Trends in dispensing oral emergency contraceptives and safety issues: a survey of German community pharmacists

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Abstract
Background Oral emergency contraceptives containing levonorgestrel or ulipristal acetate are available without prescription and only in pharmacies in Germany since March 2015. Due to this change community pharmacists are responsible for evaluating whether the product is appropriate and to educate women on proper use. Objective To measure the utilization of emergency contraceptives without a prescription and describe potential concerns and safety issues identified by community pharmacists in Germany. Setting The Drug Commission of German Pharmacists’ nationwide network of reference pharmacies which includes 860 community pharmacies. Methods Reference community pharmacies were asked to participate in the eleven-questions online survey. Respondents were asked to recall their experiences with oral emergency contraceptives in the past 3 months. Data were collected between January 8 and February 19, 2018. Main outcome measure The survey focused on the utilization of emergency contraceptives without a prescription in Germany, and on the pharmacists’ experiences with (potential) problems and concerns regarding safe use. Results In total, 555 community pharmacies (64.5%) participated. Overall 38.2% of community pharmacists stated they dispensed six to ten courses of emergency contraceptives within the past 3 months. In addition, 54.3% of the pharmacists estimated they dispensed emergency contraceptives exclusively without prescription and 35.9% dispensed more than 30% of emergency contraceptives during night-time and emergency services. Moreover, 82.8% of pharmacists stated that emergency contraceptives were requested not by the women concerned but a third person and 44.3% identified uncertainties in woman’s self-diagnosis. Three out of four pharmacists had concerns about the effective and safe use of emergency contraceptives. In situations suggesting sexually transmitted diseases, or suspicion for use of force, 59.5% and 55.8% of the pharmacists, respectively, dispensed emergency contraceptives. In cases of acute health impairment or chronic disease, or (potentially) relevant drug/drug interaction, the vast majority (91.0% and 90.5%) did not. Here, most pharmacists referred to gynecologists. Conclusion Pharmacists had safety concerns when dispensing emergency contraceptives. Professional expertise in evaluating the need for oral emergency contraceptives and the proper use is needed.

Keywords Community pharmacy · Emergency contraceptives · Germany · Medication safety · Self-medication · Survey

Abbreviations
ABDA  Federal Union of German Associations of Pharmacists, “Bundesvereinigung Deutscher Apothekerverbände”
AMG  German Medicinal Products Act, “Arzneimittelgesetz”
AMK  Drug Commission of German Pharmacists, “Arzneimittelkommission der Deutschen Apotheker”
BAK  German Federal Chamber of Pharmacists, “Bundesapothekerkammer”
CP  Community pharmacy
EC  Emergency contraceptives
LNG  Levonorgestrel
OCT  Over-the-counter
SmPC  Summary of product characteristics
UPA  Ulipristal acetate

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Impact of research findings

- Low-threshold access to oral emergency contraceptives leads to high proportions of emergency contraception dispensing during night-time- and emergency-services, as German community pharmacists confirm.
- Community pharmacists reveal awareness regarding the effective and safe use of oral emergency contraceptives, especially for self-medication, and additionally evaluate the need to refer women to a gynecologist.

Introduction

Emergency contraceptives (EC) are used to prevent unintended pregnancy after unprotected sex, contraceptive failure, or coerced sexual intercourse [1–3]. In Germany, oral EC containing levonorgestrel (LNG) or ulipristal acetate (UPA) are available without a prescription and only in pharmacies (over-the-counter, OTC) since March 2015. Here, sales figures have risen to approx. 808,000 packages in 2017 (662,000 in 2015), with 90% of the volume accounting for EC sales without a prescription [4].

Due to this change in the regulatory status (OTC-switch), community pharmacists are responsible to ensure that women use oral EC appropriately [5–8]. In 2016, the German Federal Chamber of Pharmacists (BAK) developed recommendations, a protocol for consultation, and a continuing education program for pharmacists to ensure a positive benefit/risk balance when dispensing oral EC without a prescription in German community pharmacies (CPs) [9]. The recommendations refer to the existing evidence in terms of effectiveness and safety of oral EC. Pharmacists are encouraged to refer to the early application of oral EC and to evaluate the woman’s individual characteristics e.g., age, body weight, or relevant primary and/or concomitant diseases [10, 11].

