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A Study To Evaluate The Adherence To Essential Drug List And Standard Treatment Guidelines For Gastrointestnal And Cardiovascular Medication Prescriptions In Tertiary Care Hospitals Of Sikkim.

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Abstract:
Objectives: *To identify the adherence of prescriptions for GI and CVS medications to essential drug list and standard treatment guidelines.*
Materials and Methods: *The study was conducted in the Department of Medicine, Singtam and CRH, Gangtok. 1151 prescriptions were audited on OPD basis for a period of 2 years (Dec 2011-Nov 2013). CVS and GI medications were identified and analyzed. Chi square test was used where p≤0.05 was considered as significant. Data was initially entered in excel file and later analyzed by SPSS.version 20.0*
Results: *The result showed that 488 out of 494 prescriptions were adherent to essential drug list & standard treatment guidelines in singtam hospital and 584 out of 658 prescriptions were adherent to EDL & STG in CRH, Tadong.*
Conclusion: *By analyzing the result we finally concluded that 1072 out of 1152 prescriptions were adherent to essential drug list, that means around 93.13% prescriptions were adherent to essential drug list.*
Keywords: *CVS: cardiovascular system, GI: gastrointestinal, SPSS: statistical package for social sciences, EDL: Essential drug list, STG: Standard treatment guidelines, CRH: Central referral hospital.*

I. Introduction

The essential medicines, as defined by the WHO are "those drugs that satisfy the health care needs of majority of the population"; they should therefore, be available at all times in adequate amount and in appropriate dosages forms, at a price the community can afford[1].

Essential medicines are those that satisfy the priority health care needs of majority of the population. They should therefore, be available at all times in adequate amount and in appropriate dosage forms selected with assured quality and adequate information, and at a price that the individual and the community can afford[2]. These medicines are critically required for the management of 90% of commonly occurring medical conditions specific to the area and must meet high standard of quality, safety and efficacy at a low cost[1].

According to the WHO there should be a list of essential medicines in every functioning health care system of every country. By the end of 1999, 156 countries had official essential medicine list of which 127 had been updated by 2002[2]. It is found that there are more than 60,000 drug formulations available in Indian drug market. However, 90% of the commonly prevalent diseases can be treated with about 10% of drugs available in the market[1].

The model list of WHO serves as a guide for the development of national and institutional essential medicine list. The concept of essential medicines has been accepted worldwide as a powerful tool to promote health equity and its impact is remarkable as the essential medicines are proved to be one of the most cost-effective elements in health care system. The essential medicine list also serves to guide the procurement and supply of medicines in the public sector as no health system can afford to supply all medicines that are available on the market [2].

The National List of EM is one of the key instruments in balanced health care delivery system of a country which inter alia includes accessible and affordable quality medicine at all the primary, secondary, tertiary levels of health care. Realizing this Government of India, Ministry of Health & Family Welfare (MOHFW) decided to have its own essential drugs list. The first National List of Essential Medicines of India was prepared and released in 1996. This list was subsequently revised in 2003[3]. The current version was also published in June 2011.The concept of essential medicines is relatively new to India. Tamil Nadu is the first state to develop its essential list as early as in 1994. Then Govt. of Delhi too had developed its own list[4].

The Standard Treatment Guidelines also known as standard treatment schedules, Standard treatment protocols, therapeutic guidelines, and so forth list the preferred drug and non-drug treatments for common health problems experienced by people in a specific health system. Each drug treatment should include for each health

problems, the name, dosage form, strength, average dose (paediatric and adult), number of doses per day, and number of days of treatment (STG, 2007).

Standard Treatment Guidelines in India have been developed for various diseases and ailments by clinical and professional bodies for the treatment in their respective areas. **Standard Treatment Guideline has been defined as a systematically developed statement designed to assist practitioners and patients in making decisions about appropriate health care for specific clinical circumstances.** STGs are meant to reflect expert consensus based on a review of current published scientific evidence of acceptable approaches to diagnosis, management or prevention of specific conditions. In addition to supporting rational decision making, other important uses of STGs are:

- Provide standardized guidance to practitioners.
- Guiding allocation of resources for health care and estimating cost of health services.
- Making specific decisions about what health care to reimburse, cover, or encourage and in evaluating the decisions, actions, or performance of the primary users of guidelines (STG, 2007).

