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# Total Quality Management Approach to Drug and Therapeutics Committee Guidelines in a Tertiary Care Government Hospital in Nepal

Binaya Sapkota BPharm, PharmD on behalf of Drug and Therapeutics Committee, Civil Service Hospital

Department of Pharmacy, Faculty of Health Sciences, Nobel College, Sinamangal, Kathmandu, Pokhara University

### ABSTRACT

**Background:** Drug and Therapeutics Committee (DTC) is the principal policy making and recommending body for Civil Service Hospital (CSH). Condition of no functional DTC and guidelines based on the concept of total quality management (TQM) continuously presented inconsistencies health care delivery system at CSH. The present study was carried out at CSH from March 2012 to October 2015. **Objective:** The present guidelines were targeted to the prescribers, pharmacists, and nurses for providing rational health care and disseminating uniform and state-of-art medicine information at CSH. **Methods:** The present study was carried out at CSH from March 2012 to October 2015. The FOCUS-PDCA concept of TQM included following nine aspects: F: Find role of DTC for the improvement in the existing practice; O: Organize trained team knowledgeable of the process; C: Clarify operational definitions of DTC; U: Understand functions of DTC; S: Select rules and regulations for DTC members; P: Plan improvement procedures through the DTC meeting; D: Do improvement in DTC process; C: Check and analyze the results or outcomes obtained from the implementation of DTC guidelines; A: Act to explore the extent and scope of the guidelines. **Results:** The present guidelines were developed based on the FOCUS-PDCA concept of TQM. DTC also developed quality assurance criteria, medicine information provision, pharmacovigilance center, pharmaco-economic evaluation criteria and defined roles and responsibilities of the members. **Conclusions:** DTC guidelines were developed at GoN CSH, based on FOCUS-PDCA model of TQM approach. The guidelines were based on rational pharmacotherapeutics concepts.

**Keywords:** Drug and Therapeutics Committee; guidelines; pharmacovigilance; FOCUS-PDCA; total quality management

### \*Correspondence to Author:

Binaya Sapkota. Department of Pharmacy, Faculty of Health Sciences, Nobel College, Sinamangal, Kathmandu, Pokhara University. E-mail: binaya @ nobelcollege.edu.np

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## Introduction

Drug and Therapeutics Committee (DTC) was formed by Civil Service Hospital (CSH) Management as the principal policy making and recommending body at the hospital in 2012. It manages the formulary system at the hospital and helps to provide cost effective services, taking into consideration the outcomes of pharmaco-economic studies. Since there is no provision of health premium system at the hospital, patients are compelled to pay out of pocket for their health care expenditure.

DTC in the hospital was focused to promote efficacious, cost-effective, affordable, and quality use of medicines. Concept of total quality management (TQM) approach was incorporated to achieve those objectives. Major objectives were set to develop and implement formulary system and pharmacotherapeutic policies at the hospital, to promote efficient medicine distribution mechanism, and to disseminate authentic medicine information throughout hospital.

## Aim of the study (Guidelines)

- To develop and implement efficient and cost-effective formulary system
- To ensure use of efficacious, and good quality medicines
- To ensure medication safety through monitoring, evaluating and preventing adverse medicine reactions and medication errors
- To develop and implement interventions to improve medicine use by prescribers, dispensers and patients

## Target users of guidelines

Condition of no functional DTC and guidelines based on the concept of TQM continuously presented inconsistencies in health care delivery system at CSH. So, the present guidelines were targeted to the prescribers, pharmacists, and nurses for providing rational health care and disseminating uniform and state-of-art medicine information at CSH. The guidelines might also be used as a readymade guidance for other hospitals. The guidelines were ultimately targeted for general public, who visited the hospital for their treatment. The guidelines were intended to pro-

vide consistent health service; to augment patient satisfaction towards services provided from it; to deliver safer and improved quality of care; to render less wastage of resources, and more effective and efficient service at affordable costs.

## Ethics Approval

The research protocol was approved by the Nobel College Institutional Review Committee (NIRC).

## Methods

### Study setting

CSH is a 132-bed tertiary care governmental general hospital, located at Minbhawan, Kathmandu. The annual patient flow at the hospital is 255,000 and inpatient flow is 35,000. Hospital pharmacy is open at the hospital 24 hours a day for 365 days a year. More than 700 patients are provided pharmaceutical services daily via this pharmacy.<sup>1</sup> The present study was carried out at CSH from March 2012 to October 2015.

### Consent to Participate

All DTC members (especially the member secretary) provided the written consent to participate in the guidelines development, and this became the property of DTC.

