine management cycle**

**Reading**

Read pages 21 – 22 of the Gauteng provincial guidelines on PTC’s, to read about the roles and responsibilities of these committees in relation to formularies, and assessment of medicine use; and pages 11 – 14 on procurement.

<http://apps.who.int/medicinedocs/documents/s21654en/s21654en.pdf>

The Medicine management cycle defines the pivotal role of managerial and technical support with appropriate policies and guidelines, in order for any health structure to operate efficiently. The PTC will often have to collaborate with those responsible for procurement and distribution of medicines. The PTC would not normally do the procurement itself; its role would normally be to ensure that the formulary system and other drug policies developed by the PTC are implemented by the procurement department. You need to ensure that the PTC doesn’t simple become a “moan zone” for complaining about stock-outs.

**4 FUNCTIONS OF A PTC**

The PTC has many different functions that contribute to the goal of improving medicine selection and rational medicine use. The primary functions are outlined below:

1. *Advising medical, administrative, and pharmacy departments on pharmaceutical related issues*

The PTC is a valuable information source for the medical staff, administration, pharmacy, and other departments within the health care institution. The committee provides advisory services to these departments on all aspects of

pharmaceutical selection, use, and distribution. Typically, the PTC provides

recommendations and advice, whereas the executive or medical staff

committee takes action on these recommendations and implements approved decisions. Many other departments and medical services, including

the nursing department, public health, the Infection Control Committee,

immunization programs, and dental services, would benefit from the PTC and

its advisory services in both public and private sectors.

1. *Developing pharmaceutical policies and procedures*

The PTC is responsible for developing pharmaceutical policies. These policies are necessary to adequately control important aspects of medicine selection, procurement, distribution, use, and administration. The PTC is the logical choice for performing these tasks, since its members have the most experience and training in pharmaceutical therapy and distribution. Policies and procedures are generally the first order of business in the committee, because they will provide the foundation for other functions that evolve from the committee.

1. *Evaluating and selecting medicines for the formulary and providing for its periodic revision*

One of the most important functions of the PTC is the selection of medicines for the health care organization’s formulary, according to the latest standard treatment guidelines (STG’s) and essential medicines lists (EML). Evaluating medicines and consequently approving or rejecting them requires significant expertise and commitment from the committee. Consistent decision making is necessary in the selection of medicines and involves:

* Evidenced-based medicine
* Consideration of local context
* A transparent evaluation process

A medicine use evaluation (MUE) requires a rigorous approach that looks at documented efficacy, safety, quality, and cost of all medicines requested for the formulary. Evaluating medicines for the formulary includes the review of generic medicines and other therapeutic equivalents so the most cost-effective formulary for the hospital and primary care clinic can be established. The evaluation process should include review of the primary pharmaceutical literature (especially randomized controlled trials), published STGs, pharmacoeconomic studies, review articles, and reliable textbooks.

A system of periodic review of medicines on the formulary is also needed because the information base about medicines is constantly changing. These changes may be reflected in new indications, information about efficacy and safety, and comparative information with other medicines. The cost of a medicine, whether it is a new medicine or a generic that has been on the formulary for many years, may change frequently and requires frequent evaluation.

1. *Identifying medicine use problems*

The PTC is required to assess the quality of care related to medicine use in a consistent, on-going fashion. This pertinent responsibility of PTC’s is frequently overlooked, resulting in PTCs spending most of their time on medicine selection and formulary management. When appropriate time and attention is given to assessing quality of medicine use, this will have significant return in the long term with improved quality of pharmaceutical therapy, improved patient outcomes, and decreased pharmaceutical costs. Several pharmaceutical management areas need to be assessed to identify medicine use problems:

* Pharmaceutical procurement and availability
* Pharmaceutical distribution
* Medicine prescribing
* Dispensing
* Administration and use
* ADR reports
* Medication error reports
* Antimicrobial resistance surveillance reports

As discussed in previous sessions many different methods are used to assess the quality of care, including: ABC and VEN (vital, essential, nonessential) analyses, defined daily dose (DDD) analysis, aggregate data analysis, health care facility indicators, hospital antimicrobial indicators, and medicine use evaluation(MUE).