The policy's main objective is to improve the availability and accessibility of quality essential drugs for all those in need. Now many state governments too have developed STG for use within the state government health facilities. The Armed Forces Medical College (AFMC), Pune has developed STGs for quite large number of common conditions and the treatment cost is also calculated[4].

Sikkim is the 22nd state of India, A survey of literature related to EDL & STG has not been conducted in the state so far, hence, the present study was undertaken to document the utilization of essential drugs and to generate information on the core prescribing indicators proposed by the WHO, in cardiovascular and gastrointestinal medications in urban hospitals of Sikkim.

The essential medicine concept is relevant to other health programs as well and results not only in better use of resources but also in better practice of medicines. It addresses several other issues such as good therapeutics and reduced side effects of medicines, and save money for individuals, hospitals, health care providers, and the country[6]. EDL & STGs assist in managing and budgeting for pharmaceuticals. According to Dippenaar and colleagues (2005) it was essential to manage budget for PHC in order to deliver a sustainable, accessible and quality health care service to the population.

Disadvantages Of Edl & Stgs:

The use of EDL also has certain disadvantages. The hospital drug lists are restricted to evidence based practice and they very often had a limited number of drugs from each class and the choice of drugs included in the list was not determined by evidence but by cost per tablet[9].

The procedures for updating the WHO Model List of Essential Medicines were often consensus based and not evidence based. Between 2000 and 2002 the process of updating the WHO Model List was strengthened through global consultation and since then a web based Essential Medicines Library was developed, which included information such as the reasons for medicines inclusion in the Model List[8].

The National EDL of India was meant to serve as a medicines formulary for the public sector. The EDL however, does not cover all classes of drugs and therefore institutions offering tertiary and quaternary (high specialised treatment) healthcare, formulate their own formulary lists through a drugs and therapeutic committee[10]. Managerial assessment was done at the Groningen University in the Netherlands, a study to determine adherence to a regional EDL by general practitioners. If the drug prescribed was advised in the EDL, it was considered to be globally adherent. The results showed that global adherence varied from 76% to 89%[11].

The use of STGs and EDLs was implemented as part of the EDP in India in 1997. The WHO has published a model list of essential medicines in 1997. Each country was encouraged to prepare their own list considering their local priorities.

Essential medicines list also includes medicine for prevention and treatment of diseases covered under National programme, viz. Tuberculosis, leprosy, diarrhoeal diseases, malaria, kala azar, and prevention of blindness, safe motherhood, vaccine preventable diseases and cancer[12].

Standard Treatment Guideline has been defined as a systematically developed statement designed to assist practitioners and patients in making decisions about appropriate health care for specific clinical circumstances. Clinical guidelines (STGs, Prescribing policies) consist of systematically developed statements to help prescribers to make decisions about appropriate treatments for specific clinical conditions. Evidence based clinical guidelines are critical to promoting rational use of medicines[2].

Aims and Objectives

1. To know number of drugs prescribed from the essential drug list.
2. To know whether the standard treatment guideline is being followed or not.

II. Materials And Methods

i. Setting: The study was conducted in the Department of Medicine of Singtam District Hospital and Central Referral Hospital, Tadong, Gangtok.

ii. Type of Study: Prospective prescription audit; survey and collection of information from actual prescriptions were accessed from the OPD and pharmacy after the patient finished physician consultation.

iii. Method: Collection of information from prescriptions from OPD and pharmacy.