Safety issues, from a pharmacist’s perspective, are critical to understand potential problems related to the use of oral EC. In this context, the Drug Commission of German Pharmacists (AMK) represents an independent national institution of pharmacovigilance and collects, assesses, and evaluates risks of medicinal products, spontaneously reported by German pharmacists, as defined by § 63 of the German Medicinal Products Act (AMG) [12, 13]. The AMK is organized within the ABDA—Federal Union of German Associations of Pharmacists, the umbrella organization of all pharmacists and more than 90% of German CPs.

To get access to data on safety-related issues in pharmacy practice, the AMK established a nationwide network of reference CPs. The AMK network comprises CPs of various sizes, in terms of both, staff and turnover, and geographical locations (urban, rural, peripheral and border regions). Reference CPs are appointed by the 17 State Chambers of Pharmacists and are distributed throughout Germany. For the nomination as a reference CP, several quality criteria apply: verification of an established quality management system, a high commitment in areas of education and advanced vocational training, and affinity for digital correspondence (email, Internet).

For this study, AMK reference CPs provided current data on oral EC dispensing. In particular, pharmacists were requested to report experiences in potential problems and safety issues, related to EC self-medication.

Aim of the study

This survey of the AMK reference CPs was conducted to provide data on the current practice of oral EC dispensing in Germany, with a focus on potential problems and safety issues.

Ethics approval

Ethical approval was not required for the present study. No personal identifying information was collected and no ethics committee approval was applied. The article does not contain any studies with animals performed by any of the authors.

Methods

The AMK reference pharmacy network

At the time of the survey, the AMK reference network included 860 CPs, that is 4.4% of the 19,748 CPs in Germany [4]. Upon appointment, reference CPs were asked to accept the terms of agreement to participate in surveys. However, CPs have the option not to participate or not responding to selected questions. Available characteristics of the AMK reference CPs are provided in Supplementary material 1.

Online survey

We developed a survey using the Survey Monkey online tool (Dublin, Ireland). The questions were compiled, evaluated, and reviewed by the authors until agreement (Supplementary material 2). On December 20, 2017, all reference CPs received an email about the upcoming online-survey providing the questionnaire. This approach enabled an analysis
of the requested information by the CPs. The survey was launched on January 8, 2018. An email was sent to all reference CPs with a brief preamble on the topic of emergency contraception, including a link to the eleven-questions-survey. Reminders were sent on January 31, 2018 and February 12, 2018. The survey concluded on February 19, 2018. No personal identifying information was collected and no ethics committee approval was applied.

EC used in the context of this survey equal oral EC available without a prescription in Germany since March 2015. Thus, hereinafter the term EC corresponds exclusively to LNG or UPA-containing oral EC.

Domains of interest

Participants were asked to answer in the context of the last 3 months prior to the survey. The domains of interest comprised (1) the characteristics of EC dispensing, including night-time and emergency services and prescription versus non-prescription ratios, as well as the duration of EC counseling, (2) the reasons for an EC request and the criteria determining the use of UPA or LNG, (3) problems related to EC dispensing/counseling, and (4) frequency and reasons for pharmacists’ concerns in terms of the effective and safe use of EC.

Most questions were multiple choice. For some questions, multiple answers and/or additional free-text comments were allowed. Available free-text answers were analyzed and summarized/categorized according to the content.

Statistical analyses

Descriptive statistics were compiled for each question. The data were summarized and analyzed using Microsoft Office Excel 2016 (Microsoft, Redmond, WA, USA).

Results

Of 860 reference CPs contacted, 555 participated in the survey (response rate 64.5%).

Frequency of EC dispensing after OTC-switch and time for counseling

When asked about the dispensing characteristics in CPs within the last 3 months, pharmacists declared most often (n = 211, 38.2%) to dispense six to ten EC packages, whereas others dispensed less (≤ 5 packages; n = 133, 24.1%) or more (11–15 packages; n = 101, 18.3%) (Table 1A). Moreover, 300 (54.3%) solely dispensed EC for self-medication, and further 167 (30.2%) dispensed EC on prescription to a maximum of 5% (Table 1B).