1. *Promoting and conducting effective interventions to improve medicine use (including educational, managerial, and regulatory methods)*

Earlier you have learnt that irrational use of medicines is a common problem present in all health care systems worldwide, which contributes to poor patient outcomes and wastes valuable resources. The PTC is an ideal forum for promoting and implementing effective interventions which are necessary to ensure rational use of medicines. Important interventions to improve medicine use highlighted already include:

* Educational programmes
* Drug bulletins and newsletters
* In-service education
* Managerial programmes
* Development of STGs
* MUE
* Clinical pharmacy programmes
* Structured order forms and automatic stop orders
* Regulatory programmes

1. *Managing ADR’s and medication errors*

The PTC must address the issue of ADR’s to medications on a regular basis. ADR’s are a serious problem with increasing incidence, as more medicines become available and more people become exposed to them. In the United States, a review of prospective studies showed that in 1994, hospitalized patients had 2.2 million ADR’s (6% incidence) and an estimated 106,000 fatalities. Other studies have shown that ADR’s account for 3–7% of all hospital admissions. These data become more significant when you consider that the statistics in these studies do not include errors of administration, which would only increase the total incidence of morbidity and mortality.

The PTC should have a plan to address the problems of ADR’s including regular monitoring, assessment, reporting, correcting identified problems, and prevention. Newly released medicines can be a problem because of lack of knowledge and inadequate clinical experience associated with them. The current trend to “fast track” pharmaceuticals is also increasing the incidence of adverse side effects because these new medicines may not have been adequately tested before release by regulating authorities. Older medicines may produce just as many side effects, but their effects are largely known and can be anticipated and prevented in many instances.

In order to fulfil the functions outlined above, the PTC needs to be administered efficiently. The reading below gives an idea about what this entails.

**Reading**

To find out about administration considerations for PTC’s, read pages 23 -24 of the Gauteng provincial guidelines on PTC’s.

<http://apps.who.int/medicinedocs/documents/s21654en/s21654en.pdf>

**5 PTC STRUCTURE AND ORGANISATION**

The PTC usually consists of health care professionals including medical personnel (with representatives of the major specialties), pharmacists, nursing personnel, and representatives from administration. Although this mix of personnel would provide the most input from diverse segments of the health care organization, no single recommendation dictates who is on this committee. Since PTC regulates what clinicians (nurse and doctors) will be prescribing and how pharmacists are involved with pharmaceutical management, these professionals will need a significant voice on the committee.

These individuals should be appointed by the health care organization’s administration. The committee must maintain a line of authority and support to top management in the health care system. Figure 2 illustrates a PTC’s typical organization.

Secretariat

Chairperson

Administration

Public Health

Clinicians (doctors and specialist)

Pharmaceutical Services

Nursing personnel

**Figure 2: Example of a PTC Structure**

When specific medicines are being considered, the committee may invite specialists to participate in meetings as needed; these individuals do not have voting privileges. Sub-committees may be formed to carry out specific tasks, for example, therapeutic class review of antimicrobial medicines or the development of a medication error prevention strategy. Meeting regularly, at least three to six times a year, is very important for the PTC. If necessary, the committee will need to enforce mandatory attendance to accomplish the functions of the committee. Minutes are prepared for each meeting and distributed to appropriate medical, nursing, and pharmacy departments.

The structure and organisation, member appointments, goals, roles and functions should be clearly defined in a terms of reference.

**Reading**

To find out more about the structure and organisation of PTC’s, click on the link below and read pages 6 – 11 of the MSH guide on drug and therapeutic committees:

<http://apps.who.int/medicinedocs/en/d/Js4882e/>

**6 GOVERNANCE IN PTC’S**

Governance is defined in many different ways. Mostly, governance is thought of as how governments function and how they exercise authority. Other definitions of governance address stakeholder involvement, use of public resources, leadership or direction of organizations, decision making, protection of the public interest and accountability.

