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RESEARCH ARTICLE

Pharmacist supply of sildenafil: pharmacists' experiences and perceptions on training and tools for supply

Rhiannon Braund[1] · Kaushalya Ratnayake[1] · Katie Tong[1] · Jackie Song[1] · Stephen Chai[1] · Natalie Gauld[2]

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Abstract

Background In 2014, New Zealand reclassified sildenafil (for erectile dysfunction) to allow supply by specially trained pharmacists under strict criteria. *Objective* The study aimed to determine pharmacists' experiences and perspectives on the training for, and supply of sildenafil under this model. *Setting* New Zealand community pharmacy. *Method* This qualitative study captured data with a semi-structured interview used with purposively-sampled participants. A maximum variation sample was used to select a wide range of pharmacists working in various pharmacies, including pharmacists who were trained to provide sildenafil and those not trained to supply sildenafil. Consenting pharmacists were interviewed, with interviews audio-recorded and transcribed. Analysis used a framework approach. *Main outcome measures* Topics explored included: satisfaction and experience of the training; suitability and usability of the screening tools; experiences of the supply process and why some pharmacists chose not to become trained. *Results* Thirty-five pharmacists were interviewed. Training was seen as uncomplicated and the screening tools provided confidence that key consultation areas were covered. Most consultations reportedly took 15–20 min, some up to 60 min. Pharmacists reported being comfortable with the consultations. Many men requesting supply fell outside of the parameters, resulting in medical referral. This new model of supply was seen as a positive for pharmacists and their patients. Unaccredited pharmacists reported a perceived lack of interest from men, or ability to provide the service as reasons for not seeking accreditation. *Conclusion* New Zealand's model of pharmacist supply of sildenafil appears workable with some areas for improvement identified.

Keywords Community pharmacy services · Erectile dysfunction · New Zealand · Pharmacist's training · Reclassification · Sildenafil

Impacts on Practice

- The provision of accessible and thorough training in conjunction with appropriate screening tools gives pharmacists confidence to work in the are of erectile dysfunction.
- The increased clinical component of the New Zealand supply model, specifically the cardiovascular risk assessment, and the enhanced access to sildenafil is seen as positive for both pharmacists and patients.
- The New Zealand model for sildenafil supply can enhance the primary care role played by community pharmacists.

Introduction

Pharmacy and pharmacists' roles in widening access to medicines are enabled by the international trend for prescription to non-prescription medicine reclassification [1]. Benefits of reclassification include timely self-management of common conditions, and reducing pressure on doctors and health funding [2–4]. A wider range of medicines without

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✉ Rhiannon Braund
rhiannon.braund@otago.ac.nz

[1] University of Otago, PO Box 56, Dunedin 9054, New Zealand

[2] University of Auckland, Private Bag 92019, Auckland 1142, New Zealand

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prescription, e.g. vaccinations and emergency contraception allows pharmacy to play a greater role in community health care.

While traditionally for minor self-limiting and self-diagnosable conditions, reclassifications now include medicines for chronic conditions. Examples include simvastatin and tamsulosin in the United Kingdom (UK), oxybutynin in the United States (US), and calcipotriol in New Zealand (NZ) [1]. However, there seems to have been limited uptake [5–8]. Pharmacists have been more comfortable managing acute conditions than chronic [8]. Doubts about the time taken with screening tools have been expressed [8, 9]. Research is needed around acceptability of reclassified medicines for chronic conditions and their models of care.

Following applications from Douglas Pharmaceuticals, sildenafil (up to 100 mg) was reclassified in New Zealand (NZ) in 2014 to allow supply by specially trained pharmacists under strict criteria [4]. Poland followed in 2016 with 25 mg tablets [4]. Sildenafil is used for erectile dysfunction (ED), a persistent inability to achieve or maintain an erection sufficient for satisfactory performance [10]. Reclassifying ED medicines might address unmet clinical need, reduce illicit supplies, and result in pharmacists screening men e.g. for hypertension, and referring for a medical check-up [10, 11]. ED is a common sexual health disorder, affecting quality of life and relationships [12, 13]. It is uncommon in men under 40 years (1–10% prevalence), increasing with age to 20–40% in ages 60–69 years, and 50–100% in men 70 years and over [14]. With 80% having underlying causes such as vascular changes [10], ED is typically a chronic condition.

