South african medical formulary pdf

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SAMASouth African Medical AssociationPredecessor Medical Medical Association of South Africa Progressive Medical GroupFondato21 May 1998 (1998-05-21)Pretoria, GautengLocation South AfricaMembers 17,500 Key People Dr Mark Sonderup (president of the action)DrSA Mac Lukhele (president) South African Medical JournalSouth African Medical Medicine FormularyAffilisiteationsCOSA Registered as a non-profit organization, it acts as a union for its members of the public sector. He is affiliated to the South African Trade Union Congress (COSATU). Accession is voluntary, with about 70% of doctors in South Africa currently registered as members. The main office is located in Pretoria, South Africa. History On 21 May 1998, the association was founded by a merger between the Medical Association of South Africa, founded in 1927, and the Progressive Doctors Group. In 1999, he became affiliated with the National Medical Alliance, along with the Practitioners Medical and South African Dentistry, Society of Dispensing Family Practitioners, Family Practitioners Association, Dispensing Family Practitioners Association, and the Eastern Cape Medical Guild. Activities focused on the professional and business aspects of medical practice. The mission of the SAMA mission is: "Promote doctors to bring health to the nation." Values: Learning and adapting. Building trust relationships. Evaluate diversity. SAMA – Official Site Organized Work Portal This article about a South African union is a stub. You can help Wikipedia by expanding it.vte URL consulted on 19 November 2012. ^ The World Health Organization identified pharmaceutical and therapeutic committees (PTC) at district and hospital level as one of the key models to promote rational use of medicines (RUM). This is approved by the government in South Africa. Formulary development and management is one of the main functions of PTC. This study aims to describe formulae management activities in public hospitals in the province of Gauteng, South Africa, following initiatives aimed at promoting RUM in South Africa. Quality study, not participative, observative, observing 26 PTC meetings. The data has been encoded and classified using the quality data analysis software NVivo9®. Themes and subthemes have been developed. The themes and sub-meals on formula management are the main objective of this document. More than half of the observed PTC examined their formula lists. There was variation in the review process between institutions providing differentcare. Several aspects have been considered for the management of formulas, in particular the requests for medicines to be added. These costs included(with particular attention to the acquisition costs), evaluation of clinical trials based on 'evidence, patient safety, clinical experience and changes of the national directory of essential medicinal products (NEML). Tertiary PTCs have mainly dealt with applications for new non-eml drugs, while the PTCs of other hospitals have mainly asked the removal or addition of eml drugs to the list. This is the first study conducted by the province of Gauteng, South Africa, which reports as the decisions to include or exclude drugs in the forms of public hospitals that offer different levels of assistance are actually taken. Several approaches are adopted at different levels of care when adding or deleted medicines from the form lists. Future programs should strengthen PTCs in specialized aspects of formwork management. A more structured approach to the revision of local PTC form forms should be encouraged in line with the national approach when examining possible additions to Neml.Parole key: forms, management, essential drugs, rational use of medicine, list (structure of data), pharmaceutical and therapeutic committees, South Africal 'access to drugs and their economicity is a challenge especially for medium-low incomes (limescs) including South Africa (Cameron etã, al., 2009; Leisinger Etã, at ., 2012; Attaei Etã, al., 2017; Wirtz and Moucheraud, 2017; Chigome Etã, al., 2019). A way to deal with the problem is to improve the appropriate use of drugs, since more than half of all drugs are prescribed or improperly dispensed and about the half of the patients does not correctly assume drugs (World Health Organization, 2012; Ofori-Asense and Agyeman, 2016). The appropriate use of drugs also reduces the scope of adverse drug reactions with their impact on morbidity, mortality and costs (Davies et al., 2009; Chiatti et al., 2012; Gyllensten et al., 2013; ant et al., 2018). One of the recognized ways to improve the use of medicines in all LMICs consists in ensuring the access and availability of a central list of well-tested and economically advantageous drugs, along with measures to improve health care Universal, which was the concept at the base of the list of essential medicines (EML) of the WHO (OMS Policy Perspectives on Medicines, 2002; World Health Organization, 2015; Wirtz et al., 2017; Hollo). The recommendations of the OMS for programs on essential drugs encourage the use of forms, such as essential tools for appropriate, safe and economical use of drugs in order to promote rational use of drugs (rum) (Gustafsson et Al., 2011; Schiff et al., 2012; Quick et al., September 2002). The forms are considered important to outline and address an appropriate prescription from trust in their development (Rucker and Schiff, 1990; Pillans et al., 1992; Eriksen et al., 2018). This is particularly important when the main means of medical training is through pharmaceutical companies (Spurling et al., 2010; Civaner, 2012; Jacob, 2018; Fadare Fadare2018a; Fadlallah et al., 2018). The WHO has identified pharmaceutical and therapeutic committees (PTCs), also known as Drogue and Therapies Committees (DTCs) in a number of countries (Bjorkhem-Bergman et al., 2013; Hoffmann, 2013), at a district and hospital level, as one of the pivotal models promoting RODUM (Holloway and Green, Office for Health). In addition, a limited list of medicines to be found, based on an EML or on a form, helps define which medicines should be purchased and prescribed regularly. As a result, PTC is considered one