The Practice of Counseling by Community Pharmacists in Bisha Health Directorate, Saudi Arabia – Simulated Patient Visit

CURRENT STATUS: UNDER REVIEW

BMC Health Services Research

Hassan Mohammed Al Qarni  hassan.qld@gmail.com
Sabt Al Alayah
Corresponding Author
ORCID: 0000-0002-6088-2514

Tahani Alrahbeni
Riyadh Elm University

Ayidh M AlQarni
Bisha Health Directorate, Ministry of Health, Saudi Arabia

Abdullah Alqarni
Bisha Health Directorate, Ministry of Health, Saudi Arabia

DOI:
10.21203/rs.2.16862/v1

SUBJECT AREAS
Health Economics & Outcomes Research

KEYWORDS
Community pharmacy, pharmacist, counseling, patient simulation, visit time
Abstract

Background Many organizations have suggested a minimum standard of counseling for patients, which includes information about the name of the drug, description, indication, how to use it, the method of treatment, precautions, adverse reactions, and any contraindications. Correspondingly, the World Health Organization (WHO) has recommended spending at least 3 minutes with each patient to undertake counseling. The present study aimed to evaluate the practice of counseling by community pharmacists for both over-the-counter (OTC) and prescription-only medicines in Bisha Health Directorate, Saudi Arabia.

Method This was a cross-sectional study designed to be a simulation patient visit to community pharmacies at Bisha area. The simulated patient visit were include 73 pharmacies. Two scenarios were used in the simulated patient visit. The first scenario was for a prescription-only medicine and the second scenario was for an OTC medicine. The time recorded for every visit to evaluate counseling period.

Results A total of 105 visits were conducted to the community pharmacies as follows: scenario 1 = 73 and scenario 2 = 32. The average time for the simulation was 110 seconds in scenario 1 and 73.4 seconds in scenario 2. There was a statistically significant negative correlation between the period it took for the simulation scenario and the time of visit during the day (rho = −0.396, p = 0.001) in the patient simulation.

Conclusion It that the service in community pharmacies is selling medicines and patient needs to be given a greater in these community pharmacies.

1. Introduction

Background
Pharmacists have a particular position of trust among the community. They must not abuse this position of trust, which they hold in the relationship they have with their
patients. Recently, there has been an increasing demand for community pharmacies to play a crucial role in providing safe and optimum health care services, particularly for minor cases, rather than for patients to visit emergency departments. Bisha Health Directorate is considered to be a rural area, which is part of Aseir Province. In 2007, the population was 199,613 people and there were only 25 community pharmacies. By 2017, the population had increased to 388,055 people and the number of community pharmacies had increased dramatically to 125. From this data, it can be seen that the population increased by approximately 94% over this 10 years period, with an approximately 500% increase in the number of community pharmacies during the same period. Therefore, the pharmacy business is growing rapidly in the Bisha area with no or limited information on how pharmacies can provide good pharmacy practice (GPP), especially counseling, to the community.

According to the laws and regulations in Saudi Arabia, medicines in community pharmacies, i.e. private pharmacies, are divided into two classes. The first class includes prescription-only medicines, which are defined as medicines that cannot be dispensed without an authorized prescription. The second class includes non-prescription or over-the-counter (OTC) medicines, which are defined as medicines that can be supplied without a prescription. OTCs are considered to be safe and effective if they are used according to the guidelines available on the package or the label. In addition, World Health Organization (WHO) recommended pharmacists to spend at least three minutes with every patient for orientation and counseling. However, in many developing countries they spent much less time, i.e., much less than three minutes, with patients. For example, the average time reported in Cyprus, Brazil, Sudan, Nepal, Tanzania, Nigeria and Bangladesh was 149 seconds, 53.9 seconds, 21.8 seconds, 86.1 seconds, 77.8 seconds,
12.5 and 23 seconds respectively [5, 6].