Operational modality: The focal point of collection of the data were prescriptions at the hospital OPD / pharmacy of CRH and Singtam District Hospitals. The number of the prescriptions that contain treatment for cardiovascular and gastrointestinal diagnosis were selected for the study. Necessary information, as given below, was noted for each prescription in a case record form devised for the study. Further, some socio-demographic information were collected from the patient and entered in the case record form. Therefore, the case record form was a replica of each prescription. Relevant information from prescribing physicians was also collected. Each case record form was authenticated on a daily basis by the researchers. Information thus collected was entered in MS Excel database on a regular basis for ease of statistical analysis at a later date. Verbal information was provided to each patient and prescribing physicians regarding the purpose of collection of information contained in the prescriptions and confidentiality was ensured. Before commencement of the study, written approval to conduct the study had obtained from the Medical Superintendents and Heads of respective departments from both Singtam District and CRH Hospitals. The study protocol was approved by the Institutional Ethics Committee (IEC) of Sikkim Manipal Institute of Medical Sciences, Gangtok.

iv. Data Collection: Each case record form (CRF) was contained the following information.

1. **Socio-**demographic data
2. **Clinical data:** 2.1- Diagnosis

3. Drug use data:

3.1- Number of drugs / prescription
3.2- Presence of multivitamins / tonics / enzymes
3.3- Formulation
3.4- Dose
3.5- Duration
3.6- Drugs from EDL

v. Physician information: Qualification, Years in practice, Knowledge about EDL / STG (Yes / No), Source of information were recorded.

vi. Duration: December 2011 – November 2013 (2 Years)

vii. Sample Size: The researcher calculated the average number of items dispensed at each dispensing site for the period December 2011 to November 2013. Overall, an average number of 1152 prescriptions were dispensed during the study period from the new case registered with cardiovascular and gastrointestinal diseases at both hospitals in two years, to detect a minimum 5% prescriptions following the EDL and STG with an upper limit of 10% at a confidence interval of 95% a minimum sample size of n=136 was required.

viii. Statistics: As most variables are non-continuous we used non-parametric tests for analysis of significance. Commonly Chi-Square test was used and $p \leq 0.05$ was considered as significant. Data was initially entered in Excel files and later analyzed by SPSS 20.0.

VI. Result

The present study was undertaken to evaluate data on cardiovascular and gastrointestinal medications in urban hospitals of Sikkim. The main aim of our study is to audit the prescriptions whether they are adherent to the essential drug list and standard treatment guideline or not. In this study, 1152 data were collected over the two years (**December 2011 - November, 2013)**.

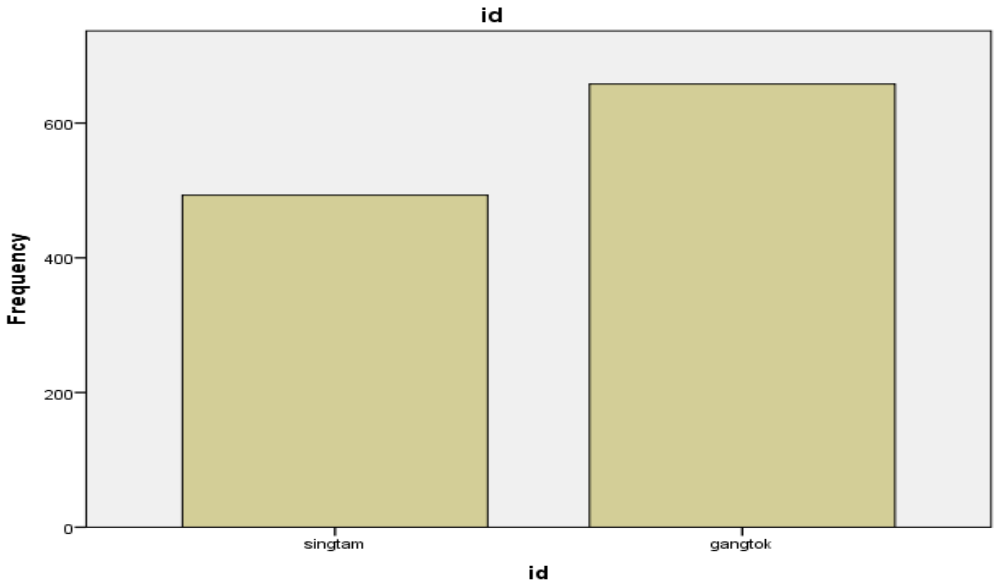

Fig-1

(Id = Identification, Singtam and Gangtok).

Out of total 1152 prescriptions collected and analysed, 42.87% (493) were from District hospiital, Singtam and 57.17% (658) from Central Referral hospital, Tadong, Gangtok, East, Sikkim(fig-1).

