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Assessment of Good Pharmacy Practice (GPP) in Pharmacies of Community Settings in India

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ABSTRACT : *Good Pharmacy Practice (GPP) is at the very heart of the profession of Pharmacy; indeed it is the very essence of the profession. Moreover, it expresses our covenant with the patient not only to 'do no harm' but also to facilitate good therapeutic outcomes with medicines. GPP is the practice of pharmacy that responds to the needs of the people who use the pharmacists' services to provide optimal, evidence-based care. The aim was to use an indicator based tool to assess and report on Good Pharmacy Practice (GPP) in the community pharmacies in Anantapur and objective to assess the availability and use of a prescribing recording system, degree of computerization, and implementation of stock management and re-order system, cleanliness of the dispensing and storage area, pharmacy hygiene, storage conditions, system and practices. In the current study the results compared to the possible score and possible maximum score of standards is not satisfactory primarily in terms of system indicators, secondarily service indicator, thirdly rational drug use indicator (RDU), followed by dispensing and storage indicators respectively. In conclusion, achieving an optimal, safe, economic and effective patient care is the primary goal of Good Pharmacy Practice (GPP), with a critically validated tools.*

KEYWORDS: *Dispensing quality, dispensing practice, indicators, medicine management, pharmacy practice.*

1. INTRODUCTION

Good Pharmacy Practice (GPP) is at the very heart of the profession of Pharmacy; indeed it is the very essence of the profession. Moreover, it expresses our covenant with the patient not only to 'do no harm' but also to facilitate good therapeutic outcomes with medicines. It is recognized that pharmacy practice varies enormously from one country to another and from one continent to another, incorporating developing, transitional and developed countries. The applicability of the 2011 update of the joint WHO/FIP guidelines on Good Pharmacy Practice [1] Standard for quality of pharmacy services is intended to take these variations in practice in to account. Under WHO's Revised Drug Strategy adopted by the World Health Assembly in 1986, WHO has organized two meetings on the role of the pharmacist in Delhi in 1988 and in Tokyo in 1993 [2] (WHO/PHARM/94.569). This was followed by the adoption of resolution WHA 47.12 on The role of the pharmacist in support of the WHO revised drug strategy in May 1994.

In 1992, the International Pharmaceutical Federation (FIP) developed standards for pharmacy services under the heading Good Pharmacy Practice in Community and Hospital Pharmacy Settings which were circulated in March 1993 to WHO Information Officers for comments. The FIP Congress held in Tokyo in 1993 adopted the FIP/GPP text under the Tokyo declaration on standards for quality of pharmacy services, which reads as follows: "Standards are an important part in the measurement of quality of service to the consumer. The International Pharmaceutical Federation (FIP) in adopting international guidelines for Good Pharmacy Practice at its Council Meeting in Tokyo on 5 September 1993 believes that standards based on these guidelines should be used by national pharmaceutical organizations, governments and international pharmaceutical organizations for nationally accepted standards of Good Pharmacy Practice.

The Good Pharmacy Practice guidelines are based on the pharmaceutical care given by pharmacists. The guidelines recommend that national standards are set for: the promotion of health, the supply of medicines, medical devices, patient self care and improving prescribing and medicine use by pharmacists' activities. FIP urges pharmaceutical organizations and governments to work together to introduce appropriate standards, or where national standards already exist, to review these standards in the light of the guidelines set out in the Good Pharmacy Practice document".

