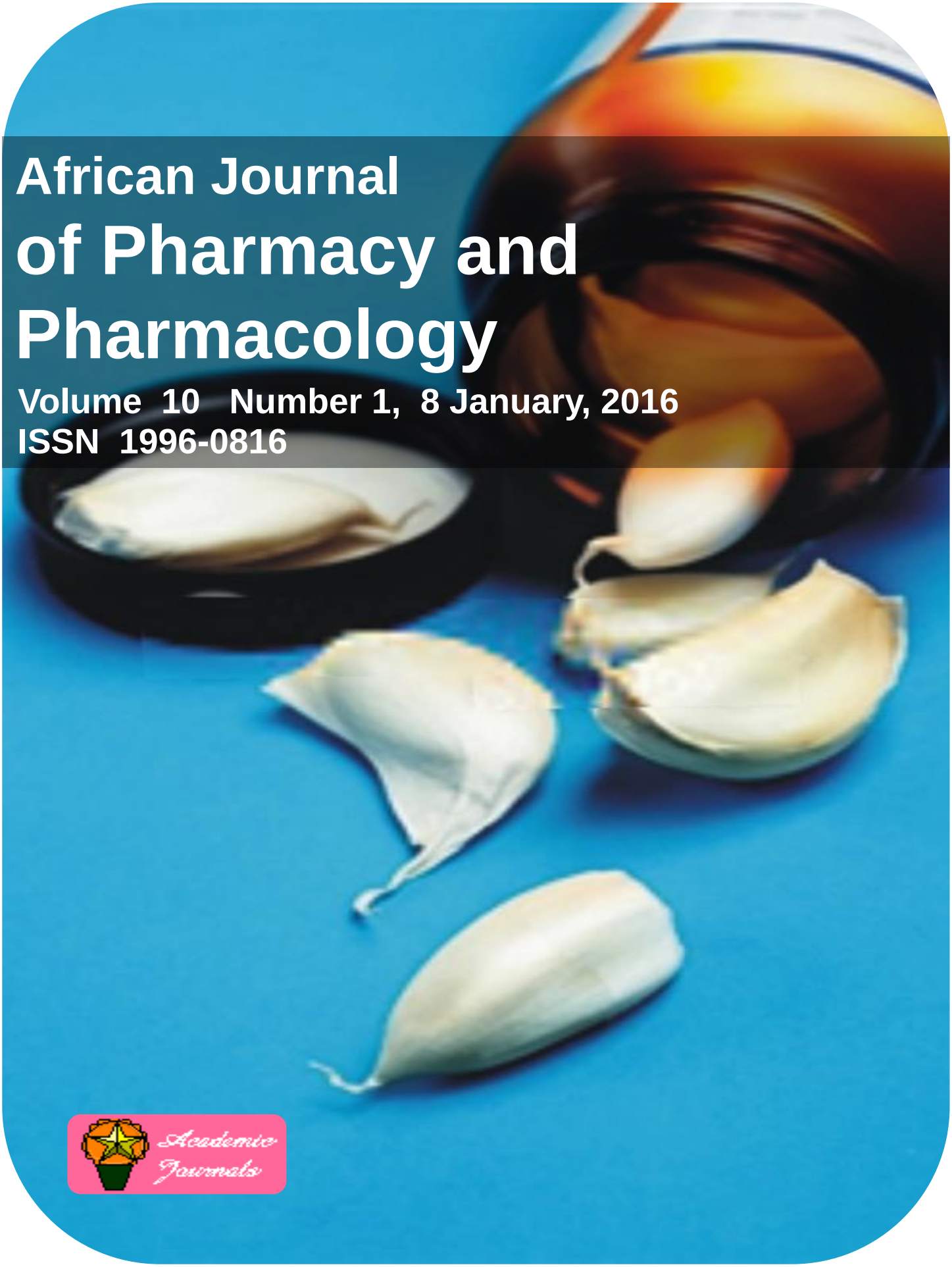

African Journal of Pharmacy and Pharmacology

Volume 10 Number 1, 8 January, 2016
ISSN 1996-0816

Academic Journals

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African Journal of Pharmacy and Pharmacology

Table of Contents: Volume 10 Number 1 8 January, 2016

ARTICLES

academicJournals

Vol. 10(1), pp. 1-6, 8 January, 2016
DOI: 10.5897/AJPP2015. 4390
Article Number: 4EF704756791
ISSN 1996-0816

http://www.academicjournals.org/AJPP

African Journal of Pharmacy and Pharmacology

Review

A review on corrective action and preventive action (CAPA)

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Received 23 June, 2015; Accepted 19 August, 2015

The primary objective behind corrective action and preventive action (CAPA) in any pharmaceutical or medical device industry is to determine the weakness, deviation or failures and to carry out its investigation with appropriate actions so that such problems are not repeated again. CAPA is also a method in which preventive measures are taken in the beginning itself so that occurrence of any incidence can be prevented. It is a part of overall Quality Management System (QMS) and also a regulatory requirement in a pharmaceutical company.

Keywords: Corrective action, preventive action, corrective action and preventive action (CAPA), action plan, root cause determination.

INTRODUCTION

Corrective actions and preventive actions (CAPAs) are a very important part of pharmaceutical quality systems and industry producing medical devices. Once it is discovered that there are weaknesses, including failures in the production and/or testing of drugs, investigations into the cause(s) should commence. Actions should be taken to correct the existing product non-conformity or quality problems (corrective actions) and to prevent the recurrence of the problem (preventive actions). FDA (Food and Drug Administration) investigators and compliance officers often refer to the practice of addressing only the immediate problem as the “band-aid approach,” which often results in a warning letter. CAPA is part of the overall Quality Management System (QMS) (Denise, 2001; ISO, 9000, 2005; US FDA website).

Regulatory expectations

International Conference on Harmonization (ICH) Q10 (Pharmaceutical Quality System)

The pharmaceutical or medical device company should have a system for implementing corrective actions and preventive actions resulting from the investigation of complaints, product rejections, non-conformances, recalls, deviations, audits, regulatory inspections and findings, and trends from process performance and product quality monitoring. A structured approach to the investigation process should be used with the objective of determining the root cause. The level of effort, formality and documentation of the investigation should be

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commensurate with the level of risk, in line with ICH Q9 (Quality Risk Management). CAPA methodology should result in product and process improvements and enhanced product and process understanding (Code of Federal Regulations CFR, 2015) (Figure 1).