### Availability of data and materials

Data will not be shared as they are the property of DTC.

### TQM approach to DTC Guidelines

The present guidelines were developed based on the FOCUS-PDCA concept of TQM, proposed by Peer et al.<sup>2</sup> This approach was applied to DTC and its guidelines for the first time in a resource constraint country like Nepal and it included following nine aspects:

F: Find the role of DTC for the improvement in the existing practice at the hospital

O: Organize the trained team knowledgeable of the process

C: Clarify the operational definitions of the DTC terminologies

U: Understand the functions of DTC

S: Select rules and regulations for DTC members for process improvement

Member

Head of Department, Anesthesiology

P: Plan the improvement procedures through the DTC meeting

Member

Head of Department, Gynecology and Obstetrics

D: Do improvement in the DTC process

Member

Matron

Member Secretary Pharmacist

C: Check and analyze the results or outcomes obtained from the implementation of the DTC guidelines

A: Act to explore the extent and the scope of the guidelines

### **F: Find the role of DTC for the improvement in the existing practice at the hospital**

DTC itself did not procure any medicine or pharmaceutical product at Civil Hospital, rather this task was performed by the separate Procurement Unit of the hospital via open tender system and sometimes via quotation and direct purchase, but at all times under the provision of the Public Procurement Act of Nepal. Main role of DTC was to ensure that formulary system and other medication policies were implemented at the hospital. Hence, it was not a forum merely for making procurement decisions and complaining the pharmacist about inadequate inventory management at the hospital. It developed formulary list and formulary manual, and based on these all medicines were made available at the hospital at all times. It collected problems from all the departments of the hospital, and expert opinions to solve them via regular meeting.<sup>3</sup>

### **O: Organize the trained team knowledgeable of the process**

DTC was chaired by the executive director of the hospital, and senior physicians/doctors, surgeons, pharmacists, matrons, and clinical microbiologists were other members. Following nine-member DTC was established at this hospital in 2012:

Chairperson	Executive Director
Member	Head of Department, Medicine
Member	Head of Department, Surgery
Member	Head of Department, Pediatrics
Member	Head of Department, General Practitioner

The membership was renewed every two years to create future leaders to impart proper health care delivery at the hospital, but the fundamental designations would remain same. Members were selected from the respective autonomous departments, on their recommendations to the chairperson of DTC.

### **C: Clarify the operational definitions of the DTC terminologies<sup>3</sup>**

- "ABC analysis" means classification of items into A, B and C categories according to the value of their annual usage. This technique was employed for analyzing medicine consumption and utilization data at the hospital, comparing actual versus planned procurement, justifying procurement budgets, guiding procurement patterns and setting priorities for stock management.
- "Adherence to treatment" (compliance) means degree to which patients adhere to the medical advice, and take medicines exactly as directed.
- "Dispensing" means interpretation and evaluation of prescription by the pharmacist, selection of pharmaceutical product(s), labeling and supply of the product according to the legal and regulatory requirements, and providing medication information and instructions to ensure their safe and effective uses by the end users i.e., targeted patients.
- "Efficacy" means ability of a medicine to produce the purported effect.
- "Formulary list" means a list of medicines approved for use at CSH.
- "Formulary system" means principles, criteria, procedures, and resources for developing, updating, and promoting formulary list.
- "Generic substitution" means dispensing of a product equivalent to the prescribed one with

the same active ingredients in the same dosage form and identical in strength, concentration and route of administration of the pharmaceutical product.

- “Medication error” means any mistake in the medication use process, including prescribing, transcribing, dispensing, administering, and monitoring.
- “Procurement” means process of acquiring supplies, including those obtained by purchase, donation and manufacture of pharmaceutical product.
- “Standard treatment guideline or protocol” means treatment practice agreed upon for a diagnosed illness at CSH.
- “Therapeutic substitution” means interchange of one pharmaceutical product with another differing in composition but having similar pharmacologic and therapeutic activities.
- “VEN analysis” means system of setting priorities for medicine procurement in which medicines are divided according to their health impact into vital, essential, and non-essential categories.

