ORIGINAL RESEARCH



Exploring learning characteristics and progression of GP trainees based in regional, rural and remote settings: A qualitative study

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Abstract

Objective: Globally, most doctors train and work in metropolitan areas but a key strategy for developing the rural health workforce is expanding rural training. The aim of this study was to describe the scope and quality of learning along with skill acquisition of GP trainees based in regional, rural, and remote settings.

Setting: Regional, rural and remote settings in Queensland Australia excluding Brisbane.

Participants: Thirty-seven general practice trainees who had undertaken their first community placement were recruited from regional, rural and remote learning settings within Queensland.

Design: Qualitative descriptive methodology based on constructionist epistemology was employed which allowed for the exploration of current GP trainees' experiences. Trainees were interviewed and data were thematically analysed as to the scope and quality of learning by the setting of training. Learning experiences were then mapped against the Dreyfus and Dreyfus model to explore skill acquisition. **Results:** In terms of the scope and quality of learning, rural and remote trainees mainly focused on the diverse and unique (sometimes challenging) experiences their setting offered compared with regionally based trainees. Mapping of the trainee comments to the Dreyfus model of skill acquisition demonstrated that regardless of setting, equivalent learning occurred by GP trainees.

Conclusions: This exploratory study provides evidence that rural and remote learning may provide a more diverse and challenging experience. It suggests an equivalence of quality of education and skill acquisition across settings rural, regional and remote. This suggests that the training distribution policies may not disadvantage GP trainees and the scope and quality of more remote learning may increase uptake of remote placements.

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KEYWORDS

education, general practice, GP trainees, remote, rural, skill acquisition

1 | INTRODUCTION

Ensuring an equitably distributed and sustainable rural medical workforce remains a critical challenge for the Australian health system. Many rural and remote communities are struggling to achieve a stable and welltrained general practice (GP) workforce to deliver the primary care needed for their community. 1-3 Although medical training is well established in metropolitan areas, it is only since the 1990s that rural general practice was specifically recognized as an area needing specific skills and workforce professional development.^{3,4} This gap led to the establishment of the Australian College of Rural and Remote Medicine (ACRRM) and the refinement of pre-existing training of the Royal Australian College of General Practitioners (RACGP) to create an additional Fellowship in Advanced Rural General Practice (FARGP) for GPs to work at the wider scope required in rural areas where there are fewer other doctors. Over this time, there was increased regionalization of GP training and an official policy requiring that at least half of all GP registrars undertake their training in rural areas.⁵ To attract GP trainees to more rural and remote posts, over regional ones, relies on assurance of training quality including being able to convey that such posts offer GPs trainees an equivalent chance to progress in their learning and achieve the GP Fellowship requirements.

In Australia, general practice training takes at least 3 years with trainees undertaking 1 year as a hospital doctor, and at least two further years based in general practice under the clinical supervision of qualified GPs, in a location of the trainee's choice. However, a deficit discourse exists regarding superior offerings in urban areas compared with rural settings and rural locations can be positioned as dull and backward. This prevailing discourse may influence trainee views about whether to pursue training in more distributed rural and remote locations, fearing that such training may offer an inferior learning experience.⁷ Given that training in rural areas as a GP also increases the likelihood that trainees will continue to work in rural/ remote areas for up to 5-year post-qualification⁸ encouraging the uptake of rural and remote training remains important to ongoing rural workforce development and overcoming the maldistribution of doctors in rural and remote areas.

Medical learning in rural and remote locations is hypothesized to include diverse clinical skills and possibly more complex skills and improved critical thinking based

What is already known about this subject?

- Undergraduate placements in rural, regional and remote areas have been shown to produce positive learning outcomes.
- Doctors that train in rural areas are more likely to work in rural areas.
- The Australian Government has a policy that requires distributed learning.

What this study adds

- Remote, rural and regional training placements offer equivalent quality of learning experiences.
- Skill acquisition of GP trainees occurs across all settings.
- Findings support the distributed training model for GP registrars.

on more isolated working conditions and working at wider scope. 9-11 However, better understanding the difference between the characteristics and progression of learning of GP trainees based in more remote locations would inform the justification of ongoing policies to distribute training and assure trainees of its equivalence. 12 Currently, there is little data investigating the value and outcomes of learning in different geographical locations specific to GP training, even though this workforce is the most important to the development of rural medical services.

