ACTIVITIES, FUNCTIONS AND STRUCTURE OF PUBLIC SECTOR PHARMACEUTICAL AND THERAPEUTICS COMMITTEES IN THE EASTERN CAPE PROVINCE, SOUTH AFRICA

Dr. V. Henge-Daweti

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Supervisor: Dr Susan Burton

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DECLARATION

I, Vatiswa Henge-Daweti hereby declare that this dissertation as submitted to the University of Nelson Mandela Metropolitan, for the degree of Master of Science in Welfare and Public Health Management, in the Faculty of Health Sciences, has not been previously submitted by me or anyone whatsoever for degree purposes at this or any other institution and that the work is entirely mine and all sections of this work that have been cited from other sources have been acknowledged as such.

V. Henge-Daweti

20 December 2016

Vatiswa Henge-Daweti (Dr)

Date

DEDICATION

I dedicate this dissertation to my family:

My loving and caring husband for his patience, understanding and support throughout this journey.

My late mother for her spiritual support.

My little blessings (Wanda, Zimi and Zama) for bearing with me when I could not avail myself for them and their nanny for her assistance. Without her I would not have managed to be where I am today.

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ABSTRACT

The Council of Australian Therapeutic Advisory Groups (CATAG) (2013) define a Pharmaceutical and Therapeutics Committee (PTC) as a 'multi-disciplinary team committee with a commitment to the overall governance of the medicines management system in health service organizations to ensure the judicious, appropriate, safe, effective and cost-effective use of medicines'. The multidisciplinary team includes the health care providers, who are actively participating in the health care systems, such as doctors, pharmacists, nurses, administrators, finance officers, quality improvement managers and other staff members who participate in the medicine use processes according to their knowledge and skills. The major role of this committee is to evaluate and promote rational drug use by health care providers and consumers. In addition, this committee is responsible for developing systems and strategies to prevent adverse medicine reactions and medication errors, enhance rational prescribing and dispensing, provide educational activities and ensure the use of quality and cost-effective medicines.

This is a cross-sectional study that was aimed at exploring the structure, activities and functions of public sector institutional Pharmaceutical and Therapeutics Committees (PTC) in the Eastern Cape (EC) Province in South Africa (SA). The primary objectives of the study were to (i) investigate and describe the structure, functions and the activities of the institutional PTCs, and (ii) explore and describe the perception of PTC secretariats on the functionality of the institutional PTCs.

A purpose-designed questionnaire including both quantitative and qualitative aspects adapted from other international studies was piloted prior to being used for data collection. The secretariats of the institutional PTCs were requested to complete the questionnaire. Data were analysed using descriptive statistics for the quantitative aspects and thematic analysis for the qualitative component of the questionnaire. Data collection commenced after approval by the relevant ethics committees had been granted.

The findings of the study reflected that the majority of the PTCs in the EC province, SA are district/sub-district PTCs which are a cluster of a number of health care institutions in close proximity. The PTC members were appointed by the executive authority as recommended by the literature and other guiding documents. As expected the nurses were dominant as the members of the PTCs in these district/sub-district PTCs. The secretariats were the pharmacists where pharmacists were available and chairperson were doctors. These findings correspond to the recommendations by the National Department of Health PTC policy (2015) and the studies conducted in other countries.

A number of PTCs had sub-committees formed e.g. ABC analysis review committee, medicine utilization evaluation (MUE) committee and pharmacovigilance committee to optimise their functionality. Out of 15 PTCs only five PTCs with sub-committees reported functions and interventions, establishment of policies and SOPs. The rest had no outcomes or interventions reported. Poor production of policies and SOPs was observed which differs from other countries' PTCs. The focus of subcommittees in other countries is the development of formulary and policies related to medicine use. These findings pose a question regarding the functionality and effectiveness of the existing institutional PTCs in the province. In addition, the basic documents that are required to run the PTC were unavailable in a number of PTCs. Barriers to the functionality of PTCs were reported i) Lack of pharmacists and training in PTCs. ii) The rural nature of the EC province and iii) Unavailability of resources including lack of re-imbursement of personal costs. These findings reveal that budget allocation for institutional PTCs is crucial for their functionality.

It can be concluded that in the EC province the institutional PTCs which are active and effective are low in number and do not cover all geographical areas. Secondly there is a need for training and educating the PTC members on the role of the PTC members, role of sub-committees, development of policies, SOPs and the basic documents for the functionality of the committee. It is also important that during training the monitoring and evaluation of the effectiveness of the committee is emphasised. Therefore, the choice of the PTC objectives should be measurable as they can assist as indicators of effectiveness. Support by the executive authority has been observed.

KEY WORDS

Pharmaceutical and Therapeutics Committee, Pharmacy and Therapeutics Committee, institutional, hospital

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ABREVIATIONS AND ACRONYMS

- ASHP Australian Survey of Hospital Pharmacy
- CATAG Council of Australian Therapeutic Advisory Group
- COMED Coordinating body for procurement
- EC Eastern Cape
- EML/STGs Essential Medicines List and Standard Treatment Guidelines
- GPP Good Pharmacy Practice
- MUE Medicine Utilization Evaluation
- NDP National Drug Policy
- NEDLC National Essential Drug List Committee
- NHI National Health Insurance
- NMMU Nelson Mandela Metropolitan University
- PTC Pharmaceutical and Therapeutics Committee
- SA South Africa
- ToR Terms of reference
- VEN Vital, Essential and Non-Essential

CHAPTER ONE

RATIONALE FOR AND OVERVIEW OF THE DISSERTATION

1.1 Introduction

Pharmaceutical and Therapeutics Committees (PTCs) are well established in developed countries such as Australia and Canada (Duran- Garcia et al 2011, Gul 2014). However, in the Eastern Cape Province of South Africa (SA) the functionality of the existing PTCs is questionable. For this reason, this research seeks to address questions regarding the activities, functions and structure of the existing PTCs in the province.

The Eastern Cape Province is a rural province located between the Western Cape and KwaZulu Natal Province. It is divided into two metropolitan municipalities, namely: Buffalo City Metropolitan and Nelson Mandela Bay Metropolitan and six district municipalities. The six district municipalities are further divided into 37 local municipalities.



Figure 1.1 Map of the Eastern Cape showing the six district municipalities (Source: The local government handbook; 2015)

The Eastern Cape Department of Health Provincial data suggests that there are 18 functioning public sector PTCs dispersed throughout the Amathole, Chris Hani and

Cacadu districts. ¹ For the purpose of this study functioning PTCs refers to PTCs that are known to the Provincial PTC and have been submitting minutes of meetings.

A secretariat of the Eastern Cape Provincial PTC committee has deduced from the minutes received during 2012 - 2015 that some PTCs do not have clarity of structure or of the activities and the functions that should be performed by institutional PTCs.² However, from the minutes alone it is difficult to identify the exact nature of the difficulties and the problem. Therefore, this study aims to answer questions about the structure, activities and functioning of the institutional PTCs in the EC, SA.

1.2 Study objectives

With regards public sector institutional PTCs in the Eastern Cape, the primary objectives of this study are to:

- Investigate and describe the structure, functions and the activities of the institutional PTCs
- Explore and describe the perception of PTC secretariats on the functionality of the institutional PTCs.

1.3 Importance or significance of the study

The findings will assist in the development of well-structured and well-functioning institutional PTCs, thereby, promoting the rational use of medicines with the intention of improving the quality of healthcare provided by the institutions.

1.4 Overview of the dissertation

¹ Data from the EC Provincial PTC records

² Data from the EC Provincial PTC minutes

Chapter 1 introduces and highlights the background and rationale of the study. The aim and the objectives are laid out. Chapter 2 provides the literature review specifically focusing on the functions and roles of PTCs in the context of healthcare policy and guidelines in South Africa. Furthermore, it outlines previous research conducted in this particular field of practice. In Chapter 3 a detailed description of the methodology of the study is given. Chapter 4 presents the results of the study with a relevant discussion of the findings. Chapter 5 provides a summary of the results, overall conclusions, recommendations made based on the results of the study, and the limitations of the study.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This section describes the functions and roles of PTCs, in the context of healthcare policies and guidelines in SA aimed at rational and cost-effective medicine use. Section 2.2 presents sub-sections of the National Drug Policy (NDP), EML and Standard Treatment Guidelines (STGs), 10-point plan, National Core Standards followed by the introduction of the National Health Insurance (NHI) for South Africa, Good Pharmacy Practice (GPP), National Department of Health Policy and Pharmaceutical and Therapeutics Committees (PTCs). The definition, structure and functions of the PTC in other countries are explained in this Section 2.3 with possible strategies for improvement detailed in Section 2.4. Section 2.5 illustrates the importance of PTCs interventions for PTC establishment in South Africa.

