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Patient Safety Culture in Pharmacies in India: A Cross-Sectional Study

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Abstract: ***Introduction****: Medication errors are common in community pharmacies. Safety culture is considered a factor for medication safety but has not been measured in pharmacy setting. In order to analyse factors influencing overall patient safety, the Community Pharmacy Survey on Patient Safety Culture conducted by the Agency for Healthcare Research and Quality (AHRQ) was utilised to evaluate safety culture.* ***Methods****: It is a cross-sectional study designed to be carried out in pharmacies in rural India. A study conducted between March to August 2021, e-Survey on Google Forms were sent to registered Karnataka Pharmacist via email. To obtain patient safety culture in pharmacies using AHRQ (Agency for Healthcare Research and Quality) for assessing safety culture.* ***Results****: A total 731 registered pharmacists respond to e-survey, among 68.1% were male and 31.9% were females. Based on age groups most of them 43% were under 31-40 years of age.37.5% belongs to the category of 6 to 10 years of experience of registered pharmacist. Among 51.7% are under category of independent pharmacy and 51.3% were completed B. Pharm.60.6% of pharmacy located in urban area and among 41.3% are 24 hours working pharmacies.56.2% of pharmacies having only one pharmacist and among 45% of pharmacies received > 250 prescription volume per week. Among 42.4% of pharmacies are somewhat similar with patients. Based on the patient safety in the pharmacy 44.4% of them expressed having very good safety practice in their pharmacies.* ***Conclusion****: It might be useful to determine areas for improvement and places where pharmacies are strong in terms of safety culture. In community pharmacies, initiatives to improve staffing, job pressure, and pace may contribute to a stronger safety culture.*

Keywords: Medication errors, community pharmacies, prescription, safety culture, of registered pharmacists

1. Introduction

Patient safety is an important aspect of providing high-quality health care. The increased interest in the subject has prompted studies to assess and report on organisational characteristics that are thought to influence patient safety. For instance, safety culture is described as a collection of individual and group beliefs, attitudes, perceptions, competences, and behavioural patterns that influence an organization's commitment to, as well as the effectiveness of, its health and safety management. Communication within organisations that value safety is built on a foundation of trust, agreement on the value of safety, and confidence in the efficacy of preventative measures. The Institute of Medicine of the United States recommended in its key report on patient safety in 1999 that health-care organisations build a culture of safety in which their staff and the methods are aimed at improving the treatment of patients' safety and reliability.[1]

Medication errors make up the majority of medical mistakes, accounting for around a quarter of all instances that endanger patient safety. Every year, an estimated 770 000 people are wounded or die in hospitals as a result of adverse drug events (ADEs), which are injuries caused by drug use. Approximately 28% of ADEs are linked to a pharmaceutical error and are therefore considered avoidable. A pharmacist may have prevented 50% of these adverse events. Pharmacists and clinical pharmacy services appear to be able to significantly enhance patient safety while also lowering hospital expenses related with prescription errors. Meanwhile, the study's strengths and shortcomings were presented in a report. This is the first study of its kind to look at patient safety culture in a pharmacy setting in China. The results of this study may help healthcare decision-makers or policymakers in developing country pharmacy settings create effective ways to evaluate their patient safety culture's strong points and pinpoint areas for development. This is part of their efforts to improve their quality.[2]

Measuring and understanding an organization's safety culture is evolving into a critical diagnostic tool while attempting to analyse the quality of care provided. In order to measure the safety culture in healthcare systems, surveys are frequently used to look at people's attitudes on things like the workplace, following rules, and safety issues. Target population makes a difference; some surveys include all employees at a single workplace, providing a snapshot of the safety climate there, while others focus on the managerial perspective on organisational safety.[3]

In a variety of high-risk businesses, safety culture assessments have been established. Despite recent advances in tools for analysing the current safety culture in general practise, studies on safety culture in health care have primarily focused on the hospital setting. The goal of this research was to create a framework that community pharmacies could use to evaluate their present degree of safety culture maturity. We sought to develop a self-

evaluation instrument with high face validity that would be practical and acceptable for use in community pharmacies.[4]