Predisposing factors to ED include hypertension, atherosclerosis, hyperlipidaemia, cigarette smoking, and diabetes [15, 16]. ED can indicate cardiovascular disease, particularly in men under 60 years [18]. Early presentation enables lifestyle advice, medical review and encouraging adherence to treatments for underlying conditions. However, many men delay discussing, or never discuss their ED with their doctor [17, 18]. Some men purchase online treatments instead [19], but much internet-supplied sildenafil is counterfeit [20], and typically no health professional consultation occurs. Men may consider that it is not a medical issue, be embarrassed, or be unwilling to pay for a doctor's visit [21]. Doctors often do not raise the topic with patients [22, 23]. Thus, ED is under-diagnosed and under-treated which pharmacist-supply might help.

Phosphodiesterase 5 inhibitors (PDE-5Is, including sildenafil) are recommended first-line for ED [12] with good efficacy and tolerability [16].

In NZ, sildenafil became available from specially trained pharmacists for the treatment of erectile dysfunction, in males aged 35–70 years [24]. An extensive screening tool helps identify the low-risk population of men suitable for supply. Exclusions include men who smoke cigarettes, have had a heart attack or stroke, or many other heart conditions, are taking certain medication, have penile deformation, or are outside defined parameters for pulse and blood pressure. These men would receive medical referral without sildenafil supply. The pharmacist conducts a full screening at first supply and annually thereafter. Resupply prompts questions about changes in health and medication, adverse effects and efficacy. Consultations and supplies are documented, and the man's usual doctor is informed of supply, unless he opts out. The Pharmacy Council's protocol for pharmacist-only medicines for chronic conditions applies, including privacy, comprehensive documentation, and providing the patient written and verbal information [25].

Distributors of sildenafil each provided on-line training programmes approved by the Pharmaceutical Society of New Zealand (Douglas Pharmaceuticals, Pfizer and Mylan). All included pathophysiology, diagnosis, referral, treatment of erectile dysfunction, sildenafil dosing, contraindications, interactions, side effects, patient counselling points, and a test which must be passed to supply sildenafil without a prescription.

The companies provide screening tools with similar exclusion information. All tools prompt the pharmacist to refer men for a cardiovascular and diabetes screening if he has not had one recently. The Douglas Pharmaceuticals tool included other advice point prompts and recorded resupply details, but the other two tools did not. Only Douglas Pharmaceuticals provided a patient information sheet specific to pharmacist-supply.

In NZ, some reclassified medicines are limited to pharmacists who have undertaken additional training, typically with strict criteria for supply, an extended consultation, and documentation. Such "controlled pharmacist-supply" [4] is developing internationally, for example, with pharmacist-delivered vaccinations [26] and oral contraceptives in some US states [27] and availability of various medicines through pharmacists under patient group directions in the UK [4]. Research supports the use of this model in vaccination [28], for oral contraceptives [29, 30] and with trimethoprim [31, 32]. There is no knowledge of this model's workability for managing erectile dysfunction, and little evidence on pharmacists' perceptions and experiences with reclassified medicines for chronic conditions, apart from simvastatin in the UK [33, 34].

Aim of the study

This study had three aims, to ascertain across a diverse range of pharmacists and community pharmacy practice settings:

1. Pharmacists' experiences and perceptions of non-prescription sildenafil supply.

2. Pharmacists' perceptions and experiences of the sildenafil training programme and tools for supply.
3. Why some pharmacists chose not to become sildenafil-accredited.

Ethics approval

University of Otago departmental-level ethical approval (Reference 10/16), Māori consultation (Reference 18923).