2.2 Policies and Guidelines impacting on rational and cost-effective medicine use in South Africa

2.2.1 National Drug Policy

The National Drug Policy (NDP) was established in 1999 in response to concerns about the availability and accessibility of essential medicines, the irrational use of medicines and the use of expensive medicines. It was aimed at ensuring the availability and accessibility of safe, cost-effective medicines, as well as promoting rational use of medicines by prescribers, dispensers and consumers. In order to promote rational use of medicines and to implement the NDP, an Essential Drug Concept was introduced. The aim of this programme was to develop, implement and maintain an Essential Medicines List (EML) and Standard Treatment Guidelines (STG). Development of the EML and maintenance of the list through a bi-annual review is the responsibility of the National

Essential Drug List Committee (NEDLC). This committee is appointed by the minister and consists of medical and pharmaceutical experts from three levels of health care primary, secondary and tertiary hospital care. The responsibility of the NEDLC is to ensure that the selection of medicines is rational and meets the needs of the majority of South African citizens. (National Department of Health, 1996)

Furthermore, the selected medicines should be procured at reasonable prices and distributed to the consumers timeously. The Coordinating Committee for the Provisioning of Medical Supplies (COMED) is accountable for procurement. The COMED makes use of a national and international tender system, grants contracts and issues authority to the provinces to procure these medicines straight from the suppliers and to distribute to the demanders for use (National Department of Health, 1996).

2.2.2 The 10 point plan 2012 – 2014 for South Africa

In 2010, as part of its Medium Term Strategic Framework, the National Department of Health (NDH) published its priorities for the period of 2012 to 2014 in the form of a 10 point plan (National Department of Health, 2010). The existence of this plan was to assist the country in meeting the Millennium Development Goals (MDG) and with the implementation of the National Health Insurance (NHI) for South Africa. The aim was to improve the quality of health care services and one of the points was to specifically review the drug policy. However, there has to date not been a revised drug policy.

The implementation process did however result in the establishment of the National Core Standards for Health Establishments in South Africa in 2011. The National Core Standards are basically to assist as a monitoring tool for assessing the gaps and devise strategies to ensure the rendering of safe, effective and high quality health care (National Department of Health, 2010).

2.2.3 National Core Standards for Health Establishment in South Africa

One of the strategies derived to ensure the implementation of the NDP was the establishment of the National Core Standards for Health Establishments in South Africa in

2011. The National Core Standards were established to ensure that monitoring systems were in place for ensuring that medicines are prescribed according to the standard treatment guidelines and patients are educated on medicine use. In addition, patient safety and security is one of the priorities of health services to ensure the implementation of National Core Standards. Patient safety talks to pharmacovigilance which is monitoring for both the reporting and prevention of medication errors and adverse drugs reactions. In addition the National Core Standards also assess the functionality of the PTC, ensuring that the medicines are prescribed in adherence to the STGs, drug stock-outs are monitored and prevented, reporting and prevention of medication errors and adverse drug reaction reporting (ADRs) systems are in place. Under the domain of clinical support services one of the criteria for meeting the core standards is the establishment of a functional PTC in health establishments and districts (National Department of Health, 2011).

2.2.4 National Health Insurance and National Quality Improvement Policy for South Africa

It was noted that although in 1999 the NDP was established, access to affordable medicines continued to be a challenge. In 2011 the government published a green paper proposing NHI. The purpose of the NHI is to promote access to appropriate, efficient and quality health services to all citizens regardless of their socioeconomic status. The policies emphasize the importance of devising strategies to prevent medicine stock outs, and ensure constant and continuous availability of good quality medicines. In 2007, the National Quality Improvement Policy (NQIP) was established, entitled *Fast Track to Quality – The six most critical areas for patient-centered care.* The NQIP (2007) together with NHI (2011) promotes access of safe and good quality medicines to South African citizens (National Department of Health 2007, 2011).

2.2.5 Good Pharmacy Practice Standards for South Africa 2010

As can be seen in the previous sections Government policies support and promote

the development of functional PTCs. This is further supported by the South African Pharmacy Council's Good Pharmacy Practice (GPP) requirements which identify the role of PTCs as follows:

- Advise and educate health care professionals on medicines
- Develop policies and standard procedures regarding the selection and the promotion of rational use of safe and effective medicine (South African Pharmacy Council, 2010).

It is for this reason the National Department of Health developed a policy that will serve as a guiding document for the establishment of the PTCs in the country.

2.2.6 National Department of Health Policy for the establishment and functioning of PTCs in South Africa

The purpose of the policy is to provide the standards for the establishment of PTCs in all provinces in South Africa. It aims at ensuring or seeing or assisting with equitable and reliable access to good quality medicines through effective medical systems even in resource constrained environments. The policy recognizes the basic human rights and access to health care of South African citizens that has to be fulfilled. For these goals to be achieved the policy suggest that institutional PTCs function under the following scope and functions:

- Oversee medicines management systems
- Evaluate, advise and educate on all medicine-related activities
- Act in the best interest of the public, maintain patient confidentiality and ensure fair treatment.

- 1. participate in the development and review of medicine-related policies and procedures and to advise on their implementation in support of good governance
- evaluate and select essential medicines for the formulary on an ongoing basis to support equitable access to medicines
- participate in the development and review of treatment guidelines and protocols and to advise on their implementation
- 4. monitor and investigate medicine use
- 5. design interventions and to support their implementation to promote rational medicine use among healthcare professionals and patients
- 6. monitor and investigate matters related to the safety and quality of medicines and to advise on the implementation of preventative and corrective action
- advise on and support sound practices for effective procurement, distribution and storage of medicines
- 8. advise on the pharmaceutical budget, analyse the expenditure and make recommendations for the implementation of appropriate control measure

It further advises that all institutional PTCs should have an operational plan which will assist in giving direction to the members for the implementation and monitoring of its activities. It is therefore deemed vital to monitor the functionality of the PTCs against the operational plan and ensure sustainability. Communication is emphasized as essential where feedback and reliable information is furnished to all health care professionals (National Department of Health Policy 2015).

2.3 Pharmaceutical and Therapeutics Committees

The use of medicine is complex and dangerous. The process requires constant monitoring and evaluation to ensure safety standards are in place, meaning that it is necessary for institutions to implement strategies necessary to ensure that the medicines are used safely and effectively. The establishment of a PTC is seen as a strategy to achieve the goal of effective and safe medicine use (ASHP, 2001). It is, therefore, expected that each province has a functional provincial PTC, and that districts and/or

hospitals have PTCs (Pharasi & Miot 2013).

A PTC can be defined as "a multi-disciplinary team committee with a commitment to the overall governance of the medicines management system in their health service organizations to ensure the judicious, appropriate, safe, effective and cost-effective use of medicines", Council of Australian Therapeutic Advisory Groups (CATAG) 2013.

In Western countries, PTCs have existed since the 1960s (Duran-Garcia, Santos-Ramos, Puigventos-Latorre, Ortega 2011) and they are common in developed countries (Duran-Garcia et al 2011). The main function of a PTC is to select drugs to be used in health care institutions. The existence of PTCs may result in improved health care costs, thereby, promoting the use of cost-effective medicines. Furthermore, PTCs have the role of implementing standards for the management of medicines (Holloway & Green 2003, Duran- Garcia et al 2011, Shulkin 2012). For effectiveness PTCs should have clear terms of reference (ToR). The ToR should articulate the structure, activities, functions and decision-making processes followed by the committee (CATAG 2013).

2.3.1 Pharmaceutical and Therapeutic Committee Structure

It is recommended that the members of a PTC are actively practicing health care professionals (American Society of Health Systems Pharmacists 2008). They should be officially appointed by the executive authority for a fixed period as stipulated in an institutional PTC's terms of reference. The appointees should be accountable to the institutional executive authority. The structure should consist of a range of experts and skilled health care professionals to cover the scope and functions of PTCs (National Department of Health Policy 2015). The literature advises that the following health care providers be part of the committee; physicians, other prescribers, pharmacists, nurses, administrators, quality improvement managers and other staff members who participate in the medicine use processes, according to their personal expertise. Although the majority of the members should be experienced clinicians with expertise in therapeutics and literature review, and have an ability to understand financial and clinical pressures, the inclusion of junior staff is also important. The junior staff in the PTC can bring about

innovative ideas. (American Society of Health Systems Pharmacists 2008, Holloway & Green 2003, CATAG 2013)

Duran-Garcia and colleagues (2011) in their study showed that the structure of committees in various countries is similar with hospital pharmacists often serving as secretariats. The role of the secretariats was to prepare and present medicine evaluation reports. Whilst pharmacists were secretariats, the chairpersons were medical practitioners (Duran-Garcia et al 2011).

