Assessing hormonal contraceptive dispensing and counseling provided by community pharmacists in the United Arab Emirates: a simulated patient study

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Abstract
Background: Hormonal contraceptive pills have evolved as a common form of contraception worldwide. Pharmacists play a vital role in providing safe and effective access to these medicines. In many developing countries such as the United Arab Emirates (UAE), these medicines are available to the general public without the presentation of a prescription which requires the pharmacist to shoulder responsibility by assessing and educating patients to assure their appropriate use.

Objectives: To evaluate community pharmacists' current practice of dispensing and counseling on hormonal contraceptives.

Methods: Simulated patient methodology was used in this study. A single simulated patient visited community pharmacies requesting an oral contraceptive as per a preplanned scenario. Information from the visits were recorded on a data collection form including: pharmacist assessing patient eligibility to take hormonal contraceptives, selecting the appropriate oral contraceptive, providing complete counseling on how to use the pill, adherence, missed dose handling and side effects of the medication. The pharmacist was prompted by the simulated patient to provide the information if they did not provide spontaneous counseling. The quality of pharmacists' counseling was rated and consequently coded as complete, incomplete or poor.

Results: A total of 201 community pharmacies were visited. More than 92% of the pharmacists did not ask the simulated patient any question to assess their eligibility to use contraceptives. Twenty three pharmacists (11.4%) selected the proper product. One hundred seventeen (58.2%) of the pharmacists provided spontaneous counseling on how to use the pill, 17 of them had their counsel rated as complete, but none of the pharmacists provided spontaneous counseling regarding adherence or side effects of the medications. On prompting, 10 pharmacists (12%) provided complete counseling regarding how to use oral contraceptives, 14 pharmacists (7.0%) provided complete counseling on adherence and missing dose handling and five pharmacist (2.5%) provided complete counseling about expected side effects.

Conclusions: Pharmacists' practice regarding hormonal contraceptive dispensing and counseling was suboptimal in this study. Areas needing intervention were related to pharmacist assessment of eligibility for oral contraceptive use, choice of optimal oral contraceptive for patient-specific co-morbidities and provision of adequate counseling on proper use, adherence and missed dose handling.

Keywords
Contraceptive Agents; Contraception; Counseling; Professional Practice; Community Pharmacy Services; Pharmacies; Pharmacists; Quality of Health Care; Patient Simulation; United Arab Emirates

INTRODUCTION

In 1999, the Center for Disease Control and Prevention (CDC) considered family planning as one of the greatest achievements in public health in the 20th century. Family planning allows families to attain their desired number of children and determine the spacing of pregnancies. A variety of contraception methods are available; hormonal and non-hormonal. Over 100 million women worldwide are using oral hormonal contraceptive pills, a combination of the synthetic estrogens and progesterin, or the progesterin only pills, making “The Pill” the most common form of contraception in western countries. Oral hormonal contraceptives are above 99% effective in preventing pregnancy with perfect use, are convenient and their effect is reversible. In addition, oral contraceptives have numerous non contraceptive health benefits including improving regulation of menstruation and reducing the risk of endometrial, ovarian and colon cancers. Despite the contraceptive and non-contraceptive benefits of hormonal contraceptives, surveys from around the world have reported that as many as 60% of their users report irregular use due to fear of side effects, which would result in unintended pregnancy. Less common side effects of hormonal contraceptives include an increased risk of venous thromboembolism and breast cancer development. Common reported side effects by users of these products include headache, mood changes, nausea and breast discomfort which mostly improve by the second or third cycle of use. Studies have found that the lack of appropriate counseling regarding proper use and expected side effects of these medications is a leading cause of their incorrect use, premature discontinuation and missing dose mishandling leading to failure of the regimen and possibly increased side effects.

