



Quality assurance auditing of community pharmacies across the state of Kerala

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ABSTRACT

Quality standards are an essential component of community pharmacies, as they determine the extent of professionalism and the quality of services provided by the pharmacist to the patients. The objective of the study was to conduct a quality assurance auditing of community pharmacies across the state of Kerala. The study design was a descriptive cross-sectional study and the study duration was 10 months. The study was conducted in 112 community pharmacies spread across every district in the state of Kerala. The investigator made a personal visit to these community pharmacies and the basic background and the objective of the study was explained to the Pharmacist/ In-charge of the respective pharmacy. A scoring worksheet for carrying out quality assurance auditing of community pharmacies in the state of Kerala was developed, that was based on the GPP guidelines developed by IPA in March 2002. It was found from the study that 4 (3.57), 33 (29%), 66 (59%) and 9 (8%) community pharmacies obtained A, B, C and D grades respectively. The study highlights that the adherence of community pharmacies in Kerala to the good pharmacy practice guidelines were quite poor. The time has come to necessitate immediate changes to the system of community pharmacy practice by the concerned regulatory authorities and in the attitude of pharmacist with respect to his professional duties and ethics.

INTRODUCTION

Good Pharmacy Practice (GPP) is the essence of pharmacy 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. To support this practice it is essential that there be an established national framework of quality standards and guidelines. [1]

Clearly, an adequate pharmaceutical service, ideally provided by pharmacists, is a vital component of primary health care. This is recognised by the World Health Organization (WHO), and several publications of the WHO has emphasised the service of the pharmacist in the health care system. Standards are an important part in the measurement of quality of service and at the International Pharmaceutical Federation (FIP) Congress in Japan in 1993, the 'Tokyo Declaration on Good Pharmacy Practice (GPP)' was first adopted. [2]

Both FIP and WHO believe that national pharmaceutical associations in individual countries are best able to decide what can be achieved in terms of GPP and within what timescale. It is recognised and accepted that conditions of pharmacy practice vary widely from country to country, but it is also possible that conditions of practice may vary between different sectors/areas within a country.

For example, in developing countries there is likely to be a significant difference between the health service available in urban and rural areas. In many cases this difference is due to the fact that the number of pharmacists is less than desirable. The benefits that accrue from the direct supervision of the pharmacist in ensuring the quality of pharmaceutical products and services throughout the distribution chain cannot be realised in areas where there are insufficient numbers of pharmacists, or at least persons with formal pharmaceutical training. It has to be accepted that, for the foreseeable future, pharmacists will continue to be in short supply in developing countries. For this reason, there is a real need and role for trained support personnel, such as pharmacy technicians. In developed countries such personnel would

probably work only under the direct supervision of pharmacists. In developing countries, in most cases they will work alone, without any meaningful supervision. They may have duties and responsibilities which are inappropriate to their level of training. [3]

The FIP has developed a set of GPP guidelines specifically for developing countries. These guidelines provide a step-wise approach for their implementation according to the resources available and focus on areas that are applicable and most relevant to pharmacy practice in developing countries. The guidelines consist of four major areas: personnel, training, standards, legislation and national drug policy (FIP 1998). National pharmaceutical associations of individual countries are encouraged to adapt the GPP guidelines. [4]

The practice of community pharmacy in its true professional sense is still in its infancy in India. In India, ownership of a pharmacy is not an exclusive domain of the pharmacist alone, as in many European countries. Pharmacists own many of the pharmacies, but a larger majority is owned by non-pharmacists. Many of the owner-pharmacists do dedicate themselves to serving the profession and the public in the proper use of medicines, however, many of them are unaware of the professional role of a pharmacist, or how they could use their education and professional competence in the practice of pharmacy, simply because it has never been told/ demonstrated to them. The time has come for the situation in India to change from a product oriented approach to a patient oriented approach with pharmaceutical care, the ultimate goal of pharmacy practice. As the pharmacist is expected to cover the roles of a caregiver, decision-maker, communicator, manager, life-long learner, teacher and leader with the concept of "seven-star pharmacist" introduced by WHO and taken up by FIP in 2000 and new medicines being introduced in India at the global pace, our standards of pharmacy practice will have to be set on par with standards of other pharmaceutically evolved countries sooner than later. [5, 6]

The Indian Pharmaceutical Association in March 2002 has developed good pharmacy practice guidelines which is based on the GPP guidelines developed by WHO FIP for developing countries, for ensuring quality assurance in the community

pharmacies in India. These guidelines were used to develop a novel quality assurance auditing scale for community pharmacy practice and the scale was used for conducting quality assurance auditing of community pharmacies across the state of Kerala.

