It is widely accepted that community pharmacies have a key role to play in the provision of health services. Such pharmacies are also the most readily available healthcare facilities in every healthcare system. Pharmacies often have longer and more consistent opening hours than general medical practices or sexual and reproductive health services, and do not require patients to make an appointment or to expect a long wait for attention (1). A visit to a pharmacy should provide the patient with an excellent opportunity to talk to the pharmacist in confidence even about the most embarrassing and intimate matters. Services provided in pharmacies include the dispensing of medicinal products and the provision of information, under conditions which ensure the potential for the complete consideration of patients’ rights, including the right to confidentiality, intimacy, and dignity. A comprehensive emergency contraceptive service also includes education on reproductive health.

Hormonal contraception (HC) is one of the most effective methods of birth control. Emergency contraceptive pills (ECP) are also frequently used. ECPs are intended to be used soon after intercourse (2). One of the most commonly used ECPs contains levonorgestrel at 1.5 mg; whereas second-generation ECPs are progesterone modulators containing 30 mg of ulipristal acetate. ECPs are highly effective as a contraceptive and are very well tolerated (3).

When ECPs were first marketed, they were only available on prescription. However, it was noticed that the key factor determining the efficacy of the product was the timing of its administration. Therefore, since 2001 there has been a global trend to improve the availability of ECPs to reduce the percentages of unplanned pregnancies and uncontrolled abortions. As the length of time elapsed between intercourse and taking the pill determines the contraceptive’s efficacy, the necessity of making a medical appointment to obtain a prescription can

EVALUATION OF PHARMACEUTICAL EMERGENCY CONTRACEPTIVE SERVICES IN POLAND

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Abstract: Pharmacies are acknowledged to have a key role in the provision of health services, including emergency contraceptive services and under the right circumstances could meet the growing expectations for reproductive health education and consultations. Pharmaceutical emergency contraceptive service provided by pharmacists include ensuring the availability of required medicines, correct dispensing, providing comprehensive information, all of which requires not only consultations that are health-oriented and educational, but also providing the patient with an adequately private situation to talk with the pharmacist. The aim of the paper is to evaluate pharmaceutical emergency contraceptive services provided in polish pharmacies. The observational study included 60 community pharmacies of different profiles located in Gdańsk (Poland). Our method was to use “standardized (simulated) patients”. The study revealed the low availability of emergency contraception in Gdańsk pharmacies. Pharmacy employees provided drug-related information in 51.6% of study’s visits. None of the pharmacies provided patients with educational information on reproductive health. Regarding the respecting of patients’ rights privacy and intimacy, overall, the pharmacies scored 4.41 on a five-point scale. Our study sought to identify both the developed and underdeveloped aspects of a comprehensive emergency contraceptive service. Pharmacy employees in the study provided patients with a narrow range of information on hormonal medications and they failed to include sexual health education in their work. The patient’s right to expect that intimacy and privacy will be respected during their consultation was met to a satisfactory degree.

Keywords: emergency contraceptive pill, simulated patient, community pharmacy, pharmacy consultation

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significantly impede the timely administration of the drug. Studies conducted in Canada, the USA, and the UK showed that the pharmacy could be a suitable place for distributing, and improving the availability of, ECPs due to pharmacies’ qualified personnel, locations and opening hours (4–8). In many countries, the availability of products containing levonorgestrel was changed from “on prescription” to “over-the-counter” (9). In August 2006, the US Food and Drug Administration approved the “behind the counter” status for ECPs; meaning the medication can be dispensed after consulting a pharmacist (10–12).

Many countries have rules in place allowing pharmacists to write prescriptions for HC (13–15). However, in Poland, pharmacists are only authorized to issue pharmaceutical prescriptions in medical emergencies, and consequently, using a pharmaceutical prescription to supply a patient with HCs is considered unlawful.