CORRECTION

It is an action to eliminate a detected non-conformity. A correction can be made in conjunction with a corrective action. A correction can be, for example, rework or regrade. ISO 9000: 2005 (E). (Michael, 1997; James and Terry, 2000)

CORRECTIVE ACTIONS

A corrective action is to eliminate the cause of a detected non-conformity or other undesirable situation. There can be more than one cause for non-conformity. Corrective action is taken to prevent recurrence. Corrective action may arise from manufacturing deviations, OOS (Out Of Specification) investigations, complaints, audit findings, recalls, etc (ICH, 2005; US FDA website, Michael, 1997; Corrective Action Preventive Action, 2015). The process includes:

1). Reviewing and defining the problem or non-conformity.
2). Finding the cause of the problem.
3). Develop an action plan to correct the problem and prevent a recurrence.
4). Implementing the plan.
5). Evaluating the effectiveness of the correction.

PREVENTIVE ACTIONS

A preventive action is a process to eliminate the cause of a potential non-conformity or other undesirable situation. There can be more than one cause for a potential non-conformity. Preventive action is taken to prevent occurrence. Preventive action may result from trending of in process data, of analytical data, of audit findings, trending of root causes for non-conformities or complaints, from annual product reviews, quality risk analyses, etc (ICH, 2005; US FDA website, Michael, 1997; Corrective Action Preventive Action, 2015). The process includes:

1). Identify the potential problem or non-conformance.
2). Find the cause of the potential problem.
3). Develop a plan to prevent the occurrence.
4). Implement the plan.
5). Review the actions taken and the effectiveness in preventing the problem.

Note: Corrective action is taken to prevent recurrence whereas preventive action is taken to prevent occurrence. (ISO 9000:2005)

PROCESS OF CAPA

There are 7 basic steps of CAPA for pharmaceutical or medical devices industries (Joseph, 2006; Kimberly Lewandowski-Walker, 2008; MarliseGyger, 2012):

1). Identification - Define the problem.
2). Evaluation - Appraise the magnitude and potential impact.
3). Investigation - Identify the root cause of the problem.
4). Analysis - Perform a thorough assessment with documentation.
5). Action Plan - Define corrective and preventive actions.
6). Implementation - Execute the action plan.
7). Follow UP - Verify and assess the effectiveness.

21 CFR (Code of Federal Regulations) 820 regulatory requirements (Procedures)

They establish and maintain procedures for implementing corrective and preventive action (Code of Federal Regulations CFR, 2015).

Preamble on procedures

The procedures (for implementing corrective and preventive action) must provide for control and action to be taken on devices distributed, and those not yet distributed, that are suspected of having potential non-conformities (Preamble, comment 158).

ESTABLISHING DATA SOURCES

Data can be established from internal sources as well as external sources. Examples of internal data sources are: Process control data, test/inspection data, device history records, internal audits, non-conforming material reports, rework and scrap/yield data and training records. Examples of external data sources are: Supplier controls, customers, complaints, servicing repairs, adverse event reporting (MDR), FDA and similar devices from competitors.