1.1 | Aim

This study aimed to explore the scope and quality of GP learning and any differences in skill acquisition of GP trainees by their training setting: regional, rural and remote.

2 | METHODS

2.1 Study design

This study was led by James Cook University GP Training which is the regional training organization that operates general practice training for a region which covers around 90% of the geography of the state of Queensland, Australia and notably excludes Brisbane which was selected because of its diverse regional, rural and remote trainee cohort. Queensland has an area of 1727000 square kilometres with half of its population (approximately 2.5 million) living outside the capital city of Brisbane and First Nations people making up approximately 8% of Queensland's non-metropolitan population and over 28% of its remote population (AIHW¹³). This study applied qualitative descriptive methodology based on constructionist epistemology which allowed for the exploration of current GP trainees' constructs of knowledge to be developed relative to their setting of work, regional, rural or remote. ^{14,15}

Ethical approval was obtained from James Cook University Human Research Ethics Committee (H8241) and then ratified by The University of Queensland Research Ethics Committee (No. 2020002764). All methods were performed in accordance with the relevant guidelines and regulations by including a statement in the Ethics approval.

2.2 | Learning setting

Learning setting was allocated into three categories for this study, which were defined in two steps which recognized both rurality and a functional typology of the scope of work and dynamics of the practice which confirmed regional, rural or remote classification. Step one related to rurality and Australia's national rurality measure, the Modified Monash Model (MMM) rurality classification was applied, 16 with MMM1-2 (metropolitan and regional centres) defining 'regional'; MMM3-4 (large- and medium-sized rural towns) defining 'rural'; and MMM5-7 (small rural towns and remote/very remote communities) defining 'remote'. Step two involved two senior medical educators with intimate knowledge of the work within GP learning settings in the region, assessed the extent to which the learning setting involved a greater breadth of practice typical of more remote GP work. This was informed by the characterization of rural generalist scope, as defined in Australian policy, typified as working independently of specialist back up and providing emergency and other advanced services as well as general practice or the trainee being present in the setting as an outreach service. ¹⁷ From this process, five locations that were initially classified 'remote' were reclassified as 'rural', including because it was part of an outreach learning experience, rather than a residential experience in that setting. Additionally, 56 'rural' locations were reclassified as 'remote' if trainees resided in-situ full time, worked at generalist scope, did not regularly meet their supervisor face to face and thus relied on distant education. This two-step method ensured

that the rural location of learning settings was informed by national standards for rurality as well as functional aspects of the context of practices and how doctors worked in those practices.

2.3 Data collection

Registrars who had undertaken their first community placement for at least 6 months were sent information about the study and were invited to take part by completing an online research study enrolment form. Study details were sent by both email and SMS with one reminder. Completion of the online form and providing their contact details indicated consent to be contacted. Interested participants were then invited by the project officer to undertake an interview (25–30 min) describing their learning experiences.

Interviews were undertaken by two female PhD-trained qualitative researchers (EA & TG) using a semi-structured interview guide which was informed by literature based on theorizing about differences related to the performance of undergraduate medical student learnings in different community settings.¹⁸ The guide explored GP trainees' placement experiences including learning progression, supervision and the advantages and disadvantages of their current location. It was piloted with experienced rural GPs and refined based on their feedback. Interviewers were not linked to the assessment of GP training, nor were they known to the participants. Interviews took place via Zoom or by phone depending on each participant's preference between the interviewer and participant with no-one else present and ranged between 25 and 40 min. Each interview was then transcribed verbatim, and any identifiers removed. Participants received a \$50 gift card in respect of their time. By the end of October 2021, 37 interviews were completed, and recruitment ended as the research team, after discussion, considered that data saturation had been reached.

2.4 Data analysis

Two members of the team who undertook the interviews independently coded five interviews of the data inductively using interpretative thematic analysis. ¹⁹ Emerging themes were then discussed with consensus reached between researchers before coding and recruitment continued. Data were analysed iteratively with the majority of themes occurring in the early interviews and thematic saturation reached by around 30 interviews but seven more were done to confirm findings and ensure inclusion of women interested in participating in the study. ²⁰



TABLE 1 Dreyfus and Dreyfus model.

| | Skill level | | | | |
|-----------------|-----------------|-------------|-------------|-------------|-------------|
| | Novice | Competent | Proficient | Expert | Master |
| Mental function | | | | | |
| Recollection | Non-situational | Situational | Situational | Situational | Situational |
| Recognition | Decomposed | Decomposed | Holistic | Holistic | Holistic |
| Decision | Analytical | Analytical | Analytical | Intuitive | Intuitive |
| Awareness | Monitoring | Monitoring | Monitoring | Monitoring | Absorbed |

Note: Dreyfus and Dreyfus 1980.