When dispensing an HC at a pharmacy, especially ECP, the pharmacist should above all keep in mind the obligatory standards related to dispensing the product to the patient and giving information on its use. The pharmacist is also obliged to follow the Pharmacist’s Code of Ethics. It is the pharmacist’s duty to respect the patient’s privacy and provide access to the medicinal product, regardless of their personal convictions or the pharmacy’s stock levels. During the consultation, the pharmacist should consider information on the phase of the menstrual cycle, the time elapsed since intercourse, the patient’s age, and her health. Situations in which the patient requests the medication for future use does not exempt the pharmacist from the obligation to provide information on its correct use, paying attention to the expiry date of the product. To fully take care of the patient’s health, contraindications and precautions, as well as possible drug interactions, should also be carefully analyzed. Instructions on how to use the medication can be given to the patient in writing, including the dosage regimen, possible ADRs and the management of contraceptive failure. It is also recommended to advise the patient on a regular method of contraception and the risk of contracting sexually transmitted diseases. If during the conversation the pharmacist realizes that the woman is a victim of sexual violence, the pharmacist should offer her support and help in informing the police about the incident (16).

Introduction of HC pills to the pharmaceutical market in the early 1960s initiated a debate on pharmacists’ conscience clause in the US and the UK (17). The “conscience clause” is a legal suggestion for getting out of circumstances in which there is a conflict between the norms of law and ideological or religious norms. Pharmacists in Poland do not have the right to a “conscientious objection”. In a situation where a patient presents a prescription (e.g. for hormonal contraceptives, or anti-implantation drugs) the pharmacist is not legally permitted to refuse to issue them, citing personal convictions, despite Art. 3 of the Pharmacist’s Code which points to the role of the conscience in the pursuit of the pharmacist’s profession, because the document is of deontological rather than legal value. The general rule regarding the conscience clause is that reference to it cannot constitute a barrier to a patient accessing medical services that are guaranteed by law. Community pharmacies have been obliged by the legislation to have medicinal products in those quantities and assortments necessary to meet the health needs of the local population. This obligation precludes any unjustified restriction of access to HC in the pharmacy. It should also be noted that a desideratum was drawn up by the Petitions Committee concerning the possibility of pharmacists citing the conscience clause. According to research, 15% of professionally active pharmacists declare their willingness to rely on the conscience clause (18).

Objectives

The aim of the paper is to evaluate emergency contraceptive services in the pharmaceutical practice, including verifying pharmacies’ provision of patient access to medicinal products the completeness of their consultations, and to their observation of patients’ rights to intimacy and privacy.

The results obtained were analyzed to search for relationships between the quality of pharmaceutical consultations and the gender and education of pharmacy staff, or the location and type of pharmacy.

Material and methods

The study was conducted in 60 community pharmacies in Gdańsk (Poland); accounting for 30% of all community pharmacies in the city. The overall number of pharmacies was established from the open register of public pharmacies maintained by the State Pharmaceutical Inspection. The facilities were selected by systematic random sampling. The survey commenced on the 1st of February 2017 and ended on the 28th of February 2017.

The study used the so-called “standardized patient” method, which is one of the possible methods for assessing the quality of service through the presence of an active observer of the drug release
process (19). The study used the classic version of the method in which the visit of a “simulated patient” to a pharmacy was staged (20). The role of the patient was played by a fifth-year pharmacy student from the Medical University of Gdańsk. Prior to the study, the Independent Bioethics Committee for Scientific Research at the Medical University of Gdańsk was asked to issue its opinion. In compliance with the Commission’s requirements, the intention to carry out the anonymous study was announced on the website of the Gdańsk District Chamber of Pharmacists.

For the needs of the study, the characteristics of the fictitious patient and the scenario of the visit were defined, and they were duplicated each time a pharmacy was visited. A form was also prepared to record the observer’s analysis of the pharmaceutical consultation provided during the dispensing of post-coital hormonal contraceptives by the pharmacy staff. The person conducting the study was obliged to complete the observation report immediately after leaving the pharmacy. The assessment included the availability of the drug in the pharmacy, the quality, and type of information provided about the drug, and respect for the patient’s privacy and intimacy.

