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### Pharmacists' roles in assisted reproductive technology



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### ABSTRACT

*Background:* The global issue of infertility has prompted an increased reliance on Assisted Reproductive Technology (ART) for conception. In Australia, patients have previously accessed ART medications through specialist clinics, however recently due to modifications in ART medication subsidisation, community pharmacists now dispense and counsel patients on ART medications. Patients residing in rural and remote locations face challenges in accessing fertility clinics, which are primarily located in metropolitan and large regional cities. *Objective:* To investigate the perceived role, experience, confidence, and training requirements that pharmacists

have in relation to providing ART medications and counselling to patients. *Methods:* Purposive sampling related to location of practice, pharmacist experience with ART and self-classification as an ART specialist was used to recruit 19 Australian pharmacists from rural, remote, large regional, and metropolitan areas, who participated in semi-structured interviews based on the Consolidated Framework for Implementation Research (CFIR). Interview transcriptions were transcribed, imported into NVivo, analysed using thematic analysis and mapped to CFIR domains and constructs.

*Results*: Of the nineteen pharmacists interviewed, six were from rural and remote areas and thirteen were from metropolitan or large regional areas. Eight participants perceived themselves as specialist pharmacists in ART, all of which were in metropolitan or large regional locations. Three CFIR domains were identified as relevant for this study, which were further developed, with data mapped to eleven constructs under those domains. Emergent themes were identified that contributed to the pharmacist role including patient needs, external policies, fertility clinics, pharmacist experience and training, procuring ART, and the personal attributes of participants. Some constructs and themes differed between participants dependent on self-reported specialisation status and geographical location (e.g., self-efficacy), whereas others were consistent (e.g., knowledge and belief about the intervention). Pharmacists considered their role not to be limited to the supply and counselling of medication, but to also involve a support role for patients undergoing an emotionally difficult and sensitive journey, without guaranteed success.

*Conclusion:* This study reveals the diverse role of Australian pharmacists in ART, influenced by location, experience, and confidence. Pharmacists have an important role to play in reducing barriers to ART access by offering fertility education, addressing concerns, providing medications and counselling, and monitoring patient wellbeing, improving outcomes for this cohort of patients particularly in rural and remote areas.

### 1. Introduction

Approximately 15% of couples worldwide are affected by infertility, which is defined as the failure to achieve pregnancy after 12 months or more of unprotected intercourse.<sup>1</sup> Assisted Reproductive Technology (ART) is a group of procedures used to treat infertility, of which the most commonly known is in vitro fertilisation (IVF).<sup>2</sup> The number of initiated ART cycles in Australia and New Zealand is increasing, with the latest

statistics showing a 5.8% increase from 2018 to 2019.<sup>2</sup> In Australia, the Federal Government partially funds ART procedures, however the outof-pocket cost to the patient are still considerable, often resulting in expenditure into the tens of thousands of dollars.<sup>3–5</sup> Costs to patients in many other countries are also high, with variable funding models in place.<sup>6–10</sup>

In 2015 in Australia, changes were made to the way ART medications were supplied to patients.<sup>11</sup> Previous to this, medications were supplied

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directly through a fertility clinic, however changes were made as to how these medications were subsidised by the government, which resulted in supply (dispensing) of ART medications now being a responsibility of community pharmacists.<sup>11,12</sup> For pharmacists, this was a new area of pharmacy practice, with many unknowns, new drugs and/or indications. In ART, medication regimens vary depending on the type of infertility being experienced, from tubal disease to severe male factor infertility and unexplained infertility.<sup>3</sup> The medication regimens are often complex and require the pharmacist to have knowledge of the drugs as well as a good understanding of reproductive systems and the processes of ART.<sup>2,3,13</sup>

The dispensing of medication and education of patients on how to safely and effectively use medication are core to a community pharmacist's role, however the education element is not compensated in Australia.<sup>14</sup> Community pharmacies are highly accessible, provide health care without appointments, and are located Australia wide, from metropolitan areas to small rural and remote towns.<sup>15</sup> When considering ART medications, adherence, administration and storage of medications is even more crucial than for most other medications.<sup>16</sup> This is due to precise timing of administration required to ensure optimal chance of success, and the temperature sensitivity of a number of products used.<sup>16</sup> A failure to comply to the strict regimen can lead to an unsuccessful treatment cycle and it is for this reason that pharmacists are well situated to convey correct administration techniques (including injection), instructions on how and where to store the large number of prescribed medications, and emphasise the importance of timely administration to patients.<sup>16</sup> The effectiveness of pharmacists delivering this information was highlighted in a study in Spain, which identified that patient medication knowledge increased from 60.9% before pharmacist counselling to 90% after counselling.<sup>16</sup> In this same study, it was identified that patients were receptive to being counselled and were satisfied with the pharmaceutical care provided.1

Of the few studies that have investigated the pharmacist role and/or patient satisfaction with pharmacist services in ART, it appeared that the role was quite varied and could be dependent on the pharmacist's experience and whether they are regarded as a specialist pharmacist in ART.<sup>17–19</sup> In Australia, there is no formal qualification that determines whether a pharmacist is a specialist in this area. A 2009 study in Ireland compared community and self-designated specialist pharmacies in regards to pharmacy performance and satisfaction with fertility medication supply from a patient perspective.<sup>17</sup> Patient perspectives of their experiences in this study, as well as another study conducted in America suggested that the experience of the pharmacist with ART medications potentially influences the service provided.<sup>17,18</sup> The Irish study reported fertility patients experienced disproportionate and more significant adverse pharmacy encounters in community pharmacies, when compared to perceived specialist pharmacies.<sup>17</sup>

Pharmacists are involved in the supply of medications which are used in the multiple and varied steps of the ART process, however the pharmacist role beyond supply is unclear, with limited papers available in this unique area of pharmacy practice.<sup>2</sup> The lack of research into this topic combined with changes to the supply of ART medications contributed to consideration of what the pharmacist's role is, and should be. The aim of this study was therefore to investigate the perceived role, experience, confidence, and training requirements pharmacists have in relation to providing ART medication and counselling to patients. Barriers to accessing ART, relationships between ART clinics and pharmacies, as well as the experiences of metropolitan, rural and remote, and "perceived specialist" versus "general" pharmacy practice was also investigated.