One of the most crucial pillars for improving patient safety is encouraging a "culture of safety" inside healthcare organisations. Healthcare organisations are becoming more conscious of the need to alter organisational culture in order to improve patient safety since the 1999 publication of the US Institute of Medicine's (IOM) research. The commitment of an organisation to the method and competency of health and safety management is what determines the safety culture of that organisation. Individuals' and groups' beliefs, attitudes, perceptions, competences, and behavioural patterns make up this commitment. It is critical to uncover the underlying cultural characteristics present inside an organisation in order to modify the safety culture. Achieving a culture of safety needs an awareness of the values, beliefs, and norms about health and safety within the organisation. Frameworks, surveys, and assessment tools have been developed over the past ten years to analyse and measure the culture that exists inside healthcare organisations and to pinpoint its strengths and weaknesses.[5]

It has been determined that there are three components of safety culture: situational characteristics, which relate to "what the organisation has, " behavioural aspects, which relate to "what individuals do, " and psychological elements, which relate to "how people feel" (also known as safety climate). In order to increase patient safety, healthcare organisations must become more aware of their current patient safety culture. In a range of healthcare settings, there has been an increasing trend in recent years to develop and test measures to assess safety culture. For instance, a number of patient safety culture surveys that may be utilised in a range of hospital settings have been created with funding from the US Agency for Healthcare Research and Quality (AHRQ). The first survey was developed for use in US hospitals before being validated or modified for use in the healthcare systems of other nations or languages. The patient safety culture survey was subsequently made available by the AHRQ for use in medical offices and nursing homes.[6]

The AHRQ created the Pharmacy Survey on Patient Safety Culture (PSPSC) questionnaire to address the lack of validated PSC questions in the US pharmacy setting. The PSPSC is a tool that allows pharmacies to assess their PSC based on individual pharmacy employee responses. Despite the fact that the PSPSC has been validated in community pharmacies, no data on PSC measurement from a pharmacy setting in an integrated health system has been provided. The objective of this study was to apply the PSPSC to evaluate PSC in the pharmacy department of an integrated health care system in order to provide benchmark data on PSC for other health systems and to support PSC improvement.[7]

2. Method

Study design

Prior to the start of the trial, the Institutional Ethics Committee of Adichunchanagiri Hospital and Research Centre, B. G. Nagara, gave their approval. We conducted a prospective study utilising the e-Survey to analyse the pharmacists in order to determine their areas of strength and those that need improvement in order to improve the safety culture in India.

Study Instruments

The Community Pharmacy Survey on Patient Safety Cultural, which was issued by the AHRQ in October 2012, consists of 36 questions that evaluate the 11 organisational culture traits that have an impact on patient safety (Table 1) [8]. The survey makes use of frequency scales or 5-point agreement scales (from "strongly disagree" to "strongly agree") (from "never" to "always"). Participants were asked to rate the patient safety at their pharmacy on a scale from poor to outstanding in one survey question. The survey included a "does not apply" or "don't know" option. There were also questions about the participants' acquaintance with their patients and additional demographic information, such the pharmacy's zip code.

The AHRQ survey was chosen to evaluate safety culture because the instrument underwent pilot testing before being made available for general use in the United States. Furthermore, utilizing a standardized approach allows for easier comparisons between pharmacies and areas.

Table 1: AHRQ's Community Pharmacy Patient Safety Culture Composites[9]

Overall perceptions of patient safety	There is a strong focus and emphasis on patient safety, and the pharmacy is good at preventing mistakes.
Communication openness	Staff freely speak up about patient safety concerns and feel comfortable asking questions, and staff suggestions are valued.
Teamwork	Staff treat each other with respect, work together as an effective team, and understand their roles and responsibilities.
Organizational-learning–continuous improvement	The pharmacy tries to figure out what problems in the work process lead to mistakes and makes changes to keep mistakes from happening again.
Patient counseling	Patients are encouraged to talk to the pharmacist; pharmacists spend enough time talking to patients and tell them important information about new prescriptions.
Response to mistakes	The pharmacy examines why mistakes happen and helps staff learn from mistakes, and staff are treated fairly when they make mistakes.
Staff training and skills	Staff get the training they need, new staff receive orientation, and staff have the skills they need to do their jobs well.
Communication about mistakes	Staff discuss mistakes that happen and talk about ways to prevent mistakes.
Physical space and environment	The pharmacy is well organized and free of clutter, and the pharmacy layout supports good workflow.
Staffing, work pressure, and pace	There are enough staff to handle the workload, staff do not feel rushed, staff can take breaks, and work can be completed accurately despite distractions.

