ORIGINAL

Allocation and development of hospital formulary for obstetrics and gynecology department in a tertiary care teaching hospital of southwest India

Asignación y desarrollo del formulario hospitalario para el departamento de obstetricia y ginecología en un hospital universitario de atención terciaria del suroeste de la India

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Abstract

Objective: The goal of the research is to Preparation and implement a hospital formulary in the obstetrics and gynecology department. To provide updated information about the use of medicines to physicians, pharmacists, and other health care professionals in the hospital for appropriate use of the drugs in Tertiary Care Teaching Hospital of Southwest India.

Methodology: Prospective study is conducted for 6 months in the department of obstetrics and gynecology of CSI Holds worth Memorial (Mission) Hospital Mysore, Karnataka, India. A survey was conducted using a validated questionnaire for the identification of the need and content of obstetrics and gynecology formulary among physicians in the hospital. The obstetrics and gynecology formulary was developed and the quality was evaluated using a validated questionnaire form. The content of the formulary was framed based on the opinion of physicians. Finalized drug list was obtained from the P & T committee and monographs were prepared as per the recommendations of the P & T committee.

Result: The total number of drugs evaluated was 195. With the help of listed drugs of WHO model formulary and master drug list, some more sources and suggestions from Doctors of OBG department and decision of P and T committee, 61 more drugs were included in the OBG hospital formulary. Out of 61 drugs included in the formulary, 45 (43.26%) were available in the Oral route (Tablets, Capsules, Syrups, Suspensions, and other solutions) followed by Parenteral route (IV, IM, SC) 44(42.30%), Topical preparations 10 (9.61%) followed by rectal, vaginal, nasal and parenteral routes. 11 (18.03%) were Anti-infective medicines (Antibiotics) and 11 (18.03%) were drugs affecting endocrine and hormones followed by Vitamins and Electrolytes 8 (8.19%).22 (36.06%) drugs were under pregnancy and lactation category-C, 14 (22.95%) dugs were under category-B, 10 (16.39%) drugs were under category-A. The feedback questionnaire containing the objective type of questions was distributed to all eight gynecologists and PGs who responded to it thoroughly.

Conclusion: The formulary was handy, user-friendly, and saves the precious time of busy physicians. It may promote the safe and effective use of medicines thereby minimizing drug-related problems in the obstetrics and gynecology department.

Key words: Formulary, obstetrics and gynecology, physicians, drug use pattern.

Resumen

Objetivo: El objetivo de la investigación es preparar e implementar un formulario hospitalario en el departamento de obstetricia y ginecología y proporcionar información actualizada sobre el uso de los medicamentos a los médicos, farmacéuticos y otros profesionales de la salud del hospital para el uso adecuado de ellos en el Hospital Docente de Atención Terciaria del Suroeste de la India.

Metodología: Se realizó un estudio prospectivo durante 6 meses en el departamento de obstetricia y ginecología del CSI Holds worth Memorial (Mission) Hospital Mysore, Karnataka, India. Se realizó una encuesta mediante un cuestionario validado para identificar la necesidad y el contenido del formulario de obstetricia y ginecología entre los médicos del hospital. Se elaboró el formulario de obstetricia y ginecología y se evaluó su calidad mediante un cuestionario validado. El contenido del formulario se elaboró basándose en la opinión de los médicos. La lista de medicamentos finalizada se obtuvo del comité de P y T y las monografías se prepararon según las recomendaciones del comité de P y T.

Resultado: El número total de medicamentos evaluados fue de 195. Con la ayuda de la lista de medicamentos del modelo de la OMS y la lista maestra de medicamentos, algunas fuentes más y sugerencias de los médicos del departamento de obstetrician y la decisión del comité P y T, se incluyeron 61 medicamentos más en el formulario del hospital de obstetricia. De los 61 medicamentos incluidos en el vademécum, 45 (43,26%) estaban disponibles por vía oral (comprimidos, cápsulas, jarabes, suspensiones y otras soluciones), seguidos por la vía parenteral (IV, IM, SC) 44 (42,30%), preparados tópicos 10 (9,61%), seguidos por las vías rectal, vaginal, nasal y parenteral. 11 (18,03%) eran medicamentos antiinfecciosos (antibióticos) y 11 (18,03%) eran medicamentos que afectaban al sistema endocrino y a las hormonas, seguidos de vitaminas y electrolitos, 8 (8,19%). 22 (36,06%) medicamentos pertenecían a la categoría C (embarazo y lactancia), 14 (22,95%) a la categoría B y 10 (16,39%) a la categoría A. El cuestionario con preguntas objetivas se distribuyó a los ocho ginecólogos y médicos de cabecera, que respondieron de forma exhaustiva.