The FIP developed special FIP Guidelines for Drug Procurement [3]. There are numerous reports about an unacceptable prevalence of substandard and counterfeit pharmaceutical in international trade. Developing countries are the ones most frequently exposed to such products which may be inefficacious or toxic products, and which threaten to erode confidence in the healthcare system. It was for this very reason that resolution V on the role of the pharmacist in support of the WHO revised drug strategy [4] adopted by the World Health Assembly in May 1994, when calling on the collaboration of pharmacists, started with the pharmacists's responsibilities in assuring the quality of products they dispense. The current study entitled "Assessment of Good Pharmacy Practice (GPP) in Pharmacies of Community Settings in India" aimed to use an indicator based tool to assess and report on Good Pharmacy Practice (GPP) in the community pharmacies in Anantapur with following objective:

[1] Assess the availability and use of a prescribing recording system, degree of computerization, and implementation of stock management and re-order system.
[2] Assess presence of pests, cleanliness of the dispensing and storage area, pharmacy hygiene, storage conditions, system and practices.
[3] Assess prescription load, opening hours, staff availability and qualifications, availability of services, and tests and health promotion activities.
[4] Assess information available to dispenser, product range, dispensing time, packaging material, dispensing equipment, dispensing procedure and contact with prescribers.
[5] Assess information available to patients, patient care, labelling, rational prescribing, dispensing of 'Pharmacist initiated medicines', dispensing of antibiotics without prescription and generic substitution.

II. METHODOLOGY

It was a cross-sectional, observational study conducted in the community pharmacies in Anantapur town for a period of 6 months duration. 100 community pharmacies which agreed to participate in the study were included. The survey manual and Excel based data analysis tool were downloaded from www.birnatrap.dk. The survey applied both retrospective and prospective data collection using direct observations, records review and interviews. The data collection form was developed in Telugu, based on the survey manual.
The content and language was validated by experts. Questionnaire consists of 34 questions grouped into five areas

[1] Five system indicators: to assess the availability and use of a prescribing recording system, degree of computerization, and implementation of stock management and re-order system.
[2] Seven storage indicators: to assess presence of pests, cleanliness of the dispensing and storage area, pharmacy hygiene, storage conditions, system and practices.
[3] Six service indicators: to assess prescription load, opening hours, staff availability and qualifications, availability of services, and tests and health promotion activities.
[4] Eight dispensing indicators: to assess information available to dispenser, product range, dispensing time, packaging material, dispensing equipment, dispensing procedure and contact with prescribers.
[5] Eight rational use indicators: to assess information available to patients, patient care, labelling, rational prescribing, dispensing of 'Pharmacist initiated medicines', dispensing of antibiotics without prescription and generic substitution.

The data collected was entered in the Excel spread sheet for data entry and analysis. The findings were depicted in the form of a histogram and a spidograph for all five components calculated for each facility, as well as a mean for all assessed facilities**.**

III. RESULTS

Table 01: Assessment of System Indicators

S.NO	COMPONENTS	SCORES
1	Possible Score	3.86
2	Actual Score	0.72
3	Possible Max Score	5

Table 02: Assessment of Storage Indicators

S.NO	COMPONENTS	SCORES
1	Possible Score	4.53
2	Actual Score	3.25
3	Possible Max Score	7

Table 03: Assessment of Services Indicators

S.NO	COMPONENTS	SCORES
1	Possible Score	3.57
2	Actual Score	1.25
3	Possible Max score	6

Table 04: Assessment of Dispensing Indicators

SNO	COMPONENTS	SCORES
1	Possible Score	4.23
2	Actual Score	2.50
3	Possible Max Score	8

Table 05: Assessment of Rational Indicators

SNO	COMPONENTS	SCORES
1	Possible Score	3.75
2	Actual Score	1.35
3	Possible Max Score	8

Table 6: Final Assessment of all Indicators

S.NO	AREA	SYSTEM	STORAGE	SERVICES	DISPENSING	RDU
01	Possible score	3.86	4.53	3.57	4.23	3.75
02	Actual score	0.72	3.25	1.25	2.50	1.35
03	Possible max score	5	7	6	8	8

All the above mentioned results of indicators were compared, tabulated and figured in Table. 06