of the most effective ways to control the use and expense of drugs (Norman et al., 2009; Bjorkhem-Bergman et al., 2013; Tseng et al., 2016; Shirneshan et al., 2016; Meyer et al., 2017; Leporowski et al., 2018). PTCs (Holloway and Green, 2003; Hoffmann, 2013; Plet et al., 2013; Lima-Dellamora Eda et al., 2014; Matlala et al., 2017). A PTC can also provide the leadership and structure necessary to select the appropriate drugs to include in the form, promote RUM, educate doctors to evidence-based medicine (EBM) and reduce waste, thus optimizing medical spending and improving patient outcomes within the available resources (Wu and Miao, 2008; Bjorkhem-Bergman et al., 2013; Hoffmann, 2014; Bjorkhem-Bergman et al., 2013; Hoffmann. Decisions on the inclusion of medicinal products in formulations, including new medicinal products, must be based on clinical, ethical, legal, social, philosophical, quality of life, safety and economic (Holloway and Green, 2003; Jenkings and Barber, 2004; Tyler et al., 2008; Puigventos et al., 2010; Gustafsson et al., 2011; Hofftmann, 2013; Plet). Decisions should also take into account issues such as access and implementation, as well as follow-up and procurement (Pharasi and Miot, 2013; Lima-Dellamora Eda et al., 2014; Meyer et al., 2017; Matlalala et al., 2017). In addition, local knowledge should be taken into account, although decisions should be based on scientific rationality (Jenkings and Barber, 2004; Bjorkhem-Bergman et al., 2013). In South Africa, in recent years, there has been considerable development towards universal health care, in preparation for the implementation of National Health Insurance (NHI) to address previous inequalities for most patients in South Africa (Meyer et al., 2017). In this system, public hospitals are funded on the basis of activities which include medicine costs. Therefore, recommendations for prescribed drugs must follow a rigorous and complete process to optimize the use of available resources (Meyer et al., 2017). The use of EBM as a key criterion for the selection of medicines to be included in the standard guidelines for the treatment and list of essential medicinesIn South Africa it has become solid and rigorous over time (Republic of Africa, 2018; National Health Department, 2019). The basic criteria for selecting drugs in South Africa are established in the National Drug Policy, with EEML as a basis for developing STG aimed at improving patient care (South African National Department of Health, 1996). STG/EML are regularly updated and available electronically to improve their use (Meyer et al., 2017). The selection of drugs available in the public health sector is currently carried out through the National Committee of the List of Essential Medicinal Products (NEMLC) and provincial PTC and structures (Meyer et al., 2017; Republic of South Africa, 2018). Two essential tasks of the PTC within the public health system are to develop and revise institutional STGs (usually adapted to national guidelines) and maintain an institutional form based on the national EML (Laing et al., 2001; Holloway and Green, 2003; Fadare et al., 2018b). The process of formula development follows a hierarchical approach according to the level of care, as described in the national guidelines of the PTC (Department of Health of South Africa, 2019). The list of Master Health products, which contains both EML and non-EML medicines, is the main document used to obtain the respective lists of institutional or level assistance formulas, as shown in Figure 1 . Tertiary-level PTC may assess potential non-EML drugs for inclusion in the hospital form; with secondary assistance and other hospitals confined to EML in their deliberations. In addition, PTC monitors the use of drugs against the agreed guide (Bjorkhem-Bergman et al., 2013; Eriksen et al., 2017; Leporowski et al., 2018). PTCs within hospitals or primary health facilities (PHC) through their PTCs district, which are considered as expert review committees, then make recommendations for new drugs to include in STGs/EML (Matla et al., 2017; Meyer et al., 2017; Mashaba et al., 2019). National policy for the establishment and operation of PTC in South Africa has outlined the standards for PTC at all levels in the South in 2015 (NDOH, 2015). The policy also provides that the PTC should exist at the provincial, district, subdistrict (where applicable) and health (regional hospital, tertiary, central and district) with, as mentioned, different degrees of freedom depending on their level of specialization. As a result, the number of PTC in each province depends on the number of hospitals and districts. The composition and functions of PTC in public sector hospitals within Gauteng province were discussed in previously published studies (Matla et al., 2017; Mashaba et al., 2019), including the number of meetings per year, the activities carried out by these PTC, the types of subcommittees within the PTC and their (NDOH, 2015; Matlala et al., 2017). Gauteng National and Provincial Guidelines for PTCs in South Africa South Africa that PTCs should develop a form aligned with agreed treatment guidelines and protocols, and subject to robust evidence-based interrogations (Gauteng Province Department of Health, 2013; NDOH, 2015). This assessment process should be conducted using explicit documented criteria, allowing for a transparent assessment of the decision and facilitating possible reviews. This includes information on the pharmacological action of the drug, as well as its health gain compared to current drugs on the form and strength of evidence (Gauteng Province Department of Health, 2013,) with applications made on official forms. Although PTCs have been active in South Africa since the mid-1990s, little is known about the effective management of formulas within South African public sector hospitals (Matlala et al, 2017; Perumal-Pillay and Suleman, 2017). This study aims to describe the formulas management practices in public sector hospitals in the province. Gauteng of South Africa, and to recommend strategies to improve the management of formulas by PTCs in this province and wider, if necessary. This builds on our recent publications describing the processes underway in the public health system in South Africa to improve the quality and efficiency of drug use (Meyer et al,. 