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## TITLE PAGE

### **An evaluation of community pharmacists' responses to legally and ethically challenging requests for the emergency contraceptive pill**

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Keywords: pharmacy services, emergency contraception, ethical and legal scenarios

## **ABSTRACT**

### **Background**

Requests for the supply of the emergency contraceptive pill (ECP) through Australian community pharmacies require consideration of a range of factors and the application of professional judgment. Pharmacists need to consider the patient's clinical information and comply with legal requirements. In addition, there may be a need to apply ethical reasoning principles. Pharmacists should therefore be able to follow a structured process when requested to supply the ECP.

### **Objectives**

The aim of this study was to assess the management of legally and ethically challenging requests for the ECP through a mystery patient approach. The research involved assessing semi-covert pharmacy data obtained through pharmacy staff interactions with mystery patients.

### **Methods**

Two case scenarios that involved the management of legally and ethically challenging ECP requests were developed with assessment tools that included essential criteria. A project information package with an expression of interest form was posted to 135 Gold Coast pharmacies and the total number of pharmacies that agreed to participate was 23 (17%).

### **Results**

Pharmacy staff was exposed to one of the two scenarios during December 2010 through mystery patient visits. Staff interactions were recorded on the assessment tools, analysed and rated. The results indicated identifiable practice gaps amongst pharmacists and pharmacy staff with respect to information gathering, provision of advice, privacy and confidentiality, and the application of legal and ethical principles.

### **Discussion**

Community pharmacy staff may not be sufficiently prepared for challenging ECP requests. Further training is required across the profession in order to enhance pharmacy staff confidence in providing advanced services. However, the impact of time pressures and financial burdens on the quality of pharmaceutical services need to be acknowledged. More studies could enable development of training tools and support mechanisms to address identified practice shortcomings.

## INTRODUCTION

Requests for the supply of the emergency contraceptive pill (ECP) through Australian community pharmacies require consideration of a range of factors and the application of professional judgment. Pharmacists need to obtain relevant clinical information from the consumer to be able to make informed decisions as to whether the supply is therapeutically appropriate. A request for emergency contraception also involves consideration of and compliance with legal requirements and could require the application of ethical reasoning principles.<sup>1-4</sup> Pharmacists should therefore be able to follow a structured process when requested to supply the ECP and should apply sound reasoning skills to the specific presenting circumstances.

The ECP Postinor-2<sup>®</sup> (levonorgestrel) was down-scheduled in Australia in 2004 from a Prescription Medicine (Schedule 4 medicine) to a Pharmacist Only Medicine (Schedule 3 medicine).<sup>5-6</sup> This down-scheduling of the ECP in Australia followed an international trend of making the ECP more readily available and the ECP is in fact currently available on a non-prescription basis in approximately 60 countries.<sup>7</sup> Various international studies have indeed indicated that pharmacy availability of the ECP without a prescription enables most women to receive the ECP within 24 hours of unprotected sexual intercourse.<sup>8-10</sup> Research has also indicated that the non-prescription use of the ECP is appropriate in that it is only used as an emergency measure when there was failure of another contraceptive method, such as a condom.<sup>11</sup>

The over the counter availability of the ECP does not seem to lead to increased use, an increase in unprotected sex or a decrease in the use of more reliable methods of contraception.<sup>8, 11-12</sup> However, a recent Australian telephone survey of a random sample of 632 women aged between 16-35 years indicated that less than half of the women were aware of it being available without a prescription, and the researchers subsequently recommended that a media campaign be implemented to promote its availability from pharmacies.<sup>13</sup>

Pharmacists supported the down-scheduling change and the profession accepted additional responsibility in terms of professional judgement required to determine appropriateness of supplies, although there is no need to undergo specific ECP training or credentialing to supply the ECP, as is the case in New Zealand.<sup>14</sup> Issues involving pharmacists' potential risk of legal liability are often raised after the down-scheduling of a product.<sup>15</sup> This is mainly due to the fact that it is a legislative requirement that advice on the selection and use should be provided during the supply process, and potential drug-drug or drug-disease interactions or contraindications should be taken into consideration when a non-prescription medicine is requested.<sup>1, 16</sup>