2.3.2 Functions and responsibilities

Pharmaceutical and Therapeutics Committees are responsible for monitoring rational prescribing thereby managing the formulary system (American Society of Health Systems Pharmacists 2008). A formulary is a tool that is used to ensure the quality and costs of drug. It consists of a list of medicines, medication use policies and clinical practices decided by PTCs. It can be a hard copy (e.g. book) or a soft copy (e.g. electronic version). It benefits the institutions by providing a list of medicines to keep in institutions and provides guidance for pharmaceutical depots regarding the medicines to procure and distribute. It is, therefore, important that the institutions should keep medicines that are only available on the formulary. For items that are not on the formulary there should be channels available to procure such medicines, if necessary (American Society of Health Systems Pharmacists, 2008).

Furthermore, PTCs play an advisory role thereby conducting educational activities and develops clinical standard operating procedures and policies for safe, effective and rational use of medicines. The PTC functions extend to the analysis of the medicine budget, conducting Medicine Use Evaluation (MUE) and the establishments of sub-committees to focus on certain specialty areas e.g. pharmacovigilance subcommittee – monitoring and prevention of ADRs and medication errors - and an antimicrobial stewardship subcommittee – monitoring and prevention of irrational use of antibiotics (American Society of Health Systems Pharmacists 2008; Canadian Agency for Drugs and Technologies in Health 2011 & National Department of Health Policy 2015).

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2.3.3 PTC decision-making processes

The PTCs follow evidence-based medicine processes when making decisions and evaluating medicine inclusion into formularies (American Society of Health Systems Pharmacists 2008, Afghanistan's Ministry of Public Health 2009, Canadian Agency for Drugs and Technologies in Health 2011). The decision-making processes must be clearly stipulated and appropriate management structures should be followed. All institutional PTCs are advised to have formalized reporting structures (National Department of Health Policy 2015).

2.3.4 Barriers to the functionality and sustainability of the PTCs

As much as the PTC is a useful system in promoting rational use of medicines, in most developing countries they are not functioning well due to a number of reasons;

- chairperson not committed to his/her duties,
- membership is not well represented by the key health care professionals,
- lack of trained members,
- lack of support from the executive authorities,
- poor implementation of interventions,
- lack of recognition and remuneration of time needed for the work and personal resources that might have been used (Green, Beith & Chalker 2015).

Furthermore, work overload may result in irregular meetings and hence poor attendance. This is evident by the results of the study conducted by Vang, Tomson, Kounnavong, Southammavong, Phanynouvong, Johansson, Eriksson & Wahlstrom (2006) where health care professionals were given a chance to express possible reasons of poor performance of their PTCs. The functionality of the institutional PTCs highly depends on the availability of the resources including a budget. It is advised that institutional PTCs should be allocated budgets for their functionality (National Department of Health Policy 2015).

2.3.5 The activities, structure and function of PTCs in other countries

In 1997 in Thailand at the first International Conference on Improving Use of Medicines (ICIUM) PTCs were recommended as major strategies for improving rational medicine use. This view was also supported by the WHO Global Strategy for Containment of Antimicrobial Resistance 2001. The suggestion was based on the evidence coming from developed countries with effective PTCs. PTCs were seen as structures with a potential of coming up with strategies to reduce adverse drug reactions (ADRs) thereby decreasing hospital costs and mortality rate. In addition PTCs are also critical in the process of medicine selection, procurement, distribution and use. The establishment and implementation of formulary lists, standard treatment guidelines and education granted to health care professionals are enough evidence of the effectiveness of the PTC. The effectiveness of the PTC may depend on organization of that PTC in providing the structure that will assist in the management of PTC activities (Green, Beith & Chalker 2015).

In developed countries such as Australia and Canada PTCs are well functioning and almost all hospitals have PTCs. Brazil and Germany are still developing PTCs. In South Asia, most of the hospitals have no PTCs. This might be due to the fact that in a number of small hospitals in this country there are no pharmacists. The pharmacy is run by other health care professionals such as nurses (Gul 2014).

A study was conducted where questionnaires were distributed to 43 hospitals (3 = large, 24 medium sized, 16 small hospitals) in Kalachi. Questions were about the existence of the PTC structure, membership, PTC role and responsibility and activities performed by the committee. The response rate was 53.5%. The findings revealed that 65% of hospitals in Karachi had PTCs. Large hospitals had well-functioning PTCs compared to the smaller ones. In such hospitals meetings were held three to four times a year. Members were physicians, pharmacists, nurses, administrators, and purchasing supervisors. The chairperson was a physician and pharmacists were playing the role of secretariat. This study concluded that the lack of functioning PTCs in Kalachi had a negative impact on the designing and development of the formulary (Gul 2014).

In a study conducted in United States between 1994-1995, questionnaires were emailed

to 267 teaching hospitals to be completed by the person responsible for the PTC. The questionnaire consisted of the following questions: composition, functions, roles of members, policies and procedures and formulary maintenance activities. The findings of their study revealed a mean PTC membership of 19.3 members with an average of 12.3 physicians and 3.2 pharmacists respectively. Physicians were thus dominating the PTCs. About 69.5% of PTCs reported having a secretariat as a pharmacist with a role of writing minutes, prepare for formulary review documents (e.g. submitted medicine motivations to be reviewed by the committee) and responsible for monitoring formulary activities outside the meeting. The committees were responsible for changes in the formulary and were active in formulary management (Mannebach 1999).

In 2013 Plet, Hallas, Nielsen & Kjeldsen conducted a study aimed at describing a) Organizations, functions and activities of PTCs in Denmark b) How medicine formularies are developed and implemented c) To what extent policies and activities support the use of formularies. This was a descriptive, cross sectional survey. Data was collected from June – October 2010. A questionnaire consisting of 20 questions about the structure, activities, drug selection and implementation was emailed to the chairperson of the PTC. A 100% response rate was observed. The results showed that the PTC meetings varied between 2 - 6 times a year with a duration of 1 - 2.5 hrs. It was further observed that regional PTCs had more members than hospital ones with a chairperson being a physician specialist (n=6; 67%) or hospital pharmacy managers (n=3; 3.3%). Members included specialist physicians (48%), pharmacists (12%), general practitioners (8%), managers of hospital pharmacies (7%), nurses (7%), clinical pharmacologists (6%) and other health care professionals (11%). Out of nine PTCs, seven had sub-committees with policies and guidelines to support rational medicine use. Eight PTCs developed formularies and policies and guidelines for medicine use. Newsletters, staff meetings and education were used as means of communication. In this study it was observed that the numbers of PTC members depended on the needs of an institution. In Denmark, the PTC responsibilities varied, with greater focus being given to the development of the formularies, policies and guidelines and less emphasis placed on the surveillance of medicines and implementation of PTC decisions.

Mittmann & Knowles (2009) conducted a study determining the activities of hospital PTCs across Canada. Questionnaires were emailed to 856 Canadian Hospitals with questions asking about PTC membership, and scope and responsibilities. The response rate experienced was 24%. The results revealed six as the average number of meetings held in a year, and an average size of the committee of 11 members. Physicians constituted 50% of the membership. In this study the representation of the nurses and pharmacists was equal. Other members were dieticians, quality assurance personnel, administrators and community representatives. The dominating PTC responsibility was formulary management (93%), followed by reviewing policies related to medicine use (92%), monitoring of the ADRs (83%), patient safety (80%) and drug use monitoring (80%). It was reported that some of the tasks such as medication safety and nutrition subcommittees were utilized. The financial aspects of medicine expenditures were also reviewed and mostly done by a pharmacist with previous pharmacoeconomic experience.

In Spanish hospitals, a study was conducted by Puigventos, Santos-Ramos, Ortega & Duran-Garcia (2010) aimed at defining the structure and working procedures of the PTC. It was a cross-sectional descriptive study conducted in all regions of the Spanish State. A questionnaire consisting of 138 questions was put online. Recruitment of the participants was done telephonically and by post and email. The questionnaire was divided into structure, composition, performance and evaluation and selection processes. The response rate was 39%. All hospitals had documents produced by the PTC, drug formulary (95%), therapeutic interchange programme (71%) and terms of reference (91%). The mean number of participants was 11.84. The mean size of the committee was 12.2 and the meetings were mostly chaired by the pharmacist and the secretary was also a pharmacist (87.5%). Pharmacists were observed to dominate the committees. The members were officially appointed by the hospital management, or elected to represent a certain specialty or department in the institution. The annual mean number of medicines evaluated was 10.35. The authors concluded that in Spain PTCs have similar structure and functions and are constituted with multidisciplinary membership.