2017,) as well as the structure and functioning of PTCs among public sector hospitals (Matlala et al,. 2017; Mashaba et al,. 2019). A qualitative, non-participatory and observational method was used for this study. The data collection involved the observation of a total of 26 PTC meetings (at least two meetings per PTC), conducted by 13 PTCs in Gauteng Province, over a 12-month period from February 2013 to February 2014. Requests to attend each of the scheduled PTC meetings were sent by e-mail to all responsible hospital pharmacists, the district pharmacist and the president of the provincial PTC. A letter outlining the objectives of the study, proof of ethical clearance and proof of provincial approval was included in the submission. In cases where the Chair of the PTC did not allow the recording of the proceedings, the discussions were noted and subsequently checked against the minutes of the meeting of the Secretariat of the particular PTC. However, this was only the case for provincial PTC meetings. The comments were undertaken as discreetly as possible so as not to affect the proceedings of the JWP meetings. Observations were made until saturation of the data was reached. The recorded data was transferred from the digital voice recorder to a computer and stored as a Windows Media Audio file. Recording of every meeting was transcribed verbatim, typed into Microsoft Word® and stored as a separate document. The transcribed observations were then checked against the audio recordings for accuracy, after which a software program was imported into NVivoÂ® (Version 9) for data analysis. The observers typed of PTC meetings that have not been recorded audio recorded, have also been imported into nvivoâ®.two of the authors (mm and JCM) performed a thematic data analysis using the open encoding (Table 1) (Braun and Clarke, 2006). The transcriptions and observational notes were first read and re-read to explore and obtain an understanding of the data. A list of possible codes has been compiled by the initial reading of the data, which were used as a starting point for coding with the software. Through the consensus discussions between the two programmers, the code recimited procedures were used to increase the consistency (reliability) of the results. The connections between the codes have been identified and the categories created. The additional codes and categories were created as new arguments that emerged. The categories have been reviewed and discussed with the other coautors for the consent of encoding and emerging themes and subthemes. The themes and suds specifically related to the management of formulation were identified as a focal point for this focus for this document. SUPTIGLIGLIGLIO DI ANALISISBASKS Completed Step 1: Family data data, verification of transcriptions against audio recordings and field notes, as well as the re-reading of transcripts Step 2: initial codes of open encoding for the entire data set Step 3: Identification of Themefulgorisation of codes in potential themes Step 4: Review of thememing themes - guaranteeing the internal homogenity and external heterogeneity of the themes Step 5: Definition and denomination of the refinement of the themes of Temiferther refinement of the themes, identification specifically of those who refer To the Management Forms Step 6: Report Finalization of the Manuscript, the selection of illustrative quotations The results are presented based on the themes and submarines that emerged from the data with Verbatim quotations of discussions from the members of the PTC entered to support the results. A coding system has been used to protect the identity of the participating PTCs and its members. The quotations were accredited on specific PTC and participant using a dedicated reference code for the observation of a particular PTC based on the level of care and the observed meeting. Quotes are presented in italics and enclosed with inverted commas. Participant identifiers are supplied in square brackets after each quote to improve understanding. The explanations included in quotes are presented as a normal text and enclosed in round brackets. Table 2 provides details of the codes assigned to the PTC.Reference observations assigned to the Pharmaceutical and Therapeutic Committee (PTC) Assembly observations. Collection method of data code of PTC Observationob PTC Level ProvincialPdistrictDtertiary HospitalThregionale HospitalRhdistrict Hospitaldh Example â¬ Â"Notes taken Observation of the PTC meeting in a tertiary hospital [OB TH PTC] The Medunsa Research Ethics Committee of the University of Limpopo (Medunsa Campus), now Sefako Makgatho Health Health University, has granted ethical space for study (MREC / H / 170/2010: PG). The approval of the Gauteng Provincial Department of the Health Research Committee was obtained prior to the implementation of the study. The Chairs of the respective PTCs allowed permission to record or take notes of proceedings. Thematic analysis of the content of the observational transcripts led to seven major themes and subtitles, which are summarized in Table 3.Summary of themes and Subthemes related to the management form. Titles and products on inputs APPLICATIONS APPLICATION OF THE MAIN PATIENTS PAZIENZA PAZIENZA PAZIENZA PAZIENZA COST KNOWLEDGE CONSIDERATION MINIMOLIZZATIONISTIMITATED RESOURCES RESOURCES EXPERIENCE EXPERIENCE COMMAND EXPERIENCE EML / STG PRINCIFICATED EML / STG Guidelines EML / STG PRENOVOLINATIVE OUTS OUTS ACCEPTANCE OF APPLICATIONS PURCHASE Decision of ManagementDevelopment of Clinical Guidelines for Accepted Medicine Demand Decline Unregistered Medicine for Indicated TrialsSupple from Data Submitted Updates Removal of Medicines from the Form List Decrea Sed Prescripingeml Changes in Carecost Deficiency Exchange of Medicines Carecost Topic 1: Application of EBM Principles When an application has been submitted new medicinal products outside the current hospital form list, and in some cases outside the EML, have been submitted to the PTC, the President or the Secretariat before submitting the application. The clinician who submitted the request, if present at the meeting, was