The changing regulatory status of down-scheduled medicines places a responsibility on pharmacists to determine the appropriateness of the product for a specific consumer, provide detailed advice and keep records when supplying these medicines to consumers or carers.<sup>17</sup> Down-scheduling of medicines hence not only provides pharmacists with an expanded range of therapeutic products available as non-prescription medicines, but it also potentially increases pharmacists' professional responsibility and professional liability risk.<sup>18</sup> It is therefore important

that pharmacy managers and pharmacists plan and implement pharmacy workflow patterns to ensure that pharmacists could be released from dispensing tasks and be available to provide non-prescription medicine related patient care services, as required.<sup>19</sup>

Certain information that should be obtained from the consumer to determine the suitability of the supply of the ECP is of a personal nature and involves details such as determining whether taking the tablet(s) will fall within the current recommended three to five day efficacy period following intercourse.<sup>7, 20</sup> Due to the nature of the information pharmacists need to ensure that the conversation takes place in an area of the pharmacy that provides appropriate privacy.<sup>21-22</sup> However, a pilot observational study conducted in South London indicated that women felt less comfortable asking for the ECP in a pharmacy compared to another clinical service such as a clinic because of privacy and confidentiality concerns at a pharmacy.<sup>23</sup> Other studies similarly highlighted a lack of pharmacy privacy as an area of concern.<sup>13, 24-25</sup> Pharmacists should also have an understanding of the various legal, professional and ethical obligations involved with confidentiality of patient information and the mechanisms by which privacy of, and access to, patient information is secured.<sup>21</sup> Certain ECP supply request situations would require pharmacists to weigh up the legal and ethical requirements regarding confidentiality against legislation that permits a breach of confidentiality. This is particularly relevant when the pharmacist determines that the sexual intercourse involved an unlawful activity.<sup>2</sup>

The ECP supply process is more complex than the supply of most other non-prescription products as it involves specific sensitive and personal information to be gathered and detailed advice to be provided on the correct use. The Pharmaceutical Society of Australia (PSA) developed a detailed ECP supply protocol to assist pharmacists with this process. This protocol provides a structured framework for complying with professional pharmacist duties.<sup>22</sup> A recent mail survey to pharmacies indicated that most of the pharmacist participants used this protocol to guide them through the ECP supply process although a need to simplify the protocol was identified.<sup>26</sup>

While surveys provide valuable information and insight into pharmacists' attitudes and opinions, covert or semi-covert observation is often used to obtain information about actual practices. This method is also referred to as mystery shopper scenarios or simulated patients and involves a trained patient to visit a pharmacy and enact a scenario to test specific behaviour of the pharmacist or pharmacy staff.<sup>27</sup> This approach has been used since 2002 to monitor the implementation of non-prescription medicine standards in Australian community pharmacies.<sup>28-29</sup> Recent Australian mystery patient research that focused on the supply of the ECP was conducted in 100 community pharmacies in Sydney, and highlighted a need to standardise procedures regarding emergency contraception services.<sup>24</sup> Similar United Kingdom (UK) research in 2004 indicated that most pharmacists followed the prescribed protocol although more recent UK research indicated that pharmacists' counselling needed improvement.<sup>30-31</sup> Mystery patient research conducted in Canada during 2003 indicated that pharmacists followed ECP supply protocols most of the time but there was scope for improvement.<sup>25</sup> Research in the United States of America involving mystery patients either visiting pharmacies in person or telephoning pharmacies with ECP requests had mixed responses and reflected a

need for continued education of pharmacy staff.<sup>32-34</sup> Various studies have also identified that pharmacists need to focus more on the provision of advice regarding future contraception and sexual health issues when supplying the ECP.<sup>9, 23, 35</sup>

The identified research focused on the supply of the ECP, involving mystery patients representing uncomplicated practice requests. Research involving the dispensing of prescriptions has indicated that pharmacists often struggle to follow a structured reasoning process when confronted with legally and ethically challenging scenarios.<sup>36-37</sup> However, there is a lack of Australian information about pharmacists' behaviour when confronted with requests for emergency contraception that involve legally or ethically challenging scenarios. A need was therefore identified to specifically evaluate the management of legally and ethically challenging requests for the ECP to determine pharmacists' cognitive moral reasoning and ethical decision-making skills through a mystery patient approach.