Conclusión: El formulario era práctico, fácil de usar y ahorra el valioso tiempo de los ocupados médicos. Puede promover el uso seguro y eficaz de los medicamentos, minimizando así los problemas relacionados con los mismos en el departamento de obstetricia y ginecología.

Palabras clave: formulario, obstetricia y ginecología, médicos, patrón de uso de medicamentos.

Introduction

The hospital formulary is expected to help the physicians in choosing appropriate medicines, upgrade the chance of rational drug use, and assist the stock control with using the spending plan allocated most appropriately. By designing a formulary, hazardous and inadequate drugs can be eliminated which can subsequently diminish morbidity and mortality. Studies have shown that models help health care practitioners in executing quality care. Hospital models originally began life in hospitals as a collection of commonly prescribed drug arrangements, delivered primarily for reference purposes. As time continued, the hospital formulary was adjusted to the definite data on the expanding number and variety of medicines. It advances the great evidence-based recommending and lessens variety in the degree of treatment given to patients and can be used as an apparatus to rationalize the medicines used in standard practice¹.

The World Health Organization (WHO) release the principal edition of the WHO model rundown of drugs in 2002. The core of the Formulary System is the Pharmacy and Therapeutics Committee (PTO) Membership will be included agents of the expert offices/administrations, pharmacy, house staff, nursing administration, and other invested individuals.PTC reviews the formulary one or more times in a year, for the addition and deletion of drugs. The study was to prepare a hospital drug formulary for the specialty departments in tertiary care hospitals. Consequently, the developed formulary will be useful for reducing the brands accessible in the hospital which helps in rational drug use. Several different issues known to exist in most health care systems are restricted drug financial plans, expanding the number of drug options, irrational prescribing and use of medications, rate of perilous and on-useful medications, being shy of fair-minded drug information, high costs of medications².

The rationale for formulary advancement is that prescribers come out as comfortable with the pharmacological activities, signs for treatment, secondary effects, cooperations and contraindications for a defined range of drugs for normal Formulary systems are used in various settings and associations with strategy articulations on the use of models and formulary systems in hospitals and health care systems. Several different issues known to exist in most drug systems are restricted drug financial plans, expanding the number of therapeutic other options, ill-advised prescribing and use of medications, presence of perilous and non-solid drugs, absence of impartial drug information, high costs of dealing with an enormous number of drugs, drugs of questionable quality on the market³. The Formulary system is used in many different settings, and including hospitals, acute care facilities, home care, settings, and long-term-care facilities as well as by payers such as Medicaid, insurance companies, and managed care organizations⁴.

Consequently, hospital pharmacists evolved to improve physician prescriptions through pharmacy and therapeutics committees, the development of clinical pharmacy services, and formulary systems⁵. Pharmacy and therapeutics committees are using the medicine formulary to facilitate prescribing⁶. The importance of formulary development is that the prescribers have a complete understanding of the pharmacological actions, indication for treatments, adverse effects, possible interactions, and contraindications to be used in the specified group of drugs for common diseases⁷. Many organizations have some policies in case of using the formularies. Hospital formulary systems are being used in different settings, including, but not limited to, payers, such as Medicaid, Medicare, managed care organizations, and insurance companies. Furthermore, they are used at in-home care settings, hospital acute care facilities, and hospital long term care facilities⁸⁻¹³.

To provide information about the use of medicines. Consequently, the focal goals of the formulary are to help prescribers in the appropriate drug of the decision to the reasonable treatment and to settle on prescribers follow the uniform selection of medicines. The advancement of the formulary will significantly affect prescribers and health care professionals' for clinical practice to support the quality of life in the patients, by promoting rational use of drugs towards patient care to improve therapeutic outcomes ensure efficacy, safety, and quality of the drugs to promote rational use, thereby ensuring the availability of drugs according to the needs of the population. To help the transformation of the handbook into electronic format made the drug information available at the fingertip of the healthcare professionals.