Communication about prescriptions across shifts	Information about prescriptions is communicated well across shifts, and there are clear expectations and procedures for doing so.

Ethics approval: Prior to the start of the trial, the Institutional Ethics Committee of Adichunchanagiri Hospital and Research Centre, B. G. Nagara, gave their approval**. (I. D – IEC/AH&RC/AC/006/2021)**

Survey Sample

A list of registered pharmacists in Karnataka received the survey through mail. Pharmacists had to have worked in a community/retail pharmacy in the past 12 months to be eligible for the study. The Karnataka Registered Pharmacist Association (R.) provided a sampling frame that included a list of 1250 registered pharmacists who were currently working in Karnataka. In March 2021, a random sample of 900 pharmacists received a screening questionnaire. All survey questionnaire mailings took place between March and August of 2021.880 pharmacy staff members were questioned after the screening. There were 731 participants that returned completed questionnaires. An 83.06% response rate was achieved with no questionnaires being rejected due to incomplete, insufficient, or inappropriate responses.

Statistical Analysis

There are composite scores and the proportion of affirmative responses for each item. The percentage of "strongly agree" and "agree" responses, or "always" and "most of the time" responses, was added up according on the response categories used for the issue. To calculate the percent positive for negatively phrased issues, the total proportion of respondents who provided a negative response was used. Specifically, the percentage of respondents who chose "strongly disagree" and "disagree, " or "never" and "rarely, " respectively.

We contrasted our results with those of the AHRQ's pilot study, which gathered a voluntary sample of pharmacists, technicians, and other pharmacy staff from 55 community pharmacies across the United States to carry out the Community Pharmacy Survey on Patient Safety Culture. In order to determine whether there was a difference in proportions between our study and the AHRQ pilot study, we performed a 2 analysis on the 11 patient safety culture composites and the overall safety rating.9 Only the pharmacist data was compared because the AHRQ pilot research included both technicians and pharmacists. In order to identify factors that influence total patient safety ratings, logistic regression analyses were completed utilising pharmacy and pharmacist characteristics as covariates (pharmacy type, pharmacy work hours, prescription volume, location of pharmacy, sex, age, tenure, pharmacist position, and degree of familiarity with patients). The data was assessed when statistical significance was required, and the outcomes were summarised in tables. Before being used, the data was placed into a Microsoft Excel spreadsheet and verified for accuracy a second time. For categorical variables, frequency and percentage were calculated. The data was analysed using IBM SPSS 20.0.

3. Results

There were 68.1 percent males and 31.9 percent females among the 731 participants, with the majority being between the ages of 31 and 40.37.5% having 6-10 years of experience in pharmacy and 17.9% having >15 years of experience in pharmacy. Among 51.7% was independent pharmacy while 48.3% was chain pharmacy.51.3% were completed D Pharm and 48.7% were completed B. Pharm.56.2% of pharmacies having only one pharmacist, 7.8% of pharmacies having >5 pharmacist and 36% of pharmacies having 2 to 5 pharmacist. Among 60.6% of pharmacies are in urban area and 39.4% pharmacies are in rural area.55.0% of pharmacies have receiving ≤ 250 prescription volume per week and 45.0% of pharmacies have receiving > 250 prescription volume per week.41.3% of pharmacies are 24 hours working pharmacies and 58.7% of pharmacies are not working 24 hours in a day. Patients were known to 42.4% in a fairly familiar way, 38.6% in a very or extremely familiar way, and 19.0% were unknown or only slightly familiar. The characteristics of the pharmacies and pharmacists surveyed are shown in Table 2.