One of the essential services of a community pharmacy is patient counseling, either for prescription-only or OTC medicines. Many organizations have provided suggested guidelines and recommendations to pharmacists about patient education and counseling for both prescription-only and OTC medicines. Pharmacists should provide the following information to their patients: name of the drug, description of the drug, indication, how to use it, the method of treatment, precautions, adverse drug reactions, and any contraindications [7, 8, 9, 10]. In addition, all the guidelines emphasize the importance of gathering enough information from the patient to ensure patient safety, patient understanding about the medication, and whether the medication will meet patient needs [7, 8, 9, 11]. Okumura et al. (2014) found in their systematic review study that patient counseling can improve drug and disease knowledge, clinical outcome, patient satisfaction, and the quality of life of patients. Moreover, by law, pharmacists are not allowed to dispense any medicine without a prescription, written by an authorized person, unless the medicine is categorized as OTC [3].

In addition, Toklu et al. (2010) focused on implementing GPP in a specific district in Istanbul, Turkey. They found that GPP was poorly applied in community pharmacies [20]. Also, Gokcekus et al. (2012) conducted a similar study in the northern Turkish region of Cyprus. They concluded that GPP in that region was insufficient and needed improvement [6]. Halial et al. (2015) studied the evidence-based practice of community pharmacists for OTC medicines in Parana State, Brazil. They concluded that there was a major problem of poor knowledge regarding evidence-based practice among community pharmacists, which negatively affected the counseling practice [21]. Tully et al. (2011) studied the predictors of no counseling, no questioning, and no information provided to patients during
counseling in community pharmacies in Sweden. Their conclusion suggested the importance of therapeutic classes and busy times as predictors of no counseling about prescription medicines in Swedish pharmacies [22].

GPP, mainly counseling, has been investigated during the past years in Saudi Arabia, especially in the legal perspective of prescribing medicines. In addition, many studies have been conducted on the misuse of antibiotics in community pharmacies. Patient counseling was included in the evaluation process in some of these studies. Many studies from 1992 until now described the level of GPP especially patient counseling and following Saudi regulations. Three different studies found that community pharmacies did not adhere to pharmaceutical law and regulations [12, 13, 14]. A systematic review study in 2016 concluded that the dominant service of the community pharmacy in Saudi Arabia was in selling medicines without providing any pharmaceutical care to the patients [15].

Since there is limited information about counseling in Bisha Health Directorate. The present study aimed to evaluate the practice of counseling by community pharmacists for both OTC and prescription-only medicines in the Bisha Health Directorate, Saudi Arabia.

2. Methods
2.1. Study design
The present study was a cross-sectional study of simulated patient visits composed of two scenarios. The simulated patient visits were developed to investigate the real practice of counseling by community pharmacists.

Inclusion and exclusion criteria
The study included any private pharmacy, i.e., community pharmacy, in the Bisha Health Directorate. Government and non-profitable pharmacies were excluded from the present study.

Sample selection
The investigators randomly selected 90 pharmacies out of 125 community pharmacies.
The power of analysis was estimated at 90% confidence and 10% interval. Bisha Health Directorate is divided into three parts, which are the center (Bisha city and its close villages), east (Tathleeth and its close villages), and west (Sabt-Alalaya and its close villages). A random selection of pharmacies (n = 30) from each part of the Bisha Health Directorate was the original plan for the present study. However, if the number of pharmacies could not be achieved in one area, then it was compensated from another area. Therefore, in theory the total number of community pharmacies included in the study should be 90. It took three months to complete the simulated patient visits of both scenarios started from August 2017 to October 2017.

Assessment method
Simulated patient visit

The simulated patient visit used to determine the current service provided by the pharmacists in community pharmacies. This assessment method was derived from pharmacy practice-based research in Saudi Arabia in 2015 [16]. The simulated patients were pharmacists who were trained to perform specific scenarios to test specific behaviors, attitudes, and reflections from community pharmacists [23]. Two male pharmacists were trained to perform two different scenarios. Participation by the pharmacists was voluntarily. The participating pharmacists performed role-plays before starting their visits and collecting data to ensure the scenarios were suitable and compatible with real cases, see appendix 1. Additionally, to avoid bias, the participants were requested to use simple Arabic language and avoid any jargon. Also the trained pharmacist request not to provide any further information that could affect the result. The simulated patient was expected to have become familiar with the standard information of the counseling process and the law and regulations in Saudi Arabia because at the end of every visit they were asked to complete a checklist of counseling, see appendix 2. The
first scenario was related to prescription-only medicines (Amoxicillin + Clavulanic acid), whereas the second scenario focused on OTC medicines (Ibuprofen), see appendix 1. The time of each visit was recored by another pharmacist who was outside the pharmacy watching the discussion between the simulated patient and the pharmacist, i.e. recording time from starting conversation until the conversation ended per seconds.