Materials and methods

This Prospective study was conducted in Obstetrics and Gynaecology the departments of CSI Holdsworth Memorial (Mission) Hospital Mysore, Karnataka. Inpatients' profile forms/data were collected from the OBG department. From the WHO model formulary 2010, we prepared a list of drugs that were being used in the OBG department and submitted it to the staff for selecting the drugs to be included in the formulary. Subsequently, a discussion was held in the P & T committee regarding the design of the hospital formulary. By soliciting suggestions from the committee members, contents to be added, monographs, appendices, and the overall design of the formulary were specified. Also, the purpose was to design the formulary in a concise, precise, and handy form. Furthermore, all the members of the P & T committee were asked to select the drugs and brands to be included in the formulary as per the requirements of the health care needs of the local population. Committee members, under the suggestion of OBG doctors, selected the drugs and brands coming under the drug classes relevant to the

OBG department after which a comprehensive finalized hospital drug list was prepared. Two questionnaires with the objective type of questions were prepared with the help of clinical pharmacists and OBG doctors. These questionnaires were designed to gather information like indications, precautions, dose, interactions, and adverse drug reactions for them to be included in each drugs monograph. The drugs in the finalized list were classified based upon Pharmacologic-Therapeutic classification into classes or categories. In addition, the monographs for those drugs were prepared as per the recommendation of the P & T committee members with the help of the Master Drug List (which contains total brands of drugs available in the hospital with their generic name, guantity, and cost per unit) together with some standard drug information from such sources like, British National Formulary (BNF) 2017¹⁴, WHO Model Formulary 2008¹⁵, Martindale The Complete Drug Reference¹⁶, Comprehensive Pharmacy Review¹⁷, Essentials of Medical Pharmacology¹⁸ and CIMS¹⁹. As suggested by committee members, information regarding indications, mechanisms of action, pharmacological classes, doses, contraindications, precautions, adverse effects, pregnancy risk category, and counseling points in each monograph of the drugs were all included.

Result and discussion

The total number of drugs evaluated was 195. With the help of listed drugs of WHO model formulary and master drug list, some more sources and suggestions from Doctors of OBG department and decision of the P and T committee, 61 more drugs were included in the OBG hospital formulary.

Out of 61 drugs included in the formulary, 45 (43.26%) were available in the Oral route (Tablets, Capsules, Syrups, Suspensions, and other solutions) followed by Parenteral route (IV, IM, SC) 44 (42.30%), Topical preparations 10 (9.61%) followed by rectal, vaginal, nasal, and parenteral routes as shown in **table I**.

Out Of 61 drugs included in the formulary, 11 (18.03%) were Anti-infective medicines (Antibiotics) and 11 (18.03%) were drugs affecting endocrine and hormones followed by Vitamins and Electrolytes 8 (8.19%) as shown in **table II**.

Out of 61 drugs, 19 (29.23%) drugs were available in three brands, 18 (27.69%) drugs were available in four brands, 13 (20%) drugs were available in five brands, 7 (10.76%) drugs were available in single-brand as shown in **table III**.

Out of 61 drugs, 22 (36.06%) drugs were under pregnancy and lactation category- C, 14 (22.95%) dugs were under category- B, 10 (16.39%) drugs were under category- A as shown in **table IV**.

Table I: Route of administration of drugs in the prepared Formulary.

Routes	No. of Drugs (n=61)	Percentage (%)
Oral route- (Tablets, Capsules, Syrups, Suspensions and other solutions)	45	43.26
Parenteral route (IV, IM, SC)	44	42.3
Inhalations	0	0
Topical route	10	9.61
Rectal route	3	2.88
Vaginal route	1	0.96
Nasal route	1	0.96

Table II: Drug use pattern in prepared OBG formulary.

Routes	No. of Drugs (n=61)	Percentage (%)
Anesthetics	1	1.63
Analgesics, antipyretics, NSAIDS	6	9.83
Anticholinergics, (Antihistamines, Antipruritic, Antispasmodics, Antifibrinolytics)	7	11.47
Antidote, Alkalysing agents	3	4.91
Anticonvulsants, Antianxiety agents (Barbiturates, Phenobarbital)	2	3.27
Anti-infective medicines (Antibiotics)	11	18.03
Anticoagulants	1	1.63
Alpha/ Beta adrenergic agonist	1	1.63
Antiarrhythmic	1	1.63
Calcium channel blockers	1	1.63
Diuretics	1	1.63
Vasodilators	1	1.63
Drugs affecting endocrine and hormones	11	18.03
Gastrointestinal medicines	5	8.19
Respiratory system medicines	1	1.63
Vitamins and electrolytes	8	13.11

Table III: Patterns of brands available for generic drugs in the OBG hospital pharmacy.