### 2. Methods

The reporting of this manuscript was completed following the COREQ (Consolidated criteria for reporting qualitative research) guidelines for reporting qualitative research.<sup>20</sup>

### 2.1. Study design

This qualitative study was conducted across Australia to capture information on pharmacists' perceived role, experience, confidence, and training requirements in relation to providing ART medications and counselling to patients. A literature review was used to identify current barriers to patients accessing ART and areas in which pharmacists could have a positive patient impact in ART practice.<sup>21</sup> Semi-structured interviews were selected as the data collection method of choice due to the strength in allowing high levels of detail to be recorded. The information obtained from the literature review contributed to the development and design of the interview questions.

### 2.2. The research team and reflexivity

The research team is comprised of female researchers with backgrounds in pharmacy. The principal researcher (AMM) is an academic and registered pharmacist, with experience in both community and hospital pharmacy, in rural, remote, and large regional centres. SMT and BDG are experienced pharmacists, academics, and researchers. All researchers are aware and sensitive to the unique journeys of people experiencing infertility, and hence wanted to investigate the role that pharmacists currently have in providing ART services for patients, with a view to beginning a research journey where this experience could be improved for infertility patients. Due to the diverse cultures and geographical size of Australia, the authors are invested to consider the equality of services provided in all areas of Australia, particularly in vulnerable populations in rural and remote areas.

The Pharmaceutical Society of Australia (PSA) 'Equality Statement' describes that everyone should have access to healthcare, and that as some of the most accessible health care professionals, pharmacists need to ensure that healthcare is provided to all in an inclusive and appropriate way.<sup>22,23</sup> All authors acknowledge the need for equitable access to healthcare irrespective of socioeconomic status, geographical location, ethnicity or culture. They believe that all people should be able to access equivalent quality health services for infertility in a culturally safe way.

### 2.3. Theoretical framework

The Consolidated Framework for Implementation Research (CFIR) and themes obtained from the literature review were used to inform the design of the semi-structured interview outline.<sup>24,25</sup> CFIR was the chosen framework to guide the determination of the assessment of contextual determinants and was considered appropriate to provide a lens for understanding the multidimensional variables at play within a health service.<sup>26</sup> For this study, domains from CFIR that informed the interview design appropriate to this study included Outer setting (patient requirements for accessing ART (including barriers) and the relationships between ART providers and pharmacies), Inner setting (consideration of the pharmacy experience of, and ability to provide ART pharmacy services to patients), and the Characteristics of individuals (the pharmacist views of their role and position in ART service provision).<sup>25</sup>

### 2.4. Sample and recruitment

Inclusion criteria for participants comprised being a practising registered pharmacist in Australia, with hospital pharmacists excluded.

Recruitment of participants was via a multimodal approach using purposive sampling related to location of practice and if ART services were provided by the pharmacy. Rural and remote pharmacists were primarily recruited through the "Rural Pharmacy Support Network" (n = 2) and via the Facebook group "Rural Pharmacy Network Australia" (n = 4). Members of these groups are representative of active pharmacists in rural and remote areas and those interested in participating contacted the author via email to receive study information. Metropolitan and large regional area practicing pharmacists were recruited by emailing pharmacies located in these areas. Email addresses for metropolitan and large regional pharmacies were sourced via a government website "service finder", where a list of pharmacies could be generated by selecting location. Searches were also completed via the internet for pharmacies specifying ART or IVF as a pharmacy service. The capital city of every state in Australia, as well as large regional areas in each state had pharmacies randomly selected from the search. Pharmacies specialising in ART were identified by the listing of IVF or ART as a pharmacy service on their website, with pharmacies not listing those as a service also contacted to ensure data was collected from both perceived specialist and non-specialist pharmacists in these areas. Participants were invited to participate in an interview through an emailed invitation, which included an information sheet.

### 2.5. Data collection

A mutually agreeable time was organised to conduct the interview, via Zoom or telephone. All interviews were electronically recorded, transcribed verbatim, and allocated pseudonyms to maintain confidentiality during coding. Interview guides were developed in collaboration with experienced researchers BDG, SMT and interviews were conducted by AMM.

Data collected in the interview included the participants location of practice, experience with ART and whether they perceived themselves as a specialist pharmacist in ART or not. Pharmacist location of practice was recorded via postcode and allocated in accordance to the Modified Monash Model (MMM) as a rural and remote region (MM3-MM7) or a large regional or metropolitan area (MM1-MM2).<sup>27</sup> This was important to address the identified barrier of remoteness/distance to accessing ART, identified in the literature review.<sup>21</sup> A rating scale was used to record the pharmacists' confidence in their own knowledge and skills (Scale 1–10 with 10 being the highest confidence). There are no formal qualifications in Australia that identify a pharmacist as a specialist in ART, however pharmacists were questioned as to whether they considered themselves to be a specialist in this area of practice due to their experience and/or work environment. The classification of being a specialist pharmacist in ART was used to determine if differences existed between reported experiences, confidence and role descriptions between perceived specialist and non-specialist pharmacists.

### 2.6. Data analysis

The data from the interviews were initially analysed using thematic analysis according to Braun and Clarke.<sup>28</sup> The data was analysed by two

researchers with discrepancies resolved by discussion to reach consensus. Pharmacist interview responses were mapped to CFIR domains and constructs by deductive thematic analysis with identified barriers from the literature review incorporated.<sup>24</sup> Following review of initial deductive coding of participant quotes, code descriptions were developed under the CFIR constructs. The code descriptions reflected the constructs in view of this study and allowed mapping of the thoughts and experiences of pharmacists relating to their confidence, perceived role, training requirements, and their own thoughts of their practice and capabilities. Identified barriers from the literature were used to further scaffold the "Patient needs and resources construct" from the "Outer setting" domain of CFIR providing further insights regarding patient factors and pharmacists' potential role in addressing these barriers.<sup>25,29</sup> Three CFIR constructs from the appropriate domains were not represented in participants comments and were removed, with the remaining eleven represented. Pharmacist quotes were separated according to the self-classification as a perceived specialist or non-specialist pharmacist in ART to allow for data to be compared and contrasted.<sup>25</sup> Illustration of the relevant CFIR domains, constructs and barriers is shown in Fig. 1.