Method

This qualitative study captured data with a semi-structured interview used with purposively-sampled participants. This interview guide contained both closed questions (to gather demographic and service specification information) and open questions to gather narratives from individuals regarding their experiences and perceptions on the new service, the training, and the impact of the service. Diversity of the sample was intended to gather as many different experiences or "stories" as possible, a maximum variation sample [35]. Pharmacies were selected from throughout NZ, from the remotest rural pharmacies to central business city pharmacies; low, mixed or high socio-economic areas, and areas with high indigenous population. The sample included single (sole-charge) through to pharmacies employing multiple pharmacists, pharmacies varying in opening hours and locations (e.g. attached to medical centres, within malls and on streets of shops. Breadth in the pharmacists was also sought, including pharmacy owners, or managers, full-time and part-time employees, and locums, ethnic diversity, male and female, and differing years of experience. Personal acquaintance provided about a third of the pharmacists or pharmacies selected, including some known to be particularly information-rich [35] regarding sildenafil. Other pharmacies were selected purposively on different locations from the Healthpoint website (which identified pharmacies providing sildenafil), cross-referenced with the Otago Health Sciences Urban–Rural Profile to ensure geographic diversity. Non-accredited pharmacists were recruited via a NZ Pharmacy Online Forum. Rather than aiming for data saturation, the intention was to compare and contrast and obtain stories and perspectives from as diverse pharmacies and pharmacists as possible. A total of forty pharmacists were invited to participate.

Pharmacists were sent an information sheet, and consent form, then telephoned. Pharmacists who consented verbally or in writing, were interviewed in-person or by telephone.

The questionnaire ("Appendix A") covered demographics and semi-structured questions to determine the experiences and perceptions of the participants. Questions were determined based on the model of supply published literature [31, 33, 34]. A pilot interview (excluded from analysis) with an accredited pharmacist confirmed the questionnaire's suitability.

Questions for the non-accredited pharmacists primarily captured reasons for not becoming accredited.

Final year pharmacy students (SC, KR, JS, KT), including one male (SC) completed all sildenafil training programs before conducting interviews.

Interviews were audio-recorded and transcribed verbatim. All authors read all interviews multiple times, before and during analysis and reporting. Analysis used a framework approach [36]. Quotes from the interviews were combined under the topics identified to provide an indication of responses that were common across much of the group through to participants who answered differently. Particular attention was paid to areas of agreement and areas of disagreement to determine commonalties and divergence. Any disagreement between researchers was resolved through discussion. Case studies were developed to illustrate differences between pharmacies and provided greater depth.

Results

Thirty-five pharmacists participated in this study, covering rural (n = 8), and urban (n = 27) pharmacies. The pharmacies in which these pharmacists worked included three in tourist towns, two in communities with high Māori populations, one in an area with a high proportion of Pacific peoples, and one in an area with a high proportion of Asian immigrants. Three pharmacies were within supermarkets, four within malls, and one was an after-hours pharmacy. Table 1 provides participant demographics. Most, 24, (69%) were male. The pharmacies involved employed up to six pharmacists, most commonly three pharmacists (29%). Participants were full-time employees (n = 16), owners (n = 10), locums (n = 5) or part-time employees (n = 2).

Training

Pharmacists considered the training uncomplicated, noting convenience and accessibility of on-line availability, although a couple would prefer face-to-face contact over the web-based training for asking questions. Some wanted more detail e.g. on breaking tablets, or wanted the addition of case studies or more assessment questions in the training. Almost all participants reported the training was sufficient for dispensing sildenafil and included all the necessary material.