Brands	Number of generic drugs	Percentage (%)
Single brand	7	10.76
Two brands	2	3.07
Three brands	19	29.23
Four brands	18	27.69
Five brands	13	20
Six brands	3	4.61
Seven brands	1	1.53
Eight brands	1	1.53
Nine brands	0	0
Ten brands	0	0
Eleven brands	1	1.53

Table IV: Pregnancy categories of drugs in the prepared Formulary.

Pregnancy category	No. of drugs(n=61)	Percentage (%)
Category- A	10	16.39
Category- B	14	22.95
Category- C	22	36.06
Category- D	10	16.39
Category- X	5	8.19

The feedback questionnaire containing the objective type of questions was distributed to all eight gynecologists and PGs who responded to it thoroughly. As shown in table V, there were 3 Doctors and 5 PGs in the OBG department. Comments and answers to the feedback questionnaire distributed to the Head, Doctors, and PGs of the OBG the department was as follows. For the first question, 75% of doctors had selected the choice Above average in the form, 12.5% of them had selected Average and 12.5% selected Outstanding, for the second question 6 (75%) of them had picked Great extend and 2 (25%) of them had selected the option Somewhat; for the third question, 5 (62.5%) of them had selected Very useful and 3 (37.5%) of them went for the option Useful; for the fourth question 4 (50%) of them had selected very Helpful and 4 (50%) of them had chosen the option Helpful; for the fifth question 5 (62.5%) of they had selected the option Great to extend and 3 (37.5%) had gone for the option Somewhat option; for sixth question 1 (12.5%) of them had picked the option always, 5 (62.5%) of them had selected the option Very frequently, 2 (25%) of them had picked the Option Occasionally; for the seventh guestion, 2 (25%) of them had gone for Very Useful and 6 (75%) of them had picked the option Useful; for the eighth question, 2 (25%) of them had selected Strongly active, 5

Table V: Feedback of	Doctors on	implemented	OBG formulary.
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Feedback questionnaire/ comment	No of Doctors n= 3 (%)	No of PGs n= 5 (%)	Total n=8 (%)
The content in eac	h drug monograp	h?	
Outstanding Above average Average	0 2 1	1 4 0	12.5 75 12.5
Whether the order of	contents in each n	nonograph is conve	nient to refer to?
To great extend Somewhat	3 0	3 2	75 25
Is it useful to beco in the hospital pha	me aware of the b rmacy?	orands available	
Very useful Useful	3 0	2 3	62.5 37.5
Whether this formulary helps reduce the total cost of treatment of the patients?			
Very helpful Helpful	2 1	2 3	50 50
Whether this formulary promotes the safe and effective use of medicines?			
To a great extend Somewhat	2 1	3 2	62.5 37.5
The extent of usag	e of the formulary	1	
Always Very frequently Occasionally	1 2 0	0 3 2	12.5 62.5 25
Will it be useful in	your clinical pract	ice?	
Very useful Useful	1 2	1 4	25 75
The presence of a clinical pharmacist is essential in daily practice			
Strongly agree Agree Neither	1 2 0	1 3 1	25 62.5 12.5
Whether the formulary is handy?			
Yes No	3 0	5 0	100 0
How satisfied are you with the developed formulary?			
Very satisfied Somewhat satisfied	3 0	3 2	75 25

(62.5%) of them had picked Agree and 1 (12.5%) of them had selected neither of the options available; for the ninth question, 8 (100%) of them had selected the option Yes; for the picked the choice Somewhat satisfied as shown in **table V**.

A total of 61 drugs were included in the OBG hospital formulary based on the opinion of the medical staff of the OBG department, clinical pharmacy department, and the request from the P&T committee as per the requirements of health care needs of the local population. Our study result is consistent with the findings of the Tahniyath, F et al²⁰, and Raj, D et al²¹. As with both studies, in line with the different standard references, hospital formulary developed. To substantiate this further, using a formulary system leads to rationalization of drug use, hence reducing the medication errors in giving unbiased useful information to medical representatives. On top of it all, it is a great inventory control measure that helps to improve patient care outcomes.

According to drug use patterns in the OBG department, anti-infective medicines (Antibiotics) were the most commonly used drugs in the OBG department. Using these may be due to the susceptibility of pregnant women to infections. Hence, they are being used to treat common and severe infections before and during delivery, meant to prevent maternal and neonatal complications. Likewise, they were used as prophylaxis before any surgical procedure, such as cesarean section or uterine prolapse operations, aimed at treating infections arising from surgical wounds.²² What follows is the major group which is drugs affecting endocrine and hormones. In addition, it was discovered in the OBG hospital formulary that the administration of drugs was mainly through oral route owing to the patient compliance, its non-invasiveness, being easy to handle, and the absence of any special sterile settings²³. Moreover, in the prepared formulary, the distribution of brands available for generic drugs fell mainly under three brands. Also, the availability of more than three brands for a single drug may well be due to marketing strategies, Pharmaceutical companies, physician preference, patient financial condition, Pharmaco-economic factors, and pricing which should not be taken for granted when it comes to such a variation.