#### 2.7. Ethics

The study was approved by the James Cook University Human Research Ethics Committee (H8663) on the 14th of January 2022.

### 2.8. Research rigor

Rigor was determined by establishing the Lincoln and Guba criteria, encompassing credibility, dependability, confirmability, and transferability, for qualitative data collection and analysis.<sup>25</sup> Data saturation was attained when no new themes were reached, with 19 participants.<sup>28</sup> Credibility was established through extensive engagement with the research topic and participants.<sup>30</sup> Dependability was achieved through the transparency of documented study procedures and external review from those not involved in the interview process (SMT and BDG).<sup>30</sup> Confirmability was ensured through thorough inclusion of insightful stakeholder quotes which supported the emerging themes from both 'perceived specialist' and 'non-specialist' pharmacists.<sup>30</sup> Further enhancing confirmability was the inclusion of all data, irrespective of conformity with the interview guide, increasing the depth of data analysed and themed.<sup>31</sup> Transferability was addressed by in depth describing of participants, study context, and procedures.<sup>30</sup>

<b>Outer setting domain-</b> Patient, Policies, Infertility clinics	<ul> <li>Patient needs (and barriers)</li> <li>External policies</li> <li>Infertility centres</li> </ul>	
Inner setting domain - Pharmacy	<ul> <li>Pharmacy experience, skills, knowledge, and training</li> <li>Medication supply</li> <li>Emotional skills</li> <li>Procuring ART medications</li> <li>Internal communication</li> </ul>	
Characteristics of individual domain - Pharmacist	<ul> <li>Pharmacist role in ART</li> <li>Medication</li> <li>Emotional support</li> <li>Own capabilities</li> <li>Personal attributes</li> </ul>	

Fig. 1. CFIR domains and constructs relevant to this study.

### 3. Results

### 3.1. Participants

Nineteen pharmacists were interviewed, including six from rural or remote locations and thirteen from metropolitan or large regional areas. Participant demographics are summarised in Table 1. Eight pharmacists identified as specialist pharmacists in ART, all of which were practising in metropolitan or large regional locations. The categorisation of perceived specialist and non-specialist was self-assessed on an individual pharmacist's reflection of their own practice. Pharmacists were asked to report on their confidence in knowledge and skill in ART pharmacy practice with an average score across all pharmacists of 5.2 out of 10 (range 1-10). Perceived specialist pharmacists (all located in metropolitan areas) reported a confidence of 8.4 out of 10 (range 8-9) and non-specialist pharmacists reported their confidence as an average of 2.9 out of 10 (range 1-5). Rural and remote and metropolitan and large regional non-specialist pharmacists reported some variation in their average confidence with rural and remote non-specialist pharmacists reporting confidence as 3.3 (range 3–5) and metropolitan and large regional non-specialist pharmacists as 2.4 (range 1-4).

After 19 interviews no new themes or codes emerged. Table 2 outlines the codes and themes aligned with constructs from the Consolidated Framework for Implementation Research (CFIR).

# 3.2. CFIR outer setting - the influence of patient needs and external policies and external networking on the pharmacist's role in ART

#### 3.2.1. Patient needs

This theme primarily identifies the needs of infertility patients, including the facilitators and barriers to patients accessing ART. Timely access to the medications required for infertility treatment was identified consistently amongst participants, with difficulty in doing so acting as a barrier to treatment as well as contributing to psychological effects on the patient.

"Some patients say they don't know how hard it is to get the medication. So, they left it to the last minute and then they're stressing out because

### Table 1

Demographics of pharmacist participants (N = 19).

Participant demographics	Number (%)
Total number	19 (100)
Experience (years)	
<10 years	7 (37)
10-20 years	7 (37)
20+ years	5 (26)
Sex	
Male	1 (5)
Female	18 (95)
State	
Queensland	4 (21)
New South Wales	7 (37)
Australian Capital Territory	2 (10.5)
Victoria	1 (5)
South Australia	2 (10.5)
Western Australia	3 (16)
MMM Category	
MM3-MM7 – Rural or remote location	6 (32)
MM1-MM2 – Metropolitan or large regional location	13 (68)
Perceived specialist in ART (total participants)	
Yes	8 (42)
No	11 (58)
Perceived specialist in ART (rural or remote location)	
Yes	0 (0)
No	6 (100)
Perceived specialist in ART (large regional or metropolitan location)	
Yes	8 (61)
No	5 (39)

Exploratory Research in Clinical and Social Pharmacy 12 (2023) 100376

### Table 2

Summary	of	codes	aligned	to	Consolidated	Framework	for	Implementation
Research (	CF	IR).						