MATERIALS AND METHODS

The study was conducted in 112 community pharmacies spread across every district in the state of Kerala. The investigator made a personal visit to these community pharmacies and the basic background and the objective of the study was explained to the Pharmacist/ In-charge of the respective pharmacy. The descriptive cross-sectional study was confined to the pharmacies situated in the towns/ cities (urban) and the duration was 10 months.

A scoring worksheet for carrying out quality assurance auditing of community pharmacies was developed, that was based on the GPP guidelines developed by Indian pharmaceutical association (IPA) in March 2002. The scoring worksheet consisted of a standard which was a broad classification head of aspects related to the pharmacy/ medical store. There were 11 standards included in the Worksheet namely premises, personnel, training, complaints and recall, medicine recall, documentation, procurement and inventory, prescription handling, dispensing indicators, patient counselling and storage. Under each standard, there were one or more finer standards. For each finer standard, there are one or more criteria which were the main points to be addressed. Then a guideline for rating/scoring each criterion was developed that was a measure or indicator of compliance to the respective criteria. Based on the total score, the pharmacy was awarded the final grading. [5]

Using the scoring worksheet, a pilot quality assurance auditing exercise was carried out by the investigator in a few community pharmacies in Thiruvananthapuram before starting the study. For the purpose of this pilot exercise, the final grading were fixed as Grade A (Above 40%), Grade B (20-40%), Grade C (10-20%) and Grade D (Below 10%).

RESULTS

1. Presence of the pharmacist in pharmacies at the time of study:

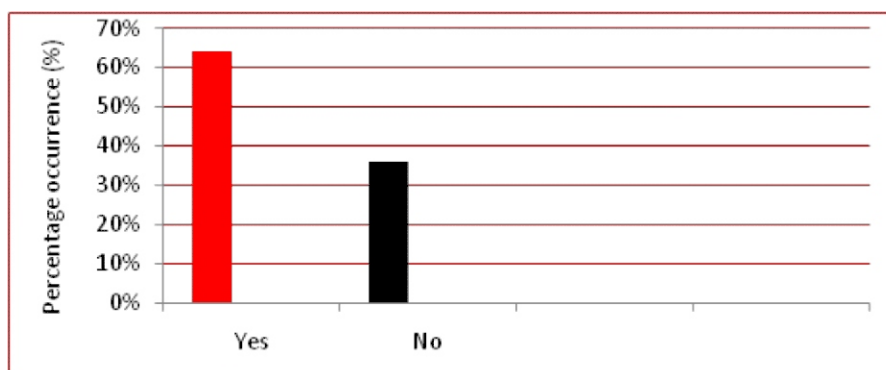


Figure 1: Vertical graph showing the percentage occurrence of pharmacist in pharmacies.

As shown above, it can be analysed that, 64% of pharmacies did have pharmacist, whereas 36% of pharmacies did not have a pharmacist, at the time when the investigator conducted the study in the pharmacies.

2. Qualification of the pharmacist:

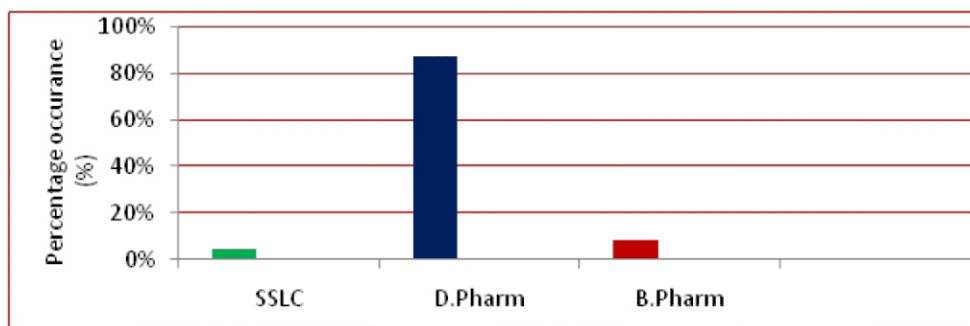


Figure 2: Vertical graph indicating the qualification of the pharmacist.