In the context of pharmaceutical management a very appropriate definition of governance is the “the process of decision making and the process by which decisions are implemented (or not implemented)”(UNESCAP 2009). Governance can then be thought of as the relationship between individuals and institutions and how decisions are made and implemented at all levels in the pharmaceutical system.

**Reading**

Refer to page 3 of the Gauteng provincial guidelines on PTC’s, to read about the selection of PTC members and governance.

<http://apps.who.int/medicinedocs/documents/s21654en/s21654en.pdf>

**6.1 Good governance**

There is no single universally accepted definition of good governance and sometimes this term is used with great flexibility. The diagram below shows some of the generally accepted characteristics of good governance.



**Figure 3. UNDP Characteristics of Good Governance**

**Strategic vision:** Leaders and the public have a broad and long-term perspective on good governance and human development, along with a sense of what is needed for such development (UNDP 1997).

**Participation:** All men and women should have a voice in decision making, either directly or through legitimate intermediate institutions that represent their interests. Effective participation occurs when group members have an adequate and equal opportunity to place questions on the agenda and to express their preferences about the final outcome during decision-making (UNDP 1997).

**Transparency:** Sharing information and acting in an open manner. Processes, institutions, and information are directly accessible to those concerned with them, and enough information is provided to understand and monitor them. Transparency allows stakeholders to gather information that may be critical to uncovering abuses and defending their interests. Transparent systems have clear procedures for public decision-making and open channels of communication between stakeholders and officials, and make a wide range of information accessible (UNDP 1997).

**Consensus-orientation:** Good governance requires mediation of the different interests in society to reach a broad consensus on what is in the best interest of the whole community and how this can be achieved (UNESCAP 2009).

**Rule of law:** The rule of law reigns over government, protecting citizens against arbitrary state action, and over society generally, governing relations among private interests. The rule of law is an essential precondition for accountability and predictability in both the public and private sectors (UNDP 1997).

**Equity:** Impartial or just treatment, requiring that similar cases be treated in similar ways (UNDP 1997).

**Effectiveness and efficiency:** Processes and institutions produce results that meet needs while making the best use of resources at their disposal (UNDP 1997).

**Responsiveness:** Institutions and processes try to serve all stakeholders within a reasonable time frame (UNESCAP 2009).

**Accountability:** The requirement that officials answer to stakeholders on the disposal of their powers and duties, act on criticisms or requirements made of them, and accept (some) responsibility for failure, incompetence, or deceit. Accountability requires freedom of information, stakeholders who are able to organize, and the rule of law (UNDP 1997).

For a PTC to be effective, the above characteristics must be entrenched and followed throughout the committee’s activities and proceedings. These principles of good governance can be applied to any committee or any function of the health care system.

**6.2 Governance issues which can impact Pharmaceutical Systems**

* Good governance requires that committees should be independent and impartial and also seen to be so.
* Political interference, nepotism or corruption must not play a role in the appointment of members.
* Poor governance may lead to corrupt and unethical practices which have a negative impact on the pharmaceutical supply chain and health care e.g.
  + Limits access to good quality essential medicines
  + Substandard / Counterfeit Medicines
  + Abuse and loss of scarce resources
  + Loss of confidence in public health systems

It is critical that a PTC has a terms of reference (TOR) which sets out the parameters within which the authority is delegated to committee members, sub- committees and standing groups, and specifies how the group is accountable. Terms of reference are written guidelines that clarify the role, purpose and responsibilities given to a committee. The TOR should always be produced in writing and made available to all members of both the PTC/administration and the relevant sub-committees. The TOR should be reviewed at least annually by the PTC and administration.

**6.3 Ethical concerns and governance**

The committee needs to operate in a manner that ensures transparency and avoids conflicts of interest with providers and suppliers of pharmaceuticals and medical supplies. For the committee to maintain objectivity and credibility, a strict ethics policy must be developed and rigorously enforced at all times. The committee can have no relationship with pharmaceutical companies, representatives other than a purely professional one that encourages the acquisition of quality medicines and the flow of unbiased information about their products.