In a systematic literature review, conducted by Duran-Garcia (2011) five studies analyzing PTCs in English or Spanish in Western Countries were identified. In these studies the mean number of the committee members was between six and eight. More than 89% of the committees had a pharmacist. Standard operating procedures were implemented by 89% committees. Influential factors such as decision-making was evidence-based. The findings of the study lead to a conclusion that selected Western Countries had PTCs with similar structure and operating procedures (Duran-Garcia 2011).

The above studies reveal similarities in PTC structures, membership and functions. Most structures had their chairperson as a physician and secretary as a pharmacist. The membership was multi-disciplinary consisting of different health care providers with different expertise. Having said so the numbers of the PTC members varied. It is evident that big hospitals tend to have more PTC members compared to the small hospitals. Furthermore, the big hospital PTCs were functional and effective compared to the small ones. The lack of pharmacists in small hospitals was a contributing factor to the less functioning of PTCs in these hospitals. The development of informative documents such as formularies, policies and standard operating procedures enhancing rational medicine use were an evidence of effectiveness.

2.3.6 Possible strategies to improve the functioning and performance of PTCs

In the National Department of Health PTC policy (2015) core functions of the PTCs are listed. The policy suggests that each institutional PTC performs activities according to their environmental context. An operational plan is suggested as a map to guide and give direction of the activities to be performed with monitoring and evaluation indicators clearly described. Indicators should be measurable for easy assessment of the PTC performance. A few studies were looked at concerning the performance of PTCs and strategies that can be used for improvement.

Vang et.al (2006) conducted a study aimed at determining factors in the working environment that relate to PTC performances in Lao Hospitals. Furthermore, these

researchers sought to evaluate whether PTC performance could be improved through educative intervention utilizing auditing and feedback targeted towards PTC members. The study was a quasi-experimental study conducted in two central and seven provincial hospitals and included PTC members in these hospitals. Performance of the PTCs was measured by means of developed indicators assessing the structure, reporting systems, feedback to prescribers and rational use of medicines including adherence to STGs. Data was collected at baseline and three consecutive times thereafter for a period of three months. The results showed a significant improvement in the overall score for PTC performance (p<0001) and improved adherence to STGs was observed after the educative intervention. Feedback sessions about the research findings were shared with PTC members and interviews held to find reasons of possible underperformance. PTC members reported that being overworked has an impact and resulted in huge gaps between meetings and hence poor attendance. They concluded that self-monitoring of performance by means of indicators followed by feedback could improve the work of PTCs (Vang et.al. 2006).

It has also been suggested that a medicines selection system with a clear and easy to follow method, transparency and evidence based practice is critical for the effectiveness of the committee. Furthermore, it is essential for the hospital management to grant authority to the committee to implement interventions related to the improvement of medicine use. Irregularity of meetings have also been identified as potentially having a negative impact in the functionality of the PTC. Thus it is suggested that committees should meet regularly, minutes should be distributed and actions taken before the meeting for any tasks to be followed up. It is said that an effective committee will result to improved patient outcomes. (Green, Beith & Chalker 2015)

2.3.7 Importance of PTCs and interventions for PTC establishment in South Africa

Although inappropriate use of medicines is observed in all countries, it is greatest in developing countries. Financial, technical and management challenges are suggested to be the contributing factors. The PTCs have been identified as being an effective mechanism in improving rational medicine use and advocated by the World Health Organization (WHO). In addition, the NDP requires the establishment of PTCs as one of the strategies to fulfil its objectives. Functionality of PTCs is essential in all levels of care; provincial, district and

facility level. In all these health care levels, it is the responsibility of the PTC to ensure evidence-based selection of medicines, adherence to the essential medicine list or formularies, promotion of rational medicine use and conducting medicine evaluations (SPS & USAID 2012).

In 2011-2012 in SA, training of health care professionals regarding institutional PTC establishment was conducted in all provinces focusing on the structure, role, organization and core function of the PTC. Tools and skills to make evidence-based decisions and conduct operational research including ABC and VEN analysis (pharmaceutical methods of analysing medicine consumption according to their costs and classification), monitoring and evaluation of functioning of PTCs were shared. In the Eastern Cape 16 pharmacists were trained. Training was a three day modular course between January 2011 and July 2011. During the training it was observed that hospital management support is vital for the success of institutional PTC establishment. Training required pre-and-post assessment to determine if capacity was built. It was learnt that coaching, mentoring and encouragement is required when building capacity. It was reported that the time it takes for the PTC to function depends on the level of care, province, and support by management and individual motivation (SPS & USAID 2012).

From the above literature one can observe that the establishment of the National Core Standards for Health Establishments in South Africa was to assist and reinforce the establishment of operational committees, amongst them being the PTCs in health institutions and districts. The recently derived National PTC policy clearly describes the scope and functions of PTCs, providing the standards of PTC establishments in all provinces in South Africa. It was therefore seen vital to monitor the so sad functional PTCs in the EC province if their activities, structure and actual functionality meet the expected standards.

CHAPTER THREE

METHODOLOGY

3.1 Introduction

This chapter describes the detailed methodology used in conducting this study. Section 3.2 outlines the aim of the study followed by the study objectives in Section 3.3. The study design, site, population, method and data collection instruments are outlined in section 3.4. Section 3.5 explains the handling of data and recordkeeping. Data analysis is described in Section 3.7. The reliability and validity of the study are discussed in Section 3.7 whilst bias and ethics have been considered in Section 3.8 and 3.9 respectively.

3.2 Study design

The design of the study is cross-sectional and descriptive. A purpose-designed questionnaire was used to collect data. The questions were derived from previous studies (Dura'n-Garcı'a et.al. 2011, Mannebach et.al. 1999, Weekes et.al. 1998) conducted in developed countries and were adapted for the South African context. The questionnaire was piloted on five local PTC members who are themselves not the secretary. Comments were collected and the questionnaire modified according to responses received. The pilot was also used to determine how long it took to complete the questionnaire. The final questionnaire was sent to all of the secretariats of the institutional PTCs that are known to the provincial PTC. The questionnaires were sent back by email or fax and the respondents were requested to return the completed questionnaires via email or fax.

3.3 Study site

This study was conducted in the EC province in SA.

3.4 Study period

The duration of the study was five months from April to August 2016.

3.5 Sample population

Inclusion criteria included all institutional PTCs that are listed as functioning in the Eastern Cape Department of Health's Provincial PTC's database.

3.6 Sampling method

Purposive sampling methods were used and based on the number of PTCs currently known to the Provincial PTC it was expected that there would be a study sample of approximately 27.

3.7 Data collection instrument

A purpose-designed questionnaire was used in this study (see Appendix 1) to collect details of the structure, operations, activities and functions of the PTC.

The questionnaire consisted of 36 closed - ended questions and one open - ended question and was divided into three sections;

- 1. Structure appointment of members and composition of the committee,
- 2. Operations formation of sub-committees, establishment of standard operating procedures (SOP) and frequency of the meetings and
- 3. Activities and functions of the committee.

3.8 Data Handling and Recordkeeping

Any identifying features were removed from the source data and replaced with a participant code and it was indexed and filed securely and confidentially in the clinical pharmacy department of Cecilia Makiwane Hospital. The data were captured onto an Excel® spreadsheet using the participant code.

3.9 Data analysis

Since the study is of an exploratory nature and the sample size is small, descriptive statistics were used to analyse the data. Questions with continuous variables were summarized by sample size, mean, standard deviation, median, quartile range, minimum and maximum

values. For each percentage calculation a 95 % confidence interval was provided. The open ended questions were thematically analysed using inductive coding.

3.10 Reliability and validity

Reliability and face and content validity of the data collection instruments was tested during the pilot study. The questionnaire was piloted with five local PTC members who are themselves not the secretary of the PTC.

Face validity refers to whether, at face value, the questions appear to be measuring the construct – largely a common sense approach. Content validity refers to whether all important aspects of the construct are covered. The respondents in the pilot study were asked to complete the questionnaire but were also asked for their comments on the questions - were the questions understandable, did they appear to be determining the structure, functions and activities of the PTC – are there any further questions that should have been included? Suggestions for change proposed by the pilot study participants were used to make minor adjustments to the questionnaire.

Reliability is the extent to which a measuring instrument or tool is able to provide the same results when the entity being measured has not changed (Dorland's Medical Dictionary; 2003). Neuman (2003) states that the reliability during a research study can be improved with the use of a pilot study. A pilot allows the researcher the opportunity to become familiar with the procedures, materials and apparatus that will be used during the research study (Leedy; 2001). Using five members of the same PTC provided a means to determine the extent to which the questionnaire is reliable.