Graph 01 System Indicator

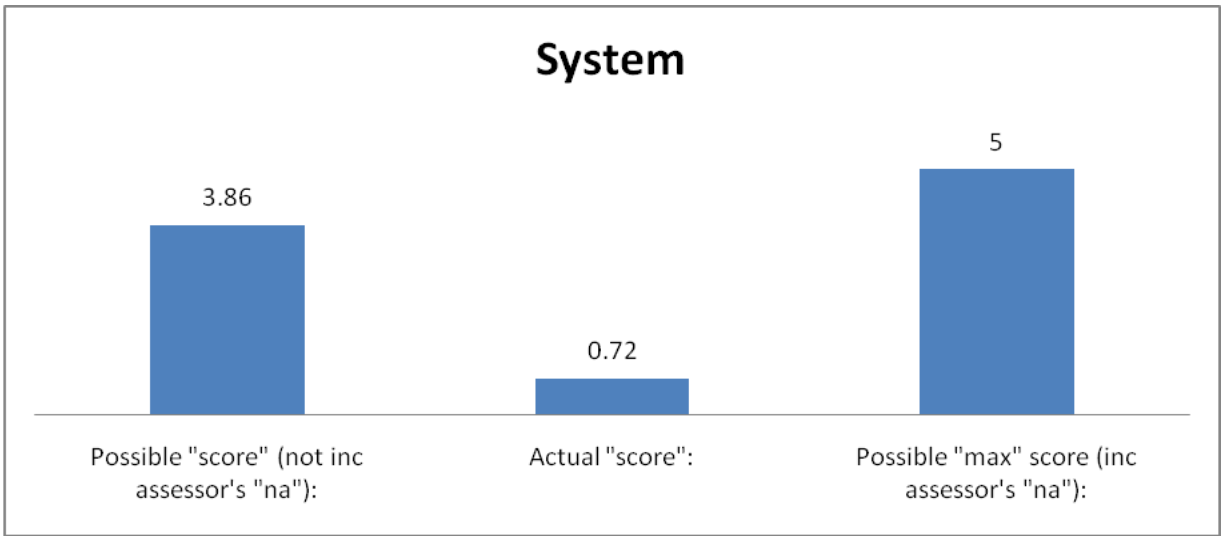


Table 01 & Graph 01 reports on the resultant value defined as actual value of the usage of system indicators (computer applications for the maintenance of inventory, storing of patient information, billing) found to be poor and ineffective (0.72) in comparison to the possible value 3.86 & possible maximum being 5.

