Participant experiences of intervention to detect and manage familial hypercholesterolaemia in Australian general practice

A qualitative descriptive study

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Background and objective
General practitioners (GPs) are ideally placed to have a much larger role in detection and management of familial hypercholesterolaemia (FH) among their patients. The aim of this study was to seek the reflections of practice staff and newly diagnosed patients with FH on the implementation of an FH model of care in the general practice setting.

Methods
Qualitative descriptive methodology was used. Interviews were conducted with 36 practice staff and 51 patients from 15 practices participating in the study.

Results
Data were analysed thematically and coded into themes – efficacy of GP training, screening for FH, model of care, patient awareness and cascade testing.

Discussion
Findings reflect the real-world clinical experience of Australian general practice and the acceptability of the model of care for both patients with FH and practice staff. Patient health literacy is a barrier to both management of FH and cascade testing. A systematic approach to cascade testing is required.

HETEROZYGOUS FAMILIAL HYPERCHOLESTEROLAEMIA (FH) is a lifelong hereditary, autosomal dominant condition that remains underdiagnosed and undertreated in Australia and worldwide.1,2 The condition has potential to hasten premature coronary artery disease and early death due to accelerated atherosclerosis if left untreated.2,3 Affecting one in 250 in the community, FH is common but treatable.1–4 The current largest gaps in early detection and treatment are in children and young adults4–7 – individuals with most to gain from early intervention and ongoing management, but least likely to seek help with preventive care.

Early intervention and primary prevention offer the opportunity to mitigate the cumulative effects of increasing cholesterol burden from birth that progresses over an individual’s lifespan.4–6,8–10

With 88% of the population attending a general practitioner (GP) at least once annually,11 general practice is increasingly recognised as providing an ideal setting to initiate FH screening and contribute to management from an early stage.4,6,8–12,15 The European Atherosclerosis Society4 and International FH Foundation6 recommend that FH should be managed largely in primary care and preferably in a family context, with support from lipid or FH clinics for more complex cases and children. A shared care approach optimising the contributions of GPs and lipid specialists is recognised as a preferred approach for such management.4,8,12,15

Our National Health and Medical Research Council Partnership study (GNT1142883)16 examined the detection and management of FH in 15 general practices across five Australian states. Our study employed a pragmatic two-stage approach to rapidly identify high-risk patients with FH through use of a data extraction tool (TARB-Ex), followed by a medical record review and clinical assessment of confirmed high-risk patients to establish a phenotypic diagnosis of FH.16–18 This current article examines the reflections and perceptions...
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Experience of being active participants.

agreed to provide their reflections on their the study consented to take part and given information sheets about FH and patients with FH who had already been verbal or written consent to record their study. Each interviewee provided educational sessions and information study process.

with phenotypic FH as part of the held. We also conducted semi-structured and general practice registrars were also Practice group meetings involving GPs (PNs) from the 15 participating practices.

Study sample, setting and practice recruitment
A description of the study practices, their mode of recruitment and their setting is as outlined in the pre-intervention article. Overall, 15 general practices across five Australian states took part in the study. Five were from Western Australia, four from New South Wales, three from Queensland, two from Tasmania and one from Victoria. Nine of the practices were in larger metropolitan areas while six were in regional towns/cities and rural areas.

Methods

Recruitment and data collection
We employed a qualitative, descriptive methodology to privilege the participant voice, providing a rich narrative of their experience. Following application of the study protocol and completion of the study, semi-structured interviews were undertaken with 28 GPs, four practice managers (PMs) and four practice nurses (PNs) from the 15 participating practices. Practice group meetings involving GPs and general practice registrars were also held. We also conducted semi-structured interviews with 51 patients diagnosed with phenotypic FH as part of the study process.

Practice staff were provided with educational sessions and information sheets about the purpose and scope of the study. Each interviewee provided verbal or written consent to record their reflections on having participated in the study. Similarly, newly diagnosed patients with FH who had already been given information sheets about FH and the study consented to take part and agreed to provide their reflections on their experience of being active participants.

Interviews were audio-recorded and transcribed verbatim. Clinician interviews explored their perspectives on knowledge and confidence in diagnosing and managing FH, the effectiveness of the model of care used as well as their thoughts on the overall screening process and potential for family cascade testing from the new index cases. Interviews with PMs, PNs and patients also investigated their experiences of the overall screening process including diagnosis and management, as well as their perspectives on potential cascade testing among close family relatives.