## **METHODS**

The research involved assessing semi-covert pharmacy data obtained through pharmacy staff interactions with mystery patients. Ethics approval was granted by the Griffith University Human Research Ethics Committee.

### **Development of Case Scenarios**

Two case scenarios were developed through input from seven focus group members that were pharmacy academics with practice experience and expertise. The focus group meeting allowed for in-depth discussions of the participants' experiences in dealing with legally and ethically challenging scenarios involving ECP requests. Two detailed scenarios were subsequently developed with essential assessment criteria for each scenario (Table 1). The overall purpose of these case scenarios was to review the management of legally and ethically challenging ECP requests and gain insight into how pharmacists and pharmacy staff dealt with these situations.

Scenario 1 involved a third party request, which is legally challenging as pharmacists should ideally have a face-to-face interaction with the patient or alternatively be able to talk to the patient over the phone.<sup>1, 38</sup> In the case of this scenario, the male (third party) would respond that the patient was not available if requested by the pharmacist to phone the patient. An additional legislative complication with this case was that the age of the female was 16 years. Although this is the minimum age requirement for the over-the-counter supply of Scheduled medicines in Queensland the PSA ECP supply protocol specifies that there is limited data available for the use of levonorgestrel for emergency contraception in females of child-bearing potential aged 14–16 years.<sup>22</sup>

Scenario 2 involved suspected sexual assault, requiring the pharmacist to offer support and assistance with reporting the incident to the police and facilitating a referral to a medical practitioner or a sexual assault referral centre for more comprehensive help and advice.<sup>22</sup> In the case of this scenario the patient would indicate that she was on her way to the police if the pharmacist offered to phone the police and that it was not necessary for the pharmacist to contact the police. The patient therefore would not consent to the pharmacist notifying the police.

The essential criteria placed particular focus on patient information that might warrant refusal of ECP supply or highlight the need for pharmacist referral. The scenarios were validated by the focus group participants and then finalised.

Table 1: Mystery patient scenarios

Scenario 1 involved an 18 year old male presenting to the pharmacy requesting the 'morning after pill', seeking extra contraception for future use for his young girlfriend. Upon questioning he described the circumstances requiring the medication 'just in case', being that the pair were travelling to a remote destination on a camping trip the following day and would not have reasonable access to a pharmacy or doctor's surgery on the off-chance that their usual method of contraception (barrier method) failed. The essential criteria for scenario 1 included to:

- Determine the nature of request, and relationship
- Determine the age of the female patient, and attempt to confirm identity
- Identify that third party supply is not appropriate
- Provide continuum of care – referral to doctor or alternative options to obtain supply
- Provide the patient with adequate privacy and ensure confidentiality

Scenario 2 involved a 30 year old female presenting to the pharmacy requesting the 'morning after pill'. She required the medication as a result of a suspected sexual assault. She had gone out for a few drinks the previous evening with friends but blacked-out soon after her first drink. She described having no knowledge of events after blacking out and was worried that her drink was spiked and that something might have happened. Essential criteria for scenario 2 required pharmacists to:

- Determine the possibility of sexual assault
- Provide referral to a doctor and/or the police and/or a sexual health clinic
- Provide adequate counselling about the medication considering the patient's lack of knowledge with first time use
- Provide the patient with adequate privacy and ensure confidentiality
- Eliminate the presence of known pre-existing contraindications to ECP

Assessment tools were developed for each scenario considering the essential criteria, good practice standards, the PSA protocol and Queensland legislative requirements.<sup>1, 17, 22</sup> The tools consisted of five different sections: *initial questioning about the ECP request; establishing patient's need for ECP; supplying ECP or referring; counselling; and privacy of the consultation*. The tools also included a section to document the mystery patients' subjective impression of the consultation.

## Pharmacy Recruitment

The Gold Coast, Queensland, was targeted for data collection. The area represents a variety of primary care settings, is reflective of a metropolitan area and

incorporates a representative sample of Australian community pharmacies, including different banner groups. A project information package with an expression of interest form was posted to 135 pharmacies, requesting pharmacists to indicate their willingness to participate in the research by returning the consent form. In order to maintain the integrity of the research intentions, the information package explained that a mystery patient would visit the pharmacy to request a non-prescription medication in a specified time period. In an effort to boost recruitment, pharmacies were also contacted by telephone to provide more detail about the research approximately one week after initial distribution of the information package.