***Activity 1****: Think about governance and ethics*

*Consider the following scenarios:*

* *A Pharmaceutical Manufacturer pays for the food served at the monthly PTC meeting.*
* *A Pharmaceutical manufacturer sends the chairperson of the PTC two tickets to the Super Rugby finals in appreciation of his seeing their representatives at the hospital.*

*Do any of these examples sound familiar? Do they constitute a conflict of interest?*

**Feedback**

The easy answer is…of course!

A conflict of interest can be defined as an action or relationship that might impair someone’s ability to make objective and fair decisions relating to the individuals or committee’s performance and is a term used to describe the situation in which a public official or fiduciary who contrary to the obligation and absolute duty to act for the benefit of the public or designated individual exploits the relationship for personal benefit, typically pecuniary (monetary). The appearance of conflict of interest is present if there is a potential for personal interest of an individual to clash with fiduciary duties, such as when a tender is awarded to a company of which the Chairperson of the PTC is a major stakeholder.

**Types of conflicts of interest**

* A direct financial interest (irrespective of how small it is) is sufficient to bar a person from the proceedings of an administrative body.
* Personal interest: An apprehension of bias arises from the fact that one of the parties in the matter is a family member or a friend of the decision-maker.
* Prejudice: An apprehension of bias will arise if an official, before hearing or even before its termination, indicated through his/her speech or actions how s/he would be deciding the matter.

**Ways to mitigate conflicts of interest**

The best way to handle conflicts of interest is to avoid them entirely, but this is not always possible. Ways to limit the influence of conflicts of interest include the following:

*Recusal*: This is abstaining from participating in an organisational decision in which one has a real or apparent conflict of interest.

*Disclosure*: This involves publicly identifying any potential conflicts of interest so that it is clear if a decision might be unduly influenced.

*Third-party evaluations:* These can include for example forensic audits, MCC Audit Evaluations of the Medicines Depot etc. These evaluations involve the hiring of an independent, well-qualified, respected organisation or group to make an organisational decision when the person who might otherwise make the decision has a conflict of interest.

*Codes of Conduct:*These are written guidelines that spell out expected behaviour, actions to be taken when a conflict of interest exists, and prohibited acts. The South African Pharmacy Council (SAPC) for example has a Code of Conduct which sets standards of professional conduct for all pharmacists and pharmacy support personnel, provides more detailed information regarding the Pharmacy Act and its regulations and sets out the fundamental duties which apply to all persons registered with the SAPC.

*Codes of Practice:* As an example, the National Department of Health has published guidelines on the control of pharmaceutical sales representatives in public health institutions.

**7 GUIDELINES FOR ESTABLISHING AN EFFECTIVE PTC**

**7.1 Policies**

The development of comprehensive policies and procedures is critical to the success of the PTC. Besides general policies about medicine use, specific policies regarding the following should be in place for optimal functioning of a PTC:

• Addition of new medicines

• Non formulary medicines (e.g. Section 21 Items)

• Restricted medicines

• Investigational medicines

• Standard treatment guidelines (STGs) & interventions to improve medicine use

• Generic substitution and therapeutic interchange

• Automatic stop orders

• Structured order forms and guidelines

• Pharmaceutical representatives and promotional literature

**7.2 Approach and principles**

When establishing a new PTC, it is important to ensure that a multidisciplinary approach is taken, involving a range of relevant stakeholders and supported by adequate technical and administrative skills. The process and committee should be sensitive to local politics, and committed to transparency and good service to the community.

For a PTC to be effective, certain principles must be adopted and followed throughout the committee’s activities and proceedings. These principles can be applied to any committee or any function of the health care system:

* Transparent and unbiased decision-making
* Explicit criteria and process
* Documentation of activities
* Absence of conflict of interest including pharmaceutical manufacturers and Suppliers
* Development and enforcement of a strict ethics policy for all committee activities
* Objectivity - Evidence-based approach and levels of evidence
* Consistency - Activities of the committee are consistent and follow established policies and procedures. Medicines in the formulary and STGs consistent throughout the health care system.
* Impact orientation - Indicators of process, impact, and outcome show improved health care results.