Results

Key themes were coded from the data, and are listed in Table 1.

Efficacy of training program for general practitioners
The information sessions on the study protocol and the overall study process were well received by most GPs:

I didn’t know much about it before we started, it was very useful. The awareness and how to diagnose was very helpful, and then what to do. [Vic GP, rural]

GPs found the information increased their knowledge and awareness regarding the prevalence, diagnosis and treatment of FH, and considered the training beneficial. GPs and practice staff noted the need for re-enforcement and refreshment of information over time:

It would have been good to have had a few more meetings with the GPs to help encourage them with what was needed. [NSW PM, metro]

Perspectives on how the education materials should be delivered varied:

I think there should have been more one-to-one training with the doctors to actually show them what to do. [WA GP, metro]

Some participants liked the structure of the education sessions:

I think the education about FH at the beginning was really good, more GPs should get that to be honest. [Qld GP, rural]

Others identified opportunities for improving educational materials for busy practices, such as provision of documentation to the entire practice including information for patients:

We could have had easier online resources for everyone to share. [NSW PM, metro]

Building better understanding regarding the use of materials improved confidence over time as GPs were able to share their learning despite differences between practices. It also provided an opportunity to trouble-shoot solutions as they arose or were experienced elsewhere. Some participants found this common approach useful in developing a greater understanding about the management of FH in general practice.

Screening for FH
The value of proactively screening patients at risk of FH was well understood. Participants found it rewarding to:

See how many patients we were able to identify through the tool who were higher risk for CVD [cardiovascular disease] than we had appreciated. This meant we were
Setting up the processes for FH screening within the clinic was not easy:

It was hard to set up systems and folders in the practice where all the GPs could access the protocol and letters to send out to family and forms to enrol in the family FH registry. [NSW PM, metro]

Some patients were very positive about being contacted for screening:

I was more than happy because I know cholesterol has been a problem in my family all my life. [Qld patient, metro]

However, patients could be frustrated with lack of response to screening among family members:

I have spoken to my brothers, my sister, my father ... I remind them every time I see them, but I can’t make them go and do it. They aren’t kids anymore. [Qld patient, rural]

The initial extraction could be conducted by practice staff/PMs:

I ran the extraction tool, and the GP then applied the definitive identification criteria. [WA PM, metro]

The process was dependent on accurate records:

It would be good if the software was better at ensuring the family history was recorded and kept up to date. And ... get patients to have more regular lipid checks. [NSW PN, rural]

The screening process for some was unexpectedly ‘labour intensive’ and did not fit a streamlined workflow, with some GPs needing further data from patients:

There were a lot of patients whose records did not have enough information to be able to do a reliable Dutch Lipid Score (The Dutch Lipid Clinic Network Criteria

[DLCNC] score is a validated tool to assess the risk of FH.) ... we needed them to come in so we could go through everything in more detail. [NSW PN, rural]

The additional time needed to review clinical notes for patients identified at high risk by TARB-Ex was not anticipated:

It would have been great if the TARB-Ex data needed less GP reviewing time before we recalled them. [NSW PM, metro]

Some GPs felt the TARB-Ex tool was too sensitive and many could not identify how DLCNC scores were derived when scoring anomalies emerged:

I felt that there were far too many patients identified as being high risk and this made the work of chasing up patients very time consuming. [NSW PN, rural]

While TARB-Ex interrogated electronic medical records, it could not account for patient compliance with lipid-lowering medication regimens:

TARB-Ex itself didn’t take into account when people were on and off or had stopped or missed their tablets. So that affected their scores. [WA GP, metro]

Both these issues took additional time to address, either during or following consultations.