3.11 Bias

This is a cross-sectional and descriptive study, whereby the questionnaires were sent for completion to the secretariats of the institutional PTCs. The researcher had no influence on the completion of the questionnaire.

3.12 Ethics

Ethical approval was sought from the Nelson Mandela Metropolitan University (NMMU) Ethics Committee and the Department of Health Research Committee. Data collection only commenced once approval had been obtained from the above mentioned committees.

Only aggregate data is presented or will be published and no individual data with any identifying features is or will be disclosed.

CHAPTER FOUR

RESULTS AND DISCUSSION

4.1 Introduction

Results based on the data collected are presented and discussed in this chapter. Section 4.2 presents the levels of institutions with PTCs and the number of members within a committee. Composition of the committee members is detailed in Section 4.3. Section 4.4 deals with the operations of the institutional PTCs. The functions and the activities of the institutional PTCs are explained in Section 4.5. Section 4.6 describes the perception of the PTC secretariats about the functionality of the PTCs, perceived barriers and possible improvement strategies.

4.2 Response rate

An email was sent to 34 potential respondents that were available from the provincial PTC mailing database requesting the names and contact details of the institutional PTC secretariats or chairpersons. A positive response was received from 31 respondents from which 25 institutional PTC secretariats were identified. A questionnaire was then forwarded to the 25 secretariats. Three institutions reported that their PTC was still to be established as it had not been formed yet, and one reported its committee to be in the early stages of formation. This resulted in the number of active institutional PTCs identified as 21. Out of 21, five of the institutional PTCs did not respond and one form was incomplete. Therefore, the final enrolment of institutional PTCs was 15. The response rate was 76% and 15 questionnaires from different institutional PTCs were analysed. This rate was perceived as good compared to the study conducted by Mittmann & Knowles (2013) and Puigventos et.al (2010) where the response rate was 24% and 39% respectively.

4.3 Composition and structure of PTCS

Because of the span of the districts concerning the distance between areas, they are divided into sub-districts. The sub-districts are clusters of nearby areas and are all managed at a district level.

4.3.1 Level of institutions with PTCs and the number of members within the committee

The findings revealed that each district municipality is represented by one or more institutional PTCs be it at a sub-district, a district level or a hospital PTC. This is perceived as potentially good as these active PTCs can form a focal point to assist the nearby institutions in establishing PTCs or form a cluster. The PTCs were from different levels of health care; primary, regionally and tertiary as illustrated in Figure 4.1.



Figure 4.1: Numbers of PTC members at the various levels of PTC facility

Figure 4.1 above reflects the highest number of PTC members at the sub-district level (mean = 31; SD = 13.5) followed by PTCs at district level (mean = 20.5; SD = 2.1). It can be expected because at both district and sub-district levels the PTCs are constituted of members from different health care facilities whom have clustered to form one committee. These numbers are comparable with the membership of PTCs at a hospital level (mean = 19.9; SD = 10.1). Some small hospitals have also grouped together with clinics (mean = 13.5; SD = 3.5) to form bigger committees with a greater spread of expertise relevant for their settings.

The findings of this study are similar to the previous studies that have been conducted in other countries where the average members were between 11–19.3 (Mannebach 1999,

Muttmann & Knowles 2009, Puigventos et.al. 2010) and the size of the committee were highly dependent on the size of the institution. In clinics and small hospitals there were fewer members to make up a committee hence clustering was common. According to Pharasi & Miot 2013, district/sub-district and hospitals are expected to have PTCs.

4.3.2 Appointment of members to a PTC

The majority (n = 15, 80%) of the committees have their members officially appointed (Figure 4.2). This is line with recommendations in the literature, that members should be actively working as health care providers and appointments should be made by an executive authority for a specific period of time (American Society of Health System Pharmacists 2008 & National Department of Health PTC Policy 2015).



Figure 4.2: A graph illustrating the official appointment of PTC members to committees

The members were thus appointed by either the chief executive officer (CEO), hospital manager/clinical manager or district/sub-district manager as illustrated in the Figure 4.3 below.



Figure 4.3: A graph illustrating the authorities who appointed PTC members

Thus, as suggested in Figure 4.3 most of the members of the institutional PTCs were appointed by executive authorities of the sub-districts, districts, clinics and hospital. Appointments by the CEO are seen to be more common in institutional PTCs. This possibly occurs in hospitals. Having said that, in districts and sub-districts managers take responsibility for appointing PTC members. This demonstrates support from the executive authorities for these PTCs and therefore increases their chance of success. Lack of support by the executive authorities poses barriers to the success of the PTC (Green, Beith and Chalker 2015). The appointment of members by the chairperson is questionable. The chairperson does not have executive authorities but is someone who has been tasked to facilitate discussions and lead the meetings. This is one area where feedback can be provided for educational and corrective purposes.

4.4. Composition of the committee

District and sub-district PTC membership was dominated by pharmacists. This is similar to the findings of the Spanish study conducted by Puigventos et.al. (2010). Having said this, in one of the sub-district PTCs the number of pharmacists were equal to the number of nurses. In 2009 the study conducted by Mittmann & Knowles in Canada also reflected similar findings. Ironically PTCs in big hospitals were dominated by doctors. This is similar to the findings of the studies conducted by Mannebach (1999) and Plet et.al. (2013).

In small hospitals and where clinics have clustered with hospitals the majority of members were nurses. This is expected as this clustering was occurring at a primary health care level where nurses are in the majority. Other health care providers that were called to be part of the meetings at *ad hoc* bases were the administrators, financial managers, infection control nurses, quality assurance officers, dieticians, laboratory representatives, clinical associates, accountants, training officers, and dentists.

It is noted that in hospitals or clinics where there are no pharmacists the pharmacist assistants or the dispensing nurse represented pharmacy. However, this has been identified as a reason for a lack of PTCs in Asia or failing of those PTCs that do exist (Gul 2014). However, 93% (n = 15) of PTCs in our study had pharmacists. These findings are close to the 89% (n = 15) of PTCs with pharmacists that was found by Duran-Garcia (2011) in his study.

In the current study, no representation of community on PTCs was observed. Community involvement in the PTC is an important aspect as it might bring about social accountability and an opportunity for community participation in decision-making processes at an institutional level. In some other countries, for example Canada community participation on PTCs is encouraged (Mittmann & Knowles (2009).



Figure 4.4: A graph illustrating the composition of PTC members

Figure 4.4 reflects the overall spread of the professions of PTC members. It can be observed that when all the professionals from the different PTCs are combined the nurses 26

become dominant followed by doctors, pharmacists and other supporting professionals. These findings are not unexpected since six out of 15 PTCs are sub-district/district or hospitals clustered with clinics and furthermore, the number of members in sub-districts, districts and clustered PTCs are large compared to the hospitals. In addition, nurses are dominant in the sub-districts, districts and clustered PTCs. The findings of this study appear to be different to the previous studies reported in the literature. In the study conducted by Mannebach (1999) physicians were dominant, and in Spain pharmacists were dominant (Puigventos et.al. 2010). However, there are similarities with the members of the districts/sub-districts and clustered PTCs having big numbers compared to the hospitals (Plet et.al. 2013). Other professionals that form part of the PTC membership include the sub-district/district/hospital managers, laboratory representatives, quality assurance personnel, dentist, financial officer, infection control nurse, pharmacist assistants, dieticians, clinical associates, accountant, information manager, training officers and administrators. The sub-district/district or hospital managers were the most dominant supportive professionals (n = 26; 16%) followed by laboratory representatives (n = 26; 12%) and dentists, financial officers, quality assurance personnel and CEO forming 8% (n = 26). These findings are similar to the findings of Mittmann & Knowles (2009).

In most of the PTCs the secretariats were pharmacists (n = 15, 93%) and the committees were chaired by doctors (n = 15, 60%). In those committees where the chairperson was not a doctor; pharmacists, clinical governance, nurses or district managers would serve as chairperson of the committee. This is similar to the Asian study conducted by Gul 2014.

4.5. Operations of the PTCs

According to the National Department of Health PTC Policy (2015) PTCs should be established by, and be accountable to, the organisation's executive authority. These committees are expected to have formalised reporting structures that form part of the organisation's governance framework and membership include a range of expertise and skills to reflect its scope and functions. The policy further suggests that the members should be appointed by the organisation's executive authority for a fixed period of time based on the Terms of Reference (TOR), TOR that are aligned with the policy and approved by the organisation's executive. It is in the TOR where the process of making future

decisions should be documented. TOR should clearly describe the structure, organisation and operation of the committee so that all members are clear about their roles and responsibilities. The scope of the institutional PTCs is an oversight of the medicine management systems, evaluate, advise and educate on all medicine-related activities. The activities of the PTCs should be characterised by transparency, evidence based medicine, accountability, participation by all the relevant involved stakeholders, rule of law and responsiveness.