subsequently asked to present the rationale behind the request. In tertiary and regional PTC submissions, physicians typically provided a summary of a clinical trial that demonstrated the benefits of the medicine required for inclusion. SUBTHEME 1A: The Benefit of the Patient Common features of the trials presented were the comparison of a new drug with an existing drug in a cochrane revision (e.g. a balanced saline solution). Survival rates have also been reported in some cases (e.g. for a proposed oncology medicine). In the case of a proposed oncology medicine, several clinical trials have been presented to indicate improved survival. In other cases, clinical trial information has been used to demonstrate better morbidity. Â"ÂDiffuse Large B-cell lymphomas are potentially curable variables and pre-treatment predict for prognosis and response to treatment. With an IPI score of zero there is about a survival of 94% at 4 years, if patients are treated with standard chemotherapy, including Rituximab, and a lower IPI score then there is about 50% survival at years. [Ob th ptc] It was clear that the principles of EBM were used in decision-making at PTC of the tertiary hospital. The clinician also discussed the results of treatment when it was an alternative management approach Use of the medicinal product concerned. Â «Results in the treatment of large-cell wide lymphoma b, if the untreated survival can be measured in months. Radiotherapy was studied in large B cell lymphoma, but a 70% recurrence occurs, so radiation therapy is not a first-line or second-line therapy and only in some cases it is indicated as therapy of Consolidation. Â «They were able to demonstrate that Rituximab in association with Chop has led to a significant improvement of overall survival at 7 years and survival free from events of about 32% and a global survival at 10 years of 44%." [OB TH PTC] Subtem 1b: patient safety also the PTCs of secondary hospitals and other hospitals have taken into account the EBM principles, although to a lesser extent. The relative risk or side effects of the new drug were mentioned with reference to international comments, as shown below. Â «There has been no difference between efficacy and side effects when used in children. Although in this European comment that the zelondronic acid can cause some minor complications such as the type of inflammatory reaction, inexplicable tachycardia, acute phase response and decrease of calcium levels, are more obvious with the use of zelondronic acid . Side effects are often related. [OB TH PTC] In some cases, patient safety has also been a motivation when drugs have been removed from the module. Â «Phenytoin IV is not sure to use primary care level due to the requested monitoring, other anticonvulsants can be used to control patients who present an epileptic attack in the primary clinic and the patient can be transferred to the hospital once checked . The oral anticonvulsisings can be administered at patients able to swallow much more confident than there; There may be administered in hospitals in which monitoring is performed. [OB D PTC] In all cases, the presentations were followed by questions from the members of the Commission and discussions, before deciding whether to accept or reject the request. Set: Cost Considerations The cost was one of the Main considerations when you wondered new drugs to add to the request form at all levels of assistance. The cost was typically indicated as the cost per dose, cost per patient, or an estimate of the total annual drug expenditure. Subtem 2a: cost minimization analysis was a difference in cost considerations regarding the hospital level. Most of the new medical considerations at the tertiary hospital PTC level were primarily for non-EML drugs. In such cases, the costs of acquiring new drugs were compared with similar agents in hospitals. In some cases, additional costs were also considered, such as the method of administration and the costs of other monitoring measures. âThe cost of ActilyseÂ® is about R3,000.00 or R4,000.00 per ampoule, which is marginally cheaper than the cost of MetalyseÂ®, but MetalyseÂ® is more effective as there are no infusion pumps. and set of drops, so it ends up working to be much cheaperâ. [Ob Th PTC]Subtheme 2b: Estimated Annual Expenses The estimated annual expense was often reported when the proposed new medicine was about to be used in a few patients. â€œIt's terribly expensive, and this is a lifelong treatment, this was discussed with the finance officer. Often acromegals can be treated with up to 1 mg per day; the LAR is 20 mg per month, which works up to R21 000.00 per month. The annual cost is more than R210 000.00â. [ObTh PTC]Similarly, the cost per patient was often used in discussions, especially when the cost of acquiring the proposed medicine was high. âIn severe reactive bladder need botox intravisicle once turned off and is then repeated once a year. It's a very important problem. The cost will be R1 950.00 per patient which adds up to R4 000.00 per year for the two patients. It could be repeated after a year." [Ob Th PTC]Theme 3: Competence and Experience Sub-theme 3a: Pharmacoeconomic Competence There was a perceived lack of competence in pharmacoeconomic assessments among PTC members. In one of the comments, a member of the TPC at tertiary level pointed out that they had no experience in the business or in the full evaluation of a formal economic evaluation when considering whether to list new drugs on the form. This is an area that needs to be addressed in the future. âOne of the things that are needed at the hospital is a health economist, because the committee is only looking at the costs of drugs, instead of looking at all the other costs. If a cost-minimization analysis has been done, you might find that it is cheaper to give the medicine than treat heart failure with all the other things patients get." [Ob Th PTC]Subtheme 3b: Clinical Experience When proposing a new drug especially for a non-EML drug, the indication of the drug was outlined and the clinician sometimes highlighted his clinical experience with the use of the particular drug, e.g. a new treatment for B cell lymphoma: Diffuse B are potentially curable and pretreatment