The design of the original assessment form for recording the analysis of the quality of consultations was based on the collected literature, the experience of other researchers (21-23) and after adjustment to account for the realities of Polish pharmaceutical practice. It consisted of two parts. The first part comprised four questions regarding the course of the visit to the pharmacy. It used semi-open, multi-choice questions, each with the possibility of multiple answers based on a five-point Likert scale. The second part of the document included four questions about the pharmacy and pharmacy personnel; to characterize the pharmacy (local community pharmacy, outpatient clinic pharmacy, shopping mall pharmacy) and to determine the gender and level of education of the person providing the consultation (Master of Pharmacy or pharmaceutical technician). This section used closed questions with the possibility of single answers only.

All statistical calculations were carried out using the IBM SPSS 23 statistical package and an Excel 2013 spreadsheet.

The W Shapiro-Wilk test was used to check whether quantitative variables were derived from a normal distribution population. The significance of any differences between more than two groups was verified using the Kruskal-Wallis non-parametric significance test (if statistically significant differences between groups were found, Bonferroni post hoc tests were used); and the significance of differences between the two groups by using the Mann Whitney U test. In all calculations, p < 0.05 was assumed as the level of significance.

RESULTS

In only seven pharmacies (i.e. 11.67% of all the visited outlets) did a pharmacy employee ask at least one question during the administration of post-coital contraception. In pharmacies in which the sought-after drug was available, pharmacists asked an average of 0.33 questions. In the interviews conducted by pharmacy staff, there was a minimum of one, and a maximum of three questions asked of the patient.

During the study, 31 visits recorded incidences of the pharmacist giving information about the medicine. This represented 51.6% of all the pharmacies visited. During consultation, the issue most frequently discussed was when the medicine should be taken. This information was obtained in 44.4% of visited pharmacies. One-third of the pharmacies (n = 12) informed the patient about the ADRs that were possible after taking the drug. Other issues discussed during consultation: the mechanism of action of the medicine (n = 9); the effectiveness of pregnancy prevention (n = 8); and instructions for using the product (n = 7). Only four pharmacist personnel informed the patient about the probable time of the next menstrual period. The most rarely discussed issues were the contraindications and possible interactions (n = 2); what to do in case of diarrhea or vomiting (n = 2); and instructions for dealing with the next menstruation being delayed (n = 1). In no case did the pharmacy employee give advice on forms of regular contraception or protection against sexually transmitted diseases.

There was no statistically significant relationship indicating the consulting pharmacist’s gender

<table>
<thead>
<tr>
<th>Number of pharmacies where a patient was asked a question</th>
<th>% of all pharmacies visited (n = 60)</th>
<th>% of pharmacies in which the drug was available (n = 36)</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>11.67%</td>
<td>19.44%</td>
</tr>
</tbody>
</table>
influencing the scope of the information provided ($Z = -0.12$, $p > 0.05$).

Information about when to take the medicine was communicated significantly more often in chain pharmacies than in independent pharmacies, $Z = -2.41$; $p < 0.05$.

In most pharmacies, employees do not wear ID badges. During the study, it was impossible to verify the level of education of 75% of the pharmacy staff. In the case of only 11 pharmacists and 4 pharmaceutical technicians was identification without doubt possible.

Information about possible ADRs was statistically more often passed on by a Master of Pharmacy than by staff not wearing IDs $H(2) = 15.94$; $p < 0.001$. Unfortunately, it is difficult to assume with certainty whether it was only technicians who failed to wear ID (as one might suppose).

An interesting result seems to be that significantly more information on ADRs was provided in chain pharmacies than in independent pharmacies, $Z = -2.50$; $p < 0.05$.

