Pharmacy student decision making in over-the-counter medicine supply: a critical incident study.

Abstract

Background: Various factors influence decision making in over-the-counter (OTC) medicine consultations, yet limited studies have focused, in-depth, on the thought process of pharmacy staff. This includes pharmacy students as pharmacists-in-training.

Aim: To explore the factors that influence pharmacy students' decisions in relation to OTC consultations and choice of OTC medicine/s.

Methods: Semi-structured interviews using the critical incident technique were undertaken with ten pharmacy students in Australia, who also worked as part-time pharmacy staff.

Results: Nine key themes were identified to influence pharmacy student decision making in OTC consultations, including customer response, confidence and scope of practice. Product requests were reported as more challenging due to customer expectations and experiences in other pharmacies, states or countries. Although negative customer response influenced some students to supply medicines in contradiction of evidence, an overarching concern for safety meant that a medicine was only supplied if unlikely to cause harm**.** Students reported developing confidence in OTC decision making more from real-life practice than university training; greater confidence was identified for inquiries more frequently experienced in the pharmacy. Students perceived that customers had assumptions around support staff, and were happier to talk to students than assistants.

Conclusion: This study further identified that OTC decision making is a complex process for pharmacy students. Additional opportunities for experiential learning within this area are suggested, such as work-based placements or in-class activities such as role-plays with simulated patients.

Introduction

Community pharmacy is an accessible healthcare destination for the public to seek advice around management of minor ailments. Medicines are grouped into schedules to balance customer access and public safety and these can be broadly categorized as prescription or over-the-counter (OTC) medicines.[1] These schedules regulate where medicines can be sold and who can supply them.[2] For example, OTC medicines are classified as Unscheduled or General Sale, Pharmacy medicines, and Pharmacist Only or restricted medicines in Australia, New Zealand and Canada.[3-5] The United Kingdom has General sale and Pharmacy medicines.[6] Pharmacy medicines are generally restricted to pharmacy supply and Pharmacist Only medicines require the involvement of a pharmacist; this varies between countries, and Australian states.[7] Pharmacy support staff, such as medicines counter assistants, pharmacy assistants, pharmacy technicians, interns and pharmacy students, are generally the first staff members customers interact with upon entering a pharmacy. Consequently, pharmacy support staff handle the majority of OTC consultations,[8] and have identified themselves as healthcare advisors.[9]

Overall, various factors influence OTC consultations, including staff knowledge and confidence, customer responses and expectations, the pharmacy environment, consumer-related clinical factors, evidence and/or professional protocols and scheduling rules. These factors are discussed in further detail below. For example, differences in knowledge between support staff and pharmacists may affect the outcome of an OTC consultation, i.e. medicine supply or referral.[10] Discourse analysis of interactions between pharmacy staff and customers highlighted that the hierarchal relationship between Welsh support staff and pharmacists affected the overall outcome of an OTC consultation.[10] When pharmacy interns lacked self-confidence, they sought the advice from, or mirrored the actions of, their preceptor.[11]

The outcome of OTC consultations is also influenced by customer interest and commitment to interacting with pharmacy staff.[9] This includes open (elaborative) or closed (one word) customer responses to staff enquiries,[9, 12, 13] with open responses supporting decision making and appropriate OTC supply by support staff.[12] Conversely, customer resistance to answering questions challenged OTC decision making;[12] a cold, detached customer manner affected pharmacy staff consultations.[9] Hibbert et al. reported challenging responses from customers who had experience of their minor ailment and were focused on buying a product rather than seeking a professional service.[12] Such resistance provides limited scope for staff to tailor

60 treatment to the individual or address any associated risks. As suggested by Banks et al., risk

61 assessment, i.e. to ensure the safe and appropriate choice of medicine/s, can be affected when

62 customers are not comfortable answering personal questions.[9] Cooper reported that negative

63 customer response came across as aggression when pharmacy assistants refused product

64 supply.[14] Several assumptions have been made by support staff in relation to customers they

65 suspected to abuse medicines, including requests for a specific medicine, e.g. codeine-

66 containing analgesics, or frequent purchasers of such medicines.[14]

67 Research has suggested that customer response can be affected by their own expectations.[12]

68 Pharmacists believed that customer expectations were more influential in OTC decision

69 making than utilising an evidence-based approach, particularly when there was customer

70 pressure to supply.[15] A similar situation has been observed with doctors and antibiotic

71 prescribing.[16] Banks et al. observed that most customer consultations involved a specific

72 product request and suggested these were more difficult because pharmacy support staff need

73 to establish safety and appropriateness, which the customer could disregard.[9] However,

74 researchers were required to observe multiple people and other findings may not have been

75 identified.[9] Furthermore, the busyness of the pharmacy environment may have affected the

76 quality of consultations, protocol adherence and staff decision making.[9] Time constraints in

77 the pharmacy have been proposed by researchers as a barrier to applying evidence-based

78 practice,[15] professional protocols or asking questions.[17]

79 Risk assessment and clinical factors also feature in OTC decision making. Studies carried out

80 in Northern Ireland found that establishing safety was the main focus of newly registered

81 pharmacists before meeting patient expectations.[11, 15] Hanna and Hughes found that a

82 customer's age, medical conditions or current medicines were considered prior to OTC

83 supply, and that sometimes customer expectation superseded evidence.[15] The majority of

84 participants referred back to university teaching on the effectiveness of OTC medicines as an