	0.1.1	n · 1	
Construct	Code description	Perceived	Non-specialist
		specialist	pharmacist
		pharmacist	examples
		examples	
Outer setting domain			
Patient needs and	Facilitators and	"I think a lot of	"It's not
resources	barriers to	them are so	uncommon for
	patients	overwhelmed,	somebody to cry
	accessing or	they just need to	when picking up
	continuing ART.	be told what to do	the medication,
		with their modications " [D0	it's important to
		nharmacist _	enhanced
		perceived	privacy and
		specialist	sensitivity." [P4
		metropolitan]	pharmacist
			owner - non-
			specialist rural/
			remote]
Geographical		"Most of them	"The IVF process
location barriers		seem to be in a	is quite a
		capital city	stressful process
		many clinics	for people, so if
		located in	four weeks
		regional areas. So	holiday a year
		certainly, there is	and you've used
		discrepancy of	up all your weeks
		access between	in your traveling
		different	for IVF you don't
		locations. There's	have your
		travel, potentially	downtime. [P11
		accommodation	pharmacist
		and work." [P14	owner – non-
		pharmacist –	specialist rural/
		specialist	Temotej
		metropolitan]	
Time barriers		"People come in	"Those patients
		with Excel	were located
		spreadsheets of	quite a distance
		their	away from the
		appointments,	clinic. These
		their medicines,	injections had to
		when they must	be at a certain
		take it, how many	time, within a
		and how long it's	frame and that's
		going to last. It's	why they
		verv time	approached the
		consuming." [P1	pharmacy
		pharmacist	because they
		manager –	didn't think they
		perceived	could get to the
		specialist	clinic in time."
		metropolitan]	LP2 Pharmacist –
			non-specialist
Financial barriers		"In the last two	"The ones that
Thancial barriers		weeks I've had	get referred to a
		women ask me for	private clinic
		quotes on their	report that the
		medications	money gets
		emailed through	bigger and
		on official	bigger and
		letterhead	bigger. I think
		Decause they can	that as well as
		apparentiy access	traveling
		superapputation	often take a dav
		(pension) for IVF"	off, that impacts
		[P1 pharmacist	finance as well.
		manager –	[P6 pharmacist
		perceived	in charge – non-
		(conti	nued on next page)
			1.07

### A.M. Mackay et al.

### Table

able 2 (continued)				Table 2
Construct	Code description	Perceived specialist pharmacist examples	Non-specialist pharmacist examples	Constru
Psychological barriers		specialist metropolitan] "It's a stressful situation for the patient and it makes people behave in different ways. And there's that emotional cost as well as financial involved, which can compound the situation." [P13 pharmacist owner – nerceived	specialist rural/ remote] "She lost a little one at 24 weeks, and that was 10 years ago, and she said, it's taken this long for her to mentally try again but for some reason it didn't sit right with her to go in Australia, so she chose Europe" [P6 Pharmacist	Extern and in
Minority group barriers		specialist metropolitan] "There is a challenge in many non-English	in charge – non- specialist rural/ remote] "Some people are used to not having access to	
<ul><li>Cultural</li><li>Race</li><li>Languages</li></ul>		speaking people. We have a multicultural team, the brochures in other languages, use translators and somebody in the family. It's	a lot of health care. They might just think, now I'm just going to keep trying the natural way, because what are they going to do?" [P12	Inner se Struct charae
		about getting the correct communication across. [P7 pharmacist – perceived specialist metropolitan]	Pharmacist manager – non- specialist rural/ remote]	
Educational level of patient – barriers		"Some patients don't have good health literacy. They don't understand the storage of the medication. They think to the eight degrees is where they make the	"Because of the investment, emotionally, financially etc., some people may educate themselves more in that area than they normally would do." [P16	Netwo comm
Cosmopolitanism	Networking and relationships between fertility clinics and pharmacies	ice." [P10 pharmacist – perceived specialist metropolitan] "We worked hard to get that relationship going. The professionale	pharmacist in charge – non- specialist rural] "It's getting better, the clinic seems to have a 24-h support now but confige	
	pharmacles	need to be in an	on that wasn't	Suppl

established

have good

because ultimately, we want patients to have a better outcome." [P10 pharmacist – perceived

relationship and

communication,

able 2	(continued)
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Construct	Code description	Perceived specialist pharmacist examples	Non-specialist pharmacist examples
External policies and incentives	External government policy regarding ART medication supply and guidelines to appropriate prescribing, dispensing Benchmark reporting	specialist metropolitan] "It is not in the AMH (Australian Medicines Handbook), it's not something that we learned at uni, the doctors have their own knowledge, and they are quite experienced in what they're doing. We have resources available to us in other areas of health, but not ART [P1 pharmacist manager – perceived specialist metropolitan]	"Some of these things, used to be done in clinic and now with the medication, patients can fill the script and do it themselves. There's a little bit more autonomy for the patient to do it." [P4 pharmacist owner -non- specialist metropolitan]
Inner setting domain Structural characteristics	Experience in the pharmacy in ART and ability to perform ART dispensing for patients	"T m in a clinic. It's a setting that I can take the time and I have access to private rooms, where I can do that. My pharmacy is not accessible to the public, my pharmacy is purely IVF related." [P1 pharmacist manager – perceived	"I've had really limited exposure as a community pharmacist in IVF. It is usually someone asking about is this medicine safe or if this medicine will interfere." [P6 pharmacist in charge – non- specialist rural]
Networks and communications	Communication and support within a pharmacy relating to ART	specialist metropolitan] "We must be a specialist pharmacy, so we get the extra accessories and training material. There's a lot more involved than you'd expect in a normal pharmacy." [P8 pharmacist manager – perceived specialist	"We've got a good dispensing team of people that are really good at communicating and will speak out if they've got a difficult script and ask if you can look out for me for a minute." [P12 Pharmacist manager – non- specialist rural/
Supply issues	Ability to source and supply ART medications to patients	metropolitan] "If there's something special, then we must run around and try to figure out how we can get it on time. But being in Sydney, we do have another backup." [P10 pharmacist _perceived	specialist rural/ remote] "A pharmacist from another pharmacy called me and said, I'm the only pharmacist today, I'm really struggling can you take care of this if I send this patient over. He just hadn't seen this before. so I

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the case" [P4

pharmacist

owner -non-

specialist metropolitan]