Newer graduates did not differ in their views of the training to those pharmacists who received their undergraduate training many years before. One pharmacist did not like the pharmaceutical companies providing the training,

Table 1 A summary of the demographics of the interviewed pharmacists

Pharmacist	Accredited: Y/N	Gender: F/M	Year(s) of experience	Ethnicity
1	N	F	5.5	Chinese
2	Y	M	17	NZ European
3	Y	M	35	NZ European
4	N	M	5	African
5	Y	F	41	European
6	Y	M	20	NZ European and Maori
7	Y	M	29	NZ European
8	Y	F	29	NZ European
9	Y	M	7	Chinese
10	Y	F	5	Egyptian
11	N	M	5.5	NZ European
12	Y	M	7	Chinese
13	Y	M	36	European
14	Y	M	6	Pacific Islander
15	Y	M	34	NZ European
16	Y	M	2.5	Cambodian
17	Y	M	35	European
18	N	M	13	NZ European
19	Y	M	26	NZ European
20	Y	F	20	NZ European and Maori
21	N	F	7	NZ European
22	Y	M	35	NZ European
23	N	M	15	Middle Eastern
24	N	F	23	NZ European
25	Y	F	4	NZ European
26	Y	M	1	Indian
27	Y	F	2	Malaysian-Chinese
28	Y	M	13	Chinese-New Zealand
29	Y	M	3.5	NZ European
30	Y	M	36	NZ Maori
31	N	F	6 months	NZ European
32	N	M	9	NZ European
33	N	M	55	European
34	Y	M	4	Korean–New Zealander
35	Y	F	3.5	NZ European

and preferred the Pharmaceutical Society run the training instead; another thought the assessment too easy.

> I don't like the way that the companies sort of did the…trainings,… even though it was done in conjunction with the Society, I think the Society should've done one outright…. you sort of just feel like, they're making it sort of easy to pass so that they can sell more products. [P6, employee pharmacist, suburban pharmacy, Male].

No participants expressed any negativity or concerns about the requirement that only pharmacists with the training could supply sildenafil.

Consultation process

All pharmacists reported using an approved screening tool at all initial patient consultations. Some preferred the screening tool that included counselling points and recorded resupply details. Several pharmacists avoided asking the question about a deformed penis.

Pharmacists' estimated the initial consultation ranged from 5–10 min (2 pharmacists) to 30–60 min (one pharmacist), with 15 or 15–20 min most commonly reported. Generally pharmacists managed to fit in the consultation around other work. Most pharmacists saved time by asking certain questions first, particularly smoking and age, and also other

medications taken, identifying common reasons for referral. One participant had men self-complete the form.

> …the people … are really embarrassed. I have to calm them down quite a lot before they can actually start answering all the questions. [P26, pharmacy in a supermarket, Male]

Consultations were conducted in a private consultation room, except for two pharmacies using a private area, one of which had stopped supplying sildenafil.

Most pharmacists reported providing written information for sildenafil pharmacist-supply at the initial consultation. However, some did not know they were expected to provide written information.

The patients

Overall, pharmacists tended to report that Caucasian men above fifty presented most frequently. Other ethnicities such Māori, Pacific Islander and Indian were reported. Men from East Asia were thought to be less likely to present for sildenafil, one male Indian pharmacist speculated this was because they were too embarrassed.

For most pharmacies the men requesting sildenafil were usually locals, often men dispensed prescriptions from their pharmacy before. A few pharmacists saw some people from further afield. Two pharmacists in tourist areas reported little supply to tourists, another reported stopping supply, being uncomfortable supplying to tourists.

> We've got no knowledge of their backgrounds or anything else like that. Um, we're likely to see them once only. And so, we figured that to get any any health information's going to be an issue for us. Apart from what they just choose to choose to tell us… And so we decided that it's easier for us to just to send them to the local doctors, who are pretty obliging about writing prescriptions for that. [P05, tourist town pharmacy, Female]

Men outside of the criteria for supply

Many pharmacists estimated that over half (range 10–80%) of new requests for sildenafil resulted in medical referral without supply, commonly because of smoking, age over 70 years, or elevated blood pressure, occasionally diabetes and multiple medications were mentioned. Some pharmacists never saw the referred men again, while others reported some or most returning with a prescription after consulting a doctor.