#### **U: Understand the functions of DTC<sup>3,4</sup>**

Regular functions of DTC were formulated based on WHO DTC Practical Manual<sup>3</sup> as well as the need of the hospital, and expectation of patients from the hospital. They were enumerated as below:

- To advise medical staff, nurses, administration, pharmacy, and other departments regarding rational medication use at the hospital
- To prevent medication error(s) at the hospital throughout all medication administration process, beginning from prescribing to dispensing and patient counseling.
- To develop medicine use policies at the hospital, based on:
  - Formulary list and formulary manual
  - Restriction or facilitation of non-formulary use of medicines
  - Investigational medicine or health prod-

uct/device use from safety or efficacy perspectives

- Generic substitution and therapeutic interchange, whenever necessary
- Medical representative (MR) and promotional literature: The MR was suggested to submit his/her promotional literatures to the DTC. The member secretary would review them and arrange meeting, where the MR would be invited to present his/her scientific information.
- To assess medicine use to identify problems by adopting:
  - Review of aggregate medicine consumption data including ABC and VEN analyses
  - Monitoring medicine use indicators, including adherence to standard treatment guidelines
  - Adverse medication event monitoring and reporting
  - Surveillance of antimicrobial resistance

All DTC members at the hospital were recommended to exhibit proof of no relationship with any pharmaceutical company or declare it openly to avoid any conflicts of interest.<sup>3</sup>

#### **S: Select rules and regulations for DTC members for process improvement**

DTC would manage conflicts arising among clinicians and pharmacy/administration, concerning the prescribing restrictions. DTC members should not have been influenced or guided by inappropriate or misleading, and false medicine advertisements, promotional activities or personal financial interests. Rather, they should have decided on the basis of evidence based medication practice. All the DTC recommendations would be disseminated to the medical staff and other concerned authorities.<sup>3</sup> DTC would be liaised with other committees of the hospital, and national committees organized by Government of Nepal (GoN) Department of Drug Administration (DDA) to harmonize related activities such as surveillance of antimicrobial resistance, to share common information such as monitoring of adverse medication reports, and educational

strategies such as continuing professional development programs.

### **P: Plan the improvement procedures through the DTC meeting**

Regular meetings were held monthly, and length of a meeting was fixed to be 60-90 minutes, taking into consideration the busy schedules of the physicians, and the pharmacist. Agenda, supplementary materials, and minutes of the meeting were prepared by the member secretary, and distributed to the members for review in sufficient time prior to the meeting. All the decisions of DTC, once documented in the minute, were shared as the common property of the hospital, and they must have been compulsorily followed by all the staff of the hospital.

### **D: Do improvement in the DTC process**

Schachtner et al. reported that 88% teaching hospitals and 89% non-teaching or general hospitals annually saved up to \$1 million employing therapeutic substitution.<sup>5</sup> These pharmacoeconomic data were considered while developing key strategies for the improvement in the DTC functioning at the hospital. The hospital would develop strategies for the measurement of its own cost saving by carrying out pharmacoeconomic researches at the hospital.

### **C: Check and analyze the results or outcomes obtained from the implementation of the DTC guidelines**

Pillay et al. reported that complex decision making about medicine selection was influenced by evidence based criteria, and political, social and ethical values.<sup>6</sup> Wood et al. determined decision making criteria for selecting oral antidiabetic agents. These criteria included indication, safety, interactions, efficacy, pharmacokinetics, convenience, and cost benefit.<sup>7</sup> These all studies and their outputs were discussed and considered by the DTC during guidelines development.

### **A: Act to explore the extent and the scope of the guidelines**

DTC guidelines were developed at the hospital to address and solve the problems related to improper selection of medicines; inefficient procurement practices resulting in non-availability, inadequate quality, wastage or use of irrational-

ly expensive medicines; prescribing not complying with STGs; improper dispensing practices resulting in medication errors, and patients' lack of knowledge about dosing schedules; and non-adherence of patients to dosing schedules, and treatment advice. The guidelines were developed by the DTC and were implemented at all the departments of the hospital, including medicine, surgery, gynecology/obstetrics, orthopedics, clinical laboratory, pharmacy, nursing, and others.

### **Results**

Following roles, responsibilities and quality assurance parameters, pharmacoeconomic evaluations criteria were mentioned after development of the guidelines. These were not in function prior to the development and implementation of the DTC guidelines. (Table 1)

### **Discussion**

DTC at the hospital was nine-member committee, representing the executive director, dignified representatives from medicine, surgery, pediatrics, family medicine and emergency medicine, anesthesiology, gynecology and obstetrics, nursing and pharmacy departments. All other departments, not included in the committee, were represented via invited membership on need basis.