Statistical analysis
Quantitative data were entered into a computer for analysis using the Statistical Package for Social Science (IBM SPSS) version 22 for Windows software program. The continuous data were reported as the mean and standard deviation (SD). Categorical data were expressed as frequencies and percentages. Comparisons between groups were performed using the Mann-Whitney test and correlations were performed using Spearman’s rho. A p value of < 0.05 indicated statistical significance.

3. Results
A total of 73 pharmacies out of 125 were visited in the Bisha area. Almost all pharmacies, which was opened at that time, were visited. The closed pharmacies were excluded. The total number of visits to community pharmacies was 105. Scenario 1 = 73 visits, scenario 2 = 32 visits, see figure 1. Figure 2 shows the time of day of the simulation visits for both scenarios 1 and 2. Data, which is collected from the checklist, regarding the presence and content of counseling during dispensing, the types of questions asked, and the information measured is reported in Table 1. The majority of pharmacists did not ask about previous use of requested medications, i.e., 4% for scenario 1 and 14% for scenario 2, or any history of drug allergy, i.e., 2% for scenario 1 and 0% for scenario 2. Moreover, none of the pharmacists asked about whether concomitant drugs were being taken or if the patient had any concerns regarding their medication. No pharmacist offered any written information about the medication. Information on dose was the most common type of
information provided during the visits. The mean (± SD) time for the simulations for scenario 1 and 2 was 110 (± 54.8) seconds and 73.4 (± 35.4) seconds, respectively. A total of 27.4% of the pharmacists were able to detect the drug allergy side effects in scenario 1, whereas no pharmacist was able to detect the problem in scenario 2. Correlation between the time taken for the simulation and working hours, which was taken from the survey, showed no statistical difference (rho = 0.074, p = 0.559). Conversely, there was a statistically significant inverse correlation between the time taken for the simulation and the time of day of the simulation visit (rho = -0.396, p = 0.001).

Mann-Whitney tests showed a statistically significant relationship between the time taken for the simulation and the ‘drug-drug’, ‘drug-food interaction’, and ‘side effects from the scenario identified’ (p = 0.000). No significant relationship was found between the time taken for the simulation and the statement ‘was a choice offered between products’ (p = 0.472). Additionally, a statistically significant relationship was found between the time taken for the simulation and the statement ‘ask for prescription’ (p = 0.000).

4. Discussion

The present study focused on the counseling practice in community pharmacies in the Bisha Health Directorate in Saudi Arabia. The simulated patient visits showed that approximately 50% of pharmacists informed patients about the dose of the medication. Additionally, 8% in scenario 1 and 15% in scenario 2 explained to the patients about the duration of use. However, none of the pharmacists explained to the simulated patients about the possible side effects. Almost 27% of the participants in scenario 1 provided information about drug interaction and 15% in scenario 2 provided written information. The reported average time required for dispensing a single medicine, i.e., from the survey, was 34.6 seconds, whereas the actual average time obtained from the simulation was 110 seconds.
Many organizations recommended spending sufficient time with each patient for orientation and counseling. In the present study, the investigators focused on the World Health Organization’s (WHO) suggestion to spend at least 3 minutes, which is 180 seconds, with each patient \[^4\]. However, the present study showed that the pharmacists spent less than 2 minutes, i.e. 110 seconds, with each patient. This was not only part of the simulation; the pharmacists also reported in the survey that they dispensed medication in an average time of 34 seconds. By comparing the obtained times from other international studies, the findings in the present study were better than those obtained from Brazilian, Sudanese, Nepalese, Tanzanian, Nigerian and Bangladeshi studies \[^6, 5\]. However, the Cyprus study showed that pharmacists spent more time, i.e., 149 seconds, dispensing medication, than in the present study \[^6\]. Even though the 110 seconds obtained from the present study was higher than that in other studies, this is still not enough to provide each patient with proper counseling. The reason why the pharmacists did not spend enough time with each patient is not entirely known. However, it could be said that the pharmacists were not concerned with patient counseling practice \[^17, 19\]. The pharmacists might not be used to asking about the patients’ current medication, medical history, and or any other issue that are required for counseling. Additionally, the pharmacists might not have proper knowledge about GPP \[^17, 24\]. There was no correlation between the time of day of the simulation visit and the working hours of the pharmacists, which were obtained from the survey. However, there was a statistically negative correlation between the period of the simulation and the time of day visit that was obtained from the simulation component. The Spearman’s rho was -0.396 with a p = 0.001 and it was shown that the pharmacist in the morning visit, which had low customer visiting times, was able to spend much more time with the customer than during the rush
hours, which was during the evening time \[^{22}\]. Another possible explanation is that the pharmacist in the morning is just starting the day with full energy to give their best, more so than during the evening time at the end of the day. Furthermore, there was a statistically significant relationship between the time of the simulation and the statements ‘drug-drug’ ‘drug-food interaction,’ and ‘side effects’ from scenario 1 with \( p = 0.000 \). If the pharmacist spends more time with a patient, then they can provide better patient counseling. Therefore, they can reduce misuse and patient harm, and optimize the quality of life of the patient \[^{6, 24}\].