> there is quite a number we're actually referring to the doctor… because of the, underlying heart issues and there's been a few, couple with their blood pressure, doesn't meet the criteria, so they've been referred to the doctor, so again, it's an opportunity to discuss with the individual. And you know, one of them's actually looked at going on smoking cessation, 'cos he … couldn't buy it over the counter… but he got it on prescription eventually. [P2, Rural pharmacy, Male]

Several pharmacists noted refusing men under 35 years old, often thought not to be genuine.

> there are people who do come when they don't need it, … in their 20s or early 30s, just to get their own boost, and obviously it's a medication not for those reasons. So in those cases you just say no. [P34, City pharmacy manager, Male]

A small minority of participants reported their belief that a patient had lied to them, e.g. to fit under the 70 year age limit, or about smoking. These pharmacists reported refusing these supplies and referring to the doctor.

Resupplies

Many pharmacists reported using the resupply checklist, some opting for a conversational approach involving major factors requiring consideration or a general check that all was okay. Most utilised the screening tool and the dispensing computer when resupplying, but one noted inefficiencies finding the form.

Some used ways to reduce embarrassment to the man. One mall pharmacy made up a card themselves for patients to show when presenting to avoid needing to ask for sildenafil aloud, and reduce embarrassment.

Some men wanting resupplies from a different pharmacy were surprised to need another full consultation.

All but one pharmacist reported conducting the full consultation annually. Some noted this consultation was easier and patients were more comfortable. One pharmacist reported patient displeasure at sitting through a consultation again. Another pharmacist reported increased blood pressure at the annual consultation prompting a medical referral.

Number of supplies

Twenty participants estimated usage. Supplies varied from under one supply per month to 30 or more packs per month. Some pharmacists were surprised by low demand; about half had fewer than 6 requests per month.

> I would, I would've expected more but I'm not surprised by the amount that has come in. I feel like it's fairly stable now…. whenever it's on TV you always get a little bit more interest, like it's amazing that effect of TV adverts. [P25, Supermarket pharmacy employee supplying few packs, Female]

Pharmacists reported charging for initial consultations NZ$15 to $45 (US$11-33), mostly $35. The supermarket pharmacies; some rural pharmacies; and an urban pharmacy charged no fee. Most participants reported charging $32-40 (US$23-29) for 4 tablets.

Additional comments

Most pharmacists supplying sildenafil were positive about their experiences, despite early apprehension for some.

> it's probably exceeded [my expectations] 'cos I was a bit sceptical, I wasn't quite sure what we were going to be in for and whether we were going to get lots of the recreational type users… but actually what we've found is that by and large, we're making a real difference for some people … one person that, came back, to get his repeat, he thanked us profusely and said, that it's just made such a difference and now his relationship, it was the one thing that it's, been been missing, I remember him saying he hadn't been able to have sex for two years. …. it's been really quite um… satisfying…. [P3, Rural pharmacy owner, Male]

Managing workload arose often, particularly for those in a sole pharmacist position. Some pharmacists appreciated the openness of the conversation, and sharing of very personal information.

> I guess it's sort of a joy to sort of improve the health of the community just in general. The downside is that sometimes it can be a little bit awkward, you know, the conversation can get quite graphic, and it does take time … when we are really busy. [P12, locum in a city mall pharmacy, Male]

Some appreciated the resulting patient rapport, and ability to engage with and help men, e.g. a patient concerned about effects of his ED on his marriage.

> I've built up a really good relationship with the guys that come in. So it's nice to be able to, you know, greet them by their first name and just have a chat. And it's nice that they don't feel awkward sort of talking to a youngish woman about too. Yeah, I'm really pleased I've done it. [P35 – Employee pharmacist in a suburban pharmacy, Female]

Two pharmacists who worked as locum sole charge pharmacists only at the weekend in city pharmacies, with limited opportunity to get to know patients, and limited staffing were positive, but reported downsides of not knowing the patient and having to refer men.

Some pharmacists noted additional benefits, such as easier access and no appointment for consumers, and upskilling and raising pharmacists' profile.