The total number of pharmacies that agreed to participate was 23, thus 17% of the community pharmacies on the Gold Coast.

### **Mystery Patients**

Two mystery patients with characteristics that suited the chosen research scenarios and with the required skill set and expertise to act the scenarios and effectively recount details of the interaction for data collection purposes were recruited. One was a female in her early 30's with extensive health practitioner experience in midwifery and the other a male in his late teens (over 18 years old) who was a university student with science background and 12 months prior experience in pharmacy students' counselling assessments. Both of the mystery patient participants were provided with details of their scenario, assessment tools and training for the pharmacy interactions.

### **RESULTS**

The participating 23 community pharmacies were separated into north and south with Scenario 1 assigned to all of the north participants and Scenario 2 to all south participants. The mystery patient visits took place over two full workdays, one week apart, during December 2010. Members of the research team accompanied the mystery patients but remained concealed throughout the interactions. The mystery patients reported all details of the interactions to the researchers immediately after each interaction and the responses were recorded onto the assessment tools.

Letters were sent to the participating pharmacies once all visits were completed, providing details of the mystery patient visits and advice that dispensing software and recording details of the interaction required amendments to reflect the pseudo research nature of the request.

### **Data Analysis**

Assessment tool data was evaluated and the pharmacies' ratings in each of the sections were assessed and classified into 'comprehensive', 'moderate' and 'poor' performance. This classification of the pharmacies' performance was done by assessing the depth of patient questioning, the degree with which the pharmacy met the details of the PSA protocol and the essential criteria, and the patient's subjective impressions. In addition, the overall performance was rated via the integration of their performance across all assessment tool subsections, the essential criteria, the patient's outcome and the subjective data reported by the mystery patient.



A summary table was compiled for all of the participating pharmacies and three broad practice areas or themes were identified:

- Information gathering
- Provision of advice
- Privacy and confidentiality

### **Information Gathering**

Information gathering encompassed the fundamentals of history taking and included determining the intended user of the ECP, indication for use, current medication, medical and allergy history, history of ECP use and scenario-specific essential criteria. Five of the 12 pharmacies presented with scenario 1 determined the intended ECP user, while eight of the 11 pharmacies presented with scenario 2 determined the intended patient with the remaining three pharmacies assuming that the presenting patient was the-intended ECP user.

Five of the 12 pharmacies presented with scenario 1, involving a third party request for the ECP, determined the relationship of the mystery patient with the intended user but none of the 12 pharmacies determined the age of the requesting male mystery patient. Supplying to a third party is a legislative grey area and pharmacists need to use their judgement as to the appropriateness of supply, depending the specific circumstances.<sup>38</sup> Staff at three pharmacies determined the history of previous ECP use, and two of these supplied the ECP to the mystery patient. The overall rating of pharmacies presented with scenario 1 showed that staff at two pharmacies obtained a moderate history while the remaining 10 pharmacies obtained no history or a poor history from the mystery patient. Ten pharmacies presented with scenario 1 refused to supply the ECP.

All 11 pharmacies presented with scenario 2 supplied the ECP to the mystery patient. The overall assessment of the pharmacies showed that staff at six pharmacies obtained a comprehensive history, one pharmacy obtained a moderate history and four pharmacies obtained poor patient histories. Information commonly omitted from patient histories included allergy and breastfeeding status, and details of the patient's menstrual cycle. Staff at eight pharmacies utilised ECP questionnaires for data collection, of which six determined the mystery patients' reason for ECP request, thus indicating that five pharmacies supplied ECP without a comprehensive understanding of the scenario.

Overall, pharmacies presented with scenario 2 performed better in data collection when compared with pharmacies presented with scenario 1.

### **Provision of Advice**

This theme encompassed all aspects of the provision of medication information relevant to patient including details of dose, adverse effects and advice on management, risks of therapy, follow-up advice, written information (where appropriate), and essential criteria for the specific scenarios.

Essential criteria required for scenario 1 included the provision of information on long-term options for contraception (e.g. the Combined Oral Contraceptive Pill), education on alternative contraceptive methods, and if not supplying the ECP some information on alternatives to non-prescription ECP (e.g. obtaining a prescription from a doctor). The essential criteria required for pharmacies presented with scenario 2 included referral to one or more external agency for review of the patient's situation, including the police to report suspected sexual assault, a sexual health clinic or a doctor for support and testing of sexually transmittable infections and drug testing to examine the nature of the alleged drink-spiking incident.