The policy clearly explains the core functions of institutional PTCs as to;

- 1. develop, review and implement medicine-related policies and procedures
- 2. participate in the development and review of treatment guidelines and protocols and to advise on their implementation
- 3. monitor, investigate medicine use, design and implement interventions to promote rational medicine use e.g. conducting MUEs
- monitor and investigate matters related to the safety and quality of medicines and to advise on the implementation of preventative and corrective action e.g. pharmacovigilance committees
- 5. advise on and support sound practices for effective procurement, distribution and storage of medicines
- 6. advise on the pharmaceutical budget, analyse the expenditure and make recommendations for the implementation of appropriate control measures

To perform the above mentioned functions, formation of PTC sub-committees may be necessary.

4.5.1 Sub-Committee structures within PTCs

Many of the PTCs (67%; n = 15) employed a sub-committee structure for facilitation of operations. The sub-committees were responsible for the following;

- formulary and standard treatment guideline reviews,
- medicine utilization reviews (MUE),
- antimicrobial consumption review,

- ABC analysis review for medicine expenditure monitoring,
- infection control and prevention monitoring,
- quality assurance monitoring,
- clinical audit and
- pharmacovigilance.

Although many sub-committees exist and appear to play a seemingly important role, only a few were functional. ABC analysis is a medicine expenditure report produced by a computerized system used in the public sector, called Rx Solutions. It provides a basis for reviewing medicine consumption and expenditure, identification of cost drivers, promotion of rational and cost-effective prescribing. However, the ABC analysis sub-committee appeared to be functional in only six PTCs, suggesting that the remaining eight PTCs in the province are not monitoring the medicine expenditure.



Figure 4.5: A pie chart illustrating the ABC analysis reviewed by PTCs

This is a concern as the medicines are expensive. Recently at one of the Pharmaceutical Imbizos (2015), it was highlighted that medicine expenses cost about 2.2 billion over a 29

period of one financial year and are consuming a huge percentage of the national department of health's budget. The provinces were then requested to come up with strategies of minimizing wasteful expenditures and promote rational and cost-effective prescribing. It is thus in my opinion that a skills transfer or training of health care provider, specifically pharmacy personnel, in analysing the medicine expenditure report is vital. However, having said this, in many institutions Rx Solutions is not available and dispensing is manual. In such institutions other means of medicine consumption and expenditure recording and reporting methods can be pursued. Financial management in institutions should also be emphasized.

Other functional sub-committees conducted MUEs and pharmacovigilance. These subcommittees both appeared to be active in three separate PTCs. A low number of MUEs is expected as it correlates with the analysis of the medicine expenditure reports.



Figure 4.6: A graph illustrating the percentage of PTCs conducting MUEs

A need for conducting an MUE arises from a problem identified after a detailed analysis of a medicine expenditure report. It is a tool used to find a root-cause of the problem and possible solutions. Therefore, if the analysis is not conducted, problems will not be picked up and the need for an MUE will not be identified. The reason for less MUEs might again be the lack of skill to conduct the project. Training in conducting MUEs specifically is required or project management may be of assistance. This is similar to the lack of ADRs and medication error reports which are supposed to be submitted to and analysed by the pharmacovigilance committee. It was observed that no institutional PTC was reviewing medication errors and there were no reported reports. Only one institutional PTC reported that their medication error reports go to be analysed in detail at a pharmacovigilance subcommittee and reported to quality assurance committee. The report only comes to the PTC on request. An awareness of the importance of post-marketing surveillance and the importance of reporting medication errors to the health care professionals is vital.

In other countries such as Canada and Denmark, formulary development, policies and guidelines on safety use of medicines were the main functions of subcommittees (Mittmann & Knowles 2009, Plet et. al 2013). The practice in these countries is similar to the findings of the systematic review conducted by Mannebach (1999). It is evident that in the Eastern Cape province of South Africa the function of sub-committees focused more on safety and rational use of medicines reflected by the pharmacovigilance, ABC analysis and the MUE subcommittees. There were reported sub-committees on formulary reviews but with no outcomes of any policies or guidelines concerning medicine use. Although this is so, there were five PTCs that reported outcomes of policy development and standard operating procedures for medicine use. Such PTCs worked together as a group with the secretariat and the chairperson facilitating the dialogues and decision-making processes in coming up with a final document. Other interventions that were taken by the PTC committees as a whole were the education of the health care professionals on identified subjects of need and cost-saving strategies were developed. The lack of reported interventions and outcomes by many PTCs raises questions regarding their effectiveness. It would therefore be interesting to see their standing agenda of meetings. One might ask if they are discussing subjects relevant to PTCs, were they inducted or trained in running PTCs? There is an obvious need to support such PTCs.

4.5.2. Documentation produced by PTCs as evidence of outcomes

As indicated in the literature the effectiveness of the committee is measured by its outcomes (Green, Beith & Chalker 2015). Furthermore, the literature supports use of indicators to monitor the effectiveness of a PTC (Vang et.al. 2006). Table 4.1 below illustrates different forms or documents that have been produced by institutional PTCs.

Document / Form	% Yes	% No
Confidentiality Forms	7	93
Declaration Forms	20	80
Standard Operating Procedures	33	67
Terms of Reference	87	13

Table 4.1. Documents produced by institutional PTCs (n=15)

It can be observed that 93% (n = 15) of PTCs do not have members complete confidentiality forms. It might be that the members do not know that such forms are necessary and have never seen them. Similarly, with declaration forms 80% (n = 15) responded that they do not complete these during meeting. This shows a gap about the functionality of the institutional PTCs and the understanding of the members in running PTCs. Lack of knowledge of basic but important documents when running a PTC was observed. Education about the importance and the reasons for completing these forms is required. It is important to provide templates to those institutional PTCs that are functioning without the appropriate documentation. The production of SOPs and policies is poor. The PTCs need to be encouraged and supported in producing such important and appropriate documents.

4.5.3 Frequency and attendance of meetings

If a PTC is going to run effectively, it is important that meetings are held regularly and are attended by members. A number (n = 15; 40%) of institutional PTCs reported that they meet bi-monthly followed by those that meet monthly (n = 15; 33%) and then quarterly (n = 15; 13%). The others (n = 15; 13%) reported that they meet every 6 weeks and others reported every 4 weeks in the first trimester and 6 weeks thereafter. (See Figure 4.5). The duration of meetings was mostly reported to be 120 minutes (n = 15; 27%), 60 minutes (n = 15; 13%), 60 – 90 minutes (n = 15; 13%) and 45 – 60 minutes (n = 15; 13%).



Figure 4.7: A graph illustrating the frequency of meetings of PTCs (n=15)

Of the 82 (mean = 5.5.; SD = 2.9) meetings held by the 15 PTCs in 2015, only 62 (mean = 4.4.; SD = 2.3) were quorate (see Figure 4.6). A PTC requires a quorum in order to conduct its business and make decisions. Essentially this means that 20 PTC meetings (24%) could not sit or at least no decisions could be taken.



Figure 4.8: A graph illustrating the total number of PTC meetings and quorate meetings in 2015

Poor attendance of PTC meetings is noted as one of the barriers for the effectiveness of PTCs in the literature (Vang et.al. 2006). Although work overload is often cited as the major contributing factor, other contributing factors cited include:

- lack of commitment of members including the chairperson and the secretariat,
- lack of trained members,
- lack of support from the authorities,
- poor representation of key health care providers and
- lack of remuneration for personal resources that might have been used. (Green, Beith & Chalker 2015)

4.6 Functions and activities of the PTCs

Besides development of policies and procedures PTCs are expected to review namedpatient medicine use. The results revealed that the number of patient-named motivations submitted to PTCs is not many. Out of 15 PTCs only two PTCs reported that they had named-patient motivations submitted. One of the PTCs had ten motivations, nine approved and one rejected. Out of the approved nine, seven motivations were approved for the purchasing and use of medicine that is not on the EML. In another hospital the submitted motivations were 69, 45 approved and one was an EML item. The motivations were all submitted to the secretariat. All these motivations were reviewed for cost by the secretariat or PharmD registrars at tertiary institutions. The low number of requests for named-patient items suggest that most institutions adhere to the provincial formulary and EML/STGs. However, this may be because most of the PTCs are regional and district level committees. These institutions up-refer their patients to the tertiary institutions where if there is a need a named-patient motivation will be submitted for use for a specific rare condition with medicine not covered in the EML/STGs.