The World Health Organization (WHO) developed the Medical Eligibility Criteria for contraceptive use a classification of risks posed when hormonal contraceptives are used. Women, who smoke, are obese, who have a family history of coronary artery disease, are over 35 years
of age, or those with concomitant disease states, including hypertension, diabetes, hyperlipidemia and migraine, have been shown to be at significantly greater risk of side effects when compared with healthy women. Additionally, the use of certain drugs like rifampin and some antiepileptic agents can potentially compromise hormonal contraceptive efficacy, thus, a thorough patient history should be obtained when initially selecting a hormonal contraceptive for an individual patient and periodic evaluation is required thereafter.8

Pharmacists have a vital role in educating users of hormonal contraceptives on their appropriate use and on the importance of adherence to their regimen. This will not only increase access to these medicines in timely manner and reduce cost; it will also mitigate several risks, including side effects and drug interactions.2 They are also well positioned as the most accessible healthcare providers for the provision of contraceptive services.9,10 In these services, the pharmacist obtains patient’s relevant medical and medication history, assesses her pregnancy status, and performs blood pressure measurement. Based on the results of these screenings, the pharmacist makes a decision to dispense the medication or refer the patient to physician for further evaluation. If a product is dispensed, the pharmacist must provide proper counseling and discuss patients’ questions.11

Studies were cited from the United States and United Kingdom where protocols and programs are implemented for pharmacist prescribing of contraceptives; they concluded that trained community pharmacists could effectively screen women for safe use of hormonal contraceptives and select the appropriate products for them.12,13 On the other hand, studies from developing countries concerning pharmacists’ involvement in hormonal contraceptives reflected minimal assessment and suboptimal screening for the safe use of the products by the patients and inadequate provided counseling.14,17

In the UAE, while a prescription is not required to purchase oral contraceptive pills in Dubai and the northern emirates (i.e. Sharjah, Ajman, Umm Al Quwain, Ras Al Khaimah and Fujairah) it is required in Abu Dhabi. A search of the published literature in the UAE showed there were no published studies to evaluate the pharmacists’ practice on dispensing hormonal contraceptives in the UAE. Therefore, the main aim of this study was to evaluate hormonal contraceptive practice related to dispensing and counseling provided by community pharmacists in the UAE. Simulated patient also called ‘mystery shopper’ methodology is a research method whereby a researcher or a lay person is positioned as the most accessible healthcare providers for patients and in countries concerning pharmacists’ involvement in hormonal contraceptives reflected minimal assessment and suboptimal screening for the safe use of the products by the patients and inadequate provided counseling.14-17

In preparation for the visits, the simulated patient was the master’s student between March and May 2018. The pharmacist in charge/manager was contacted by one researcher a few weeks before the visit and informed him/her that a simulated patient would visit their pharmacy in the following weeks. They were informed about the purpose of the study but without disclosing the time of the visit, and then their verbal consent was obtained. Independent and franchised chain pharmacies were included in the study. In the UAE, the law mandates that a licensed pharmacist be on the premises whenever the pharmacy is open, assistant pharmacists and trainee pharmacists work behind the counter as well, but as per regulation this should be only under a licensed pharmacist supervision, however, to insure that only pharmacists were included in this study, the simulated patient requested to speak to the pharmacist particularly.20 In Abu Dhabi the simulated patient presented the pharmacist with a prescription of progesterone-only pill, which was the product of choice to be recommended for the pre-determined scenario. Consenting pharmacies were visited by the researcher simulated patient to meet one pharmacist from each pharmacy and posed as a simulated patient acting according to a standardized scenario. As a prescription was needed in Abu Dhabi, it was obtained from a gynecologist practicing in the emirate for the purpose of our research. The physician was not reimbursed for this. So that Abu Dhabi was not excluded from the study, it was best seen to obtain the prescription and present it to the community pharmacist so assessment of the pharmacist handling of the encounter was carried out. Comparisons were conducted between the outcomes of encounters when the pharmacists were and were not presented with a prescription.

To minimize potential biases associated with missing information (both omissions and distortions), the simulated patient immediately recorded the data after she exited the pharmacy using a standard checklist (data collection form). Audio recording was not sought in this study as the pharmacists in charge/manager did not approve this, which could have jeopardized response.

The Scenario

In preparation for the visits, the simulated patient had a two-hour training session by one of the research team...
members who had experience in this type of research methodology. The training included role play between the investigator and the simulated patient. Guidance on how to interpret and document data after the encounter with the pharmacist was also provided to the simulated patient.