Graph 02 Storage Indicators

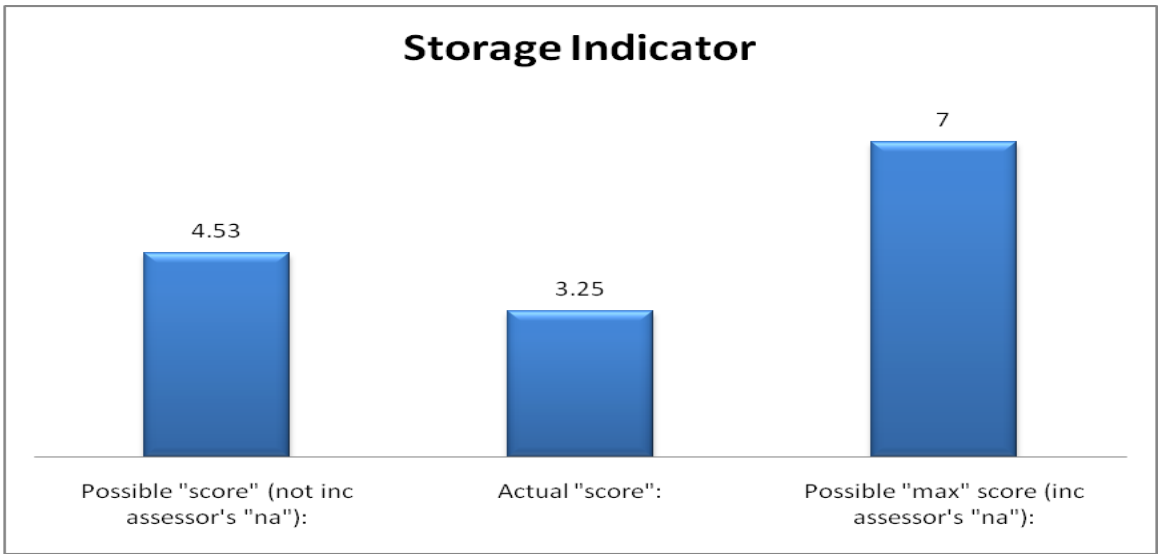


Table 02 & Graph 02 reports on the storage indicators, with criteria's like temperature monitoring and regulation, use & storage of medications in the refrigerator, protection of medicines from sunlight and adequacy of storage space. Here, the actual value calculated is 3.25, in comparison to the possible value - 4.53, and the possible maximum value - 7. The report suggested that the storage indicator criteria's are being followed but not to the optimum best.

Graph 03 Service Indicators

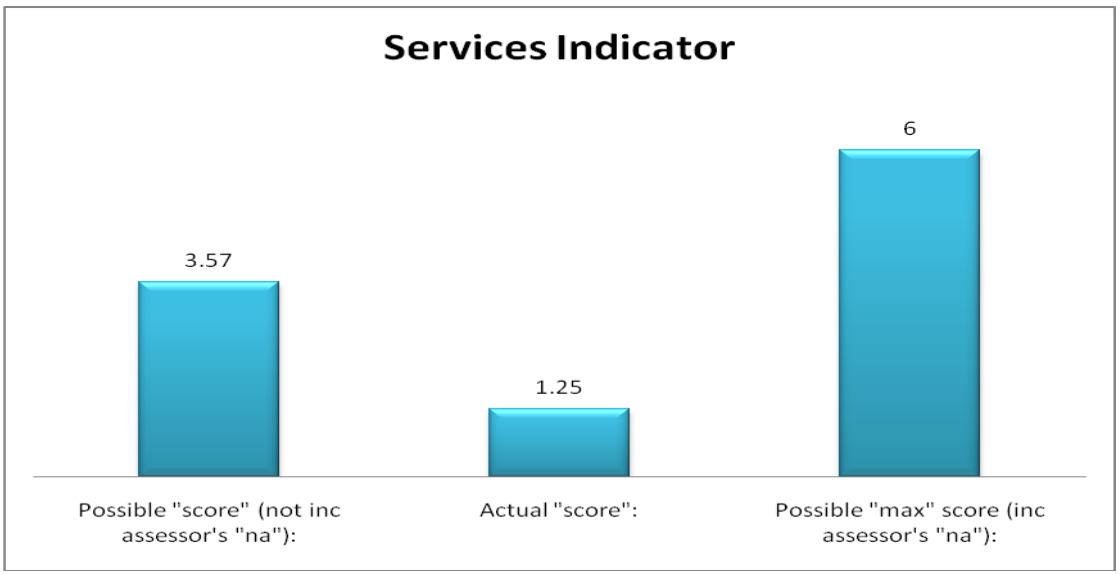


Table 03 & Graph 03 reports on the services indicators, with criteria like availability of information sources (drug catalogues, drug formulary) and patient accessibility (seating, drinking water).Here, the actual value calculated is 1.25, in comparison to the possible value 3.57 and maximum possible 6.The report suggested that the service indicator found to be ineffective.