DATA ANALYSIS

Analyze processes, work operations, concessions, quality

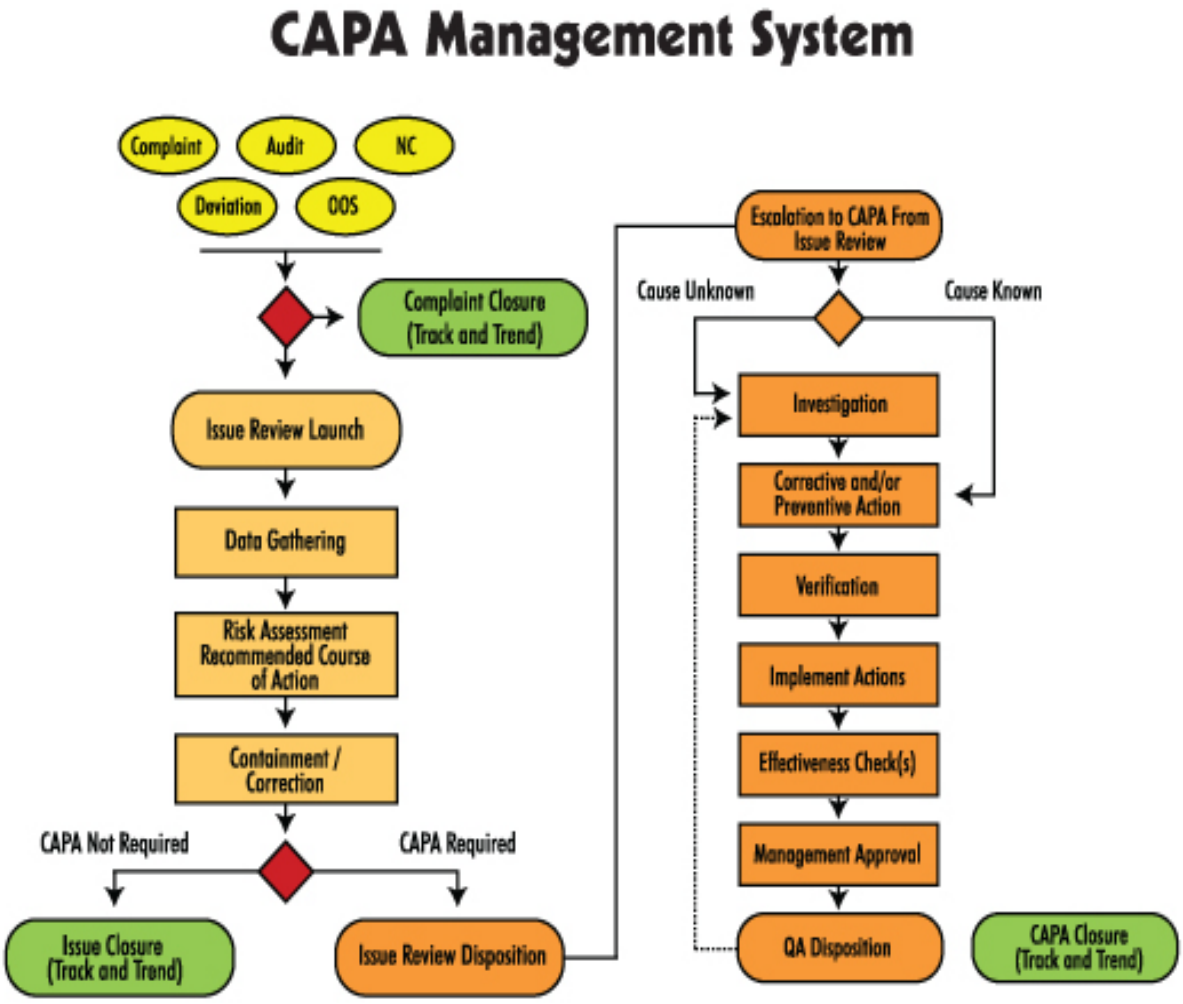

Figure 1. reference: www.mastercontrol.com/capa-software/corrective-action-capa-software.html

audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of non-conforming product, or other quality problems. 21 CFR 820.100 (a) (1).

Approach to data analysis: Non-statistical and statistical techniques

1). Use a risk-based approach to rank areas, select items with major impact, that is, product related or process related. Proceed with items from high to low impact and eventually assure all areas are addressed.
2). Use of Statistical Methodology; 21 CFR 820.100 (a) (1). Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems (Code of Federal Regulations CFR, 2015).

Investigation to determine root cause

Investigate the cause of non-conformities relating to product, processes, and the quality system. 21 CFR 820.100 (a) (2).

PREAMBLE ON INVESTIGATIONS

The requirement in this section is broader than the requirement for investigations under section 820.198, because it requires that non-conforming product discovered before or after distribution be investigated to the degree commensurate with the significance and risk of the non-conformity. The requirement in this section applies to process and quality system non-conformities, as well as product non-conformities. If a molding process with its known capabilities has a normal five percent

rejection rate and that rate rises to ten percent, an investigation into the non-conformance of the process must be performed (Preamble Comment 161) (How to create a corrective and preventive action plan, 2015; Code of Federal Regulations CFR, 2015).

Identify corrective and preventive actions

Identify the action(s) needed to correct and prevent recurrence of non-conforming product and other quality problems. 21 CFR 820.100 (a) (3) (Preamble Comment 161) (How to create a corrective and preventive action plan, 2015; Code of Federal Regulations CFR, 2015).

Identify action(s) to be taken

1). No further action necessary.
2). Correction.
3.) Corrective Action.
4.) Preventive Action.

The preamble on risk and degree of corrective and preventive action

The degree of corrective and preventive action taken to eliminate or minimize actual or potential non-conformities must be appropriate to the magnitude of the problem and commensurate with the risks encountered. (Preamble, Comment 159).

Verify/validate corrective and preventive actions

Verify or validate the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device. 21 CFR 820.100 (a) (4).

Preamble on verification and validation

FDA has revised Section 820.100 (a) (4) to reflect that preventive, as well as corrective, action must be verified or validated (Preamble, Comment 163).

Implement corrective and preventive actions

Implement and record changes in methods and procedures needed to correct and prevent identified quality problems. 21 CFR 820.100 (a) (5).

Communicating CAPA information

1). Disseminate information related to quality problems or non-conforming products to those directly responsible for assuring the quality of such product or the prevention of such problems. 21 CFR 820.100 (a) (6).
2). Submit relevant information on identified quality problems, as well as corrective and preventive actions for management review. 21 CFR 820.100 (a) (7).

The preamble on CAPA activities for management review

Only certain information needs to be directed to management. The manufacturer's procedure should clearly define the criteria to be followed to determine what information will be considered "relevant" to the action taken and why. FDA emphasizes that it is always management's responsibility to ensure that all nonconformity issues are handled appropriately. (Preamble, Comment 164) (US FDA website; Code of Federal Regulations CFR, 2015).

Documenting corrective action and preventive action activities

Document all activities required under this section, and their results. 21 CFR 820.100 (b) (US FDA website; Code of Federal Regulations CFR, 2015).

The preamble on CAPA and internal audits and management reviews

Two comments stated that the records required under Section 820.100 (b) should be treated as part of the internal audit. FDA disagrees with these comments. FDA has the authority to review such records and the obligation to do so to protect the public health. Manufacturers will be required to make this information readily available to an FDA investigator. (Preamble, Comment 166) (US FDA website; Code of Federal Regulations CFR, 2015)

FDA inspection

Manufacturers should consider that their corrective action and preventive action documentation can demonstrate to FDA that the manufacturer's quality system is effective and enables the manufacturer to identify problems quickly and implement effective corrective and preventive actions (US FDA website).

Initiation of CAPA

1). The initiation of CAPA requires submission of source document by concerned department head to QA (Quality

Assurance).
2). QA head shall decide the need for CAPA.
3). The department head shall get a CAPA form issued from QA. QA shall write the source document name and source document number on the form before issue of the form to concerned department.
4). Department head shall fill the CAPA form as under:

a). Date CAPA initiated.
b). Proposed completion date.
c). Select the department initiating the CAPA by making a √ mark in appropriate box.
d). Select the relevant system affected by making a √ mark in appropriate box. If none of the systems printed are affected, select "Not Applicable". If any other system, other than those mentioned is affected, write the system in blank spaces provided.
e). Write in brief the CAPA description from the source document and corrective and preventive action details.
f). The department head shall write their names and duly signed with date.

5). The department head shall send the CAPA form to QA.
6). QA shall allot a reference number to the CAPA form and make relevant entries in the CAPA log. Thereafter, QA shall forward the CAPA form to the concerned department.

(Nonconformance and Corrective and Preventive Action-Background and Exhibits, 2015; Ken, 2015; Difference between Containment, 2015).