variables predict a good prognosis and response to treatment. With an IPI score of there is a 94% survival at 4 years, if patients are treated with a standard chemotherapy, including rituximab and a lower IPI score then there is a 50% to five year survival". [Obst]Some cases, doctors have not made specific reference to clinical studies. In these situations, they have allused the evidence that has demonstrated the clinical benefit for the patient. The following observation illustrates how in this case the clinic used the experience from a tertiary hospital as a reference point for the request: â € "This has become the procedural selection of high-risk patient population groups, which is why ICU is used It gives a very different quality of sedation. Patients are clear, they are not sedated as they are with benzodiazepines, where there is often difficulty in differentiating between the state of the delirium and the grandfather. There is often a synergism between benzodiazepines and other agents of the buyric acid receptor site Gama Amino that leads to marked intraoperative hemodynamic instability. These medicines are now used worldwide to perform these kinds of procedures specifically in high-risk patient population groups. [OB RH PTC] Theme 4: Internal and external controls Subtheme 4A: EML / STG reviews at district hospitals, discussions typically focused on formula reviews. PTC pharmacists typically presented most of these discussions and requests. The reviews were based on EML medicines, which had to be included or removed from the list of formulas. Some of the discussions were based on doctors requiring medicines that were already on EML but not available in their respective institutions. In these cases, the cost of the medicine required was typically compared with a similar agent who was already used in the hospital to justify inclusion, as illustrated by the following example: â € "The pharmacy received a request for the capoprol, as it is on the EML. However, the price of a package of 56 CabtProPril 25mg tablets is R6.79 and the price of 28 Enalapril tablets is R2.60, and package of 28 perindopril tablets cost R14.91 â€ ". [OB DH PTC] In some cases, it was encouraged the use of a different formulation, also based on the cost, as demonstrated with the use of tablets of reeridone: â€ œRISPERDAL® (Risperidone) 1MG tablets compared to syrup - the pharmacy requested this Patients it is possible to prescribed the tablets instead of syrup, since the price of the tablet is r8.95 per package considering that the bottle, " [OB DH PTC] Provincial guidelines The fact that reviews of the formulae of district hospitals were determined by the provincial form can be confirmed by one of the provincial PTC observations: â € "There are elements that must be removed from the local Formulario to be in line with the provincial form ... [OB P PTC] The orientation of the provincial treatment Updates influenced decisions formedicines in district PTC / secondary hospital, as illustrated below. â € "It was decided to remove the following medicines: Griseoofulvin tablets because it is not in the guidelines". [OB D PTC] Form decisionNew medicines proposed as observed in this study have been accepted or rejected. The decisions were taken into consultation with the entire committee following the rigorous discussions between the members of the PTC.Theme 5: acceptance of the Subtheme 5A application: cost savings the savings of the received costs that could be achieved was one of the factors Motivating in PTC that accepts a request for a new medicine to be included in the hospital form. An observed example has been for an ophthalmic preparation, in which the proposed medicine has been identified more economical than the alternative currently used at the hospital, although it was equally effective. The Committee accepted the request based on lower acquisition costs. Ã ¢ â,¬ "The other motivation from ophthalmology is for AlphaganÂ® (bromonidine) is suitable for glaucoma, particularly for patients who do not respond to the treatment available. Patients would be on one of the medications available, if yes It wants to defer the surgery an agonist alfa-2 can then be used. The cost for betaganâ® (levobunololol) in this class is the lowest. The observed patients can be about 20 a year, but there is also the possibility of surgery. If the patient is on TruPtÂ® (Dorzolamide) and Alphaganâ® is added, it becomes expensive, but if the prescrix should stop the TruPtÂ® and then add the AlphaganÃ ¢ Â® would not make the difference because they cost the same . Â approved for 20 patients a year; it will be useful to give PTC feedback regarding the patient's progress. [OB TH PTC] Subtheme 5B: The proposals for the use of limited patients were sometimes accepted for limited use of the patient, but only where the Po Painting of the patient was clearly defined. Ã ¢ â,¬ "should be stipulated that these agents will be reserved for groups of high-risk patients in the theater and for incoming cardiology patients for vascular procedures that are made not invasively ... [OB TH PTC] Subtheme 5C: Conditional truck of a management decision Some of the new medicines proposed have been referred to the administrators of the hospital to decide whether to buy or not, in particular medicines that are perceived too expensive, following the PTC support, based on clinical motifs. The PTC agreed That the medical indication exists, was therefore up to the height of the hospital (called the charge of the Chief Executive Officer [CEO]) to decide if there is money for the acquisition of medicine. Ã ¢ â,¬ "will have to go At the CEO office; The Committee will write a letter that states that there is a clinical indication for medicine Â ». [OB TH PTC] Ã ¢ â,¬ "will have to go to the CEO's office; the Committee will write a letter stating the fact that there is a clinical indication for medicine Â». [OB TH PTC] Subtheme 5D: development of lines Clinical Guide for Medicine Accepted PTC Meeting Observations have that some of the PTC have faced guidelines for treatment in their meetings as a result of the decision to accept the new medicine on the hospital form. The doctors were. They were.Develop guidelines for non-formal medicines that