In addition, de-identified transcripts were shared with the research team and thematic codes were also discussed regularly with the wider research team for collective sensemaking from varied perspectives. This assisted to triangulate the data. QSR NVivo was used to manage the analysis.

In line with the methodology the researchers drew from the learners' perspective of developing knowledge in their context to understand how each individual constructed knowledge these were then mapped to Dreyfus and Dreyfus model stages of learning (described below) describing how the trainees' reflected in their interview, achieving novice to competent, with exemplar quotes describing how the trainees' reflected in their interview, achieving novice to competent (See Table 1).

2.5 | Skill acquisition

The Dreyfus and Dreyfus model²¹ of skill acquisition was developed in the 1980s and was modelled around pilots learning to fly a jet plane and novices learning chess. It has been applied widely by medical educators relating it to the acquisition of clinical skills and physician competence.^{22–24} The model breaks down the process of skill acquisition into five parts (novice, competent, proficient, expert, master) (Table 1). This paper focuses on the first three levels, from novice to competent and then competent to proficient on the basis of assessing learning progress specific to the early stage of GP training of the cohort in this study.

The Dreyfus and Dreyfus model describes the novice as being mainly rules driven, in this case the novice uses analytical reasoning and rote memory (pathophysiology, clinical signs and symptoms) to link to diagnosis and has limited ability to prioritize information. As the novice gains increased experience, although still using analytical reasoning, they recognize patterns in patient encounters and begin to recognize and reflect on what is important and engage in deeper learning. Novice learning then becomes more situational as the novice becomes more familiar with their environment and the skill, thereby shifting

from the abstract to the concrete task or concept. Novices then see the bigger picture based on previous decisions; at this point, the novice becomes competent although may still require some supervision. The move from competent to proficient occurs as the trainee requires less supervision and begins to work more autonomously. Learning then becomes more holistic, and patient treatment becomes increasingly based on mental and social factors rather than clinical diagnoses issues alone. The learner at this stage has not only enough experience to unconsciously recognize patterns of illness but also the confidence to consider changes to these patterns. They are also more comfortable with uncertainty, although they may still need to use analytical reasoning for complex cases.

3 | RESULTS

Of 37 trainee respondents, 17 were females and 20 were males, ranging in age from 28 to 34 years. Trainees covered regional, which included one MMM1 participant (57%), rural (27%) and remote (16%) settings. Overall, remote trainees focused mainly on their learning and the patient diversity they experienced while regional trainees focused more on resources compared with those in urban centres, as well as issues related to referrals, supports and services. Rural trainees commented on a combination of the above, often citing lack of resources but valuable learning experiences and patient diversity. The scope and quality of learning is further described by setting below followed by progression of learning.

3.1 | Location – scope and quality of setting

Trainees in regional settings commented that they valued working outside the capital cities because they may offer more varied learning opportunities. Depending on the location, access or lack of access to tertiary services was viewed by many trainees as an advantage.

but I think I'm definitely – compared to some of the colleagues I know back in Brisbane, I probably get to do a little bit more in terms of practical skills, and certainly, I feel like we manage probably some of the issues that my more urban colleagues may have referred a bit earlier.

RNR481-Regional

However, negative aspects of regional training like reduced access to subspecialties, were expressed by some I'd say a few things like a few subspecialities are not here, like neurosurgery, pain medicine, vascular surgery, and even neurology, rheumatology – rheumatology they have a clinic in the [Hospital], so there are a few limitations with specialty. RNR717- Regional.

Regional areas were noted to have a wide variety of different practice foci and patient groups which may impact skill acquisition. Trainees commented on differences between bulk billing and private practices with each practice appealing to a different patient demographic, potentially because each practice operated within a wider market.