.Graph 04 Dispensing Indicators

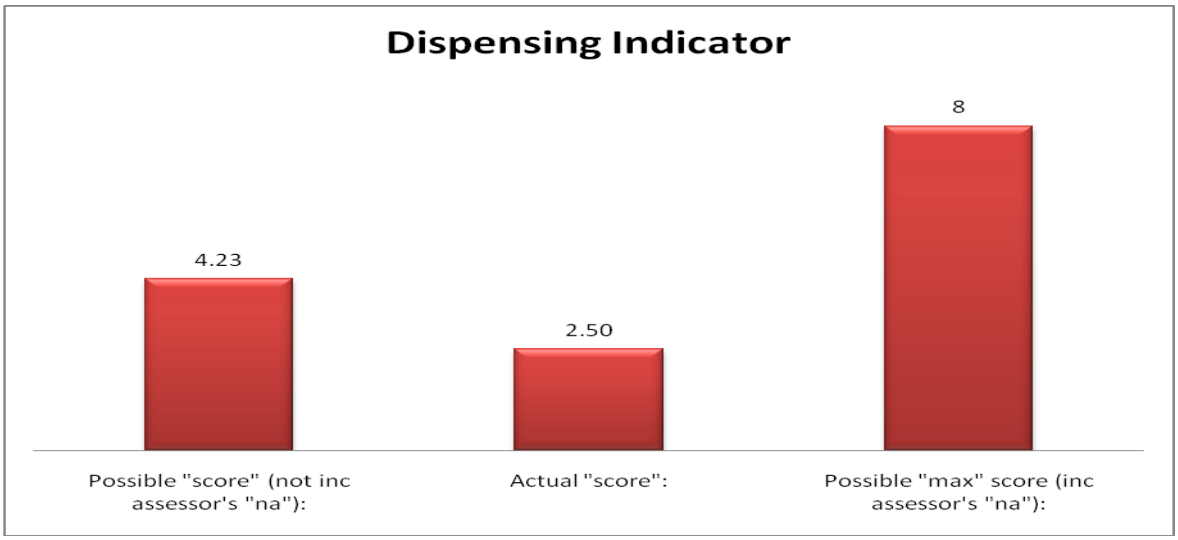


Table 04 & Graph 04 reports on the dispensing indicators, with criteria like number of items in stock (different brands, and formulations), packing material, and dispensing equipments Here the actual value obtained is 2.50, in comparison to possible value 4.23 and the possible maximum value as 8.The report suggested that the dispensing indicator found to be ineffective.