85 influential factor,[15] and as long as the medicine caused no harm, this justified sale when

86 evidence was limited. This was different from views in another study in Northern Ireland;

87 trainees reported university teaching as irrelevant, redundant and disconnected compared to

88 real life practice, which may be why an evidence-based approach was not consistently

89 implemented.[11]

90

91   Limitations of protocols have been highlighted in the context of the complexity of the OTC

92   consultation.[18] Further, scheduling rules or requirements for sale have been proposed as

93   acting as a barrier to appropriate OTC consultation and supply.[19] In Australia, real time

94   online recording systems were introduced as additional practice tools to support staff OTC

95   decisions with requests for pseudoephedrine[20] and Pharmacist Only codeine-containing

96   analgesics,[21] thereby tackling misuse. Voluntary reporting and variable implementation

97   between pharmacies have been attributed as factors influencing the success of these

98   professional practice tools.[22, 23]

99   Although comparisons have been made between pharmacists and support staff in OTC

100   decision making, literature solely focused on pharmacy students is more limited.

101   Furthermore, studies have generally reported on student views of OTC evidence-based

102   practice,[11, 15] how OTC interactions occur using linguistic or discourse analysis[10, 13] and

103   mystery shopper observations of behaviour.[24, 25] There has been limited attention to the

104   *thought process* for specific decisions in OTC consultations. This study aims to identify how

105   factors affect OTC decision making by pharmacy students, and to explore the factors which

106   influence the choice of OTC medicine supplied.

107

108 Methods

109   Semi-structured interviews were chosen to gather in-depth information on pharmacy student

110   views and self-reported behaviour in relation to OTC consultations and associated

111   decisions.[26] The critical incident technique (CIT) has been used previously to explore factors

112   which influence decision making.[27] Flanagan stated: '*The critical incident technique consists*

113   *of a set of procedures for collecting direct observations of human behaviour in such a way as*

114   *to facilitate their potential usefulness in solving practical problems and developing broad*

115   *psychological principles.*'[27] Dunn and Hamilton stated that the CIT provides details of where

116   professionals see their activities as being important, and guidelines which can be used as the

117   foundation in constructing an educational program designed to maintain and improve

118   professional standards.[28] The CIT ensured data was collected around the outcome of the OTC

119   consultation and analysed systematically.

120

121 Critical incident data analysis allows data to be summarized and described in an efficient
122 manner so it can be used for practical purposes.[27] Participant stories of OTC experiences
123 were identified as critical incidents if they related to the interview questions, to OTC
124 medicines and involved a customer interaction. Interactions involving prescription medicine,
125 or other medicines available for customer self-selection, such as complementary medicines or
126 wound care products were excluded. When information was full, clear and detailed it was
127 seen as an accurate retrospective report; general, vague or less specific reports were less
128 likely to be useful since the recounted incident may not be well remembered and hence
129 possibly incorrect.[27] For an incident report to be effective and useful, it must have contained
130 the following information: i) a description of the situation which led to the incident; ii)
131 actions or behaviours of the person in the incident; ii) results or outcomes of the behavioural
132 actions.[29]

133 *Recruitment*
134 Current pharmacy students who had ever worked, or were working, in a community
135 pharmacy were eligible to participate. The exclusion criteria included qualified international
136 pharmacists or students currently taught by members of the research team. A purposive
137 sample of pharmacists in Queensland Australia, were contacted by the research team.
138 Pharmacy students throughout Australia were invited to participate via social media or
139 student organizations; Griffith University pharmacy students were also invited by poster
140 advertisements and in-class announcements.

141 Flanagan emphasised that the sample size for a CIT study is determined by the number of
142 critical incidents observed or reported and adequate coverage of the activity being studied,
143 rather than participant numbers.[27] For this study, when similar results were being heard and
144 no new findings were found, recruitment was stopped due to data saturation, i.e. there was
145 adequate coverage of decision making by support staff.

146 The interview guide was informed by a literature review,[10-15, 30-33] including studies which
147 used the CIT.[34-36] Three pilot interviews were conducted; minor amendments were made to
148 the interview guide with the final form consisting of nine questions (Table 1). University
149 ethics approval was obtained (GU Ref No: 2017/190).

150 Semi-structured interviews were carried out in March and April 2017 by one researcher (TT),
151 who received training on interview techniques, and email debriefs provided to the research
152 team. Interviews were audio recorded, and the interviewer (TT) transcribed the majority of

153 transcripts verbatim which were quality checked by one of two researchers (FK or SM).

154 Minimal changes were made, for example, confirmation of Australian medicine names.

155 Participant confidentiality was maintained by assigning individual codes to transcripts.

156

Table 1: Interview Questions

Firstly, we would like to know about your job within a community pharmacy.
What do you enjoy about working in the over-the-counter section of the pharmacy?

In the next questions, we would like to find out what you believe makes a good OTC/non-prescription medicine consultation and why:
Tell me about a time where you think you performed well in an OTC consultation?
Tell me about a time where you think you could have performed better in an OTC consultation?

An OTC consultation can include the referral of a customer to the pharmacist; we would like to understand more about this procedure:
Tell me about a time you were sure about referring a customer to the pharmacist?
Tell me about a time you weren't sure whether to refer a customer to the pharmacist?