CPs were asked to provide the number of performed night-time and emergency services within the past 3 months, and the estimated proportion of EC dispensing. The average amount of night-time and emergency services was 5.6 days (median = 4 days, Table 2). In total, 198 CPs (35.9%) estimated that more than 30% of EC requests took place during night-time and emergency services. In contrast, only 47 (8.5%) did not dispense EC during these services (Table 1C).

Time needed for appropriate counseling (Table 1D): 313 pharmacists (56.6%) reported 6–10 min and 181 (32.7%) up to 15 min, and even more.

Table 1 Dispensing characteristics of EC

| Respondents (n, %) |
|-------------------|
| (A) Quantity of EC packages dispensed in CPs (n) |
| 0 | 1 (0.2) |
| ≤ 5 | 133 (24.1) |
| 6–10 | 211 (38.2) |
| 11–15 | 101 (18.3) |
| 16–20 | 47 (8.5) |
| > 20 | 59 (10.7) |
| (B) Ratio of EC on prescription versus OTC (%) |
| 0 | 300 (54.3) |
| ≤ 5 | 167 (30.2) |
| 6–10 | 49 (8.9) |
| 11–25 | 19 (3.4) |
| 26–50 | 14 (2.5) |
| > 50 | 4 (0.7) |
| (C) Ratio of EC dispensing during night-time and emergency services (%) |
| 0 | 47 (8.5) |
| ≤ 5 | 100 (18.1) |
| 6–10 | 68 (12.3) |
| 11–20 | 65 (11.8) |
| 21–30 | 74 (13.4) |
| > 30 | 198 (35.9) |
| (D) Estimated duration needed for counseling EC (minutes) |
| ≤ 5 | 59 (10.7) |
| 6–10 | 313 (56.6) |
| 11–15 | 150 (27.1) |
| > 15 | 31 (5.6) |
Reasons for EC request and factors determining pharmacists’ selection of UPA or LNG

Reasons for the EC request: most frequently, the following statements were given: a busted or broken condom (n = 518, 93.5%), a forgotten use of regular contraceptives (n = 368, 66.4%), and unprotected sex, but no wish for a child (n = 372, 67.2%) (Table 3A). Moreover, 140 (25.3%) referred to the woman’s concern, that the effectiveness of the regular contraception is limited e.g., due to acute diarrhea.

Using preselected statements, pharmacists informed about relevant criteria determining the selection of UPA or LNG (Table 3B). Most commonly, the duration between the unprotected sexual intercourse and the arrival of the woman at the CP was considered to be relevant (n = 335, 61%). However, 311 (56.7%) generally declared UPA as the first-line option, compared to 105 (19.1%) preferring LNG within the first 72 h after unprotected sex. Specific requests by the women relating to pricing, advertisement, or personal advice were also relevant, as 196 (35.7%) responded.

Regarding available free-text comments (n = 35), the three most common issues are outlined: for eight pharmacists, the estimated date of the woman’s next menstruation is relevant, seven considered UPA to be more safe than LNG, and six addressed potential drug/drug interactions.

Potential problems when counseling and dispensing EC

To evaluate potential problems when counseling and dispensing EC, CPs were asked to confirm selected statements. Overall, 434 (82.8%) answered that EC were not requested by the woman concerned, but a third person (Table 4A). Additionally, 232 (44.3%) confirmed uncertainties in woman’s self-diagnosis. Adherence problems e.g., due to language barriers, were stated by 110 (21.0%) and further 43 (16.1%) detected (potential) medication errors. Additionally, 101 free text answers were given, of which the two most common issues were: 31 pharmacists repeated uncertainties in women’s self-diagnosis e.g., due to limited sex education. Meanwhile, 23 explicitly reported no problems at all.
Pharmacists also estimated how often they had concerns about the effective and safe use of EC. Almost three out of four had concerns at least once within the past 3 months (Table 4B). Moreover, eight (1.5%) were concerned in more than 50% of the cases. Only 147 (26.6%) had no concerns.