During meetings it has been reported that the chairperson leads the meetings and the secretary writes minutes and prepares the agenda. These findings are in accordance with the previously conducted studies and are within the recommended standards of the National Department of Health (Mittmann & Knowles 2009, Plet et.al 2013 & National Department of Health PTC policy 2015).

Continuous and timeous communication of the PTC executive with the members is critical. Giving feedback and dissemination of information to the members and other health care professionals is important. Each institutional PTC is advised by the National Department of Health PTC policy (2015) to have a standard method of communication. Communication may also play a role in the implementation of any decisions that might have been taken by the PTC. The study looked at various methods that different institutions are using of communicating. The graph below illustrates:



Figure 4.9: Different methods of communication used by PTCs

It can be observed that the most common methods of communication is by emails, telephone, verbally and staff meetings. Some PTCs do make use of memoranda, WhatsApp groups and newsletters. Most of the PTCs use more than one method of communication. This was seen as relevant and increases chances of information reaching the targeted people. The multi-methods of communication are supported by the findings of the study conducted by Plet and his colleagues (2013). In their study newsletters, staff meetings and education of health care providers were used as methods of communication.

4.7 The perceptions of the PTC secretariats about the functionality of the PTCs, barriers and possible improvement strategies

Within the questionnaire there was an opportunity for the secretariats to voice their concerns and provide advice for possible improvement. This was a qualitative question and the respondent rate on this question was poor. Out of 15 institutional PTCs only five responded to this question. Feedback from some respondents suggested that it may have been due to a lack of time that this question was so poorly completed. Being a qualitative question it required more writing. Other respondents mentioned that their PTCs were new and therefore they could not comment as they had insufficient experience. Of those that did respond the general feeling was that the structure and function of the PTCs were not up to 36

the recommended standard. Some of the specific concerns raised are addressed in the subsections that follow.

4.7.1 A lack of pharmacists

"We do not have a pharmacist in our PTC, there are no pharmacists in the clinics". (R6)

There were concerns that in some institutions there are no pharmacists but pharmacist assistants or a dispensary is run by nurses. A pharmacist is a scarce resource skilled profession that is crucial for both the functionality and the effectiveness of the PTC. If there is no pharmacists it is not surprising that in such PTCs there are no measurable outcomes to monitor the effectiveness of the committee. As reported above, a number of PTCs are active but the documents and activities that are crucial as a measure of effectiveness were not available. A PTC should be a multi-disciplinary forum and where some of the experts are lacking the effectiveness will be affected (American Society of Health Systems Pharmacists 2008). This was listed as one of the contributing factors to the failure of functionality of PTCs identified by Green, Beith & Chalker (2015).

These findings are expected in a rural province such as the EC. I believe that recruiting scarce skilled professionals to a rural area is not an easy task. Most people prefer to be in urban areas for better education of their children and access to a number of things needed in modern daily life, such as gymnasiums, big shopping centres, entertainment places etc. Similar findings were reflected in a study by Gul (2014) in South Asia. In his study he revealed that small hospitals were run by non-pharmacists, which was the experience and the concern of the respondents regarding the functionality of their PTCs. However, South Africa is a developing country and given time and the monitoring tools like the National Core Standards such systems will developed. The findings are comparable to other developing countries like Brazil. Similarly, in these countries PTCs are still developing.

4.7.2 Rural nature of the province

"Our institutions are too far from each other and the transport is required you are told there is only one car" (R2)

The quote above from one of the respondents reflects the difficulties created by the rural nature of the EC province. Facility catchment areas are distant from each other and the lack of resources is a fact within the Department of Health. It is in my opinion that such problems of resources might take a long time to be resolved and little can be done regarding the need for transport. Perhaps alternative strategies for meetings need to be looked at. There are times where there is a need to accept the conditions and work with what is available. One strategy could be reducing the number of meetings in a manner that will not have a negative impact on the outcomes of the committee. It has been observed from the results that there are still a number of PTCs who meet monthly and mostly are meeting bi-monthly. Monthly might be too difficult if distance is a problem. If there are any urgent matters to be discussed monthly telephone conferences might be a better method of communication as opposed to a physical meeting. Video-conferences and SKYPE where technology permits might also be of assistance. Bi-monthly is reasonable if the distance and resources allow.

4.7.3 Personal costs

"If you happen to use your own car you will never get your money back". (R15)

Consistent with past studies, in this study, the issue of re-imbursement of PTC members with remuneration when they have used their personal resources has been raised as a barrier to the functionality of the PTC (Green, Beith & Chalker 2015). As stipulated on the National Department of Health PTC Policy (2015) there is a need for PTCs to be allocated a budget. Such travelling costs could be incorporated within and be covered by the allocated budget. It can be observed that lack of resources in the EC province seems to hamper the functionality of PTCs in a negative way. For better functionality and effectiveness of the PTCs in the EC such gaps need to be looked at and interventional strategies be implemented.

4.8 Summary of results

In summary, the primary objectives of the study were to investigate and describe the structure, functions and activities of the institutional PTCs in the EC province. The secondary objective was to explore and describe the perception of PTC secretariats on functionality of PTCs. The findings of the study reflected that the majority of the PTCs in the province are district or sub-district PTCs which are a cluster of a number of geographically close health care institutions. The appointments were done correctly as the members were appointed by the executive authority, only a few were appointed by the chairperson. As expected the nurses were the dominant members of the PTCs in these district/sub-district PTCs. The secretariats were the pharmacists where pharmacists were available and the chairs were doctors. These findings correspond to the recommendations by the National Department of Health PTC policy (2015) and the studies conducted in other countries.

To optimise the operations most PTCs formed sub-committees such as ABC analysis review committee, MUE committee and pharmacovigilance committee. Ironically these were not functional as no outcomes were reported. Only five PTCs with sub-committees reported functions and interventions, establishment of policies and SOPs. Therefore poor production of policies and SOPs was observed which differs from other countries' PTCs. The sub-committees of countries with effective PTCs focuses on the development of formulary and policies related to medicine use. These findings poses a question to the functionality and effectiveness of the existing institutional PTCs in the province. In addition, the basic documents that are required to run the PTC were unavailable in a number of PTCs e.g. confidentiality form and declaration forms. The underlying question is why is this so?

The qualitative response by the PTC secretariats managed to answer the question. Lack of pharmacists in PTCs especially those in the rural areas is a barrier to the functionality of the PTCs. Training is also perceived as a contributing factor hence the lack of outcomes to monitor effectiveness and basic documents are unavailable. The rural nature of the EC province poses another barrier because the institutions are too far from each other. To attend the meetings, transport is always an issue. This suggests another barrier to the functionality of the PTCs in our province being the unavailability of resources and lack of re-imbursement of personal costs. The studies conducted in other countries together with

the National Department of Health PTC policy emphasises the importance of budget allocation for institutional PTCs.

CHAPTER FIVE

CONCLUSION, RECOMMENDATIONS AND LIMITATIONS

5.1 CONCLUDING COMMENTS

The establishment of PTCs is supported by all governmental policies from the NDP in 1999 until the National Department of Health PTC Policy in 2015. The implementation of the NDP has been challenging over the last 15 years and therefore other policies to assist with implementation were developed. The goal of the NDP has always been to promote accessibility and availability of cost-effective medicines by prescribers, dispensers and consumers but has proved challenging to implement.

The formation of PTCs with sub-committees such as the antimicrobial, pharmacovigilance and formulary sub-committees as recommended by the National Core Standards are therefore strategies to assist with ensuring safe and effective high quality health care services. The GPP stipulates the role of the PTCs as advisory and educative through developing the policies and SOPs regarding the selection and promotion of rational use of safe medicines. The National PTC Policy extends this to the reviewing of the formulary & EML/STGs six monthly, monitoring and investigating the use of medicines through MUEs, conducting financial analyses, making use of ABC analyses and developing interventions that are implemented and measured for effectiveness. Communication for feedback and dissemination of important information is advisable for maintaining the effectiveness of the committee.

The results of this study suggest that in the EC province the number of active and effective PTCs is low and there is a need to assist institutions in the establishment of PTCs. However, the ones that are functioning are doing their best to enhance the standard of patient care by producing the documents that assist in the safe use of cost-effective medicines without compromising the quality. Their structure is of a multi-disciplinary nature despite a few where there are staffing problems and shortage of key professionals.