Patient requests are common in OTC consultations so in the next two questions we want to find out about the experiences you have had with customers with respect to supplying or not supplying a product:
Can you tell me about a time you have sold a medicine specifically requested by a patient?
Can you tell me about a time you did not sell a medicine specifically requested by a patient? (E.g. you recommended an alternative medicine or referred to the pharmacist).

In the next question, we want to understand your thought process and steps taken when a customer comes in with certain symptoms:
Tell me about a time where confidence has helped or hindered an OTC consultation?
How do you respond to a patient coming in with specific symptoms?

157

158 *Data analysis*

159 Initially, three researchers individually read the first transcript multiple times to become

160 immersed in the data and highlight critical incidents; the analysis process was then discussed

161 as a team until consensus was obtained. Agreement was made to enter each incident into a

162 Microsoft® Excel spreadsheet and classify it as a specific or general incident. A specific

163 incident involved a detailed story concerning a customer, whereas a general incident was a

164 more generic approach to practice, i.e. a story relating to the overall experience of the student

165 for an analgesic request. For each incident, the *trigger* was identified: (i) a product request,

166 i.e. by medicine name; (ii) symptom-based request, i.e. advice to treat symptoms or request

167 for a class of medicines such as an analgesic; (iii) request to speak to the pharmacist. The

168 *action* was the context of the incident which was entered as a participant quote, and the

169   *outcome* was the final decision. Outcomes were categorized as (i) product supply; (ii)
170   recommendation of an alternative product to that requested; (iii) no supply; (iv) referral.
171   Referral included when support staff referred the customer to the pharmacist or another
172   healthcare professional, or when they double checked information with the pharmacist as this
173   may have influenced the consultation outcome.

174   The remaining transcripts were coded for incidents (trigger, action, outcome) by the main
175   researcher (TT). If information was missing for an incident, e.g. action, then this was noted
176   for additional context only, i.e. not coded as a complete incident. A research discussion with
177   three researchers (TT, FK, SM) was held after two to three transcripts were analysed to
178   confirm findings. During this analysis, factors were identified within incidents that influenced
179   OTC decision making. These factors were reviewed and discussed and initial identification of
180   factors within incidents led to categorization into broader themes. These themes contributed
181   to, or influenced, the decision making of pharmacy support staff. For example, side effects,
182   severity of symptoms, and adverse drug reactions all related to the theme of safety.
183   Researchers discussed the definition and application of themes across multiple meetings to
184   reach consensus (Table 2); all critical incidents were categorized into one or more themes.
185   Any changes or new themes meant that previous analyses were checked for consistency.
186   More than two thirds of the data analysis were quality checked by the researchers (two of
187   which had qualitative research experience) ensuring a consensus approach to data analysis.
188   Any discrepancies were discussed between the researchers until an agreement was reached.

189

Table 2: Overview of categorized themes found in the critical incidents

Themes	Explanation
Confidence	Perceived ability to carry out a consultation and knowledge of conditions and OTC medicines.
Clinical factors	Duration of symptoms and medicine use by the customer, requests for new medicine due to current ineffective treatment, self-misdiagnosis of symptoms or request for treatment that is not indicated for condition.
Evidence	Carrying out consultations applying evidence-based practice, personal experience or professional experience.
Customer response	Customer behavior, tone and verbal reaction including expectations and previous experiences
Safety	Side effects, adverse drug reactions, potential harm, red flag symptoms and medicine misuse/abuse.
Legal/Ethics/ Professionalism	Specific medicine scheduling rules, legislation for certain medicine and best practice, recommended guidelines.
Special populations	Pregnancy, elderly, young children or specific health conditions
Scope	Perceived authority of support staff vs. students vs. pharmacists by customers, as well as pharmacy staff
Environment	The surroundings and condition of the community pharmacy

Results

Ten pharmacy students (aged between 19-30 years) participated, of which nine studied at Griffith University; six students were female. All students worked in a corporate pharmacy brand, with community pharmacy experience ranging from 8 months to 10 years (average 3 years).

Students identified a total of 131 critical incidents (58 general and 73 specific) and these were categorized by one or more themes and trigger (Table 3). Sixty-three of the 131 critical incidents were classified as product requests, 64 as symptom based requests and in four incidents students reported that the customer had asked to speak to the pharmacist. Overall, around a third of the incidents were related to pain, followed by dermatology and cough and cold related incidents. Some themes were more prevalent overall, e.g. customer response, evidence, safety and clinical factors, and by trigger compared to others. For example, when incidents were analysed according to trigger, confidence and clinical factors featured more frequently in symptom-based requests, whereas customer response and

205 legal/ethics/professionalism were identified more often in incidents related to product
206 requests. Safety was equally prevalent for product and symptom based requests.

207 **Table 3: Frequency of each theme for critical incidents by trigger**

	Trigger			
Themes	**Product request**	**Symptom based**	**Pharmacist request**	**Total**
Customer response	32	18	4	54
Evidence	20	26	2	48
Safety	22	22	0	44
Clinical factors	16	23	0	39
Confidence	8	18	0	26
Legal/Ethics/Professionalism	19	6	1	26
Scope	8	13	3	24
Special Populations	6	12	0	18
Environment	4	1	1	6
Total	**135**	**139**	**11**	**285**

208

209 Although this paper will provide evidence of all nine themes, particular attention is given to
210 customer response, confidence and scope. While customer response was the most commonly
211 reported theme, it became evident during qualitative analysis that confidence and scope were
212 of particular relevance to pharmacy students. The remaining themes are integrated into these
213 factors as they are often inter-related.