The most effective way of gaining support for a PTC is through a dynamic committee that can formulate policy and guidelines with consensus of all parties and that is seen to be sensitive to comments.

**7.3 Steps in setting up and managing the PTC**

Setting up a PTC usually involves the steps listed below:

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| * Step 1: Organising the committee and selecting members * Step 2: Determining the objectives and functions of the committee * Step 3: Determining how the committee will operate, e.g. relating to:   Regular meetings of the PTC  Regular attendance of members at committee meetings  Agenda, supplementary materials and minutes of previous meeting kept  All PTC recommendations should be disseminated  All PTC operating guidelines, policies and decisions should be documented.  Liaison of the PTC with other hospital committees   * Step 4: Seeking a mandate from senior management structures * Step 5: Identifying budgetary sources * Step 6: Forming subcommittees to address specific issues * Step 7: Assessment of the PTC’s performance |

***Activity 2***

*Watch the video of an interview with a pharmacist who has been involved in strengthening PTC’s in South Africa through training and technical support.*

*After watching the video, make notes about the main considerations and challenges in setting up and maintaining a functional PTC.*

*When making your notes, refer to the following checklist. Were these factors taken into account in the case discussed in the video?*

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| * *Establish clear goals and purpose* * *Wide representation on the committee - prescribers, nurses, pharmacists,*   *administration*   * *Permit no relationship of the committee or committee members with pharmaceutical manufacturers or suppliers* * *Communicate all PTC information, policies, procedures, recommendation, and actions to health administration and staff* * *Obtain official status approved by the administration (local hospital director and regional health bureaus) with strong management support - important issue* * *Ensure the committee has a motivated, respected, and dynamic chairperson and members* * *Develop support from medical and pharmacy departments and local professional schools* * *Ensure contextual incentives* |

**8 SUB-COMMITTEES OF THE PTC**

Sub-committees are set up so that a small group of PTC members (and sometimes co-opted experts) may focus in detail on a particular issue. This allows the PTC to ensure that sufficient attention is being paid to the detail of specific issues without one topic dominating the PTC agenda at every meeting. An example of this may be a sub-committee dealing with Rational Medicine Use, or a specific project such as a performing Medicine Use Evaluation,

The main PTC remains responsible for all decisions taken by the sub-committee so members should satisfy themselves that the process for monitoring progress is sound. As with any delegation it is also essential that the members of the sub-committees are people with relevant expertise and they are given sufficient information about the role and appropriate support in carrying out their duties.

The terms of reference (TOR) of the PTC should always be consulted in relation to sub-committees.  Confirm whether there are any barriers in relation to setting them up or limits to their operation.

Each sub-committee should have clear terms of reference agreed by the committee and regularly reviewed. A reporting mechanism should be put in place so that the main committee can be kept up to date with progress, consider proposals from the sub-committee and ratify any decisions taken by the sub-committee within its terms of reference.

For examples of TOR’s, please refer to the Gauteng provincial guidelines for PTC’s: Annex. A (Provincial level), Annex. B (District level) and Annex. C (Hospital level)

<http://apps.who.int/medicinedocs/documents/s21654en/s21654en.pdf>

We will now look at two examplesof sub-committees and how they function in relation to the PTC.