One pharmacist considered pharmacist-supply safer than online products, including herbal remedies containing undeclared PDE5 inhibitors.

Some pharmacists mentioned the opportunity for referring men for cardiovascular checks, including men who *"hadn't been to the doctor for a very long time"*.

> I actually use the sildenafil supply to have a really good cardiovascular risk assessment conversation. I often talk to them about the fact that the penile blood vessels are the smallest vessels in the body and they then therefore get atherosclerosis easier than everywhere else. And I like the fact that it goes through the psychological implications and I think it's been a very positive thing in many ways 'cos it's giving that information to a very high-risk population really. [P8, Pharmacy owner in a high-Māori rural area, Female]

In contrast to other positive rural views, one male rural pharmacy owner with few supplies, considered it useful for some, but a *"bit of a waste of time"* for most.

Supply criteria

No pharmacists complained about operating within the supply criteria, but some suggested changes or questioned criteria (e.g. heart rate, smoking). A few pharmacists mentioned *"grey areas"* around the restrictions, particularly smoking. Noting it was not a restriction for doctors, these pharmacists wondered if it was strictly necessary, but reported adhering to it.

> …why are we being so restrictive about it and whether these reasons are that for a person's quality of life, like if it's really important to have for them to have that erection and carry on the relationship with their partner, and you're telling them no because you have high blood pressure or because you're a smoker, is that really fair? [P10, Employee pharmacist in a mall pharmacy, Female]

One pharmacist recalled a patient who had recently undergone surgery but without a recent heart and diabetes screening, therefore having to be referred.

Involvement with doctors

All pharmacies had referred some men to the doctor, some of whom returned with a sildenafil prescription after a medical consultation. While pharmacists were expected to inform the GP of supply to patients, one pharmacist reported men opting out of this.

Others had 2-way communication, e.g. confirming blood pressure with a doctor after an elevated in-pharmacy reading. Some pharmacies, including 3 rural pharmacies with

relatively high supplies, and a city mall pharmacy, reported doctors referred men to the pharmacy, although some were outside of the criteria and referred back.

Two pharmacists reported written authority from doctors to supply sildenafil to specific patients outside of the criteria: "…this person had … a type of leukaemia… he got his specialist to write me a letter, to say that it was okay for him … But that put me in an awkward position 'cos I wasn't sure whether that was going to cover me or not." *[P6, Rural pharmacy owner, Male]*.

Unaccredited pharmacists or those not supplying

The 10 unaccredited pharmacists had various reasons for not doing the training. Some locums had trouble accessing the training or worked little in community pharmacy. Two pharmacists thought a doctor should supply it rather than a pharmacist, and a female pharmacist was concerned about the topic sensitivity. Three female pharmacists preferred their male co-workers supply it. One rural pharmacy owner noted likely low demand, preferred not to upset the local doctor, and had no consultation room. One pharmacy was too busy to provide the service, and a pharmacy owner in a tourist town (who became accredited then chose not to supply) was busy and uncomfortable supplying to tourists without knowing their medical history. One participant liked that pharmacists could opt out of providing the service. None indicated a personal belief against sildenafil use for erectile dysfunction.

Discussion

This study provides important insights into pharmacists' experiences and opinions with the first-in-world sildenafil reclassification. The sildenafil model appeared workable and acceptable for pharmacists, consistent with experience in NZ with trimethoprim [31] and oseltamivir [37, 38], and elsewhere with vaccinations [39]. It contrasts with UK findings of less support for reclassifications of medicines for chronic conditions versus acute [8]. Possibly pharmacists were comfortable after additional training; see ED treatment as episodic rather than chronic; or have become used to controlled pharmacist-supply.

This study did not find personal beliefs about ED medication were generally an issue with non-supply, unlike the emergency hormonal contraceptive [40]. Those with insufficient capacity or other concerns can choose not to become accredited, and some pharmacies deliberately opted out. While resulting in variable consumer access, pharmacies lacking resource to provide a quality service do not have to supply it.