Only 11% of the pharmacists requested the prescription from patients. In previous Saudi studies, it was confirmed that prescribed medicines were dispensed without a prescription \[^{13, 18, 16, 17}\]. Even though the simulated patient informed the pharmacist that he had been advised by a friend to use a particular medication to treat his condition, this did not concern the pharmacist. This point has two perspectives. The first one is the legal viewpoint. According to pharmaceutical law and regulations, antibiotics should not be supplied without an authorized prescription, which is presented and kept in the pharmacy \[^{13, 17, 19}\]. However, in the present study, the dominant service in almost all community pharmacies was in selling products. The second perspective was that not all pharmacists had graduated from Saudi universities. Therefore, they might have a lack of knowledge regarding the rules and regulations of pharmacy practice in Saudi Arabia. Additionally, they are less concerned about prescription-only medicines and OTC medicine regulations and counseling.

Almost 30% of pharmacists in scenario 1 were able to detect potential patient harm, which is that the patient could be allergic to penicillin. Furthermore, only 31.5% of pharmacists were able to provide alternative treatment or transfer the patient to a physician. One
possible explanation for this is that the pharmacists, who did not detect the potential risk, had a lack of evidence-based knowledge regarding medicines and how to search for information. Another study also highlighted this issue of imperfect knowledge by pharmacists in Brazil [21].

The limitations of the present study must be considered. The original number of samples for the study was 90 pharmacies in Bisha Health Directorate. However, when we searched for the pharmacies, it was found that many pharmacies had been recently closed or were not open at that time of visiting. Therefore, the final number was only 73 pharmacies. There was also a limitation on the resources and time available. For example, sometimes it was difficult to find the pharmacy because there was no address map or GPS location and we had to travel more than 200 km to look for the pharmacies. It was also difficult to recruit pharmacists to participate in this study, with only two pharmacists and one health professional volunteering to travel and help in the simulation patient visits and surveys.

5. Conclusion

From the results of this study, it was found that the dominant service in community pharmacies in the investigated area was the selling of medicine only. Therefore, patient counseling must be emphasized more in these community pharmacies. Also, the time of patient counseling was below the minimum WHO standard, thus community pharmacists must be encouraged to spend at least 3 minutes per patient on counseling. The stakeholders should promote an intensive training program for them and educate them about the rules and regulations in Saudi Arabia. Furthermore, the private pharmaceutical sector requires a proper collaborative plan to provide and deliver their main job, which is GPP including patient counseling.

6. List Of Abbreviations
7. Declarations

Ethical approval:

The research was sent to the institutional review board at Riyadh Elm University (Riyadh Colleges of Dentistry and Pharmacy) to obtain ethical approval. The simulated patient performers and investigators were informed to understand and comply with the ethics and code of conduct of the institutional review board at Riyadh Elm University. The research IRB approval number is RC/IRB/2016/603. The research did not contain any information that could indicate to a person, name of pharmacy, site of pharmacy and/or any personal information. Therefore, consent of participant is not included in this study and approved by the institutional review board at Riyadh Elm University.

Consent for publication:

Not Applicable

Availability of data and materials

Authors can confirm that all relevant data are included in the article and/or its supplementary information files.