This scenario involved a 30 year old woman who presented to the community pharmacists with a request: “I need a contraceptive pill, can you recommend one, please?” The woman, who was otherwise healthy, had a history of migraine with aura that was diagnosed since years (Online Appendix 1: Simulated Patient Scenario). Migraine with aura is common in women at a fertile age and is considered category 4 in the WHO Medical Eligibility Criteria for combined hormonal contraceptive (CHC) use due to its unacceptable health risk and hence, they should not be used. Progestin only containing products (POP) are considered a safe alternative for CHC in these patients. The pharmacist was expected to obtain patient’s medical history by asking the relevant questions and recommends a POP to the simulated patient and then counsels her regarding how to use the pills, the importance of adherence and missing dose or late dose handlings followed by proper counseling regarding common side effects. This scenario was standardized for all the visits, with the simulated patient being instructed not to give additional information other than what the pharmacist asked for, and not to lead the pharmacist into asking questions. If the pharmacist failed to ask the appropriate questions or provide the desired information, the simulated patient would then prompt the pharmacist by asking for the information, details of the scenario are available in Online Appendix 1: Simulated Patient Scenario.

Pilot Study

A small pilot study consisting of 10 pharmacy visits was conducted to assess the feasibility of the study. No amendments were done to the scenario as the pilot study did not reveal any need for scenario modification. The pilot sites were excluded from further visits, and results of the pilot study were not included in final data analysis.

Data Coding

The quality of information provided by the pharmacist to the simulated patient whether spontaneous or prompted) on all items related to provision of counseling was rated based on a coding scheme: Complete=3, Incomplete=2, Poor or incorrect information provided by the pharmacist=1.

The members of the research team held several meetings after data collection to agree on what constituted a code considering the NHS contraception guide on POP (Online Appendix 2), so the coding was consistent and reliable.

Sampling

This was an observational study where representativeness is more important than large sample size; stratified convenient sampling technique was used to ensure representativeness. The local business directory, the yellow pages, was used to obtain the contact details and locations of community pharmacies in the UAE. Community pharmacies were stratified by emirate, then pharmacies from each emirate (stratum) were conveniently sampled and contacted to obtain consent to participate in the study. The total number of community pharmacies in the UAE is 2000 according to a 2010 estimate. One tenth the number of pharmacies were visited: Abu Dhabi 42 (20.9%), Dubai 46 (22.9%), Sharjah 63 (31.3%), Ajman 15 (7.5%), Umm Al Quwain 12 (6%), Ras Al Khima 9 (4.5%) and Fujairah 14 (7%), to give 201 pharmacies located in the seven emirates.

Reference of Assessment

Items on the data collection form (Online Appendix 3) were derived from the “Standard Procedures Algorithm for Oregon RPh Prescribing of Contraceptives” and other studies looking at hormonal contraceptive dispensing practices. As per the procedures algorithm, the pharmacist was expected to obtain the patient’s medical history, pregnancy status, medication use, and blood pressure reading prior to dispensing the hormonal contraceptive, based on the results of these screenings, if the pharmacist decides to dispense the product, then they counsel the patient regarding proper use of the pills and on adherence and expected side effects.

Assessing: pharmacist assessment of the simulated patient’s eligibility for safe use of hormonal contraceptives:

1- Obtaining patient’s medical history regarding: age, smoking status, regularity of the menstrual cycle, presence of abnormal vaginal bleeding or chronic diseases such as diabetes. They also needed to rule out contraindicating conditions such as migraine with aura, uncontrolled hypertension, thromboembolic disorders, coronary heart disease, liver disease and breast cancer.

2- Screening for pregnancy status: to exclude pregnancy (e.g. a recently-performed negative urine pregnancy test, recent delivery, miscarriage or breast feeding, date of last menstruation).

3- Screening for medication and supplement use: To exclude significant drug-drug interactions with medications such as antibiotics e.g. rifampicin and anticonvulsants e.g. carbamazepine, phenytoin and phenobarbital.

Managing: Making a dispensing decision by selecting the progestin only contraceptive as the simulated patient has a condition of migraine with aura.

Counseling: The pharmacist should provide counseling on:

1- How to use the pill, when to use the pill and whether or not to take it with food. The pharmacist should explain according to the stage of menstruation cycle when the pill should be initiated; if there is a need for the use of an extra contraception until the pill becomes effective.

2- The importance of adherence and what to do in the case of a missed dose. The pharmacist should explain that a pill that is more than 12 hours late is considered a missed dose and the user should use extra contraception for the next two days.