CAPA closure and verification

1). On completion of actions, the department head shall certify that the proposed CAPA is completed and implemented along with associated actions.
2). QA shall verify the implementation and completion of CAPA with review of supporting documents and certify the same.
3). Any change proposed as a result of CAPA shall be through the SOP (Standard Operating Procedure) on change control reference; the same shall be mentioned in the CAPA format.
4). All change control, deviations, discrepancy, incident reports giving rise to CAPA shall be addressed through CAPA form.
5). All facility up-gradations, capital purchase requirements, major changes in quality system and compliance to regulatory commitments giving rise to CAPA shall be addressed through CAPA form.
6). The record of each CAPA shall be maintained.
7). Copy of the completed CAPA shall be provided to the concerned department head by QA.
8). QA shall compile the CAPA information and submit the summary to the management during management review meeting.
9). Management shall review/verify the same quarterly, in management review meeting.
10). Information and documents related to CAPA drawn from internal audits, external/customer audits, and regulatory inspections are considered confidential and can only be made available to regulatory review when approved by director technical and QA head.

(Tonya, 2013; Difference between Containment, 2015; Larry and Chair, 2010).

CONCLUSION

Corrective action and preventive action is an important path towards improvement and effectiveness of Quality Management System. It plays an important role in Quality Risk Management System. The root cause analysis of any problem or deviation can be easily done by implementing CAPA. Pharmaceuticals, health care and medical devices industries should strictly adhere to the implementation of CAPA in their organization.

Conflict of Interests

The author have not declared any conflict of interests.

REFERENCES

Code of Federal Regulations CFR (2015). Title 21, Part 820, www.accessdata.fda.gov on 05.05.2015.
Corrective Action Preventive Action (2015). Defining alternatives to training as a root cause, www.mnasq.org on 24.03.2015.
Denise ER (2001). The Corrective Action Handbook, 2nd Edition. 132p
Difference between Containment, Corrective and Preventive Actions in 8D report,www.8dreport.com on 02.04.2015.
How to create a corrective and preventive action plan (2015). Guidelines for writing a CAPA, www.feinsteininstitute.org on 05.05.2015.
ICH (2005). Harmonised tripartite guideline, Quality Risk Management, Q9, version 4, November 2005.
ISO 9000 (2005). 9000 Quality Management System-Fundamentals and vocabulary. ISO 2005.
James PR, Terry R (2000). After the Quality Audit: Closing the Loop on the Audit Process.
Joseph DN (2006). Good Manufacturing Practices for Pharmaceuticals, 6th Edition. 424 pp.
Ken P (2015), Improving CAPA systems with a closed-loop methodology, assessed online from www.mastercontrol.com on 02.04.2015.
Kimberly LW (2008). Food and Drug Administration, Division of domestic field investigations, office of regulatory affairs, Corrective and Preventive Action-Background and examples.
Larry K, Chair GHTF (2010). Quality Management System-Medical Devices-Guidance on corrective action and preventive action and related QMS processes, GHTF/SG3/N18:2010.

MarliseGyger Ms (2012). ETH, Corrective Actions and Preventive Actions, Quality and GMP, June.
Michael BW (1997). Total Quality Safety Management and Auditing.
Nonconformance and Corrective and Preventive Action-Background and exhibits,www.epa.gov on 28.03.2015.
Tonya W (2013). Corrective and Preventive Actions, A five step approach.
US FDA website, Quality systems approach to pharmaceutical cGMP regulations.

academicJournals

Vol. 10(1), pp. 7-13, 8 January, 2016
DOI: 10.5897/AJPP2015.4285
Article Number: 49788BD56793
ISSN 1996-0816

http://www.academicjournals.org/AJPP

African Journal of Pharmacy and Pharmacology

Full Length Research Paper

A study on the prescription pattern of drugs in Jazan general hospital, KSA

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Received 30 January, 2015, Accepted 18 November, 2015

Inappropriate drug prescribing is a global problem affecting the healthcare system. This study was performed to assess the drug prescribing pattern in geriatric, paediatric and obstetrics and gynaecology department. Patient's chances of exposure to poly pharmacy are more, therefore, this study was carried out to find out the rational use of prescribed drugs in Jazan general hospital. A prospective cross sectional (descriptive) study was carried out and a total of 3070 prescriptions were collected for the study during November, 2012 to October, 2013. 1034, 1024, and 1012 prescriptions from geriatric, pediatric and obstetrics and gynaecology department respectively were collected. The average numbers of drugs used per patient were 3.1, 7.4 and 3.3 for geriatric, pediatric and obstetrics and gynaecology department patients respectively. Prescription pattern of the drugs for pediatric patients consists of antibiotics, analgesics and antipyretics mainly. For geriatric patients among systemic route, commonly prescribed therapeutic class of medications were antibacterials (70.5%), and among oral route, pantoprazole was the most commonly prescribed medication (61.2%). For obstetrics and gynaecology department patients the most frequently prescribed drugs were oral iron, folic acid preparations, antibiotics and analgesics. There is a high level of exposure to medication in paediatric and geriatric population. In obstetrics and gynaecology department, the average numbers of drugs per prescription were slightly higher compared to the standard set by World Health Organisation (WHO) but majority of the drugs were prescribed as per United State Food and Drugs Administration (USFDA) category A (the safest category during pregnancy).

Key words: Drug prescription pattern, Jazan General Hospital.

INTRODUCTION

Rational use of drugs is one of the major problems that health care providers and hospital administrators face nowadays in many countries (Thomas et al., 1997). Various studies have been conducted in developing and developed countries during past few years regarding safe and effective use of drugs. These studies show that irrational drug use is a global phenomenon and only few prescriptions justify rational drug use (Gautam and

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Aditya, 2006; Sneha and Mathurak, 2006).

It is well documented that safe and effective drug therapy is possible only when patients are well informed about the medications and their use. The rational use of drugs requires that the patients receive medications to their clinical need in appropriate doses that meet their own individual requirement for an adequate period of time and at the lowest cost to them and their community as per defined by the World Health Organization. The five important criteria for rational drug use are accurate diagnosis, proper prescribing, correct dispensing, suitable packing and patient adherence (Alam et al., 2006).