Table 2: Characteristics of Surveyed Pharmacies and Pharmacists (n = 731)

Variables	n (%)
Experience of registered pharmacists	
≤ 5	189 (25.9)
6 to 10	274 (37.5)
11 to 15	137 (18.7)
>15	131 (17.9)
Type of pharmacy	
Chain	353 (48.3)
Independent	378 (51.7)
Qualification of registered pharmacists	
D. Pharm	375 (51.3)
B. Pharm	356 (48.7)
Number of pharmacists working in pharmacy	
1	411 (56.2)
2 to 5	263 (36.0)
>5	57 (7.8)
Pharmacy setting	
Rural	288 (39.4)
Urban	443 (60.6)
Prescription volume per week	
≤250	402 (55.0)
>250	329 (45.0)
24 hours working pharmacy	
Yes	302 (41.3)
No	429 (58.7)
Familiarity with patients	
Unfamiliar / slightly familiar	139 (19.0)
Somewhat familiar	310 (42.4)
Very familiar / extremely familiar	282 (38.6)

Table 3 displays the percentages of responses that were favourable, neutral, and negative for each survey question under the appropriate patient safety composite. The percentage of favorable replies for each of the 11 composites is shown in Figure 1. The teamwork composite had the most positive response (89%), while the staffing, work pressure, and pace composites received the lowest (45%). For comparison, Figure 1 shows the percentage of favorable

replies from the AHRQ pilot research. There were statistically significant differences between our study and the AHRQ pilot in the percentages of positive responses for six of the patient safety culture composites: response to mistakes, communication about mistakes, prescription communication across shifts, communication openness, organisational learning-continuous improvement, and overall perceptions of patient safety composites. Figure 2 compares the overall patient safety rating of the current study to the overall patient safety rating of the AHRQ's pilot study. For patient safety, the vast majority of respondents gave their pharmacy a favourable grade. About 6% of participants gave their pharmacy's patient safety a fair or poor rating. No statistically significant variations between our sample and the AHRQ pilot study's percentages of overall safety ratings were found.

Table 3: Response Types on Survey Item Level

	% Negative	% Neutral	% Positive
1. Patient Counseling			
B2. We encourage patients to talk to pharmacists about their medications	4	9	87
B7. Our pharmacists spend enough time talking to patients about how to use their medications	6	10	84
B11. Our pharmacists tell patients important information about their new prescriptions	4	5	91
2. Communication Openness			
B1. Staff ideas and suggestions are valued in this pharmacy	12	19	69
B5. Staff feel comfortable asking questions when they are unsure about something	6	8	86
B10. It is easy for staff to speak up to their supervisor/ manager about patient safety concerns in this pharmacy	9	23	68
3. Overall Perceptions of Patient Safety			
C3. This pharmacy places more emphasis on sales than on patient safety**	16	9	75
C6. This pharmacy is good at preventing mistakes	5	6	89
C9. The way we do things in this pharmacy reflects a strong focus on patient safety	3	6	91
4. Organizational Learning-Continuous Improvement			
C2. When a mistake happens, we try to figure out what problems in the work process led to the mistake	6	7	87
C5. When the same mistake keeps happening, we change the way we do things	14	10	76
C10. Mistakes have led to positive changes in this pharmacy	7	26	67
5. Teamwork			
A2. Staff treat each other with respect	5	6	89
A4. Staff in this pharmacy clearly understand their roles and responsibilities	4	6	90
A9. Staff work together as an effective team	3	8	89
6. Communication About Prescriptions Across Shifts			
B4. We have clear expectations about exchanging important prescription information across shifts	8	9	83
B6. We have standard procedures for communicating prescription information across shifts	39	16	45
B14. The status of problematic prescriptions is well communicated across shifts	10	18	72
7. Communication About Mistakes			
B8. Staff in this pharmacy discuss mistakes	11	26	63
B13. When patient safety issues occur in this pharmacy, staff discuss them	11	22	67
B15. In this pharmacy, we talk about ways to prevent mistakes from happening again	8	24	68
8. Response to Mistakes			
C1. Staff are treated fairly when they make mistakes	7	16	77
C4. This pharmacy helps staff learn from their mistakes rather than punishing them	4	7	89
C7. We look at staff actions and the way we do things to understand why mistakes happen in this pharmacy	4	14	82
C8. Staff feel like their mistakes are held against them**	15	27	58
9. Staff Training and Skills			
A3. Technicians in this pharmacy receive the training they need to do their jobs	3	6	91
A6. Staff in this pharmacy have the skills they need to do their jobs well	9	8	83
A8. Staff who are new to this pharmacy receive adequate orientation	18	12	70
A10. Staff get enough training from this pharmacy	16	10	74
10. Physical Space and Environment			
A1. This pharmacy is well organized	5	9	86
A5. This pharmacy is free of clutter	19	15	66
A7. The physical layout of this pharmacy supports good workflow	4	7	89
11. Staffing, Work Pressure, and Pace			
B3. Staff take adequate breaks during their shifts	23	24	53
B9. We feel rushed when processing prescriptions**	36	48	16
B12. We have enough staff to handle the workload	7	18	75
B16. Interruptions/distractions in this pharmacy (from phone calls, faxes, customers, etc.) make it difficult for staff to work accurately**	22	42	36

