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Quality assurance of clinical pharmacy services in a multi-speciality tertiary care hospital

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ABSTRACT

Aim
The aim of this study is to evaluate quality assurance program in clinical pharmacy services of a multi-speciality tertiary care hospital.

Methodology
The present prospective study was conducted at Aware Gleneagles Global Hospitals. The study involved assessment of QAP and QI from November 2021 – April 2022. Institutional ethical clearance was taken with approval letter. The check list was adapted from National Accreditation Board for Hospitals and Health care professionals. The data was collected by utilising check list and the data collected was analysed using Microsoft Excel, Microsoft Data Analysis Pack Tool, Microsoft Word.

Results
A total of 36 parameters were evaluated to assess the execution of QAP being implemented in the clinical pharmacy services. The existing QAP in the clinical pharmacy services was assessed in terms of structure, process and outcome. We found that most of the processes were in place as per the defined standards. The overall trend analysis of scoring showed a consistent and good performance, though there were few areas where there was scope for improvement.

Conclusion
The next few years will witness much experimentation in QA process and exciting new opportunities for pharmacist as more active participants in patient care. The study recommended the areas that have to be improved so the same will be useful to us to modify or practice with clinicians.

Keywords: Quality assurance, clinical pharmacy, Management of medication, National Accreditation Board of Hospitals.

INTRODUCTION

The modern clinical pharmacy service has progressed from a purely supporting position to one that is now an active participant in patient treatment. Raised public awareness and fear of legal consequences have increased the requirement for clinical pharmacy to adhere to strong quality assurance policies and generate quality reports since the advent of evidence-based medicine [1].

In a clinical pharmacy services, Total Quality Management (TQM) is often implemented in a cycle of 'five Qs,' namely, Quality assurance, Quality planning, Quality control in the clinical pharmacy department, Quality assessment of specific clinical services, and Quality improvement. A quality management system (QMS) is present in any pharmaceutical practise that adheres to good laboratory practice (GLP) which involves all hospital actions focused towards producing timely and accurate reports. The structure, process, and outcome categories are used to categorise these operations.

Several studies in the topic of excellent healthcare were developed in the 1950s (Daily 1949; Lyon, 1958). A significant contributor in this topic, Avedis Donabedian, created a system for more completely evaluating health services, allowing it to appraise medical treatment and offer

research paths (Best, 2004; Donabedian, 2005; Martin et al., 2008). He established a conceptual framework for health care assessment that is separated into three categories: structure (Table I), process (Table II), and result (Table III), which correspond to the input, process, and output of classical general systems.[2]

Quality Assurance

Quality assurance is a programme that involves the systematic monitoring and evalutaion of many components of a project service, or facility in order to guarantee that quality requirements are met.

Quality Indicators

Quality Indicators used in hospitals are frequently connected to structure, procedures, and results and are used to measure quantitative and/or qualitative treatment. The indicators explain specific characteristics of healthcare that are used to monitor, measure, and prioritise initiatives for on-going quality improvement. Quality Indicators are management tools that may be used to assess the cost-effectiveness of a project. Continuous scientific advancements, technology advancements, and a desire for healthcare excellence characterise specific hospital quality evaluation methods.

Indicators are created by a complicated procedure that ranges from basic straight case counting to more intricate proportions, rates, and indexes. The quality of an indicator is determined by the components employed in its construction (case frequency, demographic and health characteristics, and patient risk factors) as well as the accuracy of the data (data registration, collection, analysis and interpretation).[4]

METHODOLOGY

Study Procedure

A quality assessment of clinical pharmacy services provided in a multi-specialty tertiary care hospital was conducted. The purpose of the study was to determine the significance of clinical pharmacy and its function in the clinical sector, as well as how it may improve service efficiency and lower hospital risks for patients. Compliance with NABH guidelines was scored using a checklist, and the results were documented.

Study Site

Aware Gleneagles Global Hospitals in Bairamalguda, LB Nagar, Hyderabad, Telangana, India was chosen for the quality and MRD department. The hospital is a 300-bed multi-specialty facility with a 50-bed ICU, 80-bed general wards, 96-bed twin sharing rooms, and 74-bed medical sharing rooms, as well as a single clinical pharmacist.