The prescribers should make an accurate diagnosis and prescribe rationally and the pharmacist should ensure that effective form of the drug reaches the right patient in prescribed dosage and quantity, with clear instructions on its appropriate use (Alam et al., 2006; Lea, 1985). Prescribers need to take into account the way in which the disposition of drugs in children differs from adults both pharmacokinetically and pharmacodynamically (Sutcliffe, 1999). Infants and children suffer from frequent but usually non-serious illnesses and infections. Most of these are self-limiting and are often treated not only inappropriately, but also resorting to polypharmacy (Ghai and Paul, 1998). Unnecessary drugs are sometimes prescribed for example, antibiotics, for patients without evidence of bacterial illness or multivitamins in large quantities for patient without nutritional problems (Andreasen, 1973; Brin, 1968). There are many potential difficulties involved with prescribing to children. There is a paucity of randomised clinical studies designed to test medication use in children (Sutcliffe, 1999).

While prescribing drugs during pregnancy, the benefits to the mother and the risks to the foetus should be carefully considered. Pregnancy is a time which brings profound physiological changes in the body of a woman which challenges the clinicians in managing the disease states and selection of drugs best suited to treat them (Cheney, 2012). Reducing errors in medication and improving safety of the patient are important areas of discussion as the life and health of the unborn child is also at stake and may lead to serious functional and structural side effects during development (Benjamin, 2003). Irrational use of drugs is a huge worldwide problem and extra care should be taken especially in pregnancy, for example unnecessary drugs are sometimes prescribed like multivitamins in large quantities for patient without nutritional problems or antibiotics, for patients without evidence of bacterial illness.

In order to be rational, drug use must be effective, safe, prescribed for the proper therapeutic indication and the correct dosage in an appropriate formulation, easily available and of a reasonable cost (Akhtar, 2012). By keeping all of these issues in mind, a study was carried out in Jazan general hospital, to assess the drug prescribing pattern in geriatric, pediatric and obstetrics and gynaecology department patients as chances of exposure to polypharmacy are more. Gizan is situated on the eastern flank of the Red Sea about 1100 km southwest of Riyadh in the Kingdom of Saudi Arabia.

METHODOLOGY

A prospective cross sectional (descriptive) study was undertaken in the department of geriatrics, paediatrics, obstetrics and gynaecology of Jazan General hospital in Gizan City. The study was designed to obtain information regarding the prescribing pattern of drugs by the medical prescribers and also to analyze the basic information on the prescription for the elderly, paediatrics and obstetrics and gynaecology patients. Duration of study period was one year (November, 2012 to October, 2013). A total of 3070 prescriptions were collected from the hospital's pharmacy located in the hospital. 1034 files belonging to the hospitalized elderly patients (age >65 years), 1024 files of pediatric patients (age < 6) and 1012 files from obstetrics and gynaecology patients were collected for the study.

Parameters present on the prescription such as patient information (name, age, gender, nationality and file no. diagnosis, co-morbid condition/s, medication history and duration of hospitalization), information of hospital (name, department, unit), identity of the prescriber (name and signature), consultant-in-charge and the date, disease diagnosed and drugs prescribed to each patient were studied. The others indicators assessed during the current study were average number of drugs per prescription, percentage of types of drugs prescribed to individual patients, percentage of category of drugs prescribed as per WHO core indicator and USFDA, percentage of patient prescribed with injectables and percentage of patient prescribed with antibiotics.

All of the patient and hospital information (variables) present on the prescriptions were calculated by dividing the total no. of variables by total no. of prescriptions and multiplying it by 100. The average number of drugs prescribed per patient was calculated by dividing the total number of drugs by the number of patients. Percentage of patient with injections, and percentage of patients with antibiotics were determined by dividing the number of times the drug was prescribed by the total number of patients respectively and finally multiplied by 100. The drug prescribing pattern was evaluated as per WHO prescribing indicators, and potentially inappropriate drug prescription patterns were evaluated as per Beer's criteria.

RESULTS

The demographic characteristics of geriatric patients are shown in Table 1. Out of 1034 prescriptions studied, 648 (62.67%) belonged to males and the rest 386 (37.33%) to female patients, giving a male to female ratio of 1:0.59. Most of the patients were in the age group of 65 to 70years (57.83%) and least were in more than 90 years age group (1.45%). Based on Beers criteria, 870 (84.14%) patients received potentially appropriate prescriptions and 164 (15.86%) were prescribed inappropriately. In the later case, 126 (34.62%) were of male patients and 38(10.44%) of female patients.

This Study also revealed that patients in the age group of 65 to 70 years received maximum percentage

Table 1. Gender distribution of elderly patients.

Gender	No. of patients	Percentage
Male	648	62.67
Female	386	37.33

Table 2. Age distribution of inappropriate prescriptions in elderly patients.

S/N	Age	No. of prescriptions	Percentage
1	65-70	79	48.17
2	71-75	38	23.17
3	76-80	22	13.42
4	81-90	19	11.59
5	≥ 90	6	3.66

(48.17%) of inappropriate prescriptions, whereas the least percentage (3.66%) of inappropriate prescriptions were found in the ≥90 years age group as shown in the Table 2. Among systemic route, commonly prescribed therapeutic class of medications were antibacterial (70.5%), and among oral route, pantoprazole was the most commonly prescribed medication (61.2%). In this study, it was observed that a total number of 7336 drugs were prescribed to 1034 elderly patients. 1128 (15.38%) drugs were acting on respiratory system, on GIT 1018 (18.88%), as analgesic and anti-inflammatory drugs 948 (12.92%), 884 (12.05%) antimicrobial drugs and 739 (10.07%) for cardiovascular diseases.

A total of 643 (8.76%) drugs were prescribed for diabetes mellitus, 520 (7.09%) as antihypertensive drugs, 407 (5.55%) antihistaminic, 348 (4.74%) vitamins, minerals and dietary supplements, 241 (3.29%) for central nervous system (CNS) disorders, 214 (2.92%) for hematological system, 91 (1.24%) antimalarial drugs, 43 (0.59%) antitubercular drugs and 112 (1.53%) were used for other diseases and disorders.

