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Original research article

Mifepristone (RU486) in Australian pharmacies: the ethical and practical challenges☆,☆☆,★

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Abstract

Objective: The recent legalization of mifepristone has given women in Australia a new option for termination of pregnancy. Pharmacists are well positioned to provide information and supply mifepristone for patients. However, there are ethical and legal concerns in Australia regarding the supply of mifepristone, as pharmacists may choose to conscientiously object to supplying mifepristone and are subject to differing abortion laws between states and territories in Australia. The objective of this study was to explore attitudes and knowledge of Australian pharmacists about mifepristone.

Study design: Semistructured interviews were conducted with 41 registered pharmacists working in a pharmacy or hospital in Sydney, Australia. When data saturation was achieved, audiotaped transcripts were deidentified and transcribed verbatim. Data were thematically analyzed using a framework approach for applied policy research and categorized into the following themes: contextual, diagnostic, evaluative and strategic.

Results: Analysis of the transcripts yielded four themes: (a) pharmacists' **contextual** view on pregnancy termination, the role of the pharmacist and impact on the pharmacy workplace; (b) **diagnostic** reasons for differing views; (c) **evaluation** of actual and perceived pharmacy practice in relation to the supply of mifepristone and (d) **strategies** to improve pharmacists' services, awareness and education.

Conclusion: Australian pharmacists in this study perceived themselves to have a potentially important role as medicine experts in patient health care and safety in medical termination of pregnancy. However, there was a general lack of clinical, ethical and legal knowledge about medical termination of pregnancy and its legislation.

Implications: To ensure patient safety, well-being and autonomy, there is an imperative need for pharmacist-specific training and guidelines to be made available and open discussion to be initiated within the profession to raise awareness, in particular regarding professional accountability for full patient care.

Keywords: Abortion; Conscientious objection; Continuity of care; Pharmacy practice; Australia

1. Introduction

Every year, 80,000–85,000 Australian women undergo a surgical abortion [1]. Few had access to medical termination of pregnancy (MTOP) [1], defined as "pregnancy termination performed without primary surgical intervention, resulting from the use of abortion-inducing medications" [2]. In August 2012, after years of political opposition due to religion-based conservatism and objection to abortion, the Therapeutic Goods Administration (TGA) in Australia finally approved a combination of mifepristone (a synthetic antiprogestin for contraction induction and detachment) and misoprostol (a prostaglandin analogue for expulsion of the embryo) for termination of pregnancy at up to 49 days' gestation [2–5]. This combination has been used for MTOP in over 46 countries, including the United Kingdom, United States, New Zealand, China and Europe, since 1988 [5,6].

The mifepristone/misoprostol combination was added to the Commonwealth Pharmaceutical Benefits Scheme as a

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subsidized medicine in August 2013, thereby facilitating accessibility of MTOP for Australian women. This clearly signaled the necessity for pharmacists to be informed about mifepristone/misoprostol, including the legal framework within which it is prescribed and dispensed [4]. In some jurisdictions, abortion is now legal, but laws still differ across states and territories of Australia. In states where abortion remains illegal, it is a concern for health professionals providing MTOP [4]. The sponsor of the products (Marie Stopes International Australia) has advised that prescribers and pharmacists must comply with abortion laws within their state of practice [7].

Prescribing is authorized for physicians with a Fellowship or Diploma of the Royal Australian and New Zealand College of Obstetricians and Gynaecologists without any further training [3] and also for physicians in other specialties who have completed the Marie Stopes Two Step (MS 2-Step) Program [8]. The commercial supply of mifepristone/misoprostol is organized and distributed by MS Health, a sector of Marie Stopes International Australia [9], for pharmacies "nominated by and in agreement with a certified medical practitioner" [3].

To dispense mifepristone/misoprostol, a pharmacist must be registered with the program, ensure the prescriber is a certified physician, and confirm that the procedure has been fully explained and a consent form has been signed by the patient. Pharmacists also provide the patient with a consumer medicines information leaflet for Mifepristone Linepharma® (mifepristone) and GyMiso® (misoprostol) [10]. Currently, there are no further guidelines for pharmacists to refer to for patient care regarding these medications.

Importantly, abortion being a controversial issue, a pharmacist's personal values, spirituality or moral principles may potentially disrupt a patient's access to the abortifacient. In Australia, conscientious objection, defined as "the refusal to perform a legal role or responsibility because of moral or other personal beliefs" [11], is recognized in the Pharmaceutical Society of Australia's Code of Ethics [12]. The code states that, in the event of conflicts with personal/moral beliefs, the pharmacist has "the right to decline provision of care … [but] should inform the consumer of the objection and appropriately facilitate continuity of care" [12], thereby avoiding paternalism or impeding access. The essence of pharmacy practice is to care for patients' health, and it is considered "professionally inappropriate for health care providers who *step away* from services to then *step between* a patient and another health care provider" on purpose or by negligence [11,13]. Thus, the concept of continuity of care is of particular importance in the context of conscientious objection to supply of an abortifacient in the pharmacy setting.

It is not clear how pharmacists in Australia have adopted to the recent registration of the abortifacient and whether there will be wide uptake of its provision in community pharmacies. To date, there has been no study exploring attitudes and knowledge about mifepristone/misoprostol among Australian pharmacists. The aim of the study was to explore the attitudes and knowledge of Australian pharmacists about mifepristone/misoprostol.

2. Materials and methods

2.1. Sampling and data collection

Semistructured interviews were conducted with a random sample of pharmacists from the Pharmacy Board Register of Pharmacists [14]. The interview protocol (Table 1), based on published literature [13,15,16] and the new TGA approval of mifepristone, was pilot-tested with three practicing pharmacists. Interviews were audiotaped, deidentified and transcribed verbatim. The transcripts were thematically analyzed with the assistance of the software data management package Nvivo10 (2013; Australia) in an iterative process, reviewing transcripts as they presented, which allowed for slight modification of interview questions as themes emerged. Interviews were continued until data saturation was achieved.

2.2. Data analysis

Transcripts were thematically analyzed using the qualitative framework analysis approach for applied policy research [17]. The framework approach aims to explore and understand complex behaviors, needs, systems and cultures to develop a social policy by categorizing data into four main themes: contextual, diagnostic, evaluative and strategic. The data were reviewed independently by the interviewing researcher first and then again by each of the two supervising researchers separately. The emerging themes were discussed in depth among the researchers until consensus was reached.

3. Results

A total of 63 community pharmacies in Sydney were visited, and 40 pharmacists consented to be interviewed, while 33 pharmacists refused. Of the 33 pharmacists who refused (18 female, 15 male), some claimed to be too busy to participate (n=17), others felt they did not know enough about the topic (n=4), and some were not interested in participating (n=12).

One further interview was conducted with a hospital pharmacist for insight into pharmacy practice in a different setting.

Table 1
Key themes of the semistructured interview protocol

Interview protocol
• Opinions of termination of pregnancy and mifepristone
• Moral objections
• Opinions of dispensing mifepristone
• Perception of the legal issues regarding abortion and the dispensing of mifepristone
• Perceived role of pharmacist in regard to mifepristone availability in the pharmacy
• Interests in learning more about mifepristone