It can be seen majority of the pharmacist in Kerala were having D.Pharm qualification (87%). There were only 8% pharmacists with B.Pharm qualification while there were no pharmacists with M.Pharm qualification.

3. Salary of the pharmacist:

The study results indicate that the average monthly salary was Rs. 8116 for a pharmacist in Kerala. This amounts to a daily wage of Rs. 270.

4. Exterior of pharmacy:

The current study showed that in most of the community pharmacies had a satisfactory exterior environment (71%) whereas 25% of the community pharmacies had a good exterior environment and 4% of the community pharmacies had a poor exterior environment. None of the community pharmacies had excellent exterior environment.

5. Pharmacy accessibility to people using wheel chairs/prams:

As far as possible, the pharmacy should be conveniently assessable to people using prams or wheel chairs etc. It was found that 52% of the community pharmacies was easily accessible to people using wheel chairs/prams, whereas 41% and 7% of the community pharmacies were accessible with difficulty and not at all accessible respectively.

6. Interior of pharmacy:

The pharmacy environment should be clean with minimum dust and the pharmacy should be maintained clean as per cleaning schedules and SOPs. It was found that most of the community pharmacies had satisfactory cleanliness (70%) while 29% and 1% of them had a clean and unclean environment respectively. There were no pharmacies with highly clean environment.

7. Pest control measures:

The pharmacy should be free from rodents and pests/insects as they can affect the quality of the items as well as the business in the pharmacy. Most of the community pharmacies audited for the study had satisfactory pest control measures (87%) whereas only 12% of the community pharmacies had good pest control measures. There were no community pharmacies with poor and excellent pest control measures.

8. Water supply in pharmacy:

The pharmacies should be equipped with constant supply of water. 54% of the community pharmacies had constant supply of water whereas 46% of the community pharmacies under the study

did not have constant supply of water.

9. Air condition in pharmacy:

The current study showed that only 2% of the community pharmacies had air condition facility whereas 98% of the community pharmacies did not have air condition facility.

10. Sufficient place for the patients to stand in the dispensing area of pharmacy:

The patients should have sufficient place to stand in front of the dispensing area of the pharmacy. Only 37% of the community pharmacies had sufficient place for the patients to stand in front of the dispensing area of pharmacy whereas 63% of the community pharmacies did not have sufficient place for the patients to stand in front of the dispensing area of pharmacy.

11. Computer in pharmacy:

The pharmacy should preferably be equipped with computers and appropriate software that can manage inventory, manage invoicing, generate timely warning for expiring medicines, archive patient medication records and should also be equipped to give demonstrations to the patients. In the study, 72% of the community pharmacies had computer facilities whereas 28% of the community pharmacies did not have computer facilities.

12. Pharmacist wearing white apron/coat:

6% of the community pharmacies had pharmacist wearing white coat whereas 94% of the community pharmacies had pharmacist not wearing a white coat.

13. Percentage of the drugs dispensed in the pharmacy:

29% of the community pharmacies where the study was conducted, was able to dispense above 90% of drugs of a prescription whereas 70% and 1% of community pharmacies were able to dispense 50% to 70% and below 1% of drugs of a prescription respectively.

14. Prescription checking by the pharmacist:

It can be seen that majority of the pharmacist limited their prescription checking to just reading the name, dose, dosage, identity of client and total amount of drug to be dispensed. Only 9% of the pharmacists gave appropriate instructions regarding the proper intake of drugs to the patients. The authenticity of the prescription was verified by only 5% of the pharmacist. 6% of the pharmacist sought to send back the prescription in case they had any doubt in it.