could subsequently be approved by the Committee, the aim being to monitor the prescription of these medicines once on the form. In all cases where the development of the guidelines was requested, the PTC did not outline the detail required in the guidelines. However, guidelines were typically needed before the introduction of a new drug as illustrated by the discussion regarding the use of PreceDexÂ® (dexmedetomidine hydrochloride). â¨ "The Committee will need to develop guidelines on how to control the use of PreceDexÂ® and outline the patients who will be suitable for the agent. [OB RH PTC] Topic 6: Decline of an Application Several reasons have been identified for requests to decrease PTCS.SUBTHEME 6A: Medicine Requested Not Registered for Indication Some requests have been refused because the requested drugs have not been registered for the specific indication. This was not despite the relative low cost compared to a medicine that was already used for the particular indication. The following decision was made by the PTC of the tertiary hospital, illustrating a case where the request was not accepted: â¨¨ "The challenge is when the motivation is for a medicine that is not registered for a disease when there is already a registered product. The concern is if the PTC approves the motivation and the medicine is used and something happens to the patient then, who takes responsibility for it. Clinical data should be provided along with the rationale [OB TH PTC] NUOTHEME 6B: Insufficient evidence from data submitted Some requests were rejected by a designated reviewer in the PTC on the basis of a review of clinical trial data when it was considered that there was no demonstrated benefit to the indication/patient population The medicine was considered for. The auditor's explanation during a PTC meeting at the tertiary level hospital explains the decision taken. There are reasons why it is not used in these patients, because there are serious side effects which include 33% incidence of bone pain. There are some papers on pneumonia, any type plug and multilobar. None of the documents says unequivocally that there is a reduction in mortality in these patients. In all these publications there is no conclusion to say that in severe pneumonia there will be a reduction in mortality." [OB TH PTC] Topic 7: Removal of medicinal products from the list of forms Sub-theme 7a: Decrease in the prescription of the revision of the list of medicinal products during PTC meetings also led to the removal of medicinal products, which in some cases was based on low usage. These decisions were mostly taken at the PTC of the district hospital, with submissions to the PTC, primarily undertaken by the pharmacist. The following examples this approach: â¨ ÂClomipramine tablets – the pharmacy has suggested the decoding of clomipramine tablets due to reduced usage. [OB DH PTC] Subtheme 7b: EML changes observations of revealed provincial PTCs that are involved in extensive review of all levels of EML, which led to the removal of a number of medicines from the provincial list formulary. â € "In total there are 366 articles in the list. 71 The articles were removed, 46 elements were added. The cimetidine was discussed an example of an object that had been removed because it is more expensive than the ranitidine and has many interactions â €. [OB P PTC] In the case of Glipizide, the recommended primary care PTC of glypizide from the Gauteng form: â € "The medicine (glypizide) is not included in the EML and in the use in the province is minimal. [OB P PTC] Subtheme 7c: medical deficiency The unavailability of medicines due to manufacturing challenges such as the unavailability of raw materials has also been observed as one of the reasons for the removal of medicinal products of the form, as explained below. â € "Capsule di notrofurantoin â €" â â â€ "It was a matter of raw material for over 1 year, should therefore be removed". [OB DH PTC] Care level Another factor that has been considered When removing medicines from the list of formulas was the level of care. As mentioned, different levels of PTC serve health facilities that provide different services. Consequently, medicines that should be supplied at each level of care should be specific to the service provided, as outlined in the EML. The following example was at the district level of care, which is only allowed to keep the medicines listed in the primary assistance EML. â € "Diclofenac injection was introduced as a result of a request by family doctors; However, the district has been charged with removing it from its formulae list as it is not on the primary EML. [OB D PTC] the cost of medicines at provincial levels is the cost of the consideration when examining the list of formulas was as discussed "the review should be based on the test and the cost should be taken into account through an analysis of the cost effectiveness. [OB P PTC] The cost of medicines was also considered when considering the removal of a medicinal product from the formulae list. â € "The cream of didocortisone will be held instead of ointment due to considerations on prices; It has been decided to remove ointment ... [OB D PTC] One of the main functions of the PTC is to ensure rum through formulary management. In this study, we explored the process followed by PTC in Gauteng province in performing this function. It was noteworthy and encouraging that most of the PTC in this study reviewed their continuous form lists in line with the American Society of Health System-System-System guidelines (Tyler etâ al., 2008). However, it has been mainly limited to the EML and to measure tertiary medicines lists in case oftertiary hospital level, since at the time of the study was conducted the list of tertiary hospitals was recently introduced. While as expected between the district hospital and the PHC level PTC, there were no applications for non-EML drugs, there was a level of Available medicines, including the addition of new medicines from the EML list. Tertiary PTCs were those who tried to introduce more recent drugs, having the advantage of accessing the lists of tertiary and quaternary medicines reserved for the specialists of these hospitals. Also in these cases a high quality