Graph 05 Rational Indicators

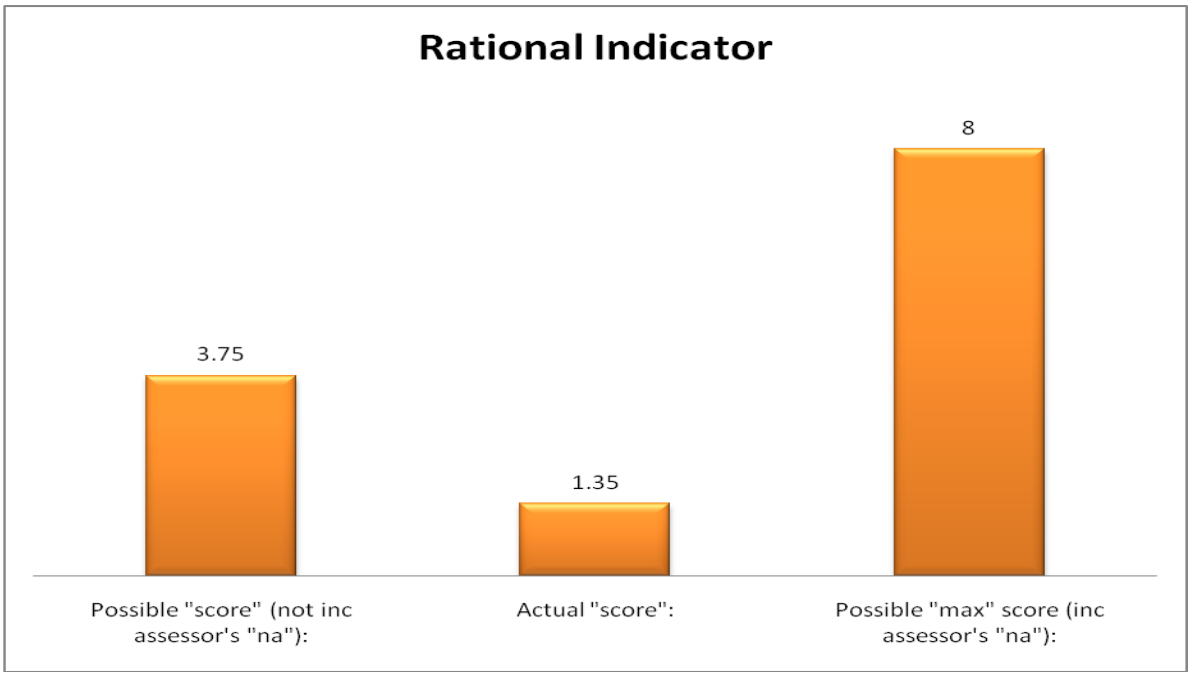


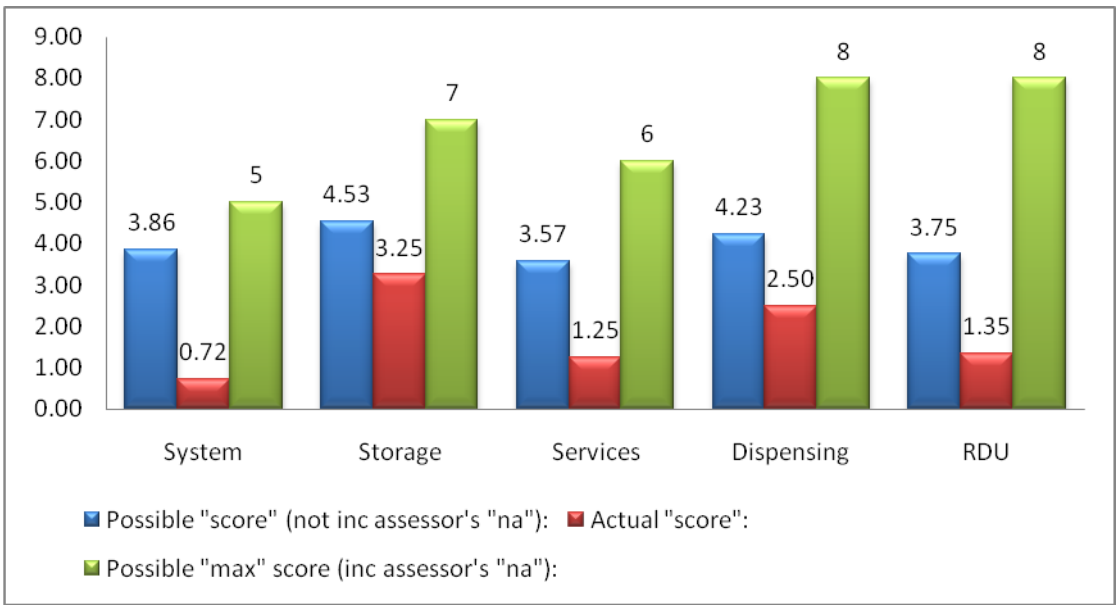
Table 05 & Graph 05 reports on the rational indicators, with criteria like number information sources (patient leaflets, medicine hand books), and generic substitution. Here the actual value obtained is 1.35 in comparison to possible value as 3.75 and possible maximum value 8. The report suggested that the rational indicator found to be very ineffective.