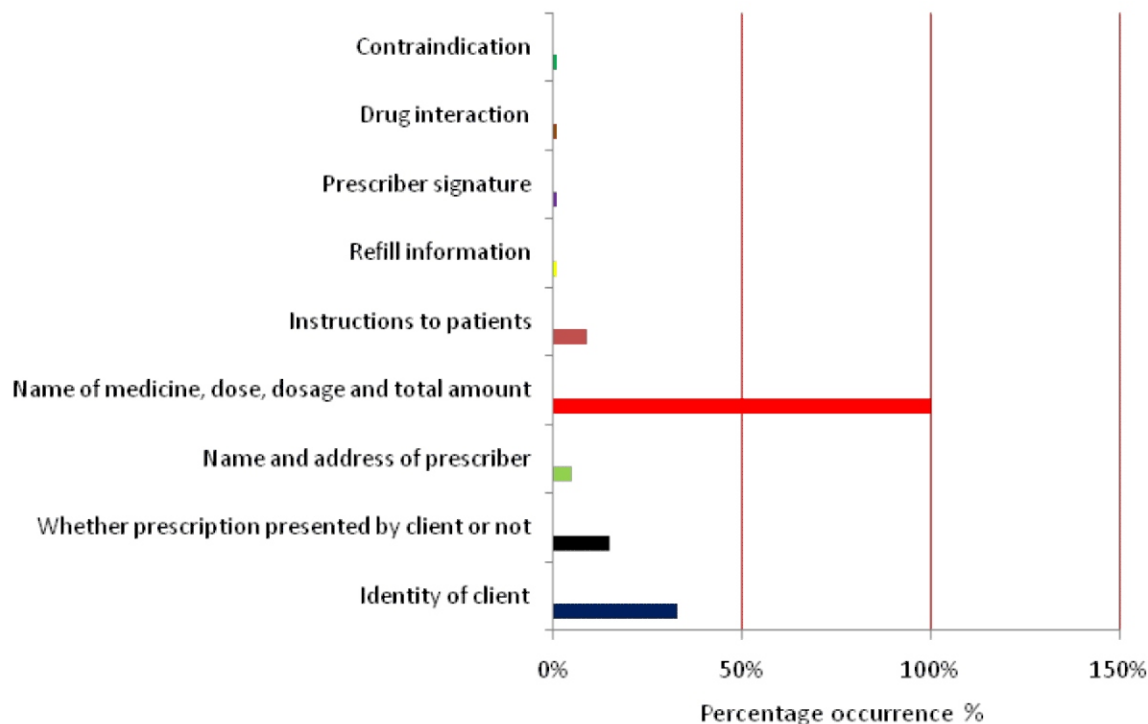


Figure 3: Horizontal graph showing the extent of prescription checking by the pharmacist.

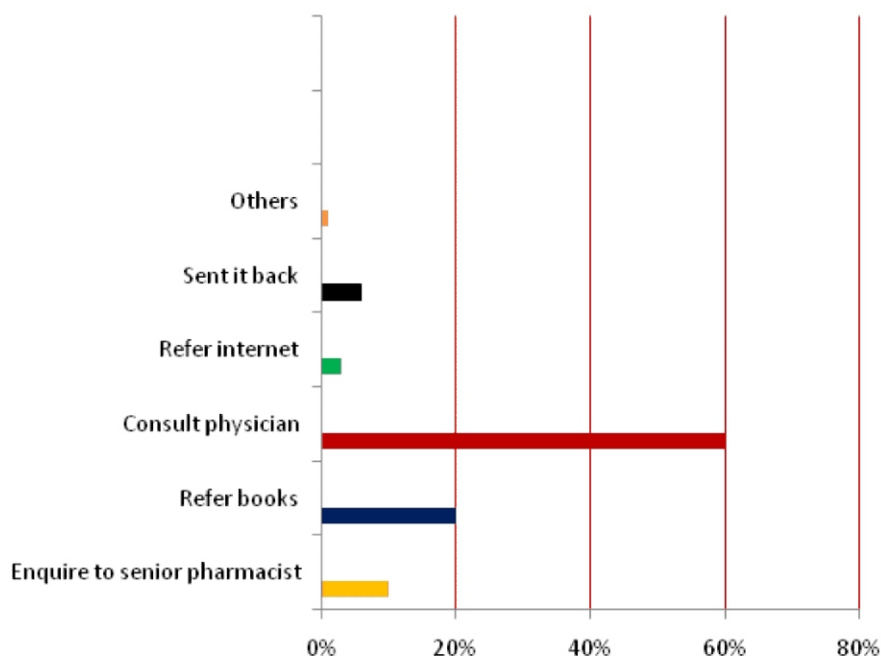


Figure 4: Horizontal graph showing the mode of clarification for doubt in prescription by the pharmacist.