### A.M. Mackay et al.

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Exploratory	Research	in Clinical	and Social Pharmacy	12	(2023)	100376
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Construct	Code description	Perceived specialist pharmacist examples	Non-specialist pharmacist examples	Cons
		specialist metropolitan]	don't know if most of the fertility patients come to us." [P12 pharmacist in charge – non- specialist rural]	Tr rec
Culture	Expectation of pharmacy participation and services provided within a pharmacy	"If I was in a normal pharmacy and this is not what we specialise in, I would have just said here's your things. If you've never dispensed that before it would be very difficult." [P9 pharmacist – perceived specialist metropolitan]	"The workload seems quite high when it comes to these medications. It's all high-cost cold chain so sometimes you're making loss. And the time that you're spending with the patient adds to the workload." [P12 pharmacist in charge – non- specialist rural/ remote]	St
Implementation climate	Capacity and support for changes to pharmacy procedures or involvement in ART services	"We talk about experiences to see if patients have a reason for behaviours. And we have conversations as to what we should do, and how could we have done this better." [P13 pharmacist owner – perceived specialist metropolitan]	"Providing patients with financial support by putting in after pay. And having an account system where they have an additional month to pay down the medication." [P4 pharmacy owner – non-specialist owner rural/ remote]	tra pa em Acc
Readiness for implementation	Commitment and ability of a pharmacy to enhance or increase ART services	"Some reimbursement, some funding for providing a professional service that would be beneficial to providing the service." [P9 pharmacist – perceived specialist metropolitan]	"There was a policy change where every fertility medication had a consult with the pharmacist, so the patient had all the information that was required." [P12 pharmacist in charge – non- specialist rural/ remote]	inf gu
Available resources - Training and education	Training and education for ART pharmacy practice	"Reps come in regularly and keep us up to date, there is also YouTube's, zoom meetings, doctors chat to us, and we're invited to a brief that regular pharmacists will not have access to "P7	"Training or education has been hard to find, there's not really any out there. A lot of what I've done has just been extra reading. "[P6 pharmacist in charge – non- specialist rural]	Char. Kn bel int

pharmacist – perceived specialist metropolitan]

Construct	Code description	Perceived specialist pharmacist examples	Non-specialist pharmacist examples
Training requirements		"You've got training to be a diabetes educator. I personally believe that IVF should as well. It's so niche, and it should have recognition that there's more than a handful of pharmacists now dealing with this." [P15 pharmacist owner – perceived specialist metropolitan]	"The basics of the different types of medications available, treatment protocols, first line, second line, at what point do you do you initiate this one, what influences drug choice. Side effects, administration techniques, timing. Monitoring cycles and knowing when to administra." [P3 pharmacist – non-specialist
Strategies and training for patients with emotional issues	Training and education for coping with patients with emotional issues	"It's something you can learn. Through customer training I have been able to develop those skills and learn how to pick up those cues a little bit faster." [P1	metropolitan] "It should be on the path to be reducing the stress of the women as much as you can." [P12 pharmacist manager – non- specialist rural/ remote]
Access to knowledge and information - guidelines	Ability to source ART information	pharmacist manager – perceived specialist metropolitan] "If the patient chooses to use their local pharmacy, it's really problematic for the pharmacies because they really don't have the access to purchase other than the list on the PBS (Pharmaceutical Benefits Scheme)." [P7 pharmacist –	"And there doesn't seem to be a lot of professional development available on these medications user for treatment, so it's really just like trying to learn as we go." [P4 pharmacist owner – non- specialist rural/ remote]
Characteristics of ind Knowledge and beliefs about the intervention	lividuals domain Consideration of the pharmacist's belief of what the pharmacist's role is in ART - medication	perceived specialist metropolitan] "We specialise so it's >50% counselling, it takes 20 or 45 min for one person. I discuss storage, then this helps to grow your eggs, and this is the trigger that releases it,	"I believe that ir a community pharmacy, it is to support the client to access the medication in a timely manner, and also to reconfirm the directions from the prescriber,

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for their call. And nurse to ensure

A.M. Mackay et al.

#### Table 2 (continued)

Construct	Code description	Perceived specialist pharmacist examples	Non-specialist pharmacist examples
		then how to use a sharps bin." [P8 pharmacist manager – perceived specialist metropolitan]	that they understand how the medication works." [P4 pharmacist owner – non- specialist rural/ ramotal
Knowledge and beliefs about the intervention	Consideration of the pharmacist's belief of what the pharmacist's role is in ART – emotional support	"I did have one lady tear up. You have those moments where you must put aside what you had planned to do, which was focus on medicines and just acknowledge that feeling of the patient." [P1 pharmacist manager – perceived specialist metropolitan]	"It's largely a supportive role; everyone's going through a very difficult time. We just need to be there to support whatever decisions they decide to make with their medications within our own limits." [P2 pharmacist – non-specialist metropolitan]
Self-efficacy	Pharmacists' belief in their own capabilities in ART pharmacy practice.	"About an eight out of ten. Because it's just so complicated it's, it's not a one size fits all. You think you've got it down pat and then they change the protocol." [P8 pharmacist manager – perceived specialist metropolitan]	"If I'm comparing it to other things that I do, I would say that I feel very much under done with my knowledge of IVF." [P11 pharmacist owner – non- specialist rural]
Other person attributes	Personal traits of individual that influence their role and/or ability to work in ART pharmacy practice	"You know I've done this for too long, too. I think the older you get, the more you're equipped to deal with it." [P8 pharmacist manager – perceived specialist metropolitan]	"As a pharmacist feel like it's just such a special connection with that customer in a real moment of vulnerability. There's a whole lot more than just providing the medication, in terms of the support." [P4 Pharmacy owner – non-specialist rural and remote]

Acronyms used in quotes: AMH – Australian medicines handbook: a comprehensive guideline and compulsory resource in Australian pharmacies which contains therapeutic information, drug monographs and drug class statements. PBS – Pharmaceutical Benefits Scheme: a formula of medications that are available to patients in Australia at a Government-subsidised price.

they can't access their medication and they need to start." [P10 pharmacist – perceived specialist metropolitan].

Pharmacists identified variations in patient counselling needs, with some patients requiring intense and repetitive counselling, and others with greater health literacy requiring less intense interventions. "The health literacy can be quite low, then there are women where I can give minimal instructions and they understand it completely, even if it's their first cycle." [P1 pharmacist in manager – perceived specialist metropolitan].

Other psychological influences related to medications included patient fear of self-injection, drawing up of correct doses, knowing which medications should be taken when as well as fear of adverse effects from medications. Potential fears are associated with the strict requirement of medications to be given at precise times, with patient errors potentially contributing to a failed cycle.

"Patients often get a shock reaction, because in their head, they just thought it's going to be an oral medication and then it's not and I explain that this one, unfortunately is an injection." [P6 pharmacist in charge – non-specialist rural/remote].