Dispensing EC (or not) and additional advice for women

Three out of four pharmacists had concerns whether the use of EC is appropriate, at least once within the past 3 months. Thus, the survey additionally asked for the reasons, why these concerns were raised and listed 13 predefined scenarios. If the scenario was confirmed, pharmacists were requested to state, whether in this specific situation EC was dispensed (or not) and if the woman was referred to a gynecologist. In fact, each of the given statements were verified by a different number of CPs, with an overall trend to restrict EC dispensing, and to refer the woman to a gynecologist (Table 5).

Most frequently (n = 212), the pharmacists stated that the need for EC was questionable e.g., when the usual oral contraceptive was forgotten and the sexual intercourse occurred less than 12 h ago. Herein, 114 (43.7%) still dispensed EC and overall 90 (34.5%) referred the woman to a gynecologist. A request to buy EC in stock was confirmed by 173 CPs. Thus, 152 (87.9%) did not dispense EC, and 52 of them referred the woman to a gynecologist. Further 128 pharmacists stated that women requested EC later than 5 days after unprotected sex, whereupon 96 (75.0%) did not dispense EC and overall 108 (84.3%) referred the woman to a gynecologist. In case an existing pregnancy was suspected (n = 104), 92 (88.5%) did not dispense EC, of whom 85 (81.7%) referred the woman to a gynecologist. When a risk of sexually transmitted diseases was suggested, 25 of 42 pharmacists (59.5%) dispensed EC and 39 referred the woman to a gynecologist (92.9%). If use of force was suspected (n = 43), 24 (55.8%) dispensed EC and 40 (93.0%) referred the woman to a gynecologist.

For other scenarios, such as the repeated use within the same menstrual cycle (n = 113), EC request by girls younger than 14 years without parental informed consent (n = 89), acute health problems or chronic diseases (n = 88) or potential clinically relevant drug/drug interactions (n = 74), pharmacists commonly denied EC dispensing and referred the woman to a gynecologist. In situations of sustained vomiting/diarrhea (n = 61), obesity (n = 52), or in case the pharmacist declared ethical/religious reservations regarding the use of EC, the proportion of dispensing versus non-dispensing EC was similar.

Overall, only a few pharmacists dispensed EC without additional referral to gynecologists.

Discussion

Community pharmacists are responsible to educate women in the proper use of EC. According to the summary of product characteristics (SmPCs), LNG can be used within 3 days and UPA within 5 days after unprotected sex or contraceptive failure [14]. High proportions of EC dispensing during

| Problems when counseling/dispensing EC | Respondents (n, %) |
|---------------------------------------|-------------------|
| (A) Problems when counseling/dispensing EC |                     |
| (Former) side effects after use of oral EC were reported | 18 (3.4) |
| EC was not requested by the woman concerned but the respective man or a third person | 434 (82.2) |
| (Potential) medication errors when administering EC were detected | 43 (8.2) |
| Compliance problems e.g., due to language barriers | 110 (21.0) |
| Uncertainties in self-diagnosis of the woman | 232 (44.3) |
| Forensic relevant evidence e.g., suspicion of use of force | 11 (2.1) |
| (B) Frequency of pharmacist’s concerns (%) |                     |
| 0 | 147 (26.6) |
| ≤ 5 | 236 (42.7) |
| 6–10 | 93 (16.8) |
| 11–25 | 55 (10.0) |
| 26–50 | 14 (2.5) |
| > 50 | 8 (1.5) |

(A) Problems when dispensing EC without prescription within the past 3 months. CPs were asked to confirm given statements; n = 524 CPs responded. Multiple answers were possible. (B) Estimated frequency of concerns when counseling/dispensing EC. Ratio ranged from 0% (no concerns) to > 50%; n = 553 CPs responded.
night-time and emergency services indicates that women are aware to use EC early. Indeed, the vast majority of pharmacists confirmed that women ask for EC within 12 h or 3 days (Supplementary material 3). However, the survey also revealed, that pharmacists had concerns about the effective and safe use of EC, at least once within the past 3 months, because women requested EC later than 5 days. Thus, evaluating the appropriate use of EC remains highly important in everyday pharmacy practice.