According to the WHO core drug use indicator pattern, average number of drugs prescribed per encounter was 7.09. The average number of diseases present was 4+1. Generic prescriptions were recorded with a very low figure of 7.24% which may not be in favor of the patients. Antibiotics were prescribed to 12.05%, while injections were prescribed to 28.45%. The percentage of drugs prescribed from national essential drugs list was 97.28% suggesting a good supply of the drugs in the hospital which is an impressive finding of the study as shown in Table 3.

The study shows the prevalence of some missing items in the prescriptions. The major missing items were the date of the consultation and sex of the patient. In contrary, almost all physicians mentioned frequency and duration of medication. Missing items included family health record number (5.4%), name of the patient (1.2%), age of the patient (18.43%), sex of the patient (22.12%), nationality of the patient (2.4%), name of physician (0.2%), date of the consultation (25.54%) and diagnosis of the disease (18.3%) (Table 4).

Frequency and duration of the medication are nil and 0.02% only which is an indicator of positive prescribing pattern. In the pediatric pateints, major diseases found were respiratory tract infections (35.62%), both upper 21.92% (sinusitis, tonsillitis and rhinitis) and lower 13.70% (bronchitis(8.90%), bronchial asthma (2.74%), pneumonia (1.37%), and tuberculosis (1.37%)) along with some skin diseases (12.33%) like diaper dermatitis, pyogenic granuloma, seborrheic and intertriginous dermatitis, eczema, and others like leishmaniasis, gastroenteritis and parotitis (Table 5).

The average number of drugs used per patient was 3±1, and antibiotics were used most frequently than others. Prescription pattern of the drugs was like analgesics and antipyretics 97.56%, antibiotics 93.55% (out of which 29.41% were prescribed two antibiotics), nasal decongestants 23.54%, anti-histaminic 19.73%, multi vitamins and iron supplement 16.21%, expectorants and bronchodilators 8.89%, germicidal and disinfectant 8.01%, anti-diarrhoeal 4.69%, antispasmodic 4.49%, corticosteroids 3.13%, gastric acid suppressants 3.03%, anti- emetics 1.95%, anti-asthmatics 1.37%, anti-helmentics 0.88% and anti-malarial 0.29% of prescriptions (Table 6).

In obstetrics and gynaecology department, the average number of drugs per patient was found to be 3.30 (range 1 to 10). Fifty-four different types of medicines and a total number of 3340 medicines were prescribed for the entire period. Table 7 shows the WHO prescribing indicators that were evaluated. The most frequently prescribed drugs were oral iron, preparations of folic acid, antibiotics and analgesics. Prescription pattern among the obstetrics and gynaecology patients observed was like minerals/vitamins 45.2%, antibiotics 19.86%, analgesics 15.61%, steroidal progestin 3.55%, antacids 3.26%, antiallergens 2.66%, antifungals 1.58%, anthelmintics 1.08%, antihypertensives 0.88%, expectorants 0.49%, antiemetics 0.49% and others 11.06%.

The most frequently prescribed medicines were minerals and vitamins of which folic acid 471 (46.4%) was the most frequently prescribed drug. Others included ferrous sulphate 369 (36.5%), calcium 208 (20.61%), some multivitamins and proteins in 24.91% cases. A total nine types of antibiotics of different classes were prescribed and the percentage of individual class in prescriptions was as cephalosporins 250 (39.99%), nitroimidazole antibiotic (Metronidazole) 196 (31.34%), β-lactam antibiotics 108 (17.29%), macrolides 37 (5.94%), tetracyclines 17 (2.70%) and fluoroquinolones 17 (2.70%).

Paracetamol 265 (53.86%) was the most frequently prescribed analgesic and other analgesics included in the prescriptions were aspirin 91(18.50%), Diclofenac Sodium 65 (13.30%), Indomethacine 44 (8.94%) and

Table 3. WHO core drug indicator for drug prescribing pattern in elderly patients.

Prescribing indicators	Findings (%)
Average number of drugs per encounter	7.09
Percentage of drugs prescribed by generic name	7.24
Percentage of encounters with an antibiotic prescribed	12.05
Percentage of encounters with an injection prescribed	28.45
Percentage of drugs prescribed from national essential drugs list	97.28

Table 4. Missing item prevalence in prescriptions of elderly patients.

Identification of data	(%)
Family health record number	5.4
Name of the patient	1.2
Age of the patient	18.43
Sex of the patient	22.12
Nationality of the patient	2.4
Name of physician	0.2
Date of the consultation	25.54
Diagnosis and medications	
Diagnosis	18.3
Frequency of medication	NIL
Duration of medication	0.02

Table 5. Major diseases present in the paediatric patients.

Diseases		Percentage
Respiratory tract infections	**Upper:** Sinusitis, tonsillitis, rhinitis	27.85
	Lower:	17.15
	Bronchitis	8.90
	Bronchial asthma	4.95
	Pneumonia	1.65
	Tuberculosis	1.65
Skin diseases: Diaper dermatitis, seborrheic and intertriginous dermatitis, pyogenic granuloma, eczema		32.33
Others: Malaria, leishmaniasis, gastroenteritis, parotitis, cuts and wounds		22.67

Ibuprofen 26 (5.28%) as shown in Table 8. Within the prescriptions, the percentage of the drugs according to the categories was: Category A drugs in which adequate clinical studies have shown no risk to foetus in any trimester were 70.12%, mainly folic acid and ferrous Sulphate. Category B drugs in which animal studies have not shown adverse effect on the foetus and there are inadequate clinical studies which were 15.31%, mainly Amoxycillin, Ampicillin/Cloxacillin, Metronidazole, Azithromycin, Paracetamol and Diclofenac Sodium. Category C drugs in which animal studies have shown adverse effects, and no adequate clinical studies, may be useful in pregnancy in spite of potential risks were 13.24%, mainly Fluoroquinolones, Ranitidine, Indomethacin and Salbutamol. Category D drugs in which there is evidence of risk to human foetus, but potential benefits may be acceptable despite potential risks were 1.33%, mainly Aspirin and Category X drugs in which animal/human studies show foetal abnormalities, but risks involved clearly outweigh benefits were 0.00%(none). Prescribing of Category X drugs during pregnancy were not seen, Category B and C drugs were common and category A drugs were maximum as shown in Table 9.