3- The pharmacist should mention common side effects, like irregular vaginal bleeding (spotting) so the user can take sensible precautions.
Pharmaceutical Practice


Table 1. Quality of pharmacists’ counseling -prompted

<table>
<thead>
<tr>
<th>Item</th>
<th>Poor</th>
<th>Incomplete</th>
<th>Complete</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quality of pharmacists’ counseling on how to use the pill</td>
<td>34 (40.4%)</td>
<td>40 (47.6%)</td>
<td>10 (12.0%)</td>
<td>84 (41.7%)</td>
</tr>
<tr>
<td>Quality of pharmacists’ counseling about adherence and missing doses</td>
<td>95 (47.3%)</td>
<td>92 (45.8%)</td>
<td>14 (7%)</td>
<td>201 (100%)</td>
</tr>
<tr>
<td>Quality of pharmacists’ counseling about side effects</td>
<td>126 (62.7%)</td>
<td>70 (34.8%)</td>
<td>5 (2.5%)</td>
<td>201 (100%)</td>
</tr>
</tbody>
</table>

Data Analysis

Data were analyzed using the SPSS version 19 (Chicago, IL). Duration of simulated patient encounter in each pharmacy visited was the only continuous variable collected. To these data normality of distribution was tested using the values of mean, mode, median, skewness and kurtosis. Descriptive analysis was employed for normally distributed data. Additionally, inferential analysis was performed by calculating the duration 95% confidence interval to compare between Abu Dhabi pharmacies encounters and other emirates. Other variables in this study (e.g. characteristics of pharmacists) were categorical and therefore chi-square or Fisher’s exact test were employed depending on the results’ frequencies. Significant differences were based on two-tailed testing with p<0.05.

Ethical Considerations

Approval to conduct this research was sought from the Research Ethics Committee at Ajman University. Reference No: F-H-18-02-03.

RESULTS

Of the 235 pharmacies contacted, 201 community pharmacies agreed to participate in this study and were later visited by the simulated patient. None of the simulated patient visits were excluded.

Among the participating pharmacists, 60% (n=121) were females. More than half of the pharmacies (56%) were located in the northern emirates, while 20.9% were in Abu Dhabi and 23% in Dubai. The majority (64%) were chain pharmacies. The number of staff on duty during the visits was one pharmacist in 25% of the pharmacies (n=50), two pharmacists in 55% of the pharmacies (n=110) and three or more in 20% of the pharmacies (n=41).

More than 92% (n=185) of the pharmacists did not ask the simulated patient any questions upon her request for an oral contraceptive. Only a few questions (1 to 3) were asked by a small number of pharmacists: seven pharmacists asked the simulated patient about possible pregnancy, six pharmacists asked about medications or supplements used currently by the simulated patient. Female pharmacists were more likely to ask question, Fisher’s exact two tailed test was used and revealed a p=0.0095.

In this study 65 pharmacists (32%) dispensed POP for the simulated patient, however, 42 of those pharmacists were in Abu Dhabi where a prescription was provided to the pharmacists as it was required by the health authority in that emirate; so actually only twenty three pharmacists (11.4%) made the correct dispensing decision and selected POP for the simulated patient, five of them were from Dubai and 18 were from the northern emirates. Without considering pharmacies in Abu Dhabi, a correct dispensing decision was not significantly different between chain and independent pharmacies using Fisher’s exact test (p=0.5552).

One hundred and seventeen pharmacists (58%) provided spontaneous counseling on the use of the oral contraceptives, 17 of which were rated as complete, 71 were rated as incomplete and 29 as poor. None of the pharmacists provided spontaneous counseling on the importance of adherence or missing dose handlings or side effects of the medications.

On prompting, the quality of the pharmacists’ counseling on the three aspects: how to use the pills, adherence and missing dose handling and side effects was as follows: 12% of the pharmacists provided complete counseling on the proper use of the pills, only 7% of the pharmacists provided complete counseling and education regarding adherence and action plan for missing doses, and around 3% of the pharmacists provided complete counseling on the expected side effects. These included mood swings (36%), weight gain (23%), acne (18%), depression (9%), headache (8.5%) and irregular bleeding (1%). Some pharmacists (4.5%) stated there were not any side effects caused by these medications. Table 1 shows more details on the quality of pharmacists’ counseling.