Pharmacists identified that in conjunction with supplying medication and instructing patients on how to take their medications (particularly in relation to the patient's specific protocol), educating patients related to the storage requirements of medications and ensuring that the patient had the correct medications and sufficient supply was also required.

"I can help a patient understand how to use the medication, but the storage is critical for a lot of their medications. Patients need to understand storage, otherwise the cycle is likely to not be successful" [P14 pharmacist – perceived specialist metropolitan].

Perceived specialist pharmacists described that a range of medications could be required by a patient and that these medications are not routinely held in a "non-specialist ART" pharmacy. If a medication was to be changed, difficulties could be experienced by a patient who did not live in close vicinity to a pharmacy, who stocked these items. This requirement particularly impacted people living in rural and remote areas.

"Let me know what medications you need, and I'll tell you like whether we keep them or not, don't leave it to the last minute." [P12 pharmacist in charge – non-specialist rural/remote].

The culture and ethnicity of patients and their partners was found at times to impact communication in the counselling process. For Aboriginal and Torres Strait Islander patients, it was stated that their culture of Men's and Women's business impacted communication between the couple themselves as well as with health professionals of the opposite sex.<sup>32</sup> This was explained as being similar in some middle eastern cultures, where the male partner communicated for the female patient, however, was not comfortable speaking with a female health professional.<sup>32</sup>

"There were situations where I have to speak to her husband, which was very difficult because the husbands don't want to speak to a woman about it." [P14 pharmacist – perceived specialist metropolitan].

"My experiences with Aboriginal and Torres Islander patients are that they are very closed, and that they don't discuss any of those issues with different gender." [P5 pharmacist owner – non-specialist rural/remote].

### 3.2.2. External policies

An important barrier to a patient accessing ART is the cost of the treatment. As several ART medications are subsidised by the Australian government, there is limited influence that a pharmacist can have on the cost of medications to the patient, with some patients not understanding that the cost of medications is separate from the cost of the fertility treatment.

"Even at the reduced prices, cost can still be a big concern. We're coming out of drought now, but for the farmers and others, it was hard. Sometimes medications just weren't really going to be an option to continue. It's a do I eat or get medicines situation. [P12 pharmacy manager – non-specialist rural/remote].

Guidelines for usual patient protocols are difficult to access and this adds to the difficulty to pharmacists in making a clinical judgement as to the suitability and safety of medications for patients.

"It was quite confusing. I do think I wasn't very confident in my knowledge. And that's because the training was never enough, and you never have that level of confidence." [P18 pharmacist – non-specialist metropolitan].

### 3.2.3. Infertility clinics

Communication and professional relationships between fertility treatment clinics and pharmacies varied considerably and was not limited to differences between perceived specialist pharmacies and nonspecialist pharmacies.

Metropolitan pharmacists had a variety of relationships with fertility clinics, ranging from pharmacists being embedded within the fertility clinic, through to the pharmacist being purely responsible for the supply of medication, with traditional pharmacist roles of counselling delegated to nurses employed by the clinic.

"One of the things I really enjoy, is that I'm in an environment where I'm able to collaborate." [P1 pharmacist manager – perceived specialist metropolitan].

"But again, we just stood in the background, got the treatment plan, organised the medicine, the only contact I had with patients would be to receive the payment and that's all we were told to do, not to discuss anything." [P15 pharmacist owner – perceived specialist metropolitan].

In rural and remote areas, of the pharmacists that had some involvement with ART, they found that they had a good relationship and ability to communicate with the infertility clinic.

"A lot of scripts come back through from the clinics now. We would like them to provide some training for us so we can better assist our clients." [P4 pharmacist owner -non-specialist rural/remote].

3.3. CFIR inner setting – the influence of the pharmacy setting on the role of pharmacists in ART

# 3.3.1. Experience and training - knowledge and skill in providing ART medications

This construct focuses on the pharmacy level and the experience of pharmacist(s) in that pharmacy and the influence on services provided. In pharmacies who specialise in ART, it is standard to stock the medicines and have the availability of equipment to ensure correct storage conditions. The exposure to dispensing ART medications also influenced the awareness and knowledge of the pharmacist. Participants noted that exposure to knowledge about these medications was limited or non-existent in undergraduate pharmacy degrees, and there was limited CPD in this area. Pharmacists who identified as specialists in ART received training "on the job", from experience in this area of practice, and from information and training from drug representatives and doctors and nurses in fertility clinics. Being involved and having accounts with suppliers of ART medications also gave those pharmacies access to resources for educating patients and themselves.

### 3.3.2. Experience and training - emotional skills

Participants reported patients undergoing infertility treatment as being more emotional than the average patient potentially due to the stress of trying to conceive and/or medication side effects. Pharmacist's confidence in their ability to communicate effectively with emotional patients varied. "They can be pushy or really stressed, and I'm trying to help, but if they are in a state of panic, then I become panicked too. I'm now not working at the same speed that I would normally work." [P9 pharmacist – perceived specialist metropolitan].

### 3.3.3. Procuring ART

The ability of a pharmacy to procure ART medications for patients was reported as dependent on several factors. Knowledge of the products and accessories required for administration had an impact on the ease of ordering the correct products.

"I think that's one of the biggest challenges in community pharmacy and with accessing those drugs, do you know where they had to be sourced from? [P2 pharmacist – non-specialist metropolitan].

How commonly these products were ordered and where they were ordered from had an impact on the price to the pharmacy as well as the availability. Those pharmacies who commonly stocked the medications could order direct from suppliers rather than wholesalers.

"But if you buy it from whichever large wholesaler you use, you actually pay more to the wholesaler than you get back on the PBS." [P7 pharmacist – perceived specialist metropolitan].

The timeliness at which the products could be sourced was also dependent on the location of a pharmacy. Rural and remote pharmacies due to distance and logistics had longer lead times and a potentially less reliable arrival date.

"It can actually take a day longer than the wholesaler website says, and even though that day doesn't sound like a lot, it is when you've got somebody at somebody that's really depending on that." [P4 pharmacist owner – non-specialist rural/remote].