*Percent negative responses are calculated by combining "strongly disagree" and "disagree" or "never" and "rarely" response categories. Percent neutral responses represent "neither agree nor disagree" or "sometimes" response

categories. Percent positive responses are calculated by combining "strongly agree" and "agree" or "always" and "most of the time" response categories. "

† Negatively worded questions. For negatively worded items, percent positive response is based on those who responded "strongly disagree" or "disagree" or "never" or "rarely, " depending on the response category used for that particular item. A1 to A10, B1 to B16, and C1 to C8 correspond to AHRQ survey items.9

4. Discussion

Prior research on safety culture evaluations mostly concentrated on hospital settings and underused community pharmacies. Medication errors are widespread at community pharmacies, according to studies, and many of them have been linked to the organization's culture.[10-12] Assessments of safety culture can therefore support organisational development. This study investigates the community pharmacy culture in India with regard to patient safety.

When compared to other composites, communication regarding prescriptions across shifts, communication about errors and staffing, work pressure, and pace all rated lower than 70% for all 11 safety culture composites. Teamwork had the most favourable rating (89%), which is better for our study than the pilot survey result from the AHRQ (86%).

The composite for patient counselling had the second-highest percentage of good results (87%). This percentage was similar to the AHRQ survey's pilot result (92%), however our study's outcome was lower. Given the evidence that pharmacists may use patient engagement to identify and address drug-related difficulties, correct mistakes, and enhance the quality of patient care, this is not a surprise, [13-16] emphasizing that it is a key role of pharmacists. Professional organisations have produced a variety of patient counselling guidelines, [17–19] and patient counselling techniques are taught in pharmacy schools, [20–21].

The percent positive score was that of physical space and environment composite (80%). This percentage was similar to the AHRQ survey's pilot finding (77%) but was higher in our analysis.

The staff training and skills composite received a 79% percent good score. This proportion was likewise comparable to the pilot survey result from AHRQ (80%).