214 *Customer response*
215 Customer response was identified as a theme in 54 of 131 critical incidents and students
216 attributed this to previous experiences buying medicine, personal expectations and medicine
217 related perceptions. Customer response was more commonly reported for the critical
218 incidents that were classified as product requests (32/63) than symptom based requests
219 (18/64), and resulted in referral for 17 incidents.

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222 Decision making was described as challenging when customers were less likely to disclose
223 information or take support staff seriously. Customers were less likely to provide information
224 when they were in a rush, expected to receive the requested product without question/s, or
225 had previously used the medicine, making it more challenging to recommend another
226 treatment. The challenge of balancing customer response with current evidence was discussed
227 by Pharmacy Student 4 in a general incident about pain:
228

> **Product request:** *Codeine containing analgesics*
>
> **Context:** *...you can't even budge people they don't even want to engage in the conversation and 'how do you feel they work for you?'...'they're great, they're the only thing that work' and so you're ah ok, um it's like what about 'have you tried anything else?' - 'of course I have.' Well what have you tried? 'Doesn't matter' It's like ahhhh...they just want the codeine...they feel that the codeine is what treats the headache...and I mean I guess it varies in evidence for it but it's not the best...we check their history I guess. I mean there's only so long that you can go...Always counsel on the fact that -are you aware that using this medication for like constantly or so many times in the month um can cause headaches...and they're like....'that's rubbish there's not enough in it to treat a headache' and I was like well then why are you using it...*
>
> **Supply**: *...I've probably successfully converted maybe 5% of the people that have come in for a direct codeine request to something else.*
>
> (Pharmacy Student 4)

229
230
231 In five incidents, a customer's previous experience buying medicine from a different place,
232 e.g. supermarket, state or country, led to specific customer expectations. One student
233 described a customer as less inclined to disclose information when they had previously
234 bought the medicine, an antihistamine, from a supermarket. For Pharmacy Student 8, a
235 customer response changed when they were made aware of the differences in legal
236 requirements for Pharmacist Only medicines between Australian states:
237
238
239
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241

> **Product request**: *thrush treatment like a lady who has to get it quite often cause she gets it quite regularly*
>
> **Context**: *I think she wanted to get a few at a time like I kind of explained to her in Queensland we can only give out one S3* [Pharmacist Only] *medication at a time and she got really agitated about it and we also have to record like name and address and that sort of thing and I think she was from a different state...she didn't understand why we had to record the information, and like asking her questions about it agitated her she was like "I've used this all the time" and I was like "yes I understand that but I still need to ask you these questions it's a requirement, I need to make sure I'm giving you the right thing that sort of thing," and yeah she was quite upset about it*
>
> **Referral**: *but in the end like she realized. I did talk to the pharmacist about it...the fact that she was using it quite regularly*
>
> <div align="right">(Pharmacy Student 8)</div>

242

243 Over a third of incidents (19/54) which related to customer response involved
244 legal/ethics/professionalism. Two students experienced aggressive customer responses in
245 relation to Australian regulations that chloramphenicol eye drops is a Pharmacist Only
246 medicine for bacterial conjunctivitis.

247
> **Product request:** *I have one guy...he comes in regularly for chloramphenicol eye drops*
248
> **Context:** *...he is continually convinced that he has an eye infection whenever his eyes are itchy...he tells me that he knows what he has and that um what would I know...just give him the drops because he's always gotten the drops before...I'm*
249
> *kinda like well it's really just eye drops...*
250
> **Supply:** *and eventually we all just breakdown and give him his antibacterial eye drops because he's making a scene in the store*
251
> <div align="right">(Pharmacy Student 3)</div>

252

253 The professional practice tool MedsASSIST was viewed as a useful way of overcoming
254 challenging customer responses for Pharmacist Only codeine-containing analgesics.
255 However, customers new to the pharmacy or who had obtained codeine from a pharmacy that
256 had not used MedsASSIST were less responsive, particularly if they knew it was not a legal
257 requirement. Pharmacy Student 3 mentioned how they use MedsASSIST to make decisions:

258

> **Product request:** *someone comes with a migraine. You try telling them codeine's not the best thing for their migraine they get stressed...*
>
> **Context**: *Well they usually respond and just say well I know what works for me...and you're like well I don't know how to argue with that...we have...MedsASSIST where you put their driver's license...you can see their recent codeine sales and then you'd assess that and then you'd say well like okay does this look like genuine need*
>
> **Referral**: *and then I would bring all that information to the pharmacist and I would discuss it with them and we'd come up with whether or not we thought it was genuine need*
>
> (Pharmacy Student 3)

259 It became clear that whilst evidence influenced OTC decisions, student understanding or
260 provision of evidence to customers did not always moderate customer response. For example,
261 student decisions appeared to be challenged by tension between customer response, evidence
262 and professional recommendations in relation to the supply of emergency contraception. This
263 led to different decisions for similar scenarios, for example, when evidence and professional
264 protocols recommended that emergency contraception was not needed. If the customer
265 accepted the evidence and did not appear concerned, then emergency contraception was not
266 supplied. However, if the student perceived a customer to be anxious about becoming
267 pregnant, emergency contraceptive was supplied as there was no perceived associated risk.
268 Alternatively, as discussed by Pharmacy Student 3, the incident was referred to the
269 pharmacist:

270

271

> **Product Request:** *...if someone came in for...oral* [emergency] *contraceptive,*
>
272
> **Context**: *... just try to get more information about their health status and, and how they're going and yeah...I um may not supply if well technically we're not supposed to supply if they have only missed one day of combined oral contraceptive however I feel like that, I probably still would because I kinda think that if it's not doing a great deal of harm it's really stressful and could affect the person um mentally to say no sorry you can't have it and just see how you go.*
>
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>
275
> **Referral**: *So, that would give me pause and if that answer came up I would definitely go and talk to a pharmacist and say what would you like to do in this situation and then just talk it through. Um where I've worked, we've always supplied it in that case.*
>
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>
> (Pharmacy Student 3)

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279

280 Customer responses featured less frequently in symptom-based requests (18/64), with
281 customers more receptive to treatment options when they had no expectations for a certain
282 product, were seeking advice and were advised on evidence supporting different treatments.

283 *Confidence*
284 Students reported varying levels of confidence depending on the therapeutic category of the
285 OTC consultation, e.g. pain or dermatology, and by the customer, e.g. pregnant woman or
286 child. Over a third of the incidents involving confidence could also be related to other factors
287 such as real-life pharmacy experience, personal experience and/or university knowledge.

288 Five students spoke about how university improved their counselling. Pharmacy Student 1
289 said *'(university) teaches us pretty well because we get training with…the simulated patients*
290 *here…it's a case with practicing it with just lots of customers'*. Students spoke about the
291 importance of university training in using professional protocols to support decision making.
292 Students also acknowledged that while they could act confident there was no point in using a
293 protocol if they had no idea how customer responses should influence treatment.

294 Students reported having greater confidence in making decisions, including refusal of product
295 supply, for more frequently experienced customer inquiries, such as gastrointestinal issues
296 and requests for codeine-containing analgesics. Meanwhile, for consultations rarely
297 experienced such as supply of sleeping tablets, under-confidence made decision making
298 harder. Lack of confidence was reported for dermatological inquiries due to differential
299 diagnosis, risk of infection or co-morbidity related risk as reported by two students who
300 referred to the pharmacist:

Symptom based: *…looked like he had eczema in behind his right knee…*

Context: *it was a weeping like it was full broken skin…However in in his elbow flexures and his knee flexures was very eczema type but because the skin was broken on the right leg it was a bit like well that's very severe just on one leg to do that so I was a bit like not really sure*

Referral: *I'd prefer a pharmacist to weigh in on what to give….if I'm 50/ 50 about a choice or these symptoms are a little bit like this but a little bit like that and I'm a bit hesitant on what to give. First thing I do is give…the pharmacist a quick ' this is the person complained with…'I think it's either this or this' and then if they're not happy with my summary they'll come out and have a bit of a chat so I always do it on differential diagnosis*

(Pharmacy Student 4)

301

> **Symptom based:** *It's generally like infected sores on I think it was infected sores on a foot*
>
> **Context:** *he was diabetic as well so I referred that one um…the healing process is less um so obviously you would be like how long has he had it for? Um, really comes into play and how severe it is*
>
> **Referral:** *and I really wanted um the pharmacist to make that determination of whether he goes to see a doctor for that one or not…*
>
> (Pharmacy Student 8)

Two other students attributed greater confidence with dermatological enquiries to increased experience with these. The value of real life pharmacy experience was highlighted by Pharmacy Student 1. This participant described being able to diagnose and counsel a customer with shingles, without referring to the pharmacist, as they had previously observed the pharmacist carry out a similar consultation:

> **Symptom based:** *a gentleman come in with a rash on his stomach just on one side*
>
> **Context:** *and because…my boss in the previous year, had positively identified…a similar looking rash as shingles, I suggested that it might be shingles, because he had the pain and that sort of thing as well.*
>
> **Referral:** *So I immediately referred to the doctor. When he came back, it had turned out to be shingles it was diagnosed as shingles and he was impressed that I was able to work that out just from looking at it*
>
> (Pharmacy Student 1)

Two students spoke about how they lacked confidence in supplying medicine to customers who were from special populations, e.g. pregnancy, elderly or children. Pregnancy was of significant concern for one participant; when it was the first time they had to deal with this special population, or they were unsure which medicine was the safest option. Ultimately, students discussed this in terms of not wanting to cause harm:

> **Symptom based:** *…a mother came in ah asking for ah some sort of hydration relief for her daughter that was pregnant…*
>
> **Context:** *the moment she said that she's pregnant I like freaked out I'm like I haven't counselled anyone regarding pregnancy…I didn't know what products were available in Australia and what exact guidelines were so I didn't want to say oh just take the hydration…*
>
> **Referral:** *so that's why I referred to the pharmacist I just wasn't 100% sure…and yeah I just went to the pharmacist…and they dealt with it and it was just like those hydration um those frezzy pops it was a pretty simple when I stopped and thought about it…*
>
> (Pharmacy Student 9)

> **Symptom based:** *Medicine for heartburn*
>
> **Context***: ...the antacids she tried all those, she's tried Rennie®, QuickEze®* [antacids] *all those sort of products so I knew from pharmacy practice here at uni I'm like there is an over the counter product that was safe to use in pregnancy but I wasn't too sure which one...so I double checked, turns out I was the right, right product at the time, but it was the double checking phase, cause you know special case, pregnant woman, don't wanna make a mistake, definitely double check......*
>
> **Referral:** *always double checking with the pharmacist*
>
> (Pharmacy Student 7)