The demographic here is very narrow, so I definitely miss out on a lot of chronic disease exposure. Yes. I'm looking at [another practice] I think basically they see a whole array of patients. But they definitely do quite a bit of chronic disease stuff as well. It's also a very optimal location for me, in terms of my kids' school and day care is right there, literally. But I am conscious that I will be sitting exams with very little hands-on experience.

RNR727-Regional

While another said An advantage I guess – because it's a private – our practice is private billing. So I spoke with a few other registrars. I guess we don't get some of the patients that they see. Like, for example, lots of Centrelink Certificates. We don't get – because of the private billing. RNR680 Regional.

In comparison, rural trainees reported they saw more differentiated patient caseload (wider variety), sicker and more complex patients requiring more active intervention like procedural work due to more limited local tertiary care options, than reflected by their regional counterparts. One participant commented.

I think it's definitely going to be a valuable experience for me. Just even working in a rural town, you get to see a lot of varieties, compared to some of the colleagues who are working in urban areas as well. Not only just in terms of the scope of patients that you see but also in terms of the variety and procedures you can actually perform and learn from your supervisors, so I think that's been really valuable for me.

RNR721-Rural

Another noted.

In [Rural Town Practice], I'm seeing patients that actually are quite ill and have not sought medical care, especially because there's no tertiary hospital nearby.

RNR480-Rural

Trainees commented on the wide scope of practice and the opportunities to become a rural practitioner (a rural generalist), and good linkages between hospitals and the private practice allowing them to cross-learn different areas of medicine for complementary practice.

I think it's really good at the start of – like still being a junior trainee – to be across both acute and community facilities. I think to do 100 percent of one or the other – like do 100 percent of GP, you'd lose some of that inpatient or acute medicine skill, which is still pretty underdeveloped. And also they complement each other a lot, I think. Certainly in a rural setting. So I wouldn't say that it's more linked in the community, but certainly in the health of the region, definitely. It's nice to be in both aspects of it.

RNR648-Rural

Another commented.

I guess initially just seeing where a patient might come into ED with – let's say a minor surgical problem, and they could go in the same day from ED to having an anaesthetic review, straight to theatre to get it sorted out and then admitted to hospital; and they're all managed by the same doctor, or two doctors, the whole time. And it was like, holy cow man. Like, you guys just flow the whole thing into one presentation.

RNR636-Rural

This wider scope of practice was discussed by trainees in remote locations reflecting that they saw a wide caseload they perceived would not occur elsewhere. They also

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commented on their speed and depth of learning with the broad scope of practice in a remote area which contributed to their overall learning.

Yeah, so I wasn't really sure what to expect, to be honest, but I definitely think I wouldn't have had the amount of exposure that I've had here, back home, just the cohort you know. I've talked to some of my friends doing physician training, they're like, 'All your patients are like a long case'. I'm like, 'I know'.

RNR503-Remote

I felt that I was quite stressed for the first 6 months, just with the on-call and making decisions and being quite autonomous, but my learning is actually much better. So if I would stayed in Brisbane or was not doing rural generalism, I do not think my learning would have peaked as much, the velocity at getting the knowledge and sitting my exams early.

RNR624-Remote

Noted disadvantages by remote trainees were the lack of specialist and ancillary health services requiring trainees to take on some of the specialist roles while waiting for patient treatment. The workload was seen to be busy and staff shortages were noted.

Oh, I see heaps, which is interesting, and then of course, within GP, see a lot of the interesting tropical disease as well. Like, well, they see it in hospital as well, leptospirosis, ross river, things like that, which is interesting. And I'm not sure if it's often just being in a rural area, because there's less services we might do a few more things in-house or make more assessments in-house rather than referring.

RNR645-Remote

'What should I do'? It's more, 'How do I go around this in this setting, in this rural setting with my lack of access'? I guess that lack of specialist care is a positive and a minus, you can argue that, because a lot of it is forced down on your shoulders that could be seen as a positive or a negative depending on how you see it.

RNR700-Remote

Participants in all locations reported they saw a variety of patients which assisted their learning. However, GP

trainees in rural and remote locations commented extensively on the range of patient's conditions and procedures they were required to manage and treat which may assist them in becoming independent practitioners.