Study Design

A hospital-based prospective observational study was done with the agreement of the medical superintendent and the hospital's quality department at Aware Gleneagles Global Hospital. The study was planned according to NABH guidelines, and a checklist was created to ensure that all of the parameters met the guidelines.

Study Period

The study was carried out for six months.

Study Approval

The ethics committee at Sree Dattha Institute of Pharmacy gave their approval to the project. Before beginning the study, permission was acquired from the HOD of the Quality Department and the Medical Superintendent. The authors were given permission to use the hospital's resources.

Sources Of Data

Case sheets.
NABH checklist.
Prescription audit form.
Medication error reporting form.
Medication prescription chart.
Pharmacy return clearance form.
Pre-OP checklist.
Crashcart list.
High risk medications list.
Emergency medications list.
High-end antibiotics list.
Medication reconciliation form.

RESULT

Table 1: Management of Medication Scoring Checklist

MANAGEMENT OF MEDICATION (MOM)	SCORING FOR COMPLIANCE
MOM-1 : Pharmacy services and usage of medication is done safely	
Functioning of drug information centre (DIC)	40/50
Functioning of pharmacy and therapeutic committee.(PTC)	40/50
Preparation and implementation of written guidance regarding pharmacy services and medication usage.	50/50
Segregation of medications by inventory control.	50/50

High risk medications are properly documented.	50/50
Indented medicines are labelled.	50/50
Establishment of proper process to inform key changes to relevant staff.	40/50
Alternate procedure to dispense medicine when pharmacy is closed.	NOTAPPLICABLE
MOM-2 : The organisation develops, updates and implements of hospital formulary.	40/50
MOM-3 : Medications are stored appropriately and available when required.	
Storage of medications as per written guidance.	40/50
High risk medications list is prepared, usage is properly documented and stored in necessary areas of the hospital.	40/50
Emergency medication list is prepared and ensure that it is always in stock.	40/50
MOM-4 : Medications are prescribed safely.	
Medications are prescribed according to good clinical practices.	30/50
Prescription Audit is done on regular basis and action taken where appropriate	50/50
Prescribing is done after obtaining drug allergies or adverse drug reactions (if any)	40/50
Organisation has developed a certain mechanism to ensure in helping the clinician in appropriate prescribing	50/50
Safe medication management through implementation of verbal orders.	40/50
Reconciliation of medications is received by the patient	40/50
MOM-5 : Medications are written in a uniform manner.	
Ensured that medication orders are written by authorised personnel	50/50
Medication orders are recorded in a uniform location which contains patient's name and unique identification number	50/50
Medication orders contain all details regarding medicine including instructions on usage, adverse drug reactions (if any) and is legible, dated, timed and signed along with registration number of the prescriber.	30/50
MOM-6 : Medications are dispensed in a safe manner.	
Medications orders and recalls are handled effectively.	30/50
Near-expiry medications are withdrawn	50/50
Proper labelling of medications to be dispensed	40/50

High-risk medications are verified before dispensing	40/50
Return of medicines followed according to guidelines	30/50
MOM-7 : Medications are administered safely.	
Administration of medicines by authorized personnel by identifying patient	50/50
Medication is properly inspected for instructions before administering	40/50
Administration is documented	40/50
Measures to avoid misconnections during medical administration are followed	50/50
Patients are governed in case of self-administration of medications	40/50
MOM-8 : Patients are monitored after medication administration.	
Capturing near-miss, medication errors and adverse drug reactions and reporting within the earliest timeframe and further analysed for corrective action	40/50
Change in medication based on analysis	50/50
MOM-9 : Narcotic drugs, psychotropic substances, chemotherapeutic and radioactive agents are used in a safe manner.	
A proper record is maintained about usage, instructions and disposal	50/50
These specific drugs are prescribed and administered by appropriate staff, stored securely and prepared properly	50/50
MOM-10 : Implantable prosthesis and medical devices are used in accordance with guidelines.	50/50
MOM-11 : Medical supplies and consumables are stored appropriately.	40/50

SCORING PATTERN FOR MOM CHECKLIST

- 50 – FULL COMPLIANCE
- 40 – GOOD COMPLIANCE
- 30 – AVERAGE COMPLIANCE
- 20 – LOW COMPLIANCE
- 10 – NO COMPLIANCE
- "Full compliance" refers to a parameter that follows the protocol to the letter.
- "Good compliance" refers to a parameter that follows the protocol 75-99% of the time.
- "Average compliance" refers to a parameter that follows the procedure 45-74% of the time.
- “Low compliance” refers to a parameter that follows the protocol only 10 to 45 percent of the time.
- "No compliance" refers to a parameter that fails to meet at least 10% of the protocol's requirements appropriately and available when required.