**8.1 AMR sub-committee & Infection Control sub-committee**

The roles and need for terms of reference of the Antimicrobial Resistance sub-committee have been discussed in Session 6. The AMR sub-committee is multidisciplinary and may consist of the following:

* Clinical pharmacists
* Microbiologists
* Quality control/assurance nurses
* Nursing representative
* Physician representative
* Chief pharmacist

Some of the roles of the AMR su-committee could be:

1. Ensure hospital antibiotics policy is adhered to in the ICU.

2. Promote rational use of antibiotics.

3. Educate the doctors, nurses, and pharmacy staff on appropriate antibiotic usage.

4. Conduct medicine usage review and regular audits.

5. Ensure sensitivity and resistance patterns are determined.

Other examples of PTC related activities that may lead to improved antimicrobial use include the following:

* Monitoring Antimicrobial Resistance: A PTC can do much to contain AMR, such as setting up programs and interventions to identify antimicrobial use problems and implementing specific interventions to improve prescribing, using, and managing antimicrobials.
* Documentation of clinical and economic benefits of the PTC will provide evidence to senior hospital administrators of the vital role the PTC plays in helping to preserve the effectiveness of existing antimicrobials. This effect can be accomplished by:
* Updating and managing an antimicrobial formulary
* Developing policies on antimicrobial procurement and quality
* Developing and updating antibiotic guidelines and protocols
* Developing policies (e.g., reserve antimicrobials, levels of prescribing, automatic stop orders, and AOFs) to improve compliance with guidelines and protocols
* Evaluating antimicrobial use based on pre-established criteria of appropriateness and applying remedial measures (DUE)
* Providing preservice and in-service education on rational use and AMR
* Liaising with the Infection Control Committee with regard to assessment and use of data obtained from monitoring antimicrobial resistance
* Providing education to patients on the use and abuse of antimicrobials and encouraging adherence
* Supporting pharmacovigilance activities for antimicrobials

**8.2 Pharmacovigilance sub-committee**

The PV sub-committee, like the AMR sub-committee, is responsible for reporting “findings” to the PTC to ensure that there is not an overload of work for the PTC. You by now will realize that the PTC is a forum through which change can occur. For example if the someone notes that there is a high percentage of dose omissions on a surgical ward of antibiotics and pain medication, they can ask the PTC to request an investigation to address this problem. If the problem is left unattended, patients are at risk of AMR as well as unnecessary prolonged hospital stays. If there is a pattern of severe ADRs occurring, this too can be addressed by the PTC, thus improving patient safety.

The two main areas of pharmacovigilance that can be addressed by the PTC’s are:

* Product complaints – such as suspected contamination, questionable stability, expired batches and poor packaging or labelling.
* Adverse drug reactions (ADR) – in which there are harmful or unintended responses to medicines. The PTC reporting ADR can reduce risks associated with drug prescribing and administration, and improve patient care.

**Reading**

Refer to the Gauteng provincial guidelines on PTC’s to read more about pharmacovigilance and the PTC’s role in this.

<http://apps.who.int/medicinedocs/documents/s21654en/s21654en.pdf>

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| ***Activity 3: Review the role of PTC’s in relation to RMU***  *This session has introduced you to the roles, functions and features of the PTC as a form of intervention to promote rational medicine use.*  *Imagine you have been asked to brief a PTC about RMU and how PTC’s can be used to contribute to improving medicines use. In your brief to the committee, consider the following aspects, which you will remember have been the focus of this module:*   * *Advocating for RMU* * *Identifying and addressing medicine use problems* * *Determining the efficacy, safety, effectiveness and cost-effectiveness of medicines* * *Using evidence in formulary management* * *Preventing antimicrobial resistance*  *Submit your brief to the convenor via File Sharing. You will have an opportunity for feedback in the Discussion Forum.* |

## 9 ASSESSMENT OF PTC PERFORMANCE AND IMPACT

## Once a PTC has been established and is operating, it should be evaluated regularly to ensure that it is functioning optimally and having a positive impact on rational medicine use in the facility, district or province. A questionnaire such as the one below can be used to give a picture of the functionality of PTC’s. This will provide the PTC with a tool to continuously monitor and assess its’ functionality, in order to identify areas of weakness for improvement, and areas of strength to reinforce.

## If you would like to use this form in your facility, you can access and copy it (PTC questionnaire) from the Module Resources.