326

327 Having a solid understanding of current evidence about effective treatments and associated

328 risk of medicines in general and for special populations assisted students to make decisions in

329 18 incidents in particular. Students were more cautious with the elderly and children, stating

330 how side effects and adverse drug reactions affected choice of medicine to supply:

> **Product request:** *...a geriatric lady...came in with her daughter...asking for Phenergan®* [Promethazine]
>
> **Context:** *and I was able to um sway her from using Phenergan® because she's very old and there's going to be potential movement problems and, and anticholinergic effects coming from Phenergan®...tell her that um Phenergan® it's on the Beales list of not being appropriate for, um people over, 60, I think it's over 65 or 75...*
>
> **Alternative:** *I was able to recommend a non-drowsy antihistamine instead*
>
> (Pharmacy Student 1)

331

332 Similarly, having a solid understanding of medicine knowledge and evidence-based practice

333 assisted pharmacy students to make confident decisions. This highlighted how clinical factors

334 are inter-related with confidence. For example Pharmacy Student 9 was confident to refuse

335 supply when a threadworm treatment was not indicated and the request was driven by public

336 misperceptions in relation to threadworms:

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341

> **Product request:** *I had ah a lady come in asking for ah Combatran* [Combantrin®; Pyrantel Embonate] *ah for ah deworming*
>
> **Context***: and so I was asking oh have you had it before, and she's like no, and I'm like can I just confirm that you have worms in the family, and she's like no and I'm like oh why do you need it, she's like oh my friend ah said that you should do it every 6 months or something like that*
>
> **No supply:** *so I'm like no unless it's confirmed and you don't' fit into the symptoms, no point getting it, like save your money...she was like oh okay*
>
> (Pharmacy Student 9)

342 Students discussed how they provided an alternative product due to concerns of how long a
343 customer had used a particular medicine for, or due to the risk of side effects from overuse;
344 these cases were linked to optimising patient safety. Again, having this clinical knowledge
345 and / or understanding of current evidence provided the *confidence* for both pharmacy
346 students to recommend an alternative, and emphasized the importance of clinical factors in
347 decision making such as asking how long a customer has used a particular product:

348

Symptom based: *cold and flu*

Context*: I feel like I do that a lot* [give alternatives] *with nasal decongestants 'cause lots of people with allergies will come in um especially if it's new to them like they're getting it quite frequently...they want a nasal decongestant and you're like oh like how long have you been using this for like, and they're like oh quite a while*

Alternative: *and then you need to swap them over to something else...because of yeah rebound congestion*

(Pharmacy Student 8)

Product request: *I had a older woman come...buying the seven day course of Nexium®* [Esomeprazole]

Context: *...I was like...how long have you been on this?...she was like about five or six weeks.' I was like are you under doctor's instructions to be doing this? She was like 'no...I had heartburn...and I don't want it to come back so I'm just still taking it.'...*

No supply: *...so I refused her the actual Nexium®...suggested obviously like a Gaviscon®* [antacid] *if they do come back for next time or otherwise if it's coming back recurrently is to see the doctor potentially for underlying cause*

(Pharmacy Student 4)

361

362 *Scope of practice*

363 Participants reported different experiences related to customers' perceptions of their scope of
364 practice across 24 incidents. While some customers would only speak to the pharmacist, three
365 students reported that customers who initially requested to speak to the pharmacist became
366 more open to disclosing information when made aware that they were talking to a pharmacy
367 student. A similar pattern was observed for preference of pharmacy student over pharmacy
368 assistant. However, one customer remained hesitant to speak to Pharmacy Student 1 even
369 though they were aware that they were speaking to a pharmacy student and the student felt
370 comfortable counselling on a sensitive topic:

> **Pharmacist request:** *someone comes up and asks to speak to the pharmacist, and then I'll say I'm a pharmacy student I'm happy to grab the pharmacist if, if I don't understand or if you'd like to speak to them, but I might be able to help you....*
>
> **Context:** *it might have been a thrush case...the fact that I'm not a pharmacist means that they're not going to listen to my advice, and they would prefer to just get what they had last time...with the Canesten® [clotrimazole] case it would've been that they asked for the pill and the cream...but the pill had worked for them before no problems so I said you don't need the cream if the pill's worked for you before, like you can get them but you don't really need to, but they'd heard from the neighbour that you should use the pill and the cream so they didn't want to listen to what I had to say*
>
> **Referral:** *I grabbed the pharmacist anyway, just because I think even though I was completely aware of what they were taking....they were hesitant to actually speak to me*
>
> (Pharmacy Student 1)

In two incidents, pharmacy students described customers listening to the pharmacist repeating the same information that they had given the customer as the 'white coat effect;' the pharmacist looked professional and therefore had higher authority:

> **Symptom based:** *mums in particular who want dry cough mixtures for well like a 16 year old kid*
>
> **Context**: *...exploring more symptoms definitely sounds like a chesty cough infection and if you know get dry cough suppressant like pholcodine it's gonna supress the cough most likely gonna result in a chest infection which is gonna be more on the health care system, antibiotics and you don't want to waste the customer's time and money...*
>
> **Referral**: *and then you just like oh get the pharmacist out, and they're like oh no we'll go elsewhere or the white coat effect maybe and then they'll listen to exactly what I just said but a pharmacist has just told them but they won't listen to me*
>
> (Pharmacy Student 7)