However, it is still impossible to confirm that low-threshold availability alone reduces the number of pregnancy terminations [15, 16]. At least in the Federal States of Germany with relatively high rates of EC use, there is a trend towards fewer terminations [17]. Moreover, a need for re-evaluating or establishing official guidelines for dispensing practices was indicated, when identifying differences in gynecologists’ and pharmacists’ views on EC [18–20]. Thus, the BAK protocol for consultation, and a continuing education program for pharmacists were developed [9, 21]. The protocol provides a checklist, which allows CPs to document each individual EC request.

Women ask for EC either due to contraceptive failure, the forgotten use of a regular contraceptive, or unprotected sex but no wish for a child, as the survey revealed. It is unknown, for the latter, whether women are aware of the risk for unintended pregnancy or misinformed about birth control. Possible considerations are manifold and include knowledge about (emergency) contraception [7], use of EC as a regular contraception [22] or rely on “fertility awareness” or “pregnancy prevention” apps [23, 24]. Moreover, the survey did not explicitly list a coerced sexual intercourse, but 43 CPs confirmed a suspicion of use of force or sexual traumatization. This request is an integral part of the BAK protocol to facilitate a structured EC counseling [9, 21].

The time lag between unprotected sexual intercourse and the consultation at the CP is relevant when selecting UPA or LNG, as most pharmacists declared. Nevertheless, a clear tendency towards UPA was noticeable. The favor for UPA might reflect the differences in the applicability (3 vs. 5 days), but it could also be speculated that UPA is generally considered an advance in EC [25]. Indeed, the recent Cochrane systematic review declared UPA to be more effective than LNG [26]. Furthermore, the use of EC is also a matter of safety. LNG and UPA are suggested to have a similar safety profile, with serious adverse drug reactions essentially unknown [27–29]. But as LNG is approved as OTC much longer, more is known about its adverse effects through pharmacovigilance activities [30].

### Table 5 Pharmacists’ decision whether to dispense EC, or not, and/or refer the woman to a gynecologist

| Dispensing EC | Referral to a gynecologist | Sum (n) |
|---------------|--------------------------|---------|
|               | Yes | No | Yes | No |
| **Scenario**  | **Respondents** | **n, (%)** | **n, (%)** | **n, (%)** |
| Request for EC in stock (no acute emergency contraception). | 52 (30.1) | 100 (57.8) | 13 (7.5) | 8 (4.6) | 173 |
| Questionable indication for EC (e.g. unusual oral contraception was forgotten and unprotected sex dates back less than 12h). | 84 (32.2) | 63 (24.1) | 87 (33.3) | 27 (10.3) | 261 |
| Unprotected sexual intercourse or contraception failure was more than 12h (5 days) ago. | 78 (60.9) | 18 (14.1) | 30 (23.4) | 2 (1.6) | 128 |
| Present acute health problems or chronic diseases (e.g. malabsorption syndrome, severe hepatic dysfunction, previous tubal inflammation). | 71 (80.7) | 9 (10.2) | 7 (8.0) | 1 (1.1) | 88 |
| (Potential) clinically relevant drug/drug interactions suspected due to concurrent medication (e.g. cytochrome (CYP) 3A4-inducers like rifampicin, barbiturates, phenytoin). | 64 (86.5) | 3 (4.1) | 6 (8.1) | 1 (1.4) | 74 |
| Sustained vomiting/diarrhea. | 30 (49.2) | 5 (8.2) | 23 (37.7) | 3 (4.9) | 61 |
| Repeated use within the same menstrual cycle. | 76 (67.6) | 10 (8.9) | 25 (22.1) | 2 (1.8) | 113 |
| Suspection of an existing pregnancy. | 85 (81.7) | 7 (6.7) | 10 (9.6) | 2 (1.9) | 104 |
| Signs suggesting a risk of sexually transmitted diseases (e.g. syphilis, human papillomavirus (HPV) etc.). | 15 (35.7) | 2 (4.8) | 24 (57.1) | 1 (2.4) | 42 |
| Girls younger than 14 years without informed consent of a parent or legal guardian. | 73 (82.0) | 10 (11.2) | 4 (4.5) | 2 (2.3) | 89 |
| (Massive) obesity of the woman. | 25 (48.1) | 3 (5.8) | 22 (42.3) | 2 (3.9) | 52 |
| Personal ethical/religious reservations regarding EC. | 11 (44.0) | 3 (12.0) | 3 (12.0) | 8 (32.0) | 25 |
| Suspection of use of force/ sexual traumatization. | 17 (39.5) | 2 (4.7) | 23 (53.5) | 1 (2.3) | 43 |