test of the efficacy and effectiveness of the medicine was needed. Generally, doctors who requested the new drug in the form were often present during the discussion of their application, which provided opportunities to clarify any doubts. This contrasts with Spain, where applicants did not participate in the evaluation process of new drugs in 57% of cases (Duran-Garcia et al., 2011). We would certainly support the involvement of doctors more widely, where possible, especially since it improves adherence to forms, as seen for the Swedish Â «Wise List» (Gustafsson et al., 2011; Bjorkhem-Bergman et al., 2013; Eriksen et al., 2017). In cases where expensive drugs were required mainly at the Tertiary-level PTCs, more in-depth assessments were carried out. These studies included the effectiveness analysis, effectiveness and considerations relating to this practice is similar to forms management processes carried out in the private sector by medical care programs in South Africa (Pharasi and Miot, 2013). Among Danish hospitals, the criteria used for the inclusion of medicines in forms were the recommendations of professional associations, the tests of the literature, the results of the national tender and the price of the medicine (plet et al., 2013). Similarly, Martin Etã, at. (Martin Etã, al., 2003) and Jenkings et al. (Jenkings and Barber, 2004) found in the United Kingdom that formal decisions were based on a set of factors including clinical benefits and the degree of certainty, with local knowledge used also in the United Kingdom (Martin et al., 2003; Jenkings and Barber, 2004). This is a situation very different from that of some other countries of Subsaharan Africa, where the activities of the PTC are very variable even among the tertiary hospitals, but not universal (Directorate of Pharmacy Services, 2012; Office of Director of Pharmaceutical Services (ODPS) Ministry of Health Ghana, 2015; Ashigbie et al., 2016; Mudenda et al., 2016; Fair Etã, al., 2018B; Anand Paramadhas et al., 2019). Although there were concerns for the ™ Amplitude of PTC's activities between rural Thailand hospitals, exacerbated by concerns for funding and lack of standard criteria for drug selection (UmnuayPornlert and Kitikannakorn, 2014). However, the review process has not been uniform for all PTC hospital levels in our studio, despite the fact that the local EML has specific guidelines for the request for new drugs Add to the EML and then to the local form list. As seen, the standard information modules were generally used between the different levels of hospital care in our studio, although it is requested (Gauteng province). Gauteng). health, 2013; Meyer et al., 2017). This is a concern and contrasts with a study undertaken in Jordan where the majority (77%) of DTCS followed structured guidelines for form applications (Alefan et al., 2019). The practice of lower-level PTCs (District Hospital and District PTCs) Referring again to the EML during the revision of the Level Specific Forms was in accordance with GAUTENG Provincial Guidelines (GAUTENG Province Department of Health, 2013), and in line with the findings of Perumal-Pilay and Suleman (Perumal-Pilay and PTCs). Suleman, 2017). This has also been influenced by the fact that at these levels, there is a limitation to the types of medicines that can be used due to the lack of specialized care. However, there is concern that PTC members among these hospitals lack expertise in EBM. This is important as the doctor's trust in the recommended medicines improves their adherence to the recommended medicines (Gustafsson et al., 2011; Bjorkhem-Bergman et al., 2013; Eriksen et al., 2017). The use of EML in formulary list reviews has also taken place in Thailand; However, there were concerns about defining the role of TCP members and monitoring policy outcomes (sudchada etÃ¢ al., 2012). The considerations of the point were important among all hospital levels both in terms of evaluating new, more expensive drugs and in a more economical way but also more economical but equally effective drugs. This is consistent with GAUTENG provincial guidelines where if multiple drugs are equally clinically effective, cost considerations should be a key criterion (GAUTENG Province Department of Health, 2013). This is in line with other countries (Manneбach et al., 1999; Eddama and Costa, 2008; Duran-Garcia et al., 2011; Gustafsson et al., 2011; Bjorkhem-Bergman et al., 2013), with typically indirect costs considered only in a minority of situations (Mannebach et al., 1999; Eddama and Costa, 2008). Cost considerations have also led to restrictions on patients receiving new medicines primarily in tertiary hospitals, similar to a number of European countries (Godman et al., 2012; Malmstrom et al., 2013). A key consideration certainly for tertiary hospitals was whether the local submission committee verified the costs of the application and made available the necessary funds (Department of Health and Health of Gauteng Province, 2013). The lack of pharmaco-economic skills certainly among tertiary hospitals should be kept in mind when considering formulation management in developing countries in the future (Matlala etÃ¢ al., 2017), as the lack of expertise can lead to inappropriate use of drugs that are not convenient (Pharasi and Miot, 2013). Co-opting health economics skills, if That might be a way forward. However, this will depend on issues of affordability in LMICS struggling to fund, such as biologics for immune conditions and insulins and new oral anti-diabetic drugs for patients with diabetes (Williams) (Williams) bryan, 2007; putrik et al, 2014; baumgart et al,. 2019; godman et al,. 2020a; godman et al,. 