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| **Pharmaceuticals and Therapeutics Committee Questionnaire**  Town/city \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of work site \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Province/Region/District**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  Does your hospital have a PTC? Yes \_\_\_\_ No \_\_\_\_  If yes, how many years has the PTC been established? Number of years \_\_\_\_\_\_\_  Does your PTC have a Subcommittee on Antimicrobials? Yes \_\_\_\_ No \_\_\_\_  Does your hospital have an Infection Control Committee? Yes \_\_\_\_ No \_\_\_\_  What are the major functions of your PTC? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Does your PTC have guidelines and procedures that regulate the functions of the  PTC? Yes \_\_\_\_ No \_\_\_\_  What professional staff members are represented on the committee?  Please list them   |  |  | | --- | --- | |  |  | |  |  | |  |  | |  |  | |  |  |   How many members typically attend PTC meetings?  Please list those who usually attend.  Who serves as the PTC chairperson?  Who serves as the secretary?  How often does the PTC meet?  What topics are covered in the regular meetings of the PTC?  Do you maintain minutes of the PTC meeting? Yes \_\_\_\_ No \_\_\_\_  Does your hospital have a medicine formulary? Yes \_\_\_\_ No \_\_\_\_  Does your committee routinely evaluate new requests for the formulary or  essential medicines lists? Yes \_\_\_\_ No \_\_\_\_  Does your committee regularly review the formulary for availability of the  most effective, safe, and cost effective medicines? Yes \_\_\_\_ No \_\_\_\_  How many chemical entities are in your formulary?  How many medicine products (including different formulations and different banded  products of the same chemical entity)?  Approximately how often do prescribers prescribe medicines that are not in the  formulary list?  Is there a medicine information center in your hospital?  If no, does your hospital have plans to institute one? Yes \_\_\_\_ No \_\_\_\_  What sources of pharmaceutical information are used to evaluate medicines for the  formulary? (Please list each source.)  Does your PTC have an Internet connection for pharmaceutical information searches? Yes \_\_\_\_ No \_\_\_\_  Who provided the medicine information sources for your hospital and when  did this occur?  What is the role of pharmaceutical companies or suppliers in providing information on new medicines and promoting medicines in your institution?  Does your PTC have established policy for evaluating adverse drug reactions? Yes \_\_\_\_ No \_\_\_\_  Does your PTC have established policies to assure product quality? Yes \_\_ No \_\_\_\_  Does your PTC participate in evaluating pharmaceutical costs? Yes \_\_\_\_ No \_\_\_\_  Does your PTC have established methods for periodically evaluating the use of medicines in the hospital? If yes, what methods are used? Yes \_\_\_\_ No \_\_\_\_  Has the committee detected any problems in the use of medicines? If yes, please  describe the problems. Yes \_\_\_\_ No \_\_\_\_  Does your PTC have programs or strategies to improve pharmaceutical use problems? What are these strategies? Yes \_\_\_\_ No \_\_\_\_  Does your PTC participate in preparing technical specifications for procurement of  medicines? Yes \_\_\_\_ No \_\_\_\_  What are some major accomplishments of the committee?  What are major problems of your committee?  What would you like to see accomplished with your committee? |

**10 SESSION SUMMARY**

The establishment of Pharmaceutical and Therapeutics Committees (PTC’s) has been advocated by the World Health Organization (WHO) as one of the 12 key interventions to promote rational medicine use. This final session of the module has given you an overview of this intervention.

Key points to remember about supporting and strengthening the work of PTC’s are:

## Get buy-in and support from top management, Head of Health (to sign off on PTC policy / TOR), as well as other relevant personnel;

## Decision-making should be a fair process, which is clear, actionable and formally implemented, and included an appeal process;

## There should be consistency in relation to meeting dates, processes, information dissemination;

## Consulation is essential; even if it takes longer to implement, respond rationally to inputs and comments

## Membership of the committee should be representative of a range of relevant stakeholders, with clearly designated roles, and appointments made through a fair, democratic process.

To sum up, a functional PTC will require a strategy based on local conditions and local data; choosing problems that can easily be addressed (for example by starting small and then scaling up); good governance; transparent decision making and solid political and administrative support.

**11 REFERENCES AND FURTHER READINGS**

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