COMPARISION OF MOM PARAMETERS BY TAKING AVERAGE OF EACH PARAMETER

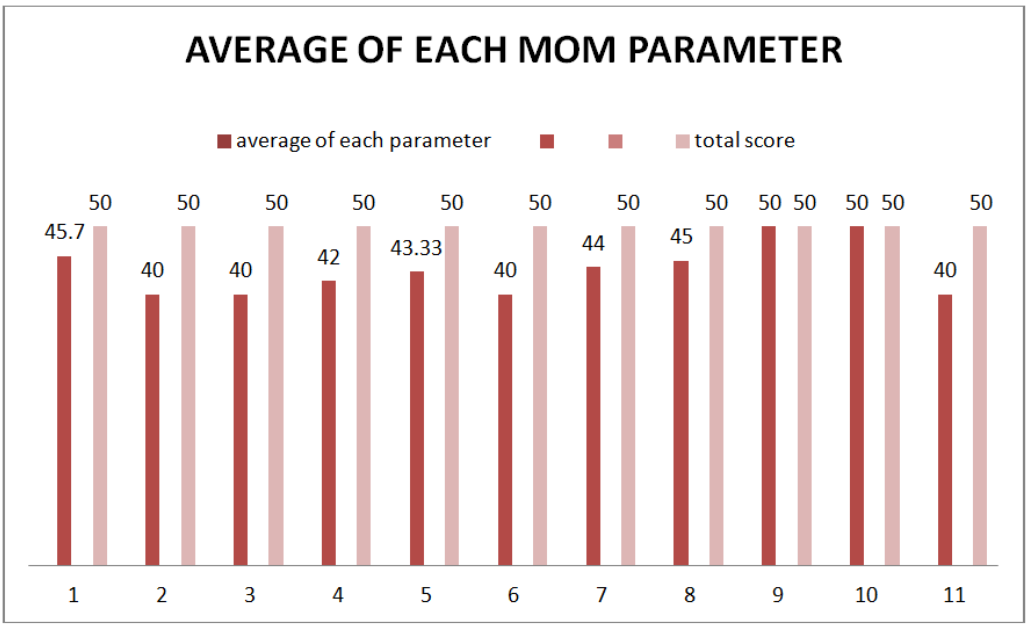

Fig 1: Column Graph Representation of Average of Each Mom Parameter.

Table 2: Structure-Process-Outcome Checklist

			Compliance (Score Achieved)				
			10	**20**	**30**	**40**	**50**
Category 1 = Structure							
i.	Infrastructure availability						√
ii.	Adequate manpower and staffing						√
iii.	Quality policy:	Scope of services					√
		Pharmacy personnel					√
		qualification					√
		Reporting of results					√
		Quality Assurance Programme					√
iv.	SOP for collection, dispensing, handling and storage of medication						√
v.	SOP for experimental procedures						√
vi.	Signboards/Posters displaying the activities and services in the pharmacy and the important contact numbers for communication at prominent areas.						√
	Score		500				
Category II = Process							
i.	Availability of all the necessary medications reaching to patient						√
ii.	Initial and on going medication review to address safety and adherence concerns						√
iii.	Daily documentation of medical records						√
iv.	Monthly External Quality Assurance Records						√
v	Documentation of corrective and preventive actions					√	
vi.	Adherence to safety precautions checklist like pharmacy services and periodic training for the same						√
vii.	Process of ordering/prescribing, transcribing, verifying, dispensing and delivering, administering.					√	
viii.	Process of monitoring and reporting of medication						√
ix.	Dispensing of narcotic and psychotropic medications without consent forms.						√
x.	Adherence to high risk medications without consent.						√
xi.	Adherence to Medication Turn Around Time						√
xii.	Adherence to safety medication concern						√
	Score				580		
Category III = Outcome							
i.	Assessment of self-audit					√	
ii.	Assessment of therapeutic drug monitoring of medication						√

iii.	Feedback from patients regarding usage of medication					√
	Score	140				
	Overall Scores				120	900
	Total Score	1020/1050				