Four students expressed an appreciation of the difference in responsibility and knowledge between them and pharmacists, and accepted that this contributed to customer preferences. Difference in responsibility and risk of potential implications for the pharmacists if OTC supply was unsafe contributed to perceived pressure for students to follow pharmacist preferences. For example, this influenced the decision of Pharmacy Student 5 for requests to treat a cough:

> **Symptom based:** *a lot of people come in…tell you they've got a dry cough*
>
> **Context:** *I went up to show the pharmacist what I was selling* [cough medicine] *and she just hated one of the products and she was like I never ever recommend that one…this thing's useless there is no evidence and she full shut me down…*
>
> **Referral:** *from then on I sort of made sure that products I was recommending the pharmacist was happy with and so I'll always ask the pharmacist…what they like to sell because you know I'm representing their pharmacy I want to sell the ones that they think are the best for them, but it's hard cause…I work at a ton of pharmacies*
>
> (Pharmacy Student 5)

397

Discussion

399 In this study, nine key themes were identified to influence pharmacy student decision making
400 in OTC consultations. Three key factors were perceived by students as particularly influential
401 over their decisions; customer response, confidence and perceived scope of support staff.

402 **The influence of customer response**

403 Customer response was the most frequently coded theme and this highlighted the importance
404 of an open customer response, whereby customers answered questions, disclosed information
405 and were amenable to student recommendations of more appropriate treatment options. While
406 previous literature focused on how customer response influences the interaction or
407 conversation between staff and customers,[9, 12, 13] this study looked at how customer response
408 influenced students' decisions to supply an OTC medicine or refer to the pharmacist.
409 Customer expectations and negative response influenced some students to supply medicines
410 in contradiction of current evidence or professional guidelines. However, an overarching
411 concern for immediate customer safety meant that whilst supply may not have always been
412 indicated, medicine was provided if it was unlikely to cause harm. Hanna et al. reported
413 similar views amongst newly registered pharmacists who had been taught about OTC
414 medicines using evidence-based approach.[15] It is clear that negative customer response could
415 override evidence as a factor in OTC decisions even when students understood and/or
416 provided evidence to the customer.

417

418 *Application of legalities and scheduling restrictions*

419 Negative customer response influenced application of guidelines yet it did not overcome legal

420 rules, e.g. supply of cold and flu medicine to under six year olds. A recent Australian study

421 involving pharmacy students as mystery shoppers demonstrated that clinical reasoning and

422 regulatory guidelines were common reasons for modifying a product request for cough and

423 cold medicine for children.[37] Customer expectations have been reported as challenging for

424 OTC consultations and decision making in the UK,[9, 12, 13] particularly when people are

425 focused on buying a product, less amenable to recommendation of more appropriate medicine

426 and respond aggressively to support staff.[12] In this study these challenges were exacerbated

427 by customers' previous experience of being supplied medicine from a different country, or

428 state within Australia. In Australia, the medicines schedules are the same across states yet

429 how these are implemented differ[7] and standardization may simplify OTC decision making

430 and minimise associated negative customer response. Current literature on OTC scheduling

431 has compared Australia nationally with countries with similar schedules, e.g. New Zealand

432 and UK; [2] further research exploring the impact of differences between states is

433 recommended.

434 Students' descriptions of customer pressure to supply codeine-containing analgesics,

435 suspicion of abuse with frequency of purchase and customer aggression when requests were

436 challenged aligned with views reported by Cooper et al.[14] Reliance on pharmacy procedures

437 and professional guidelines to manage potential abuse were similar to strategies used by UK

438 support staff.[14] In this research the online monitoring system used to detect over-supply of

439 codeine-containing analgesics, MedsASSIST,[21] was perceived as an effective tool and was

440 highly used in the pharmacies that these students worked in. Variable use of this tool by staff

441 in other pharmacies meant that some customers were less receptive to this procedure based on

442 previous experience. Voluntary and variable implementation of these tools between

443 pharmacies have been attributed as limiting to their success[22, 23] and the online recording

444 system for pseudoephedrine supply is now mandated across a number of Australian states.[20]

445 Consistency in application of OTC related legal requirements at times contrasted with

446 application of professional guidelines, possibly because professional guidelines are perceived

447 as more optional. It is important to note though that sometimes scheduling restrictions meant

448 to facilitate safe OTC medicine supply can inhibit appropriate access, such as the initial

449 requirement for customers with influenza to be present in the pharmacy to be eligible for

450 OTC oseltamivir supply in NZ.[19] Periodic review of the relevance of scheduling rules

451   coupled with consistent application of professional guidelines should ideally balance

452   appropriate access with public safety. Pharmacy education should highlight the value and

453   relevance of professional guidelines and develop students' capacity to make professional

454   judgements and decisions that balance these key factors. If inappropriate medicine supply

455   causes customer harm, pharmacists may be required to justify to registering authorities why

456   guidelines were not followed.