Lehmann et al. concluded that physicians were ready to accept formularies when they felt that cost and clinical considerations were in equilibrium with each other.<sup>10</sup> In the USA, expenditures on the prescription medicines in 2000 were 9.4% of total health care costs, mainly in medicines. Australia, Canada, the UK, New Zealand, Sweden, and other European countries made pharmacoeconomic evaluations [especially cost-effectiveness analysis and cost-benefit analysis], economic modeling techniques, and conducting local pharmacoeconomic researches, mandatory for the formulary selection and use of medicines at their respective setting.<sup>11</sup> DTC at the hospital was focused on maximization level of utility of the treatment at the budget constraint. Pillay et al. also found that new medicines would offer only marginal improvements over the existing therapies but at substantially high costs.<sup>6</sup>

### **Limitations of implementation of the Guidelines**

**Table 1. Comparison of the improvements in the existing practice after implementation of the DTC guidelines**

<b>Study characteristics</b>	<b>Pre-implementation of DTC guidelines</b>	<b>Post-implementation of DTC guidelines</b>
<b>Roles of DTC chairperson</b>	Not defined	To permit to call of the DTC meeting; To assume leadership for DTC activities; To approve decisions endorsed by DTC meeting; To recommend, and forward decisions to all departments for mandatory implementation
<b>Roles of DTC member secretary</b>	Not defined	To recommend chairperson to call DTC meeting; To document all the minutes of the meeting; To arrange and process the agendas of the meeting; To evaluate medical literatures objectively; To present progress in the existing clinical practice
<b>Roles of other members</b>	Not defined	To present novel evidence based clinical practice modalities in their related areas; To discuss pharmacoeconomic evaluations of medicines and surgical items; To recommend procedures for development of STGs; To develop medicines selection criteria at the hospital; To recommend procedures for quality evaluation and recall, if any.
<b>QA criteria</b>	Process not in system	DTC adopted QA procedure recommended by GMP of the WHO. <sup>8</sup> Information regarding domestic and international GMP licensed pharmaceutical companies were retrieved from DDA, and WHO certification scheme on the quality of pharmaceutical products respectively. <sup>9</sup>

Product recall and test for assay of functional medicines	Procedure for functional	not	DTC developed strategies for quality assay of medicines, and system of product recall for the damaged or date expired or counterfeit products. Accordingly, DTC submitted samples of Azithromycin 500 mg tab., and Amoxicillin 500 mg cap. for quality testing to a QC lab., approved by GoN NML. The lab. tested them, and showed that they were within the range of quality standards for the final approval for use at the hospital.
Medicine information provision	System implemented	not	DTC decided to establish PIC to provide current, unbiased medicine information to HC providers, patients and needy people. DTC critically evaluated all the related literatures, and promotional literatures for their authenticity, reliability, and validity. They were presented at the meeting, and decisions regarding them were disseminated to every department.
Pharmacovigilance (PV) Center	Not established		DTC decided to establish PV Center at the hospital, and recommended GoN DDA to establish it. Accordingly, DDA permitted to establish the Center as one of its sixth regional PV centers in Nepal to collect and report adverse medications reports.
Key performance of DTC	Not set		Performance of DTC activities and output were evaluated, based on decisions taken by the committee, and its impact on quality of service. Objective evaluation matrix was developed, based on objectives, and functions; evidence based decision making criteria; pharmacoeconomic studies, STGs, and its impact on clinical decision making. <sup>3</sup>

**GMP= Good Manufacturing Practices; QC lab.= Quality Control laboratory; NML= National Medicine Laboratory; GoN= Government of Nepal; PIC= Pharmaceutical Information Center, HC= health care**

The main barriers in the effective implementation of the guidelines were found to be attitude problems of health care providers, prescribing in trade names, and ineffective patient counseling and information dissemination by the pharmacists at the hospital.

## Conclusion

The DTC guidelines were developed at GoN CSH, based on FOCUS-PDCA model of TQM approach. The guidelines were based on rational pharmacotherapeutics concepts. Therefore, it helps to provide guidance to the policymakers in Nepal to develop and implement DTC guidelines for the benefit of the wide range of public.

## Future plans

DTC at the hospital would recommend mandatory adverse medication reporting, preventing and mitigating strategies via PV Center. It would also develop strategies for essential medicine information provision, which were being practiced as volunteer basis till date. DTC would develop strategies to impose prescribing restrictions by the prescribers, and promote clinical pharmacist monitoring for the medication therapy management at the hospital. Feedbacks from all the departments would be collected to perform pharmacoeconomic researches, and to evaluate services to determine the outcomes of the implementation of the guidelines. The guidelines would be reviewed after every two years.

## Acknowledgements

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## List of abbreviations

DTC: Drug and Therapeutics Committee; CSH: Civil Service Hospital; TQM: total quality management

## Conflicts of Interest

The author declares no competing interests.

## Authors' contribution

BS designed the study, actively participated in the guidelines development, and prepared man-

uscript.

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## Consent for publication

Not applicable

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