COMPLIANCE SCORING

- 50 - FULL COMPLIANCE
- 40 - GOOD COMPLIANCE
- 30 - AVERAGE COMPLIANCE
- 20 - LOW COMPLIANCE
- 10 - NO COMPLIANCE

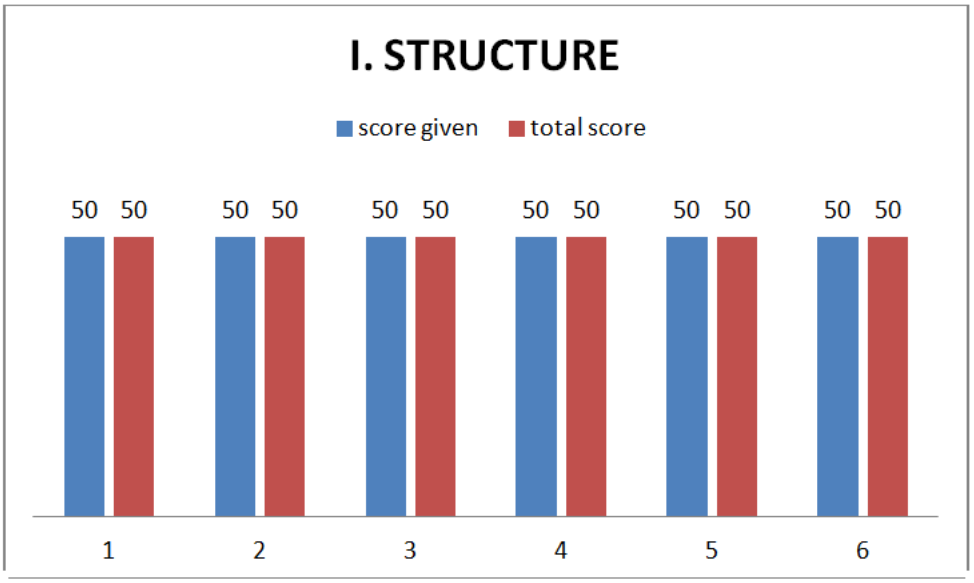

Fig 2: Column Graph Representation of Parameters under Structure

PROCESS

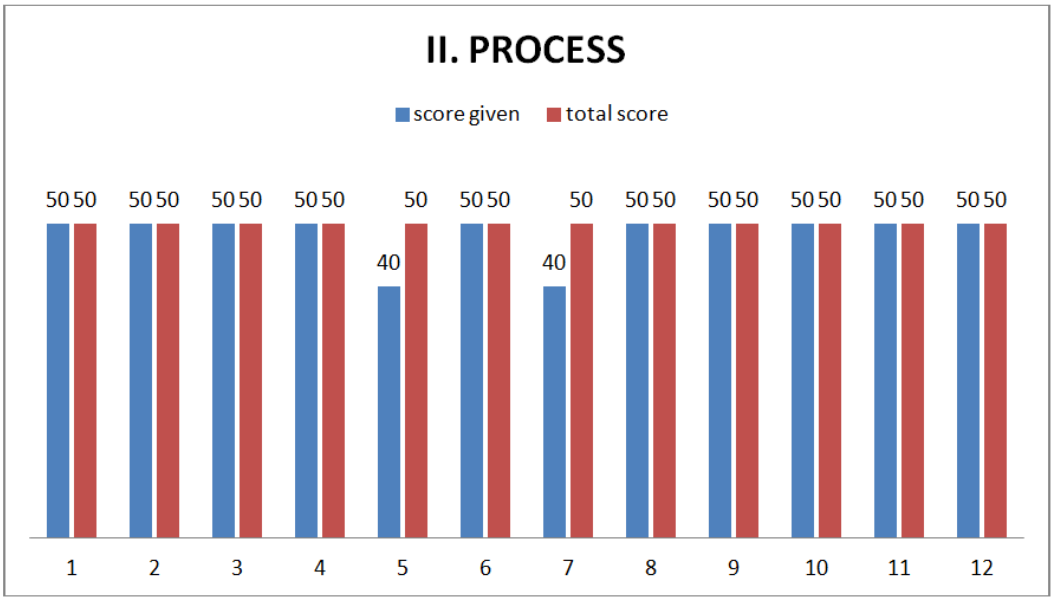

Fig 3: Column Graph Representation of Parameters Under Process.