3.2 | Learning progression by setting

Learning progression was then aligned with the Dreyfus stages of skills acquisition and compared between trainees in regional, rural and remote locations. Trainees early in their placement tended to be rule driven suggesting the novice stage of thinking. However, as trainees obtained more clinical experience in their placement they gave accounts consistent to the Dreyfus competent and proficient stages.

3.3 | Skill level – Novice

In the early days of the placement that trainees in all settings (regional, rural and remote) were performing at the novice level relying mainly upon learned rules and supervision to perform their role, with limited differentiation in learning progress.

My supervisor Dr X- if you have talked with her, she will tell you I needed a tremendous amount of support at the beginning, OK. Nearly every other patient I have to talk with the supervisor, because I come from the hospital system. So this is the way how it was. Like I said, nearly every other patient I have to ask them for some advice.

RNR680 - Novice Regional

While another said, 'I think clinical knowledge in – potentially I think only retrospectively, I appreciate how much I grew. I think at the time, I was just floundering; and I suspect that was more so just because I was PGY3'. RNR631 – Novice Rural.

Many trainees, regardless of setting, commented on the difficulty of the transition from hospital to fee-for-service community practice which involved not only clinical skills but also a demand for time management and administrative skills, especially in the early days of training. One trainee commented.

so it's just more that going back and figuring out what could these things potentially be, what's my differential list, what's more likely, how do I organize that, and then on top of that, where do I organize that, because in a rural town, like, who on earth is going to do what I need. Yeah.

RNR391 - Novice Remote

3.5 | Skill level – proficient

A smaller proportion of trainees gave accounts that suggested proficiency. Demonstrating skills that allowed them to recognize what is meaningful and more importantly what is not relevant or important. Less supervision was required and decision making improves as shown in the following statement:

this; I've done this before; this is how things

RNR494 - Competent Remote

work. We can do this safely and effectively.

Yes. I think I'm confident that I know that whatever comes in the door, even if it's an emergency, I can deal with it.

RNR645 - Proficient Rural

Trainees at this level of skill acquisition showed a level of comfort in their management of patients, especially around risk and uncertainty where their learned experience could help them extrapolate the known situation to the unknown situation.

> And it's like anything, once you start to build your knowledge, and get more comfortable with it, and you start to enjoy it a bit more as well, don't you? So, you know what was once scary, then becomes interesting.

> > RNR684 - Proficient Regional

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I guess the main thing for me was becoming more comfortable with uncertainty and being more comfortable with being uncomfortable just not knowing what's going to happen to the patient when they walk out of my consult room or ED or on the ward, there's no time to observe and change your mind.

RNR503 - Proficient Remote

All locations provided clinical learning and development of skills through the Dreyfus stages novice to proficient, indicating that regional, rural and remote locations provided extensive and relevant learning opportunities. Trainees in rural and remote locations may appear to progress to the competent and proficient stages of skills acquisition more quickly with more comments focusing on them becoming clinically independent, having to show initiative and self-reliance in managing their diverse clinical caseloads.

3.4 | Skill level – competent

Achievement of competency, the second stage of the Dreyfus and Dreyfus model was also demonstrated in all settings as trainees gradually built experience of consultations which helped them to recognize patterns and similar situations. There were increased accounts that they were able to interpret meaningful signs and symptoms. This suggested that learning was no longer purely abstract, and that supervisors were used more for guidance with trainees commenting on requiring less supervision. With increased exposure to patient encounters learning became more situational and past experience impacted on clinical reasoning and trainees became more comfortable within their roles in the practice irrespective of whether they were in regional, rural or remote locations:

I definitely feel a lot more confident now in October compared to six months ago in April, where I will be asking my supervisor for every third or fourth patient – it's quite common now the whole day I don't actually need to run anything by my supervisor, so I think it's progressing well. So I don't feel like I will be completely able to be independent just yet; I think it just needs a lot more time and experience.

RNR481 – Competent Regional

Probably getting to the point where you think you don't need – you don't want to ask dumb questions anymore. So sometimes you have to go – notes to the reg, important to keep getting feedback on the way you're doing things. Yes, pretty confident. I'm still early in the training, but I could definitely see – we don't have a lot of – use a lot of supervisor support at the moment'.