Table 6. Drug category used in the paediatric age group.

Most common pharmacological group (Drug Category)	No. of patients	Percentage
Analgesics and Antipyretics	999	97.56
Antibiotics	958	93.55
Nasal decongestants	241	23.54
Anti-histaminic	202	19.73
Multi vitamins and iron supplement	166	16.21
Expectorants and bronchodilators	91	8.89
Germicidal and disinfectant	82	8.01
Anti-diarrhoeal	48	4.69
Antispasmodic	46	4.49
Corticosteroids	32	3.13
Gastric acid suppressants	31	3.03
Anti- emetics	20	1.95
Anti-asthmatics	14	1.37
Anti-helmentics	9	0.88
Anti-malarial	3	0.29

Table 7. Drug prescribing indicators (as per WHO) in the paediatric age group.

Prescribing indicator	Value obtained	Reference value (as per WHO)
Average number of medicines per patient	3.30 (range 1-10)	1.6 -1.8
Percentage of patients receiving injectables	5.8	13.4 -24.1
Percentage of patients receiving antibiotics	19.86	20 -26.8

Table 8. Frequency distribution of the medicines prescribed in the obstetrics and gynaecology patients.

Prescribed medicines	Total (%)
Minerals /Vitamins	1430 (45.2)
Antibiotics	626 (19.86)
Analgesics	492 (15.61)
Steroidal progestin	112 (3.55)
Antacids	103 (3.26)
Antiallergens	84 (2.66)
Antifungals	50 (1.58)
Antihelmintics	34 (1.08)
Antihypertensives	28 (0.88)
Expectorants	16 (0.49)
Antiemetics	16 (0.49)
Others	349 (11.06)

Most common antibiotic prescribed was Cefalexin. Most common antacid prescribed was Ranitidine hydrochloride. The dose and duration of drug usage was clearly mentioned. Nearly all of the prescribed drugs were from the essential drug list of the hospital. Missing items included family health record number(7.81%), legible name of the patient (0.79%), age of the patient (16.70%), sex of the patient (19.66%), nationality of the patient (2.47%), name of the physician (7.41%), date of the consultation (36.07%) and diagnosis (12.55%) as shown in Table 10.

DISCUSSION

Use of five or more medications is considered as

Table 9. Percentage of drugs used in different categories in the obstetrics and gynaecology patients.

Category	Percentage of drugs
Category A	70.12
Category B	15.31
Category C	13.24
Category D	1.33
Category X	0.00

Table 10. Missing information on the prescription in the obstetrics and gynaecology patients.

Prescription details	No. of prescriptions (n = 1012) (%)
Patient information	
Name	0.79
Age	16.70
Gender	19.66
Nationality	2.47
File no.	7.81
Prescriber's identity	
Name	7.41
Signature	6.52
Date of Consultation	36.07
Diagnosis	12.55

polypharmacy, which was observed in this study. More medicines adversely affect the patient compliance, increase the risk of drug interactions and hike the cost of treatment (Mirza et al., 2009). The average number of drugs per elderly patient was found to be 7.09 which demonstrate high prevalence of polypharmacy (67.02%). Similar data was found in some other studies in Nepal (Joshi et al., 1997) and in India (Veena et al., 2012), where the incidence was 73 and 88.67%, respectively. In this study, a total of 7336 drug formulations were prescribed to 1034 patients for different diseases. To evaluate the appropriateness prescribing for geriatric patients, Beers criteria was first developed in 1991 and was recently updated in 2012.

In the present study, according to Beers criteria, it was revealed that 15.6% of total drugs prescribed were inappropriate. These findings are not significantly different from that found in a study from India (Zaveri et al., 2010; Shah et al., 2011) and Japan (Niwata et al., 2006) in which use of at least one or more inappropriate medicine was used per prescriptions. This suggests that drugs 'to be avoided in elderly' are among the most frequently inappropriately prescribed drugs. The common morbidities included respiratory tract infections followed by GIT disorders. Higher incidence of these respiratory tract infections may be due to the high percentage of airborne Amaranthus pollen in Jazan which potentially causes allergic respiratory diseases as reported by Hasnain et al. (2007).

In paediatrics department, an average prescription rate of 3+1 per consulting child was seen. This high rate of prescribing may be a reflection of increased vulnerability of children to various illnesses. Prescribing for children was from a limited formulary of medications, which is consistent with evidence found in other countries (Sanz and Boada, 1998). The most frequently prescribed medications were antibiotics, analgesics and antipyretics, and nasal decongestants. In discriminate or prolonged prophylactic use of new antibiotics has been shown to contribute to the emergence of multi-resistant hosocomiat strains in the hospital setting (Sande and Scheld, 1980). As with antibiotics, it is difficult to justify the use of analgesics on such a large scale, taking into account that prolonged and excessive use of analgesic compounds may be potential hazards (Bulger and Sherris, 1968). Hence, there is a strong call for studies into how medicines are being prescribed to children in various settings and populations (Sanz, 1998). Studies that have investigated prescribing in paediatric populations have found high prescribing rates, although a limited formulary of medications is used (Straand et al., 1998).

The average number of drugs per prescription in this study (3.30) was higher than the range of the standard set by WHO (1.6 to 1.8) but percentage of patients prescribed with injection was 5.18%, which is low as compared with the range of the standard set by WHO. The most frequently prescribed drugs, was in accordance with earlier studies done in the other countries like Ethiopia (Mereke et al., 2013), India (Rathod et al., 2012; Jayawardhani et al., 2012), Finland (Heikkila et al., 1994) and Australia (Maats et al., 2002).

The prescribing indicators also showed that the percentage of prescribed antibiotic was in the range of the standard set by WHO. This is also encouraging, since antibiotics are routine drugs used for most bacterial infections and this could help to minimize drug resistance problems that could be promoted with over usage of antibiotics. The results revealed that the majority of thedrugs were from category A, there were no drugs prescribed from the category X. This type of pattern of category wise prescription was reported from similar studies conducted in other countries like India, Netherland, Finland etc. (Joshi et al., 2012; Bakker et al., 2006).