Results of the bivariate analysis showed independent relationship of encounter duration and counseling on how to use the medication, medication adherence and missing dose handling (p values ranged from 0.1220 to 0.3685). Table 2 shows more details. There was no significant association between pharmacist counseling (how to use the pill, adherence and missing dose handling and side effects) and the different characteristics of the community pharmacies/ pharmacists. The mean duration of the visit was six minutes, with a range of 3 -10 minutes. The time spent showed to be normally distributed for all visited pharmacies. Because visits to Abu Dhabi pharmacies provided the pharmacists with prescription, less time was expected to be spent in the pharmacies. In fact significant differences in the durations were observed between Abu Dhabi pharmacy visits (4.6; SD 0.5 min) and the rest of emirates (6.3; SD 0.3 min).

Table 2. The independent relation between the duration of encounters > 6 minutes or ≤ 6 minutes and community pharmacists’ complete counseling.

<table>
<thead>
<tr>
<th>Pharmacist Practice</th>
<th>Significance of the Duration of Encounter</th>
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<tbody>
<tr>
<td>Overall counseling</td>
<td>Fisher’s exact test p=0.1526</td>
</tr>
<tr>
<td>Counseling on how to use the pills</td>
<td>Chi-square p=0.2339</td>
</tr>
<tr>
<td>Counseling on adherence</td>
<td>Chi-square p=0.1220</td>
</tr>
<tr>
<td>Counseling on side effect</td>
<td>Fisher’s exact test p=0.3685</td>
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DISCUSSION

This study revealed that there is substantial room for improving pharmacist dispensing and counseling regarding oral contraceptive use among female users in the UAE. The findings will help to recognize areas needing intervention and further development. In Abu Dhabi, a prescription was provided to the pharmacists as it was required by regulation; unfortunately, pharmacists dispensed the prescription without much patient questioning. Overall none of the pharmacists conducted a systematic medical or medication history checking, which could present unacceptable health risks to the patient.

Our findings were comparable to findings in a study from Brazil that also used simulated patient methodology where more than 90% of the participating pharmacists did not ask the simulated patient any questions before dispensing the oral contraceptives, a few pharmacists provided counseling when dispensing the medications, which was rated as poor by the evaluators. In a study from Iran using the same methodology, about 41.43% pharmacists did not ask the simulated patient any questions, and none of the pharmacists asked questions about blood pressure or medication history of the patient before dispensing, more than 40% of the pharmacists did not provide any counseling, and overall the counseling quality was rated as poor. Also, cross-sectional studies from Mexico and Thailand, found that a significant proportion of pharmacists did not ask any questions to women before dispensing oral contraceptives. The limited evidences from developing countries concerning pharmacists’ involvement in hormonal contraceptives reflected infrequent collection of patient medical history and limited engagement in patient counseling.

In our study, even when the simulated patient indicated to the pharmacists that she suffers from migraine with aura, most pharmacists were oblivious that combined hormonal contraceptives were contraindicated in women with migraine due to the estrogen content. In a meta-analysis it was suggested that women with migraine have an increased risk of hemorrhagic stroke when using CHC. Another study has shown that the likelihood of developing an ischemic stroke in combined hormonal contraceptives users with a history of migraine was approximately eight fold higher than that in women without migraine. Most pharmacists failed to recognize and discuss this condition-drug interaction thus failed to make the correct dispensing decision to select POP to the simulated patient. In agreement with our results, studies from Iran and Brazil showed that most of the pharmacists failed to discuss drug interactions with the patient when they asked for oral contraceptives.

When it came to assessing patient counseling by the pharmacists, it was found that more than half of the pharmacists provided spontaneous counseling to the simulated patient regarding how to use POP, however, the simulated patient had to prompt all the participating pharmacists for information regarding counseling on adherence, missing dose action plan and expected side effects.

The overall quality of the counseling was poor. Studies have well established that a thorough patient counseling on hormonal contraceptives regarding how to take the pills, steps to be taken when missing a pill or more, the use of backup methods, and the expected adverse effects, are important to achieve desired outcomes, improve adherence to the pills, and enhance safety and patient satisfaction with pharmacists’ services. Provision of information about side effects is specifically associated with improved outcomes. For instance when the pharmacist counsel the user about the manageable side effects such as headache, mood changes, nausea, breast discomfort and irregular bleeding, the user can use sensible precautions when possible and better cope with them and eventually improve adherence.