According to the FDA, drugs being used during pregnancy are categorized into five groups as A, B, C, D, and X in which category A drugs are the safest and category X drugs are contraindicated for the pregnancy period. Furthermore, it is integral to remember the necessity of the presence of pregnancy categories in the OBG department, as some of the patients who visit this department are pregnant. The majority of drugs included in the formulary were from pregnancy category C followed by category B and category A, of which about 39.34% of drugs were under categories A and B.

Also, a feedback questionnaire, containing 10 questions, was distributed to the medical staff of the obstetrics and gynecology wards. The overall response to the questions showed that the presence of a formulary is incredibly useful.

Selected medicines for the preparation of the Hospital Formulary satisfied the health care needs of the clinicians. The prepared Hospital formulary is unique in its features, as recommended by hospitals' P&T committee to suit its Patient' health care requirements.

Following a prescription investigation at the hospital pharmacy, it was seen that several of the medications in repeated prescriptions were not available, as the result of which patients had no options left but to rely on retail pharmacies outside of the hospital to provide their essentials, while most doctors were unaware of hospital pharmacy being devoid of the most sought after medications. As a result, the hospital formulary ensures that the pharmaceuticals needed by patients arriving at the hospital are available. Furthermore, not all hospitals in India have their formularies. In this world of the advanced health care system, hospitals in India should establish their formulary with an efficient system and P&T committee to achieve rationality in drug use. Numerous medication errors were reported by healthcare providers due to inadequate drug information. Even though our hospital is a teaching center, drug information sources were not sufficiently available for students active in their different wards (nursing, medicine, pharmacies, etc). This is the grounding behind why our department initiated drug information, ADR reporting center, and medication error monitoring as a primary constructive step. Following this further, upon the suggestion of the medical staff of the OBG department, we initiated the establishment of the Hospital Formulary, luckily facilitated with the help of PTC. Equally significant, drug monographs were organized in a way that medical, pharmacy, and nursing students could efficiently promote the concept of rational drug therapy. Not to mention, it also served as an educational tool for them.

Owing to the unsatisfactory information provided by the medical representatives to the physicians, unreasonable prescriptions are written out. To abolish this all, the hospital formulary monographs were created from standard references to provide unbiased information to healthcare professionals. As a result, it provoked the feeling of appreciation of Doctors since it contained a plethora of information about medications, making them aware of all the brands and costs available in the hospital pharmacy, allowing them to prescribe the most costeffective drug, lowering the total cost of the patients' treatment accordingly.

Conclusion

Hospital formularies are heterogeneous. The prepared Hospital formulary is unique in its features, as recommended by the hospital's P & T committee to suit its patient's health care requirements. Not all hospitals in India have their formularies. In this world of the advanced health care system, hospitals in India should develop their formulary with an effective formulary system and P & T committee to achieve rationality in drug use. P & T committees of the hospitals must implement pharmacoeconomic analysis to select drugs and their products for inclusion into formulary. Pharmaceutical promotion is a delicate area, where it is the responsibility of the hospital's P & T committee to solve if any conflicts in drug products selection and look after that, drug products are selected for the hospital by considering cost, safety, and efficacy. The prepared hospital formulary should be implemented in the hospital with an effective formulary system, which will support and contribute to rationalizing drug use in the hospital., it is informative and will be useful for the health care professionals working in the hospital. By referring to the prepared hospital formulary, prescribers of the hospital can develop of hospital formulary for a rural tertiary care teaching hospital in south India knows about the drugs available in the hospital Pharmacy. Where the prepared pharmaceutical product list can be referred for brand names and other details of the brands approved to use in the hospital. The pharmacy and therapeutics committee of any hospital must be well balanced with active health care professionals like physicians, pharmacists, and nurses. Pharmacists play important role in developing formulary and formulary systems in a hospital. Pharmacist participation in structuring guidelines, policies, and procedures for drug use in the hospital is essential. A well-developed hospital formulary. well-structured policies and procedures for additions and deletions of the drugs from the formulary and to address other drug-related issues in the hospital are essential to run an effective formulary system. Where this in turn gives rise to rational drug use.

Conflict of Interest

The authors declare that they have no conflict of interest.

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