3.4. CFIR individual characteristics – individual characteristics of the pharmacist and the influence on the role of pharmacists in ART

### 3.4.1. Pharmacists' role in ART

When participants discussed what they believed the pharmacist role in ART was, they identified that it was not just the supply of medication to the patient, but also the need to support the patient throughout their journey. It was generally believed that ART should be a team approach and that the pharmacist's role should involve all aspects of good pharmacy practice.

"It is a very personal and emotional journey. And I think the people involved in that journey and helping them, need a certain type of personality or the ability to at least acknowledge that and help, not hinder that process, that needs to be a level of care." [P1 pharmacist manager – perceived specialist metropolitan].

Participants reported variation in the pharmacist's role, which ranged from medication supply to lengthy patient counselling. Pharmacists identified a requirement for an increased involvement in ART.

"Right through from making sure that the patients have all the medications they need for a cycle, knowing how to store the medications, and how to use the medications is extremely important. They've never injected themselves before so there's a lot of understanding around confidence and understanding what the medications are used for. [P7 pharmacist – perceived specialist metropolitan].

Emotional support was thought to be required, however not the primary role of the pharmacist. Ensuring that confidentiality was maintained, in a private area was considered important for patient safety and respect but also to enable effective counselling.

"I think you have to you have to be gentle, you have to switch on all of your body language and to think as well, and we always try to be aware of privacy and confidentiality." [P4 pharmacist owner – non-specialist rural/remote].

The pharmacist's belief in their own ability to practise in this area was variable. Confidence and ability to practice in ART pharmacy practice correlated with the level of exposure pharmacists to supplying ART medications. Those who had had no exposure felt ill equipped and not confident in this area, whereas pharmacists' whose key role involved ART felt very confident in this area. In Metropolitan areas non-specialist pharmacists, selfreported a lower level of confidence in knowledge and skills than nonspecialists in rural and remote areas.

"I would say not very comfortable I think it's because we don't do it every day. I feel like every time I do it, I want to check it again and the stakes are high. [P4 pharmacist owner – non-specialist rural/remote].

3.4.2. Personal attributes of participants were felt to contribute to the ability to cope with emotional patients and to appear sensitive and caring in this role

Pharmacists reported that experience both in pharmacy and life enhanced their ability to cope in these situations.

"It's maybe a skill, that's a life skill and experience, and a level of empathy that develops. When you are an early career pharmacist, you're too busy thinking about your indemnity." [P4 pharmacist owner – non-specialist rural/remote].

Participants reported a need for training in this area. Participants reported that they felt pharmacist personality and emotional intelligence contributed highly to a pharmacist's ability to communicate under somewhat difficult situations and that these skills could not be taught.

"Perhaps some strategies to know how to respond to patients." [P18 pharmacist – non-specialist metropolitan].

"I think that more training on the empathy supply. Just the level of humanity that's required, I think that would be good to start that at university and people thinking about how they could impact somebody's journey in a positive way. [P4 pharmacist owner – non-specialist rural/ remote].

### 4. Discussion

The role of the pharmacist in ART was found to vary dependent on the pharmacist's exposure, experience, location, and confidence in this area of pharmacy practice. Pharmacists' confidence in their ability and knowledge of ART medications was found to be primarily related to their experience with ART, but also acknowledged the impact of how they are supported in that role. The years of experience that participants had spent practicing as a pharmacist did not significantly contribute to their confidence in dispensing and counselling ART medications. The main contributor to an increased confidence in ART pharmacy practice, was experience working with these medications and patients. It was noted that there are few educational opportunities in ART either as an undergraduate or after graduating and that the perceived specialisation classification was indicative of the proportion of the workday spent with ART. Training for perceived specialist pharmacists was primarily based on experience, exposure and relationships with ART practitioners and education by the drug supplier representatives. Regular exposure in this area increased the ability of the pharmacist to access these extra resources, which would not be available to all community pharmacists. Barriers to patients accessing ART identified in literature are reflected by the pharmacists view of geographical, cultural, psychological and financial barriers.<sup>21</sup>

The ability of a patient to access the medications required for their ART journey, including acute changes to their medication, is essential to the success of their treatment.<sup>7</sup> As well as timely access, instruction on

how to store, dose, and administer medications needs to be comprehensive and appropriate to the patient to enhance the potential for successful treatment.<sup>16,17</sup> Participants in this study emphasised the same points, illustrating the ideal role of the pharmacist, although it was identified that pharmacists with little experience in ART were not always confident of providing a service to this level. Studies have shown that patient anxiety around medications can contribute to being a barrier to undergoing or continuing ART.<sup>17,19,33,34</sup> A previous study had identified that patients ART medication knowledge can be been increased by 30% as a result of pharmacist counselling, emphasising the importance pharmacists have in this role.<sup>16</sup> This current study has indicated that the ability of pharmacists to deliver a good service to ART patients has been found to be related to their self-classification as a specialist or not. This has also been reported in a study in Ireland where the experience of the pharmacist and classification as a specialist was seen to have an impact on patients' satisfaction with their ART pharmacy experience.<sup>17</sup> It was found from the study in Ireland that patient experience was rated more highly from specialist pharmacists compared to non-specialist pharmacists, with more adverse encounters occurring from non-specialist pharmacies.<sup>17</sup>

Pharmacists in this study noted the lack of readily available, definitive guidelines for ART medications and indicated that it is difficult for pharmacists to check and confirm the correct doses and timing of the medications that they are dispensing. This was reported in this study to lead to a reduced confidence in pharmacists, especially when there was a lack of experience or exposure to these medications. The medications used and individualised treatment plan for patients as well as the preferences of individual prescribers or fertility clinics was described as varying significantly. When pharmacists were familiar with prescribers or fertility clinics it enabled pharmacists to generally to feel more comfortable with dispensing and counselling as the dosing regimens were consistent. Generally, relationships between pharmacies and fertility clinics were strongest with perceived specialist pharmacists who supplied medications for specific clinics. There is evidence that fertility clinics are primarily located in metropolitan or large regional areas and hence there is significant distance between the fertility clinics and the rural and remote pharmacies.<sup>35,36</sup> Rural and remote pharmacists in this study were also found to form relationships with the fertility clinics, however these relationships were less involved and existed only when they had dispensed medications from a particular clinic. This was potentially due to intermittent contact with the fertility clinics as a result of locality and volume of dispensing, as well as the decreased ability to access advice and training.