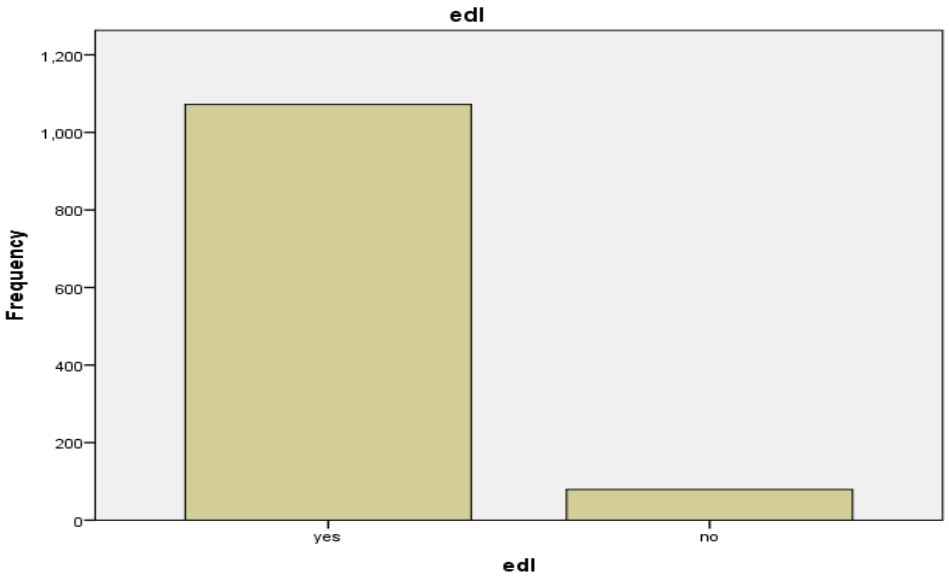

Fig-2

P value is significant as it is <0 .001

Drugs from EDL : In District Hospital, Singtam, 488(42.8%) prescriptions out of 493 were prescribed from EDL & STG and in Central Referral Hospital, Tadong, 584(57.2) prescriptions out of 658 were prescribed from EDL& STG. Overall, 1072 (93.1%) prescriptions out of 1152 prescriptions were adherent to EDL(fig-2).

VII. Discussion

The present study helped us to understand the adherence of drug prescriptions of urban areas of SIKKIM to essential drug list and standard treatment guidelines. Overall 1152 prescriptions of gastrointestinal and cardiovascular medications were laid to analysis over a period of two years.

Out of total prescriptions obtained 494 were from district hospital Singtam and 658 were obtained from central referral hospital Tadong,Gangtok. All the obtained data from the prescriptions were analyzed using the software programme SPSS: 20,and the resultant produced a figure showing that 42.8% prescriptions were

prescribed from EDL and STG in Singtam whereas 57.3% prescriptions were prescribed from EDL and STG in Central Referral Hospital, Tadong Gangtok.

Limitations

1. Our study was based on data collected from two major hospitals of Sikkim, so it is very likely that these data do not represent the whole population of Sikkim.
2. The selection of the patients in our study was random, data were not analyzed according to the age and income of the patient, as the data were not mentioned in the prescriptions, so it is very likely that we might have missed a particular age and income groups of the patient.
3. We have audited just the OPD prescriptions but not the indoor ones because it was excluded from the present study, hence, there might be the reason of some degree of bias.

Suggestions

1. Inpatients data should also have been analyzed to look into the number of injectable preparations.
2. Prescribers should be more adherent to EDL, STG & generic prescriptions.
3. To introduce a managerial, monitoring tool or system for prescribing from NLEM.
4. Highlight EDL items in Hospital formulary so that extra care can be taken by both the pharmacy personnel and the procurement section to ensure that these essential drugs are always available in stock in sufficient quantities.

Summary And Conclusion

The study revealed that the majority of the prescriptions (93.1%) were adherent to EDL.

This study shows that most of the prescriptions were adherent to EDL and prescribed by specialist. Our study also reveals that FDCs and brand names were prescribed by majority of the prescribers.

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