Competing Interest:

Not Applicable

Funding

This study did not receive any fund and the researcher did not receive any financial support.
Authors contributions:

| Name          | Contribution                                                                 | Email                      |
|---------------|------------------------------------------------------------------------------|----------------------------|
| H. M Al Qarni | Concepts, design, literature search, manuscript preparation, data analysis,  | hasann.qld@gmail.com       |
|               | manuscript editing, and manuscript review                                     |                            |
| T. M Alrahbeni| Design, data analysis, statistical analysis, manuscript editing, manuscript   | ph.tahani@riyadh.edu.sa    |
|               | review                                                                       |                            |
| A. Alqarni    | Design, data acquisition, data analysis, manuscript review                   | abuayed.alq@gmail.com      |
| A. M. AlQarni | Data acquisition, data analysis, statistical analysis, manuscript review     | ayedalqarni5@gmail.com     |

Acknowledgment

The authors extended their appreciation to Dr. Sinaa Alaqeel and Dr. Norah Abanmy for their permission to use the instrument in this study.

Afaqeel S, Abanmy NO. Counselling practices in community pharmacies in Riyadh Saudi Arabia. BMC Health Serv Res 2015;15(1):557.

Authors' information

Corresponding Author: Hassan Mohammed Al Qarni, Master of Clinical Pharmacy
Contact number: +966 591233233
Email: hasan.qld@gmail.com

Corresponding Author's Institution: Sabt Al Alaya Hospital in Bisha Health Directorate, MOH, Saudi Arabia
Co-author: Tahani Alrahbeni,
PhD, Assistant Professor of Molecular Toxicology and Genetics at Riyadh Elm University, research supervisor
Email: ph.tahani@riyadh.edu.sa
Contact number: Tel: 920000842 Ext 1106
Mobile: 00966505210114

Co-author Abdullah M. Alqarni
9. References

1. Ministry of Health, Health statistical yearbook 1428HD, Ministry of Health Riyadh; 2007. p 31-189.
2. Ministry of Health, Health statistical yearbook 1436HD, Ministry of Health Riyadh; 2015. p28.
3. The Saudi Food and Drug Authority, Saudi Code Of Pharmaceutical Promotional Practices, SFDA Riyadh; cited November 25 2017. Available from https://www.sFDA.gov.sa/AR/DRUG/DRUG_REG/Pages/drug_reg.aspx
4. WHO, "Guidelines for the Regulatory Assessment of Medicinal Products for use in Self-Medication," Geneva; 2000. p16-32.
5. Hoogerzeil HV, Bimo, Ross-Degnan D, Laing RO, Ofori-Adjei D, Santoso B et al. Field tests for rational drug use in twelve developing countries. Lancet 1993;342(8884):1408-10.
6. Gokcekus L, Toklu H, Demirdamar R, Gumusel B. Dispensing practice in the community pharmacies in the Turkish Republic of Northern Cyprus. Int J Clin Pharm 2012;34(2):312-24.
7. American Society of Health-System Pharmacists. ASHP guidelines on pharmacist conducted patient education and counseling.. Am J Health-Syst Pharm 1997;54(4):431-4.
8. Pharmacy Board of Australia, "Guidelines for dispensing of medicines," Sydney, 2009.
9. Putispitasari H, Aslani P, Krass I. A review of counseling practices on prescription medicines in community pharmacies.. Research In Administrative And Social Pharmacy 2009;5(3):197-210.
10. National Prescribing Service. National Safety and Quality Framework Australian Commission on Safety and Quality in Healthcare 2009. [Online] Available at: https://www.safetyandquality.gov.au/wp-content/uploads/2012/03/28899-47.pdf [Accessed 11 5 2017].
11. Joint Commission of Pharmacy Practitioners. Provisional draft mission statement for pharmacy practice. Am J Hosp Pharm 1991;47(1):533-43.
12. Bawazir SA. Prescribing pattern at community pharmacies in Saudi Arabia. International Pharmacy Journal 1992;6(5):222-4.
13. Al-Ghamdi M. Empirical treatment of uncomplicated urinary tract infection by community pharmacist in the Eastern province of Saudi Arabia. Saudi Med J 2001;22(12):1105-8.
14. Al-Mohamadia A, Badr A, Bin Mahfouz L, Samar D. Dispensing medications without prescription at Saudi community pharmacy: Extent and perception. Saudi Pharmaceutical Journal 2013;21(1):13-18.
15. Al-Anazi AS, Al-Fadl AA, Hussain AS. Pharmaceutical Care in the Community Pharmacies of Saudi Arabia: Present Status and Possibilities for Improvement. Saudi Journal of Medicine and Medical Sciences 2016;4(1):9-14.
16. Alaqeel S, Abnanny NO. Counselling practices in community pharmacies in Riyadh Saudi Arabia. BMC Health Serv Res 2015;15(1):557.
17. Abudul Hadi M, Karami NA, Al-Muwalid AS, Al-Otabi A, Al-Subahi E, Bamomen A et al. Community pharmacists’ knowledge, attitude, and practices towards dispensing antibiotics without prescription (DAwP): a cross-sectional survey in Makkah Province Saudi Arabia. International Journal of Infectious Diseases 2016;47(1):95-100.
18. Al-Mohamadia A, Badr A, Bin Mahfouz L, Samar D. Dispensing medications without prescription at Saudi community pharmacy: Extent and perception. Saudi Pharmaceutical Journal 2013;21(1):13-18.
19. Kashour T, Joury A, Alotaibi A, Althagafi M. Quality of assessment and counselling offered by community pharmacists and medication sale without prescription to patients presenting with acute cardiac symptoms: a simulated client study. Eur J Clin Pharmacol 2016;72(3):321-28.
20. Toklu HZ, Ahmet Akici, Sule Oktay, Sanda Cali, Sena F, Sezen, Meral Keyer-Uysal. The pharmacy practice of community pharmacists in Turkey. Marmara Pharmaceutical Journal 2010;14(1):53-60.
21. Hallila GC, Junior EH, Otku MF, Correr CJ. The practice of OTC counseling by community pharmacists in Parana, Brazil. Pharmacy Practice 2015;13(4):597.
22. Tully M, Beckman-Gyllenstrand A, Bernstein C. Factors predicting poor counselling about prescription medicines in Swedish community pharmacies. Patient Education and Counseling 2011;83(1):3-6.
23. Watson M, Norris P, Granas A. A systematic review of the study of simulated patients and pharmacy practice research. IJPP 2006;14(2):83-93.
24. Okumura L, Rotta I, Correr C. Assessment of pharmacist-led patient counseling in. Int J Clin Pharm 2014;36(5):882-91.
Table