RNR648 - Competent Rural

I think it's really shaped me very well to be a good doctor, a good generalist. It's given me a lot of confidence, practising here, training here, to pretty much practice in a different rural community and be confident that yes, I can do

4 | DISCUSSION

This study is one of the first of its kind to explore the quality and scope of learning and discuss skill acquisition by GP trainees in regional, rural and remote areas, from the perspective of trainees. Registrars in regional, rural and remote locations reflected on their learning experiences with each location having different characteristics, challenges and opportunities which suggests that quality learning may occur in diverse environments.

The context of more remote practice may enhance the scope of learning opportunities over regional settings (although this may vary depending on whether registrars work in practices that target a specific caseload or billing type which narrow the scope). This concurs with recent research where both supervisors and GP trainees who were interviewed identified seeing a wider range of cases in rural and remote areas, along with more acuity, and chronicity (Peel et al., 2020; Young, Peel, O'Sullivan, & Reeve, 2019). In addition, trainees in these settings may have to manage a more diverse range of patients with reduced reliance on referral. On the other hand, learners in regional settings identified having more access to specialist services but worried that the lack of diversity in practice caseload might limit their learning.

The Dreyfus and Dreyfus model²¹ analysis identified that the acquisition of clinical skills by transition through the novice to proficient stages had minimal specific relationship with learning setting. This study suggests that GP training in all these locations provides appropriate quality and consistent learning opportunities, with capacity for trainees to progress through the novice, competent and proficient Dreyfus stages of skills acquisition. These results challenge the deficit discourse and geographical narcissism described by⁶ indicating rural and remote GP trainee placements provide equivalent, not inferior, clinical learning opportunities for trainees.

The findings overall suggest the value of rural and remote vocational training in GP learning and help to assure the quality of the learning experience regardless of location. Research by McKendry et al. shows the equivalence of quality across locations in postgraduate training with regard to summative assessments²⁵; however, this study provides updated evidence specific to GP vocational training.

Showcasing the quality and outcomes of remote learning could reinforce government policies to maintain distributed rural vocational training in general practice. Further, it may help to attract GP learners who can be assured and confident about the quality of more remote learning, particularly with its potential to give a wider breadth of learning experience and lead to more widely skilled doctors (of rural generalist practice scope). It is hoped that improved subscription and a regular rotation

of remote placements may also assist in providing much needed increased medical services to underserved rural and remote populations.

5 | LIMITATIONS

There are several limitations to this study. This study was exploratory, and only captured the views of GP trainees at a single point in time in their learning journey. The research could be expanded by exploring this topic longitudinally and considering the latter stages of GP training and other vocational pathways in medicine. As the study was based in the unique regional, rural and remote context of regional, rural and remote Queensland the study could be repeated in other jurisdictions and include metropolitan and capital city locations. Due to the geography (large distances, extreme remoteness) and the health system governance and financing model in Queensland (which may impact scope of work) the research may not be transferable to other locations.

6 | CONCLUSION

This is the first study comparing GP trainee progression of learning in regional, rural and remote settings. The project suggests that equivalent progress in learning can be achieved across regional, rural and remote locations and there are benefits to the range of caseload and procedural work that might be available in more remote locations for trainees attracted to a wider range of training experience where good quality supervision is available. More remote GP training distribution may assist to build a more broadly skilled GP workforce who contributes longer term to addressing Australia's workforce maldistribution and health inequalities.

AUTHOR CONTRIBUTIONS

Emily Anderson: Conceptualization; formal analysis; investigation; project administration; writing – original draft. Tiana Gurney: Writing – review and editing; formal analysis; investigation. Louise Young: Conceptualization; validation; writing – review and editing; supervision; methodology. Belinda O'Sullivan: Validation; writing – review and editing; conceptualization. Lawrie McArthur: Conceptualization; funding acquisition; methodology; writing – review and editing. Matthew McGrail: Validation; writing – review and editing. Aaron Hollins: Conceptualization; writing – review and editing.

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However, the authors had full autonomy over the study design, data collection, analysis and interpretation and final manuscript.

CONFLICT OF INTEREST STATEMENT

EA, LM and AH are employed by either JCU or JCU GPT.

DATA AVAILABILITY STATEMENT

The interview protocol and datasets produced during the study are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

Ethical approval was obtained from James Cook University Human Research Ethics Committee (H8241) and then ratified by The University of Queensland Research Ethics Committee (No. 2020002764). All methods were performed in accordance with the relevant guidelines and regulations by including a statement in the Ethics approval.

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