Conclusion

This study helped in evaluating the existing pattern of use of drugs in geriatrics, paediatrics, obstetrics and gynaecology department of Jazan general hospital,

Jazan. High level of exposure to medication was seen in paediatrics and geriatrics population whereas in obstetrics and gynaecology department, the average number of drugs was slightly higher compared to the standard set by WHO. Drug therapy can be improved by introducing appropriate intervention programs for medical prescribers for better health care outcomes. This can be considered as an effort to improve the quality of life.

Conflict of Interests

The authors have not declared any conflict of interests.

REFERENCES

Akhtar MS (2012). Drug prescribing practices in paediatric department of a north Indian university teaching hospital. Asian J. Pharm. Clin. Res. 5(1):146-149.

Alam K, Mishra P, Prabhu M, Shankar PR, Palaian S, Bhandari RB, Bista D (2006). A study on rational drug prescribing and dispensing in outpatients in a tertiary care teaching hospital of western Nepal. Kathmandu Univ. Med. J. 4(4):436-443.

Andreasen F (1973). Protein binding in plasma from patients with acute renal failure. Acta. Pharmacol. Toxicol. 32:417-429.

Bakker MK, de Walle HE, de Jong-van den Berg L (2006). Drug Prescription pattern before during and after Pregnancy for Chronic, Occasional and Pregnancy related drugs in the Netherlands. Br. J. Obstet. Gynecol. 113:559-568.

Benjamin DM (2003). Reducing Medication Errors and Increasing Patient Safety: Case Studies in Clinical Pharmacology. J. Clin. Pharmacol. 43:768-783.

Brin M (1968). Blood transketolase determination in the diagnosis of thiamine deficiency. Heart Bull. 17:68-89.

Bulger RJ, Sherris JC (1968). Decreased incidence of antibiotic resistance among S. aureus. Ann. Int. Med. 69:1099-1108.

Cheney BE (2012). Management of Common Primary Care Problems during pregnancy. Programme and Abstracts of the 5th Annual Conference of the National Association of Nurses Practitioners in women's health, Scottsdale Arizona. pp. 27-29.

Gautam CS, Aditya S (2006). Irrational drug combinations: Need to sensitize undergraduates. Indian J. Pharmacol. 38(3):169-170.

Ghai OP, Paul VK (1998). Rational drug therapy in pediatric practice. Indian Pediatr. 25:1095-1109.

Hasnain SM, Fatima K, Al-Frayh A (2007). Prevalence of airborne allergenic Amaranthus viridis pollen in seven different regions of Saudi Arabia. Ann Saudi Med. 27(4):259-263.

Heikkila AM, Erkkola RU, Nummi SE (1994). Use of medication during pregnancy: A prospective Cohort study on use and policy of prescribing. In Annales chirurgiae et gynaecologiae. Supplementum 208:80-83.

Jayawardhani V, Nayeem M, Safhi MM (2012). Prescription pattern of drugs in pregnancy in a tertiary care hospital. Am. J. Pharm. Technol. Res. 2(5):378-381.

Joshi H, Patel S, Patel K, Patel V (2012). Drug use pattern during pregnancy: A prospective study at tertiary care teaching hospital. NHL J. Med. Sci. 1(1):13-16.

Joshi MP, Sugimoto T, Santoso B (1997). Geriatric prescribing in the medical wards of a teaching hospital in Nepal. Pharmacoepidemiol. Drug Safety 6:417-421.

Lea F (1985). Phidelphia, Pharmacy Communication In Hassan WE editor Hospital Pharmacy, 5th ed 154-159.

Maats FH, Crowther CA (2002). Patterns of vitamins mineral and herbal supplement use prior to and during pregnancy. Austr. New Zealand J. Obstet. Gynaecol. 42:494-496.

Mereke B, Kahaliw W, Ergetie Z (2013). Assessment of drug utilization pattern during pregnancy in Adama referral hospital, Oromia region, Ethiopia. Int. J. Pharm. Sci. Res. 4(5):1905-1911.

Mirza NY, Desai S, Ganguly B (2009). Prescribing pattern in a pediatric out-patient department in Gujarat. Bangladesh J. Pharmacol. 4:39-42.

Niwata S, Yamada Y, Ikegami N (2006). Prevalence of inappropriate medication using Beers criteria in Japanese long term care facilities. BMC Geriatr 6(1):11.

Rathod AM, Rathod RM, Jha RK, Gupta VK, Ahmed Tabish SD (2012). Prescribing trends in antenatal care at a tertiary level teaching hospital of Vidarbha region. Res. J. Pharm. Biol. Chem. Sci. 3(3):865-872.

Sande MA and Scheld WM (1980). Combination antibiotic therapy of bacterial endocarditis. Ann. Interm. Med. 92:390-395.

Sanz E, Boada J (1998). Drug utilization in pediatric outpatients in Tenerife Island. Eur. J. Clin. Pharmacol. 34:495-499.

Sanz E (1998). Drug prescribing for children in general practice. Acta Paediatr. 87:489-490.

Shah RB, Gajjar BM, Desai SV (2011). Evaluation of the appropriateness of prescribing in geriatric patients using Beers criteria and Phadke's criteria and comparison thereof. J. Pharmacol. Pharmacother. 2(4)248-252.

Sneha A, MathurAK (2006). CHAPTER–2 RATIONAL DRUG USE. Health administrator 19(1):5-7.

Straand J, Rokstad K, Heggedal U (1998). Drug prescribing for children in general practice: A report from the More and Romsdal prescription study. Acta Pediatr. 87:218-224.

Sutcliffe AG (1999). Prescribing medicines for children. BMJ 319:70-71.

Thomas M, Bykov A, Savelli T, Zagorski A (1997). Guidelines for implementing drug utilization review programs in hospital. Arlington, VA/Moscow, Russia. pp. 1-56.

Veena DR, Padma L (2012). Drug prescribing pattern in elderly patients in a teaching hospital. IOSR J. Dental Med. Sci. 1(5):39-42.

Zaveri HG, Mansuri SM, Patel VJ (2010). Use of potentially inappropriate medicines in elderly: A prospective study in medicine out-patient department of a tertiary care teaching hospital. Indian J. Pharmacol. 42(2):95-98.

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