Potential reasons for concerns regarding the effective and safe use of EC. CPs were asked to confirm given statements as reasons for concerns, and to report whether EC were dispensed (or not) and if the woman was referred to a gynecologist; n = 398 CPs responded. Multiple answers were possible.
According to the sales volume in Germany at the time of the survey, a CP dispensed on average 10.1 EC packages (9.2 packages without a prescription) within 3 months. Noteworthy, the frequency of EC dispensing, reported by the reference CPs, reveals striking consistency with these figures. The rise in OTC-use was also confirmed. Moreover, EC counseling is present and (relatively) time-consuming [31]. Pharmacists frequently advise the recommended use of EC and refer the woman to a gynecologist to maintain medication safety. They also respect duties of care obligations when dispensing to minors. The SmPCs do not specify age limits, but the BAK guidelines recommend not to dispense EC to girls under 14 without a prescription or the consent of a parent or legal guardian [9, 32]. However, it remains arguable if the overall restrictive EC dispensing due to pharmacists’ concerns about the safe use of EC may constitute an (unnecessary) barrier for women who require early and effective pregnancy prevention [33]. As indicated, EC have an adequate safety profile, and the benefit outweigh the risk [34–36]. Thus, the BAK recommendations advice not to dispense EC for self-medication exclusively in situations where the unprotected sexual intercourse was more than 5 days ago, a pregnancy is suspected, or the use of EC is contraindicated [9, 21].

However, scientific caution is advised when interpreting the individual circumstances of EC dispensing restrictions. In real world situations, different concomitant attributes may emerge e.g., an obese woman (BMI ≥ 35) with acute health problems and a request to buy EC in stock. Here, pharmacists have to decide individually whether to dispense EC or not. Moreover, some criteria addressed in the survey, e.g. the repeated administration of EC within a menstrual cycle, are not concordant for LNG and UPA. The repeated use is not advisable for LNG, because of the possibility of disturbance of the cycle. However, this safety advice is missing in the SmPC of UPA-containing EC.

**Limitations**

We do not know whether the data provided are based on pharmacy records documenting every EC request [9] or from recall; the latter leading to more subjective answers. Some aspects may have led to misinterpretation e.g., the given scenarios which did not necessarily depict real world situations. For some predefined statements, decision making by pharmacists might depend on the type of EC (UPA or LNG), which could not be considered in the multiple-choice setup of the survey. In addition, the risk of misclassification and imprecision is increased when one participant answered on behalf of several pharmacists, who likewise dispense EC in everyday pharmacy practice. To overcome these restrictions, the survey was conducted over a month long, allowing the participating CPs to comprehensively discuss and analyze the requested information internally. Finally, the AMK reference pharmacies are probably not representative of the larger population of German CPs. Notwithstanding, reference CPs revealed consistency with the nationwide EC sales figures and the prescription versus non-prescription dispensing ratios. Compared to other surveys, the response rate of 64.5% and the number of participating CPs were high [7, 20, 30, 37].

**Conclusion**

The reference community pharmacies of the Drug Commission of German Pharmacists confirm the substantial rise in OTC sales figures for emergency contraceptives in Germany. Pharmacists give advice for the correct and safe use and refer the women to gynecologists, in case of safety concerns. The professional expertise ensures a positive benefit/risk balance for emergency contraceptive dispensing and use.

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