Table 6: Final Assessment of all Indicators

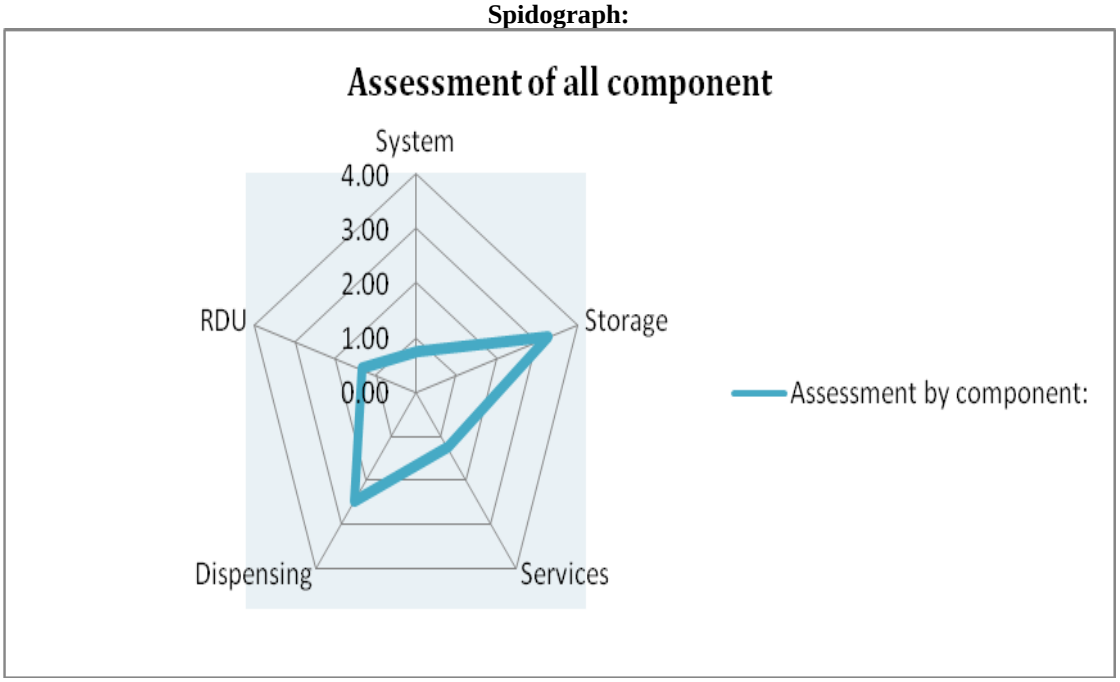
S.NO	AREA	SYSTEM	STORAGE	SERVICES	DISPENSING	RDU
01	Possible score	3.86	4.53	3.57	4.23	3.75
02	Actual score	0.72	3.25	1.25	2.50	1.35
03	Possible max score	5	7	6	8	8

All the above mentioned results of indicators were compared, tabulated and figured in Table. 06 / Graph. 06 & Figure. 01 (Final Assessment of all Indicators).

Graph. 06 Assessment of all Indicators



Spidograph:



IV. DISCUSSION

Descriptive indicators studies have been used for many different purposes.. The GPP indicator studies have also been undertaken to increase awareness of the problem of inappropriate pharmacy practices by dispensing pharmacists. Moreover, the PP indicator based assessment can also serve to describe the status of GPP implementation, provide a baseline for future interventions and form the basis for development of pharmaceutical master plans aimed at improving GPP (Good Pharmacy Practice) in community pharmacy settings. In some other comparative studies system indicators possible score to equals to possible max scores. Whereas storage indicators low score comparative to possible max score .and actual score whereas services indicators are less scores comparative to possible max score .it depends upon setting of community pharmacy in different aspects. The assessment tool applied in the study aims at achieving the (PP) pharmacy practice services of International standards in the community pharmacy settings. However, the community of pharmacy services, were less, ineffective, not so modernized & streamlined. In the current study the results compared to the possible score and possible maximum score of standards is not satisfactory primarily in terms of system indicators, secondarily service indicator, thirdly rational drug use indicator (RDU), followed by dispensing and storage indicators respectively.

V. CONCLUSION

In Conclusion, Achieving an optimal, safe, economic and effective patient care in terms of drug specific and disease specific is the primary goal of Good Pharmacy Practice (GPP), which can be attained by conducting, evaluating, validating studies like this. But internationally applicable PP indicators are critical to use, and to improve the good pharmacy practice in both hospital and community settings in developing countries like India. The pharmacy practice assessment tool used in our study provides easy and reliable way to improve the use of medicines. The data needed for the indicators were easily collected on direct observations, records, interviews and clients. Research is also required to develop and validate additional indicators on self medication and patient care.

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