OUTCOME

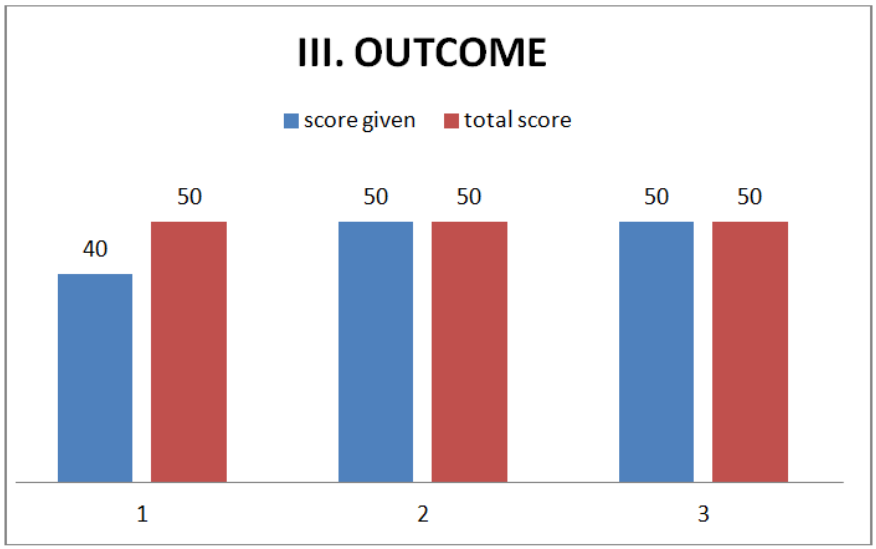

Fig 4: Column Graph Representation of Parameters Under Outcome.

DISCUSSION

MOM-1 gave full compliance (50/50) to segregation of medicines by inventory control, documentation of high-risk medications, labeling of indented medicines, and preparation and implementation of written guidance regarding pharmacy services and medication usage because they followed all procedures according to the given guidelines and ensured a smooth-running system. The functioning of the drug information centre, pharmacy, and therapeutic committee, as well as the establishment of a proper process to notify key changes to relevant staff, were only given good compliance, i.e. 40/50, because they established a system that was a time-consuming and tedious process that required improvement. These aspects were also not updated on a regular basis. When the pharmacy is closed, there is no alternative procedure for dispensing medicine because the institution operates a 24/7 pharmacy, an alternate technique to dispense medicine when the pharmacy is closed is not appropriate. MOM-2 received only good compliance since the institution did not provide an updated physical copy of the hospital formulary for reference, just a soft copy that was not updated on a regular basis based on new drug information. Because some medications were stored improperly, high-risk medications were not available in all relevant regions of the hospital, and emergency medications were in short supply in some rare cases, all sub-categories of MOM-3 received only good compliance. Prescription audits and organisations that developed a specific process for appropriate prescribing were given complete compliance in MOM-4 because there was a well-functioning system with good communication. Because there was no established system, safe medication management and reconciliation of drugs were given high priority, resulting in a time-consuming process. Average compliance was given to the prescription of medicines according to GCP guidelines because there was a risk of transcribing mistakes caused by illegibly written orders, as well as a few unusual unreported incidents of ADRs. MOM-5 gave 100% compliance to approved staff prescribing pharmaceuticals and recording orders in a standardised manner, as it was done in accordance with GCP criteria. Because the form did not include places for adverse drug reactions, usage, date, time, or the prescriber's registration number, medication orders with all pertinent information received only average compliance. Also, the legibility of written orders was poor. With the establishment of a clean system in MOM-6, the withdrawal of near-expired medicines was given full compliance. Proper labelling of prescriptions to be administered and high-risk pharmaceuticals confirmed before dispensing were awarded high marks for compliance, despite the fact that it was a time-consuming operation that occasionally revealed unreadable errors. Medication orders, recalls, and returns were assigned average compliance because recalled drugs were not returned promptly, resulting in drug waste. MOM-7 gave full conformity to the administration of medicines by authorised staff and procedures to prevent misconnections during medical administration because they followed all guidelines.Patient is governed for self-administration was adhering to good compliance as patient: professional ratio is inappropriate and time is not sufficient for administration. Medication is properly inspected for instructions before administering and it's documentation, and patient is governed for self-administration was adhering to good compliance as patient: professional ratio is inappropriate and time is not sufficient for administration. In MOM-8, collecting near-misses, medication errors, and adverse drug reactions (ADRs) and reporting them as soon as possible, followed by additional analysis and appropriate action, was given high priority, as some reporting was delayed, resulting in late remedial action. MOM-9 and MOM-10 received complete compliance because they were followed strictly.