Table 1 Description of counseling received by simulated patients requesting medication in the two scenarios.

|                                | Scenario 1 (n = 73) | Scenario 2 (n = 32) |
|--------------------------------|---------------------|---------------------|
| **Counseling before demanded information** |                     |                     |
| Asked questions                | 51 (69.9)           |                     |
| Provided information           | 28 (38.4)           |                     |
| **Counseling after demanded information** |                     |                     |
| Asked questions                | 36 (49.3)           |                     |
| Provided information           | 20 (27.4)           |                     |
| **Questions asked**            |                     |                     |
| Asked for prescription         | 11 (15.1)           |                     |
| **Information provided**       |                     |                     |
| Name of the medicine           | 38 (52.0)           |                     |
| Dose                           | 47 (64.4)           |                     |
| How to take the medication (e.g., before or after meal) | 24 (32.9) |                     |
| Duration of use                | 6 (8.2)             |                     |
| Possible adverse drug reactions, warnings, and precaution | 0 (0.0) |                     |
| Drug-drug, drug-disease drug allergy, side effects from the scenario identified | 20 (27.4) |                     |
| Was a choice offered by products | 23 (31.5)  |                     |
| Was any written information offered | 0 (0.0)  |                     |
| **Time for the simulation (in seconds)** |                     |                     |
| Mean                           | 110.0               |                     |
| SD                             | 54.8                |                     |
| SEM                            | 6.4                 |                     |
| Minimum                        | 40.0                |                     |
| Maximum                        | 320                 |                     |

Figures
Figure 1

Flowchart of the number of pharmacies visited in both scenarios.

Figure 2

Time of day of simulation patient visits.

Supplementary Files
This is a list of supplementary files associated with the primary manuscript. Click to download.

Appendix 1  Scenario 1 and Scenario 2.docx
STROBE_checklist_cross-sectional.doc
Appendix 2 Assessment tool of the counselling.docx