15. Mode of clarification for doubt in prescription by the pharmacist:

From the above graph, it can be analysed that the most common mode of clarification of doubt in prescription by the pharmacist was by consulting the physician either by phone or in person (60%). Referring the books such as CIMS, MIMS etc. was the second most sought option (20%) while enquiring the doubt to a senior pharmacist was the third most sought option (10%) by the

pharmacist in Kerala. About 6% of the pharmacist sought the option of sending back the consumers in case of a doubt in the prescription. The most common reason for this was the poor handwriting of the prescriber. About 3% of the pharmacist clarified their doubts by referring the internet. About 1% of the pharmacist chose to clarify their doubts by other means such as by enquiring to the regulatory bodies, Drug Information Centre (DIC) etc.

16. Number of pharmacies with each grade across the State of Kerala

Table 1. : Number of pharmacies with each grade.

GRADE	NUMBER OF PHARMACIES IN KERALA
A (Above 40%)	4
B (20%-40%)	33
C (10%-20%)	66
D (Below 10%)	9

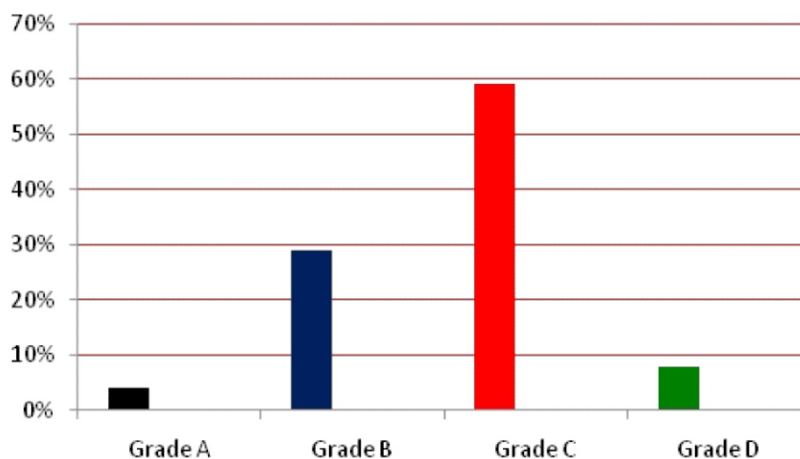


Figure 5: Percentage occurrence of pharmacies in each of the grades.

From the above table and graph, it can be analysed that 66 (59%) community pharmacies was awarded Grade C which was a satisfactory grade. 33 (29%) community pharmacies was awarded Grade B which was a good grade. 4 (3.57%) community pharmacies was awarded Grade A which was an excellent grade. Ideally all the pharmacies should strive to achieve this grade in order to reflect a professional image to the pharmacies by the public. 9 (8%) community pharmacies were awarded Grade D which was a poor grade, giving an indication that these pharmacies need to strive hard to meet the GPP guidelines.

DISCUSSION

A bibliometric review analysis of 10 years conducted in 2010 showed that there were limited studies being published which covers the community pharmacy related activities in India. [7]

The study results support the common fact that many of the pharmacies do not have the presence of a full time pharmacist, and that many of the pharmacies are run in the state by a mere display of registration certificate of duly qualified pharmacist who are not employed in their pharmacies and employing staff without due qualifications for dispensing, which is a clear violation of the section 42 of the Pharmacy Act. A study conducted by Basak S.C et al in 2005 also showed that 50% of the community pharmacies function without the presence of a pharmacist. [8]

It was found from the study that majority of the community pharmacist were with D.Pharm qualification which was similar to the findings reported by Kiron S.S et al in a cross sectional survey done in Kannur district of Kerala in 2012. The study reported that

of the total community pharmacists audited, 78% and 10% possessed D.Pharm and B.Pharm qualification respectively. [9] Further another study done by Subal Chandra Basak et al in 2010 also reported that majority of the community pharmacies were managed by pharmacist with D.Pharm qualification. [7] The presence of more number of pharmacists with B.Pharm, M.Pharm and Pharm.D qualifications can substantially improve the quality of services and outlook of the community pharmacies in India.