The ECP was supplied by only two of the 12 pharmacies presented with scenario 1. The majority of the interactions (7/12) involved a pharmacist in some capacity while the remaining five interactions involved pharmacy support staff only. Staff at four of the 12 pharmacies presented with scenario 1 provided moderate patient counselling (two of which supplied the ECP) and the staff at the remaining eight pharmacies provided no counselling. Staff at five of the 10 pharmacies that refused to supply the ECP advised the mystery patient to either return with or send in the female requiring the ECP, while the remaining five pharmacies did not offer follow-up or an alternative option to obtain supply.

A pharmacist was involved in 10 of the 11 scenario 2 consultations, while counselling was provided by a pharmacy support staff in the remaining consultation. Staff at three pharmacies provided comprehensive patient counselling, four pharmacies provided moderate patient counselling and the remaining four pharmacies provided poor patient counselling. Information about the risk of ectopic pregnancy, the need to be tested for sexually transmitted infections and the need for medical follow up were commonly omitted during counselling and only one pharmacist utilised a Consumer Medicines Information (CMI) during the counselling process. Although staff at six of the participating 11 pharmacies determined that the ECP request was as a result of suspected sexual assault (essential criteria), only five of these pharmacies offered a relevant referral to the police or health professional for follow up.

Overall, pharmacies presented with scenario 2 performed better in the provision of counselling when compared with pharmacies presented with scenario 1.

### **Privacy and Confidentiality**

The theme of privacy and confidentiality encompassed details of the physical environment and chosen location within the pharmacy utilised by pharmacy staff for history taking and counselling, degree of privacy provided including distance from other customers and the manner in which the pharmacy staff dealt with the information provided by the mystery patient. The elements of this theme relied heavily on the subjective opinions provided by the mystery patient immediately following the pharmacy interactions.

Of the 12 pharmacies presented with scenario 1 only two were considered to have provided a private consultation for the mystery patient. Of the remaining 10 pharmacies, five provided a consultation environment with a moderate level of privacy with one of the five failing to seek a private consultation area, and four of these five relying on a sense of privacy implied by an absence of other customers in

the pharmacy at the time of the interaction. In five of the pharmacies the staff neglected to seek a private environment for the consultations and provided poor or no privacy. Overall, four of the interactions with the mystery patient took place in front of other pharmacy customers.

Of the 11 pharmacies presented with scenario 2 only two pharmacies provided a private consultation area. Of the remaining nine pharmacies, two interactions offered a moderate level of privacy while the remaining seven interactions did not take place in a private or semi-private environment and hence lacked privacy. The mystery patient noted that overall five of the pharmacy interactions took place in front of other pharmacy customers at very close proximity. Additionally, the mystery patient noted that confidentiality was not adhered to in one of the 11 consultations, with three different staff members dealing with her request and with several staff reading the details of her scenario from the questionnaire while labelling the medication. Following the conclusion of this interaction, the mystery patient indicated that her feelings expressed throughout the interaction were 'ignored', she described a feeling of being 'talked about' and commented that 'there was no understanding of the gravity of the situation.'

Overall, pharmacies presented with scenario 2 performed marginally better in the provision of privacy and confidentiality, when compared with pharmacies presented with scenario 1.

## **DISCUSSION**

The analysed data provided valuable insight into pharmacy practice and suggests that there are identifiable training gaps amongst pharmacists and pharmacy staff with respect to professional and ethical obligations associated with advanced roles in Schedule 3 medication supply.