While many had time pressures, most reported initial consultations of around 15 min each. Charging the patient for the consultation might help. That some preferred the more comprehensive screening tool was interesting given previous concerns about questionnaires in busy pharmacies [9]. Symonds et al. [41] found pharmacists could generally use a screening tool to ascertain if sildenafil was appropriate. In an Australian mystery shopping study [42], a written checklist for the emergency contraceptive improved the consultation quality and consistency, but did not improve advice for the single scenario tested, and consultation time seemed short. Our findings contrast with pharmacists' concerns in the UK about sufficient resource and discomfort with using guidelines to provide simvastatin in the pharmacy [34].

Pharmacists appeared comfortable with many doctor referrals, perhaps because they had similar experience with trimethoprim [31], expected it from the training, or were identifying men needing referral efficiently. Some pharmacies with more supplies received referrals from doctors. These tended to be in rural areas and may represent a closer relationship between the professions in a close-knit community, or pressure on general practice. However, one rural pharmacist reluctant to provide the service, worried about his relationship with the local doctor. Discussing new services with local doctors might aid a collaborative approach to helping the community access healthcare needed, as sometimes occurred. This collaborative model would be strengthened if doctor's approval of supply to men outside of the criteria was enabled, currently not within the expectations of the reclassification.

Pharmacists were largely satisfied with the training, although locums need access, and it could have been more extensive. Pharmacists have accepted upskilling for new services through training before [31, 43].

Information specific to pharmacist-supply, including the potential for underlying conditions, when to see the doctor, and lifestyle advice can usefully support the pharmacist's verbal advice. For pharmacist-only medicines for chronic conditions, the Pharmacy Council of NZ advises providing verbal and written information. However, some pharmacists seemed unaware written information was needed. All companies or pharmacy organisations could provide written information, and/or ensure pharmacists know to provide written information. All screening tools could include prompts for advice.

We found reported instances of lying, e.g. regarding age or smoking, causing refusal of supply if discovered. Possibly some criteria could be reviewed, e.g. 70 years maximum age, if safe. Some men under 35 years were thought to be wanting it for non-medical reasons (reflecting the low incidence of ED in this age group) [14] and the minimum age limit appears to help minimise inappropriate use. A Spanish study [18] found similar proportions of men without ED seeking

supply of ED medicines from the pharmacy with or without a prescription (7% for both), but ages were not provided.

Supplies varied by pharmacy, which we speculate might relate to pharmacist management of the consultation and local need. In Spain, many men first discuss their ED with a pharmacist rather than a doctor [18] suggesting a level of comfort with pharmacists. Private consulting rooms should aid these conversations, as with tamsulosin in the UK [44].

The study strengths include the number and diversity of participants and their localities. There is a potential for responder bias, particularly where the pharmacist wanted to be viewed in a favourable light or may not have reported behaviour they knew was inappropriate. The interviewers would usually not have been known by the participant, reducing social desirability bias, and some did report behaviour that was not within the guidelines, or reported brief times for consultations. The relatively inexperienced interviewers may not have probed for further information where indicated. The sample was designed to reflect diversity, not be representative of NZ pharmacist and pharmacy demographics.

Further research should explore the frequency of, reasons for and outcomes of referrals, men's experiences of supply, and effect on demand for online ED medicines. Mystery shopping could ascertain the consultation quality, and auditing could assess adherence to supply criteria.

Conclusion

Availability of sildenafil through a controlled pharmacist-supply model appears workable and provides opportunities for referral for early cardiovascular risk assessment. Areas for possible improvement include better availability of written information for pharmacist-supply, and reminders to pharmacists about their obligations to provide this. The opportunity for greater doctor-pharmacist collaboration should be explored, and further research around quality of service, and the consumer experience is recommended.

Conflicts of interest NG works on widening access to medicines through reclassification, and has consulted to industry on reclassification of erectile dysfunction medicines, including receiving consulting fees from Douglas Pharmaceuticals for the reclassification of sildenafil in New Zealand. The rest of the authors have nothing to declare.

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