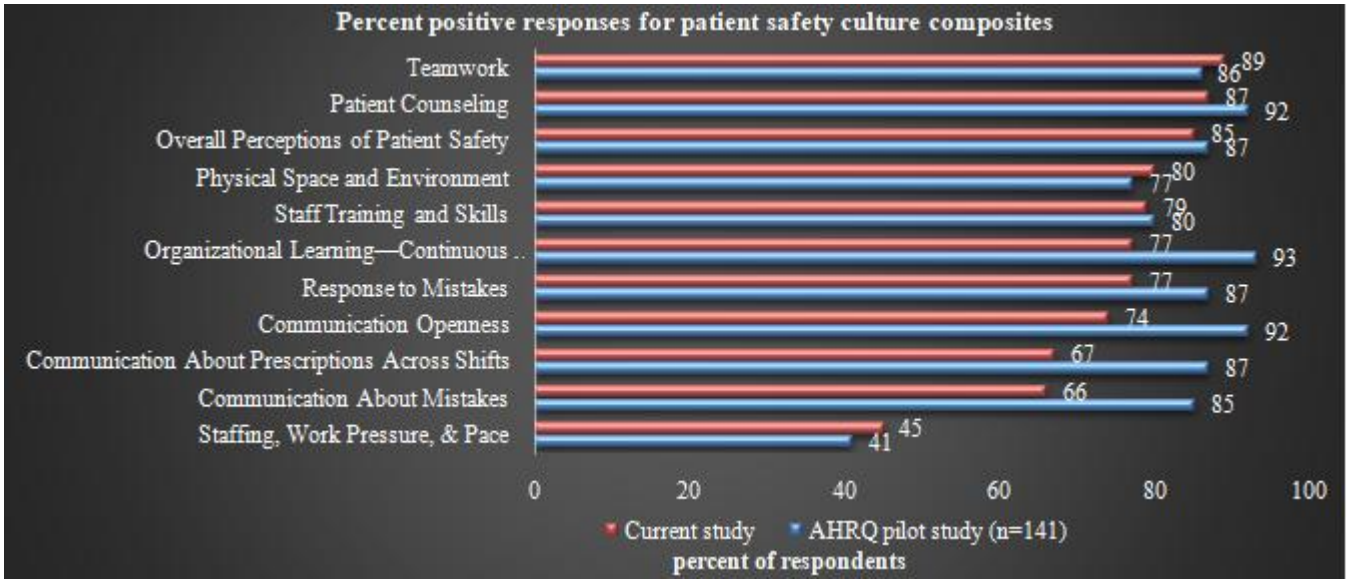

Figure 1: Comparison of percent positive responses on patient safety culture composites between the current study and AHRQ pilot study

Figure 2: Results for overall rating on patient safety

The staffing, work pressure, and pace safety culture composite received the lowest score (45%), which was comparable to the results (41%) of the AHRQ. This shows that pharmacists think their workload and pace are out of proportion to the number of staff members working in pharmacies. According to study, the workload for pharmacists in neighbourhood pharmacies has increased over time, while pharmacists who work for large national chains of pharmacies report higher levels of stress at work.[22] The need to meet specific targets in such situations is considered to be the cause of workplace stress in community pharmacies, the majority of which are owned and operated by huge corporations .[23]This conclusion is particularly troubling because insufficient staff might severely limit pharmacists' capacity to safely distribute medications, thereby putting patients at risk of damage. High workload in community pharmacies was found to be negatively associated with pharmacist-provided medication therapy services by Gadkari et al.[24]

When compared to the findings of AHRQ's pilot study, Our study discovered poorer ratings for organisational learning-continuous improvement, communication openness, responsiveness to mistakes, communication about mistakes, communication about prescription across shifts, and overall perceptions of patient safety composites. There was a statistically significant difference between the two groups.

The majority of pharmacists (94%) ranked their present pharmacy as "excellent" or "great" in terms of overall patient safety, demonstrating a strong feeling of value for their pharmacy's commitment to patient safety. However, this ranking might not fully represent the level of safety present in community pharmacies.

5. Limitations

First, our research was limited to one Indian state and may not represent the national trend. A study with a broad national sample of pharmacists would be interesting to corroborate our findings.

Second, our sampling frame contains a mailing list of pharmacists who were licenced in the state and chose to receive mail, possibly leaving them underinsured. It's not obvious how much people who weren't in the sample frame differ from those who were.

6. Conclusion

Recognizing areas of strength and need for improvement can be made easier by understanding the safety culture of community pharmacies. Positive outcomes for pharmacists and their patients may emerge from improvement initiatives that target flaws like insufficient staffing and heavy workloads. This has significant implications for pharmacy practise because pharmacists are still in responsible of managing complicated prescription regimens for patients with chronic conditions, which can result in numerous errors.

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Conflict of interest:
The authors have no conflicts of interest regarding this investigation.

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