Respecting the patient’s privacy in the pharmacy was assessed on a five-point Likert scale. Pharmacists were rated 0.55 higher (4.55) than pharmaceutical technicians (4.0). The average assessment of women pharmacy employees (4.43) was 0.14 higher than for men (4.29).

The study showed that the availability of emergency contraception in pharmacies in Gdańsk was low. The drug could be obtained in only 40% of pharmacies visited. The availability of post-coital contraception was also analyzed in relation to pharmacy type. Chances that a patient would receive a “day after” tablet in a pharmacy not affiliated to a chain was less than 50% (48.71%). The likelihood of acquiring this drug was much higher in chain pharmacies; amounting to 80.95%. Significantly greater access to the drug was guaranteed in chain pharmacies than in independent pharmacies, $Z = -2.41$; $p < 0.05$ (see Table 5).

**DISCUSSION**

The results of this study were compared with the results of research on the same subject carried out over the past 20 years in other countries.

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**Table 2.** Relationship between the type of pharmacy and the provision of information on when to take the drug.

<table>
<thead>
<tr>
<th>When to take medicine vs type of pharmacy</th>
<th>N</th>
<th>M</th>
<th>SD</th>
<th>Z</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chain</td>
<td>21</td>
<td>0.48</td>
<td>0.51</td>
<td>2.67</td>
<td>0.008</td>
</tr>
<tr>
<td>Independent</td>
<td>39</td>
<td>0.16</td>
<td>0.36</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 3.** Relationship between the education of pharmacy personnel and the provision of information on the ECP ADRs that were possible, during pharmaceutical consultation.

<table>
<thead>
<tr>
<th>Information about ADRs education</th>
<th>N</th>
<th>M</th>
<th>SD</th>
<th>H</th>
<th>df</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Master of Pharmacy</td>
<td>11</td>
<td>0.64</td>
<td>0.50</td>
<td>15.94</td>
<td>2</td>
<td>0.000</td>
</tr>
<tr>
<td>Pharmaceutical technician</td>
<td>4</td>
<td>0.25</td>
<td>0.50</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Missing ID</td>
<td>45</td>
<td>0.09</td>
<td>0.29</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 4.** Relationship between the type of pharmacy and information on the ECP ADRs that were possible, during pharmaceutical consultation.

<table>
<thead>
<tr>
<th>Information about ADRs vs type of pharmacy</th>
<th>N</th>
<th>M</th>
<th>SD</th>
<th>Z</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chain</td>
<td>21</td>
<td>0.38</td>
<td>0.49</td>
<td>2.50</td>
<td>0.013</td>
</tr>
<tr>
<td>Independent</td>
<td>39</td>
<td>0.10</td>
<td>0.31</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Table 5.** Relationship between the availability of ECPs and pharmacy type.

<table>
<thead>
<tr>
<th>ECP availability type of pharmacy</th>
<th>N</th>
<th>M</th>
<th>SD</th>
<th>Z</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chain</td>
<td>21</td>
<td>0.81</td>
<td>0.40</td>
<td>2.41</td>
<td>0.016</td>
</tr>
<tr>
<td>Independent</td>
<td>39</td>
<td>0.49</td>
<td>0.51</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
When the availability of hormonal emergency contraception was compared between pharmacies in Gdańsk and Delhi (24), Sydney (25), Scotland (26), Toronto (27) and England (28), it turned out that in Polish pharmacies the supply of this type of product is the most difficult. In Scotland, in all the pharmacies where the drug was not available, the pharmacist indicated a different pharmacy where the patient could obtain the product (26). In an Australian study, out of five pharmacies where no post-coital contraception could be obtained, two provided information on where to buy this product (25). In none of the 26 Gdańsk pharmacies, where the sought-after drug was unavailable, were appointments made to collect the drug at another date, although the obligation absolutely lies with the manager of the pharmacy to provide such a service.