Medical supplies and consumables storage were given high marks in MOM-11 because some storage conditions were insufficient and consumables were not removed before expiration, which could lead to the use of pharmaceuticals that were about to expire.

CONCLUSION

Quality assurance entails the systematic monitoring and evaluation of facility components to ensure that protocol is followed.

Generally, some indicators are used to assess quality, and improvement strategies are recommended. In a hospital context, the main goal of QA is to improve the quality of outcomes, such as patient treatment goals. The major goal of this project is to establish the value of clinical pharmacy in the hospital context, as well as the growing importance of quality assurance in the pharmaceutical industry. This project entailed quality assurance testing in a multi-specialty tertiary care hospital in accordance with NABH standards, which are India's highest quality assurance standards. While conducting the QA programme at the institution, the authors realised that all of the parameters could not be reached 100% because India is still a developing country and clinical pharmacy is still in its infancy. Clinical pharmacy's related course, Pharm.D, began in 2008 and is still in the process of establishing itself in the country. Clinical pharmacists are currently providing services, but not to their full potential due to a lack of awareness. As previously stated, clinical pharmacy is still in its infancy in the country, therefore quality assurance is becoming increasingly vital in order to provide high-quality services to the general public. And QA is even more important in a country that has drawn inspiration from countries that have previously developed clinical pharmacy services in order to provide standardised services to the general public. And, due to QA, it can be established by conducting regular self-checks and monitoring them so that recommendations can be made for implementation and implementation can take place to improve the existing standard. It is not difficult to achieve high standards in a country like India, which is the pharmaceutical hub, because there could be a lot of staff mobilisation by creating a lot of job opportunities, which should be the goal to be achieved within the next 10 years to make the country highly established in the medical and pharmaceutical setting. With a few exceptions, the authors have taken the liberty of discussing the country's medical environment.

Recommendations

Following the QA programme, the authors would suggest:

- More personnel are needed to ensure that the hospital's supply chain, particularly clinical pharmacy, runs smoothly.
- Establish a simple and easy-to-follow communication chain among all hospital employees, particularly between clinical and non-clinical personnel.
- Reduce the doctor-to-patient ratio so that staff can focus more on providing personalised treatment.
- Working together as a team, the medical and clinical pharmacy can achieve incredible results, therefore putting Pharm.D.s in leadership roles is essential, since it is past time to upgrade the healthcare system.
- Creating a QA core team that includes the quality department, clinical pharmacy, and hospital pharmacy, as well as producing a self-check rule book with protocol to follow. Meetings are held on a regular basis to discuss if the intended implementations are being carried out appropriately and whether they are having an effect.
- With the introduction of new parameters, updating all medicine lists, checklists, and hospital formulary on a regular basis would assist the setting improve quickly.
- Because our country is so densely populated, there are many people who require little or substantial medical assistance, so increasing staff recruitment in the medical and pharmacy fields would be extremely beneficial.
- The facility should hold knowledge exchange and continuing education programmes on a regular basis, as healthcare is rapidly evolving.

With the fast expanding healthcare practices and discoveries, as well as the demand, the authors argue that QA has now become the most significant aspect of the hospital facility for the world.

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