The salary drawn by a community pharmacist is very much less on par with salary drawn by a government pharmacist or even by a labour in Kerala who earns almost double their salary. The study results showed that the average salary was higher in North Kerala (Rs. 9000) than South (Rs. 7760) and Central Kerala (Rs. 7590). The salary pattern observed in the study were similar to study findings reported by Jose J et al way back in 2005 which ranged from Rs. 6000 to Rs. 8000. The study had reported that poor salary status was one of the prime reasons for poor job satisfaction among the community pharmacists. [10] In an another study conducted among community pharmacist by Akram Ahmad et al in 2013 showed that 85% pharmacist were of the opinion that the pay scale should be dependent on both the qualification and experience and not like the current practice of salary being characterised on the basis of whether a diploma degree (D.Pharm) is held by a person or not. [11] The pharmacy regulatory authorities needs to enforce strict regulations in raising the minimum wages for a pharmacist working in private community pharmacies for their better lifestyle and to attract pharmacist with B.Pharm and M.Pharm qualifications into the

private community pharmacy set up for bringing in more professionalism to a pharmacy set up.

Exterior and interior of the pharmacy should be maintained neat and clean in order to present a professional image to the public. Public entrances to the pharmacy must be clear and accessible at all times. Most of the community pharmacies across the state of Kerala had only satisfactory cleanliness, while there were no pharmacies with excellent cleanliness. In an exploratory cross sectional survey conducted in a total of 371 randomly selected community pharmacies across three cities in Pakistan, it was found that 72.0% had washable/cleanable premises while only 30.5% were totally clean. [12] Water facility could have been easily implemented in many community pharmacies, as the study was conducted only in the urban areas.

Most of the pharmacies in Kerala did not have air condition facility. Air condition (AC) facility is highly desirable in the community pharmacies of Kerala due to the prevalence of hot and humid conditions that can deteriorate the quality of drugs or surgical. The high instalment cost and electricity charge was the prime reason given by pharmacists for not incorporating AC facility in their community pharmacies. A survey conducted by David U Adje et al had reported a higher percentage of air condition facility (26.3%) in community pharmacies of Nigeria in 2013. [13]

As per the guidelines for dispensing of medicines, prepared by the Kerala State Pharmacy Council (KSPC), "All Pharmacists must, at all times, wear a neat white over coat and should additionally wear a badge prominently displaying their name and designation and registration number of State Pharmacy Council". The major reason given by pharmacist for not wearing the white coat was due to the extreme hot and humid climate conditions of Kerala. In a study conducted across the cities of Bangalore, Kolkata, Delhi and Mumbai in 2011, 50% of the general population wanted a pharmacist to wear both white coat and ID badge whereas of the remaining 50%; half of them wanted only white coat and the other half wanting only ID badge for the identification of pharmacist in pharmacies. [14]

It was found from the study that majority of the prescription checking was limited to only enquiring the name, dose and total quantity of the medicines required for the patient. Various other parameters such as verifying the authenticity of the prescription, drug interactions, contraindication, refill information and patient counselling for safe and proper intake of drug was not adequately carried out. In a prospective study carried out in 1100 bedded tertiary care hospital in Kochi in 2008, the incidence of dispensing errors was found to be 4.8%. [15] Various studies conducted elsewhere across the country have reported on the continuing crisis of irrational drug prescribing and the need of increased role of community pharmacists to avoid them. [16, 17] These studies have highlighted the need of increased prescription verification and patient counselling by the community pharmacists to avoid medication errors.

It was found from the study that adherence of majority of the community pharmacies in Kerala to the good pharmacy practice guidelines were quite poor. This has resulted in lack of professionalism in community pharmacy activities, lack of respect that a pharmacist gains from the public and other healthcare professionals unlike in developed countries, an improper patient counselling that is given by a pharmacist to the patient for proper intake of the drug and a salary drawn by the pharmacist which is well below the par based on his qualification,

knowledge and skills. The time has come to necessitate immediate changes to the system of community pharmacy practice by the concerned regulatory authorities and in the attitude of pharmacist with respect to his professional duties and ethics.

Several limitations of this study should be addressed to highlight the source of bias. The main limitations of this study were the small number of community pharmacies audited and that the study was confined to community pharmacies located in urban areas only. Hence the findings of this research cannot be extrapolated to represent the overall quality assurance of community pharmacies across the state of Kerala.

CONCLUSION

This quality assurance auditing study of community pharmacies was a first of its kind that was undertaken across a state of Kerala. As the study results highlights that the adherence of community pharmacies in Kerala to the good pharmacy practice guidelines were quite poor, routinely collected quality assurance data from the pharmacies can be used to monitor indicators of quality of community pharmacy services and improve the deficits in them, identify potentially underperforming pharmacists, measure the impact of policy changes and to determine predictors of best practices.

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