### **Overall Management of ECP requests**

The participating pharmacies that were presented with scenario 2 rated better than the pharmacies presented with scenario 1 in terms of overall history taking. This outcome was somewhat expected due to the high rate of refusal to supply ECP for scenario 1 as 10 of the 12 pharmacies presented with this scenario refused to supply. The support staff in five of these 10 non-supplying pharmacies did not involve a pharmacist in the process and the decision that the supply was not appropriate was made by pharmacy support staff. Although it could be argued that support staff sufficiently managed these cases as it did not involve supply, this was not best practice as the mystery patient should have been counselled about alternative options and ongoing management. Standard 12 of the PSA's Professional Practice Standards specifically deals with the provision of non-prescription medicines and states that pharmacists are responsible for the safe and judicious use of non-prescription medicines.<sup>17</sup> The need to refer all requests for the supply of a Schedule 3 medicine to a pharmacist is supported by the PSA protocol for providing non-prescription medicines, entitled *What-Stop-Go*.<sup>38</sup>

The majority of the pharmacies presented with scenario 2 obtained a detailed history although certain important information was commonly not requested from the

mystery patient such as allergy and breastfeeding status and details about the menstrual cycle - information needed to determine the necessity for using the ECP. Pharmacies that utilised a questionnaire fared better in obtaining comprehensive histories and pharmacy staff should therefore be encouraged to make use of standard questionnaires to assist them with this process.

The provision of medicine advice, also referred to as medicine counselling, is a pivotal pharmacist's role to promote the quality use of medicines. Standard 3 of the PSA's Professional Practice Standards covers this role, specifying that pharmacists should work with consumers to provide tailored verbal and written information to ensure that consumers have sufficient knowledge and understanding of their medicines and therapeutic devices to facilitate safe and effective use.<sup>17</sup> The counselling involved with ECP supply should include advice about the dosage and administration, potential drug interactions, side-effects and risk of ectopic pregnancy, sexually transmitted infections during unprotected intercourse, ongoing contraceptive measures and the need for appropriate medical follow-up.<sup>22</sup>

The importance to counsel adolescents about ongoing contraceptive measures and sexually transmitted infections have been highlighted in other studies; it was particularly important to cover these aspects in scenario 1.<sup>11, 39</sup> However, staff at four of the 12 pharmacies presented with this scenario provided moderate patient counselling (two of which supplied the ECP) and the remaining eight pharmacies provided no counselling. Although ten of the pharmacies refused to supply the ECP, thereby to some extent negating the need for the provision of detailed advice about the use of the ECP, these staff missed an opportunity to provide information about additional aspects such as the risk of contracting sexually transmitted diseases during unprotected intercourse and ongoing contraceptive measures. Five of the ten pharmacies at which staff refused supply advised the mystery patient to either return with or send the female requiring the ECP. Detailed advice could have subsequently been provided to the female if given the opportunity at these pharmacies.

Pharmacy staff at only three of the 12 pharmacies presented with scenario 2 provided comprehensive counselling: the majority of the staff presented with this scenario provided moderate to poor patient counselling, omitting to mention important follow up information. The data confirms results from previous studies that indicated the majority of pharmacists' ECP counselling did not comply with good practice requirements and that patients received better quality information when they attended a clinical service.<sup>23-24, 32</sup> Of particular interest with regard to the counselling of patients requesting the ECP is that research has shown that some patients are uncomfortable with pharmacists covering detailed information when supplying the ECP and some women prefer pharmacists having a limited role when supplying the ECP.<sup>8, 13, 35</sup> In contrast, a study of pharmacists' perceptions of their role when supplying the ECP indicated that pharmacists thought it was part of their role to counsel about future contraception and sexually transmitted infections. Although pharmacists therefore view it as part of their role to provide detailed counselling during the supply of the ECP, the majority of pharmacists in this study did not provide detailed counselling. This could be due to workload and time pressures to dispense medicines.<sup>19</sup>

Almost half of the pharmacies presented with scenario 2 did not collect sufficient information from the patient to realise that it was suspected sexual assault and of additional concern is that one of the six pharmacies that did establish this did not offer a referral. This aspect was not managed and should be addressed in order for community pharmacy to provide quality ECP support.