The study showed that the privacy, dignity, and intimacy of patients in Gdańsk pharmacies are rather well respected by pharmacy personnel. The average rating for all the pharmacies visited is 4.41 on a scale of 1 to 5. Pharmacies in many other countries have a special room designated for consultations with a pharmacist, which was not recorded in any of the Gdańsk pharmacies. Pharmacies in Scotland, which due to housing restrictions did not have a separate consultation room, each offered the patient a place to talk with the pharmacist away from other people in the pharmacy (26). No such arrangements have been reported in our study. Considering the realities of Polish pharmaceutical practice, our study acknowledges that formal requirements and the architectural possibilities for many pharmacies are not currently conducive to building consultation rooms. Neither are there accepted standards in Poland that can be used to ensure they are built in the future (29). Despite pharmacies lacking additional space for consultation, pharmacy staff in our study did attempt to talk to contraceptive patients more quietly than to others and they also hid the discussed product away from the sight of other patients waiting in the queue. Similarly, in the study performed in Sydney, pharmacists used nonverbal methods of communication and body language, indicating their discretion (25).

An analysis of the quantity and quality of questions asked and information provided about the medicine during pharmaceutical consultations by pharmacy personnel reveals worse results in the facilities in Gdańsk compared with the results obtained in the English survey of 2003 (28). In the pharmacies surveyed in England, a free condom was offered in 80% of cases. In the above English study, 100% of pharmacists also asked about the date of the last menstrual period and the length of the previous menstrual cycle. These questions were not asked in any of the pharmacies in Gdańsk. In terms of the level of detail in the consultations, the Gdańsk study compares unfavorably with the results in Scotland, where interviews included questions related to allergies (64%) and liver diseases (2%). In addition, 68% of the Scottish pharmacies asked about a regular form of contraception, and twenty of them (71%) asked about the date of the last menstrual period and the length of the current menstrual cycle. These issues were not addressed at any of the Gdańsk pharmacies visited.

Our study shows that pharmacy employees in Gdańsk provide a narrow range of information about the medicine when issuing ECPs. The results from Scotland (26) indicate that during pharmaceutical consultations pharmacists focused on discussing the side effects of the drug (96%), and meticulously addressed the issue of dealing with vomiting or diarrhea (in as many as 93% of the pharmacies). In contrast, this issue was raised in only 5.56% of the Gdańsk pharmacies. Additionally, in two pharmacies in Scotland (5%) patients were offered a test to detect Chlamydia trachomatis infections. The present study showed that none of the Gdańsk pharmacies conducted sexual health counseling. Neither was there any suggestion of protection against venereal diseases nor information provided about available forms of contraception.

An ordinance issued by the Minister of Science and Higher Education defines the range of knowledge and skills which every graduate of pharmacy in Poland should possess. This document indicates that a pharmacist should know and understand the etiology, as well as methods for preventing and reducing the incidence of drug-induced complications resulting from commonly available drugs, especially those classified as “over the counter” (OTC) agents. The ordinance also anticipates that a pharmacy graduate will explain to patients how to adequately handle a medicine during its use and will advise and support the patient in the choice of medicinal products or other products available in the pharmacy. The ordinance mentions other skills as well, including the ability to provide a pharmaceutical consultation while dispensing over the counter medicines and the ability to educate patients on issues associated with their current medication and other health- and disease-related problems which may affect the efficacy and safety of the pharmacotherapy (30).