Previous studies have identified that the geographical location of a patient can act as a barrier to accessing ART, particularly rural and remote areas.<sup>5,7,36–39</sup> This study it has shown that the pharmacists in these locations feel less confident in their knowledge and skill in procuring, dispensing, and counselling on these medications, which is likely due to the lack of consistent exposure to supplying ART medications and the ability to specialise. It is noted however that even though the rural and remote pharmacists had a markedly reduced confidence rating compared to metropolitan or large regional, their confidence rating when compared to non-specialist pharmacists in metropolitan areas was higher. Patient access to pharmacists who specialise in ART can act as an advantage by way of enhancing patient confidence, availability of medications, and ready access to expert information for reassurance.<sup>17,19</sup> Currently this is difficult to access in remote settings due to pharmacists not having to opportunity to train and specialise in this area.

Patient cultural backgrounds were indicated to significantly impact the communication and counselling process between pharmacist and patient. The cultural appropriateness of the pharmacist in tailoring counselling to patients of diverse backgrounds is critical to effective medication management and the psychology of the patient.<sup>32,38,40</sup> There are cultural differences around communication and acceptability of infertility, and it is important to note that particular cultures have specific needs in relation to this area.<sup>32,38,40,41</sup> The race, ethnicity, and culture of a patient have an impact on accessing ART, communicating about ART, and if not respected and understood could have a negative impact on the patient's journey.<sup>32,38,40</sup> Pharmacists being proactive and educated in the cultures of their community could contribute to reducing cultural barriers and increase access to infertility treatment.<sup>38,42,43</sup>

In Australia, although medications for ART are significantly subsidised by the Australian government, this does not apply to all medications for ART and there is also a lack of awareness from patients that the medication cost is a separate and additional cost from those at the fertility clinic.<sup>4,12</sup> The counselling of these medications is not separately reimbursed by the government or by patients, although significant time is spent on this service.<sup>4,11</sup> Pharmacies who specialise in ART report buying some medications direct from suppliers as opposed to through wholesalers, decreasing cost for the pharmacy and the patient, when not a subsidised medication. As cost has also been identified as a barrier to accessing ART, the ability for a patient to go to a specialty pharmacy can function as a financial barrier to access.<sup>21</sup> Perceived specialist ART pharmacists in this study illustrated their knowledge of how to procure items and the accessories that are required for the administration of some medications as part of the ART process. Where to procure the medications from was a concern of pharmacists who rarely dispensed these items, which was compounded by the variety of medications used to treat infertility, due to different methods and individualisation of ART. Relationships of pharmacies that specialise in ART with suppliers was reported to enable not only ready access to advice but also a potential cost saving by buying direct. As no rural or remote pharmacists interviewed had that relationship, this highlighted a greater divide in knowledge especially regarding procurement and associated devices.

Limited research has been conducted around the pharmacist's role in ART. It has been stated that the complexity associated with some ART procedures results in medication regimens that are complex for the patient, and are also complex for the pharmacist.<sup>19</sup> Experienced and confident pharmacists can be an excellent resource for medication management, counselling, injection technique guidance, managing adverse effects as well as providing understanding and emotional support.<sup>19</sup> The perceived specialist pharmacists interviewed confirmed the ability to be a valuable resource when the working conditions and business model allowed. Most perceived specialist pharmacists had a very involved role to play in ART medication management, however some were limited by internal policies where the main role was the supply of medication with restricted patient interaction.

As was suggested in the study from Ireland, a classification of specialist pharmacists via a minimum volume of fertility related prescriptions may have some merit but would require further investigation to confirm applicability.<sup>17</sup> Also considered would be a credentialling of pharmacists to identify them as a specialist in this area, however consideration and restriction to specialist-only dispensing of ART medications could potentially act as a barrier to patients accessing these medications, particularly in rural and remote areas if no specialist pharmacist was available. To address this and to increase patient access to specialist pharmacists, a mentoring and tele-health program between pharmacists located out of metropolitan and large regional centres could be introduced to enhance the services to rural and remote patients and decrease barriers to access.<sup>44</sup> An increased exposure to ART pharmacy practice in both undergraduate and post-graduate degrees and/or CPD opportunities would also potentially increase the baseline knowledge of the associated medications and procedures, allowing pharmacists in this area to have a greater knowledge.<sup>45-47</sup> Further study to assess patient experience and needs especially in rural and remote communities is recommended to further scaffold the data to allow for more informed recommendations to be made.

### 5. Limitations

This study represents the perspectives of Australian pharmacists with various levels of experience and exposure to ART medications. Limitations included the ability to define a specialist pharmacist or have criteria assigned to it, limited existing literature involving the pharmacist's role in ART, and ART patients experience with pharmacists and pharmacies. It is considered that the participants personal experiences, knowledge or interest in this area could have introduced bias into the study.

### 6. Conclusion

This study explored the role of the pharmacist in ART from the pharmacist perspective. The geographical location of the patient and the pharmacist was identified as having a major impact on the services available and the role of the pharmacist. The role of the pharmacists was shown to vary most significantly between perceived specialist and nonspecialist pharmacists, but also between metropolitan, and rural and remote non-specialists. There was desire expressed for non-specialist pharmacists to be better skilled in this area to be able to provide a better experience for patients, especially in rural and remote locations. As timing, accuracy of administration, and storage of medications by the patients themselves is critical to the effectiveness of most ART procedures the role of the pharmacist in ensuring the patient is confident and competent can add to the potential success of fertility treatment. Expanding practice to support patients undergoing ART has the opportunity increase accessibility and decrease requirements to travel as well as provide the opportunity to address psychological concerns, and decrease patient barriers to accessing ART.

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### **Declaration of Competing Interest**

None.

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