### **Privacy and Confidentiality Requirements**

ECP consultations should be conducted in a private or semi-private consultation area to ensure that personal details could not be overheard. However, only four of the 23 participating pharmacies provided a private consultation area with five scenario 1 pharmacies and two of the scenario 2 pharmacies providing a semi-private area. A significant number of both scenarios 1 and 2 interactions took place in front of other customers at very close proximity. These results support previous research and the lack of pharmacy privacy is an area of concern that requires follow-up intervention by either changing pharmacies' layout to create a professional services area, using of barriers or having an available area away from pharmacy traffic.<sup>13, 23-24</sup>

There is a combination of legal, professional and ethical obligations on pharmacists to comply with privacy and confidentiality principles, which is particularly important when providing sensitive consultations such as ECP counselling.<sup>40-41</sup> Access to patients' private and confidential information is based on the therapeutic relationship which exists between consumers of health services and health professionals who care for them. Pharmacy staff needs to comply with confidentiality requirements, honour the sensitive nature of the information and create the perception that patients' information will be kept confidential. Almost all of the pharmacy staff created a perception of confidentiality although this perception was not adhered to in one of the scenario 2 pharmacies and the mystery patient indicated that her emotional feelings were being ignored and talked about by staff members.

### **Legal Requirements and Ethical Principles**

All of the participating pharmacies had ECP stock and none of the staff members raised issues of conscientious objection. Although this area has been highlighted in other studies and there have been international court cases involving pharmacists' right to deny ECP supply, this was not identified as an issue with the participating pharmacy staff.<sup>4, 42, 43</sup>

Of the five pharmacies presented with scenario 2 that established the involvement of suspected sexual assault, only one pharmacist offered to phone the police. This pharmacist asked the patient for permission to do so and although the mystery patient said that she was on her way to the police and did not consent to the pharmacist contacting the police, the pharmacist phoned the police after she left the pharmacy (the pseudo-nature of the patient was subsequently clarified with the police). This situation required the pharmacist to weigh up the ethical principle of patient autonomy to decide what to do and the legal grounds to report the suspected rape to the police without the patient's consent and the pharmacist chose the second option.

Scenario 1 entailed a third party request for advanced supply, involving grey areas in terms of legislative requirements, requiring staff to use professional judgement regarding the suitability of supply.<sup>1</sup> In terms of this scenario, it could be argued that non-supply of the ECP was not in the best interest of the female patient. Principle 1 of the Code of Ethics for Pharmacists covers pharmacists' obligation to recognise the health and wellbeing of the consumer as their first priority and the need to utilise expert knowledge and provide care in a compassionate and professional manner.<sup>41</sup> It is uncertain whether the pharmacy staff involved with scenario 1 that decided against supplying based their decisions on legislative direction rather than the ethical obligation to provide care that is in the best interest of the patient. Research that involved an understanding of pharmacists' decision-making when confronted with ethical challenges experienced in pharmacy practice similarly indicated that ethical intention was compromised by frequent concern about legal prosecution.<sup>36</sup>

Pharmacists' ethical reasoning and understanding has been reported to be relatively limited and legalistic<sup>37</sup> with little appreciation for ethical principles when compared to the medical profession.<sup>36</sup> This study highlighted the need for targeted ethical training for all pharmacy staff and support to apply ethical reasoning in practice.

### **Study limitations**

There is a limited ability to generalise the results to all community pharmacies as the participants represented a relatively small sample of community pharmacy staff and the geographical area was limited. Pharmacies were only visited once and the staff available to manage the ECP request and other circumstantial factors occurring on the particular day or time may have impacted on the counselling processes observed.

A limitation of the mystery patient approach was that staff at the participating pharmacies could have had an expectation of the mystery patient visit and this could have influenced their behaviour, the so-called Hawthorne effect.<sup>44</sup> This effect was somewhat minimised through omitting the medication in focus during recruitment, staff not knowing the specific date of pharmacy visits and by presenting a scenario to pharmacies on the same business day to limit inter-pharmacy discussions.

Another limitation with the simulated patient methodology relate to the recording of the pharmacies' performance that relied on the mystery patients' recollection of the interactions. To minimise this limitation the assessment tool was completed immediately post the interactions to maximize recall.

### **CONCLUSION**

Community pharmacy staff may not be sufficiently prepared for legally and ethically challenging ECP requests. Further ongoing training is required across the profession in order to enhance the skills, competence and confidence of pharmacy staff in managing complicated requests for non-prescription medicines. However, the impact of time pressures and financial burdens on the quality of pharmaceutical services need to be acknowledged. More studies could enable development of training tools and support mechanisms to address identified practice shortcomings.

## **Acknowledgements**

This project was supported by a Griffith Health Institute grant. The authors gratefully acknowledge the support from the two mystery patients, the input from the six focus group members and the willingness of the 23 community pharmacies to participate.

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