The Gdańsk study failed to carry out in-depth analyses of the results reflecting the impact of edu-
cation on the quality of consultations due to the lack of access to information, i.e. the absence of IDs that would show the education levels of the pharmacy staff. In similar studies conducted in Delhi and Sydney, this problem of a lack of IDs was not observed. In India (Delhi), 70.37% of patients were served by a Master of Pharmacy. In pharmacies in Sydney where post-coital contraceptive was available, 89.47% of the staff had a higher education diploma in pharmacy. Pharmaceutical technicians in that city accounted for 5.26% it is noteworthy in our comparison of similar studies from different countries evaluating pharmaceutical consultations accompanying the dispensing of postcoital contraceptive agents, that in Canada and Great Britain (England and Scotland) such medicines are classified as “behind the counter”. This means that the drug may only be dispensed after a pharmaceutical consultation has been performed according to clearly defined protocols. In Australia, the Pharmaceutical Society of Australia developed a guide that gives pharmacists precise instructions on the correct dispensing procedure for the “morning-after pill”. Conversely, no similar standardized drug-group-specific rules for the pharmacist-patient interaction exist in either India or Poland; this lack also includes the absence of any guidelines concerning the anamnesis scenario. This fact may be responsible for the

![Algorithm](image)

Figure 1. Algorithm describing the correct handling of a situation when a postcoital contraceptive agent is dispensed in the pharmacy.
significantly lower scores accorded to pharmaceutical consultations in these latter two countries.

CONCLUSIONS

The study showed that access to ECPs in Gdańsk is difficult when compared with the availability of the medications in other countries.

Patients’ rights to respect for intimacy and privacy during consultations is observed to a satisfactory degree even though there are no consultation rooms in the Gdańsk pharmacies. Pharmacists in Gdańsk either conduct no interview with the patient while dispensing ECPs or conduct a limited interview. Sexual health education is not provided at the pharmacies in Gdańsk. Also, the employees of the Gdańsk pharmacies provide a narrow range of information on the hormonal drug while dispensing it. It was shown that information on when to take the medication was provided significantly more frequently at chain pharmacies than at independent pharmacies. The differences in the quality of pharmaceutical consultations provided in chain and individual pharmacies may result from the fact that the chain pharmacies are subjected to outsourced monitoring and quality testing of their service provision. In this regard, the pharmacies’ standards of service towards patients may benefit from the feedback in the reports prepared by the so-called “mystery patient” (31). Chain pharmacies give greater consideration to the quality of patient services (32), their staff are trained in service procedures and are aware of the possibility of being monitored through the “mystery patient” method. The evaluation provided to the pharmacy by the mystery customer is also linked to the employee’s salary (33).

Summing up the above conclusions, it must be acknowledged that pharmacies perform a key role in the provision of community health services, including emergency contraceptive services, and that studies which seek to understand how this role can be further developed to meet patient expectations and international standards of proper practice have their place. In relation to the underdeveloped areas of service revealed in our study, it can be stated that it will be necessary set clear sector-wide standards to ensure that the proper quality of pharmaceutical services are offered in all community pharmacies. To that end, it may be helpful to prepare Standard Operating Procedures (SOPs) for selected groups of medications or conditions reported by patients (34). A key outcome of our study is the development of an algorithm describing the correct handling of a situation when a female patient wishes to receive a postcoital contraceptive agent in the pharmacy. Overseas literature was also used for this purpose (21).

Despite the fact, that in Poland it is a physician’s responsibility to prescribe the medicine (including postcoital contraception), very often they do not have enough time to precisely clarify patient’s doubts and important issues associated with the drug. In many cases, the physician’s message is not understandable for the patient, as medical nomenclature is used (35). Studies demonstrated that less than half of healthcare employees inform the patient about the prescribed medication. It is estimated that during a visit to a physician’s office, patients may forget 72% of orally communicated information (36). In addition, 52% of patients lose the written recommendations they receive at such consultations (37). Therefore, it can be concluded that adequate pharmaceutical consultation may improve patient’s safety and the consequent efficacy of the therapy.

Training pharmacists to provide proper pharmaceutical consultations during drug dispensing will contribute to broadening their knowledge and skills and realizing their professional potential (30). Such training has been initiated in Canada and it authorizes pharmacists to independently issue prescriptions for post-coital hormonal contraceptives (31).

REFERENCES


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