Our findings can be attributed to several factors; the culture has an impact when it comes to this matter as contraception is considered a sensitive and a private subject especially when a male pharmacist is serving a female patient. In this study, it was noticeable that mostly female pharmacists attempted to obtain the medical history of the simulated patient by asking a question about pregnancy status and regular menstruation, this finding was also reported in a related study. Moreover, the lack of privacy induced by the absence of designated consultation areas in most of the pharmacies might have hindered proper pharmacist-patient interaction, in a study by Hasan, participants highlighted the need for a private room for counseling as community pharmacies in the UAE lack these facilities. Studies from neighboring countries have also reported similar findings; 50% of respondents stated that the lack of privacy in the pharmacy was a barrier to seeking the community pharmacist’s help. Another factor is related to work force as community pharmacies in the UAE employing on average 2.6 full-time-equivalent (FTE) pharmacists 74% employing around three-quarters of the pharmacies dispensed fewer than 100 prescriptions and responded to fewer than 100 requests for over-the-counter medicines per day. World Health Organization core health indicators (2002) estimated the number of pharmacists per 10000 population in the UAE is to be four pharmacists. Another study demonstrated that there were workforce-related conditions resulting generally in shortcomings in the quality of community pharmacy services in the UAE.

Other possible reasons for our findings could be inadequate training of pharmacists concerning this issue, unlike it is in some developed countries. For example, in the USA the Accreditation Council for Pharmacy Education (ACPE) mandates that the pharmacy colleges must ensure that graduates are competent to provide patient-centered care with proper assessment and counseling. In the USA, Gardner et al. found that trained community pharmacists can efficiently screen women for safe use of hormonal contraceptives and select appropriate products. Both the women seeking contraceptives and the pharmacists were satisfied with the service, and women were willing to pay for them. Pharmacists who wish to participate in these practices must first complete the necessary training seminars mandated by their state and work under Collaborative Prescribing Protocol. Studies from the UK aimed to evaluate community pharmacists delivering oral

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contraceptive service concluded that trained pharmacists under Patient Group Direct Protocol (PGD) were clinically competent to provide oral contraceptives in the community settings and served users were largely satisfied and had valued the service highly, in particular, the convenience, anonymity, drop-in system, long opening hours and lack of waiting time. In the UK for pharmacists to provide contraception service, they have to complete an MSc module on oral hormonal contraceptive services and work through the PGD. In the UAE there are no protocols recommended by pharmaceutical authorities or other organizations that mandate community pharmacists to screen for the safe use of hormonal contraceptives, and counseling women regarding their correct use. In the UAE, the local regulatory bodies require an internship for the purposes of obtaining a license to practice pharmacy, however, these programs need improvements to be more structured and have specific learning objectives that include hormonal contraceptive services. Many steps could be taken to improve hormonal contraceptive practice in the UAE such as utilizing the successful international models and implementing protocols and tools like patient assessment checklists and the use of patient information leaflets.

Study limitations

In this study, only one simulated patient carried out all visits to the pharmacies, the use of a single simulated patient is strength in this study in terms of consistency, standardizing the approach and eliminating inter-rater variability. The lack of audio recording could be a limitation as the simulated patient depended on memory to document the interaction with the pharmacist; however, to overcome this limitation, the simulated patient recorded the details of the visit immediately after exiting the pharmacy. The subjectivity in the simulated patient evaluation of the counseling by the pharmacist is inherently there, however, to minimize possible biases in simulated patient’s evaluation, the simulated patient received rigorous training and the research team agreed on how to rate the counseling and on what constituted a code as complete, incomplete or poor.

CONCLUSIONS

Pharmacists’ practices regarding oral contraceptive dispensing and counseling were suboptimal in the study. Pharmacists failed to assess the simulated patient for the safe use of oral contraceptive with inconsistent collection of patient history, improper selection of the product for the simulated patient’s condition and the poor quality of information given to the simulated patient. Efforts are needed to improve hormonal contraceptive dispensing practices in community pharmacies in the UAE to promote their rational and effective use. Improving pharmacist’s patient centered role by means of training and education, and designing guidelines in regards to the dispensing and use of hormonal contraceptives are essential. Future research could look at the kind of interventions specifically designed to improve this practice.

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CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

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