457   *Application of professional protocols*

458   Appropriate OTC medicine supply is important to the individual and the health system.

459   Similar pressure to supply an unnecessary OTC medicine has been experienced by

460   pharmacists[15] and doctors for antibiotics.[16] Subsequent negative implications include

461   increased antibiotic resistance leading to higher medical costs, prolonged hospital stays, and

462   increased mortality.[38] One student reported inappropriate supply of chloramphenicol eye

463   drops for a stye when pressured against Australian practice guidelines of OTC supply for

464   bacterial conjunctivitis only.[39] Customer pressure encouraged unnecessary supply of

465   emergency contraception in some cases, yet in others, students utilized professional protocols

466   and evidence to recommend against OTC supply. These differences may reflect a short-term

467   focus on individual customer satisfaction or safety rather than long-term population-based

468   safety, e.g. risk of antibiotic resistance; further research is needed. It is encouraging that some

469   students prioritized safety and in some cases effectively used evidence and professional

470   guidelines to support appropriate OTC decisions. The recurring theme of the influence of

471   customer response on OTC consultations[9, 12, 15] suggests a need to consider how this is

472   incorporated into pharmacy curricula. Additional university training on managing customer

473   pressure could support all students with these situations; i.e. to be more assertive. The nine

474   students from one university reflect two degree programs and had received different learning

475   opportunities related to communication skills development, such as eliciting open-ended

476   responses from consumers (e.g. standardised or simulated patients). The concept of

477   assertiveness had been introduced to these students in the context of interacting with doctors

478   and students may not translate this to consumer interactions. More in-depth exploration of the

479   impact of existing communication skills training would be beneficial. Educators should also

480   consider if they provide activities that support students to assertively interact with consumers.

481   Furthermore, this study emphasises the importance of experiential learning in being able to

482   make decisions but provides limited insight into how to guide experiential educators in this

483   process.

The influence of confidence

Students reported variable confidence according to a number of clinical and student related factors. The highest level of confidence was reported for more commonly experienced consultations such as pain compared to rarer requests for medicine to aid sleep; similar findings were reported by Morken et al.[30] Confidence in completing OTC consultations came mainly through real-life practice, and regular work in a community pharmacy was perceived to support students' OTC decision more than university training. Real life practice was perceived to be more effective than university training by pharmacy trainees who deemed university teaching as irrelevant, redundant and disconnected from real practice.[11] One student interviewed, believed simulated patients were an effective teaching method. Role-playing exercises with preceptors and pharmacy students have been used to expose students to quality patient care[40] and problem-based learning reported significant improvement for pharmacy students in comparison to virtual patient cases.[41] However, students may adapt and respond differently between real life scenarios and simulated scenarios. One solution would be for universities to focus on providing students with more opportunities to work in a community pharmacy, e.g. work experience or placements. Comparative evaluation of the impact of experiential learning and other teaching methods on OTC decision making is therefore needed.

The influence of scope

Perceptions of the authority and credibility of pharmacy staff can also influence customer expectations. Some customers were more open to interacting with support staff once they were aware that they were completing a university pharmacy degree; this could indicate appreciation of the level of study and/or limited awareness of the training that other support staff undertake. It should be noted that this was not confirmed by the consumers themselves and other factors may be involved. However, ambiguity around the pharmacy assistant role in NZ led assistants to feel that customers perceived them as general retail assistants with limited knowledge, who did not accept their recommendations even when pharmacists provided the same advice.[31] Support staff in NZ and students in this study attributed this to a 'white coat effect' where customers only listen to the pharmacist. Campaigns and strategies that improve awareness of the important role of support staff and their competence and training are needed to encourage customers to be more open to OTC consultations with all types of support staff. Exploration of experiences of customer response and OTC decision

516   making amongst other support staff is also needed to ensure that this supports appropriate

517   OTC medicine supply.

518   *Limitations*

519   The majority of participants were enrolled at Griffith University which is located in South-

520   East Queensland, close to the New South Wales border. As such this may not reflect the

521   views of students at other universities, and incidents involving scheduling differences may be

522   over-represented compared to other regions. All participants worked for corporate pharmacy

523   brands across different groups providing a rich diversity of experience yet the views of

524   students working in smaller, independent community pharmacies may not be represented.

525   Social desirability bias may have been introduced via use of a pharmacy student researcher;

526   interview questions were designed and tested to mitigate this by exploring both positive and

527   negative aspects of decision making. Data analysis did not question the quality of OTC

528   decisions as the study aim was to explore factors that influence these decisions. Use of the

529   CIT meant that the decision making of students who do not work in community pharmacy

530   could not be explored. Therefore, findings are not generalizable to all pharmacy students;

531   survey research using vignettes would address this. This additional work needs to include a

532   larger, more heterogeneous sample of pharmacy students across Australia. Flanagan et al.

533   suggested a number of ways to collect data using the CIT, including observations.[27] While

534   this study relied solely on student recollection of incidents, which is subject to recall bias,

535   observational work also has its limitations, such as 'observer's paradox' and a reduced scope

536   of incidents.[42] Semi-structured interviews were chosen for this study due to resource and time

537   constraints, and have been used as a sole method of data collection in other CIT studies.

538

Conclusion

In this study customer response and confidence were perceived by students as highly influential in OTC decision making and this was underpinned by a number of inter-related clinical, safety and legal/professionalism factors. Whilst tension between evidence, professional guidelines and negative customer reaction influenced OTC decision making, this was governed by an over-arching concern for customer safety. Students are conscious of the importance of balancing clinical appropriateness and evidence with customer expectations yet they may need additional skills to do this effectively. Real-life practice was proposed as more effective than university teaching for this group of students, further emphasising the importance of work-based placements or similar opportunities (e.g. simulated patients and role-plays) in pharmacy curricula. This exploratory qualitative study provides ideas on future direction for pharmacy practice, education and research to support optimal OTC decision making by pharmacy students and future pharmacists.

Conflict of Interest

The authors declare no conflicts of interest

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