2020b.) The current lack of pharmaco-economic experience at the provincial level could be faced by adopting the principles of health technology assessment (hta) included in the nhi bill (2018) (meyer et al, 2017). This is encouraged, especially in tertiary hospitals, that acceptance of new drugs on the form normally requires the elaboration of guidelines that explain its appropriate use. (2001) have found that a remarkable involvement and consultation among end users has improved the accessibility and use of the guideline once available (laing et al, 2001.) we believe that this shows that the activity of the ptc in South Africa can go beyond the dichotomic decisions defining the populations of patients relevant to the new drug, similar to what happens in schonia, the clinical involvement and a limited list of drugs improve the adhesion and quality of the treatments thanks to a greater knowledge of the doctors on the authorized drugs, such as stoccolma, svezia, with the "Wise List" of the drugs (gotafsson et al, 2011; Bjorkhem-Bergman etgeneradel, 2013). the national health department has dealt with this issue with an orientation tool, published in 2019, which includes the documentation to be compiled when such requests are submitted to the ptc (national health department of South Africa, 2019.) etâ al,. 2013; wehmeyer et al,. 2019.) however, it is necessary to increase the number of studies on the use of drugs in hospitals to improve the future use of medicines and skills in matter.It could also be improved by hospitals that share their experiences and skills. We have seen these approaches used by health authorities throughout Europe when implementing policies to improve the use of resources without compromising Cure (Godman EtÃ ¢ al., 2014a; Godman EtÃ ¢ al., 2014B; Moon EtÃ ¢ al., 2014; Godman EtÃ ¢ al., 2019). Over time this study was conducted, the only official document of the national guide that addresses the functioning of the PTC was the national drug policy (NDOH, 2015). Various provinces also had their individual guidelines on the features and structures of the PTCs, such as the Province of Gauteng (Gauteng. Health Department of the Province of Gauteng, 2013). In 2015 the first national policy for the establishment and functioning of the PTCs in South Africa was published, which was then followed by the publication of the national guideline for the establishment and functioning of the pharmaceutical and therapeutic committees in South Africa in 2019, providing practical tools and guidelines for implementing policy (national South African health department, 2019). This national guidelines (National Department of South African Health, 2019) articulates the hierarchy for form development and provides additional guidelines on other issues related to the formation at national level. These developments are important, as they will ensure uniformity in formular management throughout the country. We are aware of a number of limitations with our studio. This included the fact that the study was undertaken in a single province of the possible nine in South Africa, which can affect the generalization of views views. This lack of generalization of these results to the rest of the provinces of the country is influenced by the autonomy of the various provincial health departments. Medicine selection decisions can vary from province to Province, which can lead to unequal access to medicines and health products (Pharasi and Miota, 2013). The Province of Gauteng is also the most populated and the economic center of South Africa, therefore it has the largest number of hospitals in the central public / specialized in the country. Furthermore, PTC members could have been intimidated by the presence of an observer. We tried to make observations the most discreetly possible so as not to affect the procedure. However, in view of our methodology, we believe that our results are robust by providing the direction of the future. We believe this is the first study conducted in the public health sector in South Africa which has completely looked at the processes followed by PTC in their activities. The PTCs at all levels of assistance have been involved in the formation management, even if they have adopted all the different approaches depending on the level of assistance provided and the competence of the Committee. Primarily, the revision of local forms for the potential inclusion of new drugs was, as expected, guided by the current EML/TSG STG the tertiary list. The approach to the potential inclusion of new drugs differed between levels of care, with tertiary hospital PTCs, which deal with more specialized services such as oncology and transplant units, able to require drugs outside the current EML/TSG. Decisions were typically based on EBM at the tertiary level and typically on considerations of acquisition costs at secondary and primary hospitals. This reflects the greater freedom among tertiary hospitals to list new drugs not included in the EML standard. Gauteng's PTCs may no longer have the freedom to include drugs outside the EML or the tertiary list, but they still have applied the principles of form development, observed in the private sector and in other developed countries. However, a number of concerns have been identified. These included the limited use of standard forms for requests for new drugs to be included in formulations, the limited use of EBM principles for formulation considerations, and the currently limited use of drug use studies to monitor subsequent drug use following decisions, as well as any impact on patient care in routine clinical practice. There was also an identified need for PTCs to learn from each other. In addition, there was a lack of economic health considerations in the listing form decisions. These considerations may become more holistic with the recent HTA proposals; however, that remains to be seen. The raw data supporting the conclusions of this article will be made available by the corresponding author without undue reservation. The study has received ethical approval from the Medunsa Research Ethics Committee, Limpopo University (Medunsa Campus) and approval from the Gauteng Provincial Department of the Health Research Committee. The respective chairpersons of PTC provided permission to record the proceedings, and if permission to record was not provided, procedural notes were taken. MM, AG and JM contributed to the conceptualization and design of the study, and to the interpretation of the results. MM collected the data. MM and BG undertook a literature review. All authors contributed to the article and approved the version submitted. MM received a research and development grant from the University of Limpopo (Medunsa Campus). 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