The rural nature of the province has an impact on the functionality of the PTCs. The major gap has been observed in the operations, functions and activities of the PTCs. There is a need to educate, train and transfer skills to the members of the PTCs regarding the functioning and the role of different sub-committees, development of SOPs and policies, basic documents required to be completed in each meeting and how to implement their decision-making. Training in the review of ABC analysis and the use of other medicine expenditure reports is crucial.

5.2 RECOMMENDATIONS

There is both need for improvement in the functioning of the existing PTCs as well as increasing the number of PTCs in the province. The EC is a large province and to have only 15 active PTCs is insufficient. Furthermore, the results suggest that only six of those 15 PTCs have means of demonstrating effectiveness through the recording of outcomes measures. This alone demonstrates a need for more educational sessions with health care providers about the importance of establishing PTCs in health institutions. Furthermore, PTC members need to be educated about their role within the PTC.

An operational plan is one of the guiding documents that has been suggested by the National Department of Health PTC Policy but no PTC in this study reported having such a plan. An operational plan would assist with guidance of the activities to be conducted through the year. It should be based on the strategic plans of the particular institution linked with the vision and mission of the institutional PTC. It should also be accompanied by a set of indicators to measure effectiveness.

Many PTCs are also functioning without terms of reference (ToR). Again ToR is an important document for any committee, it defines guiding principles, the structure of the committee, core functions of the committee and processes to be followed to reach decisions. The decision-making processes should be transparent and explained on the ToR document.

Financial support of the PTC is crucial for resource allocation. It is difficult for any organization or committee to function without finances. The lack of budget for the PTCs in institutions may also pose a barrier to the well-functioning of these PTCs. The budget allocation for institutional PTCs should therefore be considered in the future. Budget requests should be one of the responsibilities of the institutional management. Executive management authorities play an important role in the functioning of PTCs, without their support, PTCs may find it very hard to function, and find acceptance within an institution. Thus, for the establishment and effective functioning of institutional PTCs, the support of the management is crucial.

Recruitment and retainment strategies of pharmacists to the rural areas is also important. It is crucial to have the relevant health care providers within the PTC structure.

Finally, it would be advisable to provide feedback from this study to all the secretariats and chairs of the institutional PTCs, and provide an educational session on the identified problems. Continuous support as recommended is crucial. For this to happen there need to be a provincial schedule for visiting the institutional PTCs. The provincial PTC in its operation plan for the year need to incorporate such a schedule.

I also recommend that this study provides a suitable framework and support for a qualitative study which explores the barriers to PTC functionality in greater depth. Such a study could provide a focus for educational programmes and support systems to further improvement the contribution of PTCs to quality and rational drug management.

5.3 LIMITATIONS

This study has its limitations that might have affected the outcomes. Certain concepts of the questionnaire might have been misunderstood by the participants. For example, in response to a question that was asking for SOPs produced by the PTC some secretariats attached a list of pharmacy SOPs which were not relevant to the function of the PTC. However, others did understand the question and responded correctly. The fact that this is a self-completed questionnaire without much explanation of the questions provided, means

that questions are answered according to the respondents' own understandings. The pilot attempted to identify such problems of question interpretation, however, occasional misunderstandings were evident.

There were no field workers to assist with questions that might be raised by the participants. Some places were left blank as people would just skip the question where they do not understand or they did not have evidence to show. There was also fear amongst some participants that the manner in which they answered the questions could lead to disciplinary action. They were reassured that this was not the case and that all responses would remain anonymous. Such fears might also have affected the way the respondents answered the questions.

The time to complete the tool seemed to have been an issue. Some secretariats complained about staff shortages and time to sit down and complete the form thoroughly was difficult to find. The respondents answered questions they felt like answering and preferred questions that only required a tick to those which required them to write. Thus, the qualitative questions were not fully answered and perhaps a future qualitative study should include interviews or an administered questionnaire rather than self-administered questionnaires.

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Appendix 1: Data collection tool

Dear PTC Secretary

This questionnaire forms part of a study which is being conducted by Dr Vatiswa Henge-Daweti toward the completion of a postgraduate programme at the Nelson Mandela Metropolitan University. The study has been approved by both the Eastern Cape Department Health and the Research and Ethics Committee of the University.

The study is aimed at identifying and describing the activities, functions and structures of PTCs in the public healthcare sector of the Eastern Cape. It is hoped that the study will provide the data necessary to assist in supporting the development of well-structured and well-functioning institutional PTCs thereby promoting the rational use of medicines with the intention of improving the quality of healthcare provided by the institutions.

Although you are asked to record the name of your PTC on the form, this information will remain strictly confidential and will be known to the researcher only and will not be used in any reporting of the data.

Your assistance is therefore requested in the completion of the form. Please could you complete the form by 31 May 2016, and return via email or fax to the researcher.

Many thanks for your participation

Dr Vatiswa Henge-Daweti

Email: vocoza@gmail.com

ACTIVITIES, FUNCTIONS AND STRUCTURE OF PUBLIC SECTOR PHARMACEUTICAL AND THERAPEUTICS COMMITTEES IN THE EASTERN CAPE PROVINCE, SOUTH AFRICA

Please complete this questionnaire by answering the questions as fully as possible. District/Sub-district/Hospital/Clinic PTC Name of PTC: QUESTIONS RESPONSES Structure of the PTC 1. How many members comprise the PTC? 2. Are they officially appointed? 3. By whom have they been appointed? Composition of the committee 1. Specify the number of pharmacists 2. Specify the number of doctors 3. Specify the number of nurses Eg Accountant (1) 4. Identify the type and specify the number of other health care professionals (Please 1. specify) 2. 3. 4. 5. 6.

5.	What profession does the secretariat belong to?	
6.	What profession does the chairperson belong to?	
Operat	tions of the PTC	
7.	Does the PTC have sub-committees, (if vesplease list the types of sub-	Yes / No (please circle)
	committees)	1.
		2.
		3.
		4.
		5.
8.	Are there Standard Operating Procedures (SOPs) available?	Yes / No (Please circle)
9.	List SOPs available	1.
		2.
		3
10	. Frequency of meetings	(Please circle)
		Monthly
		Bimonthly
		Quarterly
		Other (specify)
11	. How many meetings held in the past year (April 2015 – March 2016) with approved minutes?	
12	. How many meetings in that period were quorate?	
13	. On average how long were the meetings (in minutes)?	
14	. Was a declaration of interest signed-off at every meeting?	Yes / No (please circle)

15. Was confidentiality signed-off at every meeting?	Yes / No (please circle)
16. Is there any document with Term of Reference (ToR), explaining the objectives, goals, functions and membership?	Yes / No (please circle)
17. Date of last amendment of ToR	/(dd/mm/yy)
18. Is there a budget allocation for PTC functions?	Yes / No (please circle)
Functions and activities of the PTC (with respect to	o the period April 2015 – March 2016)
;Please circle your response and specify if 'other ' ${ m I}$	
19. Who leads the discussion during meetings? (If other specify)	Chairperson Secretary Other
20. Who prepares the meeting agenda and minutes (If other specify)	Chairperson Secretary Other
21. Who were motivations submitted to? (If other specify)	Chairperson Secretary Other
22. How many educational sessions has the PTC organized for the members in the past year?	
23. Are the motivations reviewed for cost, efficacy and safety?	Cost - Yes/ No Efficacy – Yes/No Safety – Yes/No
24. Motivations reviewed for cost, efficacy and safety by whom? (If other specify)	CostChairpersonSecretaryOtherEfficacyChairpersonSecretaryOtherSafetyChairpersonSecretaryOther
25. Is an ABC analysis conducted in reviews?	Yes / No (please circle)
26. How many Medicine Utilization Evaluations (MUEs) were conducted over the last year period?	
27. List of MUEs conducted	1.
	2.
	3.
	4.
28. Number of named patient motivations submitted	
29. Number of named patient motivations approved	
30. Number of named patient motivations rejected	

31. Number of Non-EDL items approved	
32. Number of Adverse Drug Reactions reported	
33. Number of medication errors reported	
34. Were there any interventions made to further prevent the ADRs and medication errors?	Yes / No (please circle)
35. Summary of the interventions made	
36. Methods of communicating with health	(Please circle one or more options below)
care professionals	1. Newsletter
	2 Staff meetings
	3 Fmail
	A Telenhone
	5 Verhally
	6 Momo
	0. 141110

37. (i) What are your feelings about the structure and functioning of the PTC?

(ii) How can it be improved?

(iii) Describe barriers that hamper optimal functioning.

(iv) Are there any other comments you would like to make?

Many thanks for taking time to complete this questionnaire!

Appendix 2: Nelson Mandela Metropolitan University Ethics Committee approval letter

Appendix 3: Department of Health approval letter