Some GPs expressed frustration that while TARB-Ex identified patients at highest risk for FH, it was not capable of delivering a diagnosis of FH. One would prefer:

... a tool that does your lipids screen at the same time ... sort of helping the doctors through what information they actually need to sign off formally and confirm. [NSW GP, metro]

For some, improving clarity about the reason for follow-up resulted in more proactive screening and follow-up of patients considered at high risk. The most demanding part involved:

... getting patients to come in for these recalls. It was hard to get patients in if they did not know or understand what we were trying to get them in for. [NSW PN, rural]

Although some participants spoke of issues concerning challenges in making a diagnosis of FH, use of the structured process of the DLCNC allowed GPs to develop confidence. One GP stated:

The key thing for me that changed my behaviour and approach was to learn about the Dutch criteria. That is really key to me ... it gives you a whole lot of structure. It gives you confidence ... [Vic GP, rural]

The model of care identified the role of the lipid specialist in the care of the FH patient. Although the FH guidelines recommend that patients with high complexity are seen in a lipid clinic:

It wasn’t clear when or why to involve specialists. [Vic GP, rural]

However, access to a lipid clinic was considered helpful when patients had additional complexity with their FH.

Some GPs expressed concern when referrals to a lipid clinic were not overseen by a lipid specialist. Such care was very dependent on the knowledge of the attending physician who may have:

... turned patients away ... didn’t realise that these patients were high risk and needed to actually be properly assessed. [NSW GP, metro]

The management of statin compliance among patients was supported by the model of care. Some patients had personal health beliefs, having:

... a fear of [a statin] ... All those artificial fears and things which must be acknowledged and addressed. [WA GP, metro]
Mistrust of pharmaceutical companies emerged:

[described in] an American newspaper... harmful side-effects and long-term use of a medication could cause blindness because of problems with your kidneys - so I threw them down... and for many years didn’t worry about my cholesterol at all.

[Qld patient, rural]

Other patients had statin intolerance and acknowledged that strategies for managing statin resistance provided to practices were helpful.

Patient awareness

Communicating clearly with patients regarding FH was seen as critical:

It flagged those patients that I would have probably thought not to be as aggressive with the treatment. I explained to them... why it was important... I gave

Table 1. Main themes, brief explanations and exemplar quotes

<table>
<thead>
<tr>
<th>Theme</th>
<th>Explanation</th>
<th>Exemplar quotes</th>
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<tbody>
<tr>
<td>Efficacy of training program for GPs</td>
<td>Usefulness of information</td>
<td>‘It was helpful... In general practice you learn about things and at the time it’s at the forefront of your mind and then after a while... it loses its forefront of awareness.’ [Vic GP, regional]</td>
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<td></td>
<td>Delivery of materials</td>
<td>‘... the tendency of web-based resources is that they are internally more sensitive and you could search them electronically, which of course you couldn’t do with the other stuff that was provided to us.’ [NSW GP, metro]</td>
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<td></td>
<td>Building confidence</td>
<td>‘... the person who was working with you became more confident in what she was doing and each practice has its own idiosyncrasies as to how they work... it got easier with time.’ [NSW GP, regional]</td>
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<tr>
<td>Screening for FH</td>
<td>Workflow issues</td>
<td>‘Yes, that was hours and hours of time that was unpaid for, so the notion of this TARB-Ex tool being quick and cheap is actually a cost if you rate a GP’s hours.’ [WA GP, metro]</td>
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<td></td>
<td>Sensitivity of TARB-Ex tool</td>
<td>‘I had to go through each patient’s score myself to identify how the score was derived. I spent quite some time scouring each person’s records to find out why they got that score...’ [Vic GP, regional]</td>
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<td></td>
<td>Data extraction tool</td>
<td>‘I think it is a “cry out” for one of the nice clinical algorithms. Like we have for INR [international normalised ratio] and cardiovascular risk.’ [Tas GP, regional]</td>
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<tr>
<td>Model of care</td>
<td>Supporting proactive screening</td>
<td>‘The main benefit of that is that if you are aware of the possibility of it being familial you will then do the follow-up screening of the relatives.’ [Qld GP, regional]</td>
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<td></td>
<td>Involvement of specialists</td>
<td>‘Yes, several of our patients were slightly complex and so the doctors in the practice were able to contact the lipid clinic and they really benefitted from that... how much easier it was and how helpful.’ [NSW GP, metro]</td>
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<td></td>
<td>Improving patient compliance</td>
<td>‘I didn’t know it was a reasonable thing to do in people that don’t tolerate statins to get them to take it at least twice a week... I have been doing that and it still makes a difference.’ [Tas GP, regional]</td>
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<tr>
<td>Patient awareness</td>
<td>Education of patients</td>
<td>‘So I suppose it is about educating the patient in such a way that they do come in and you get them to protect themselves, but also family members.’ [Vic GP, regional]</td>
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<td></td>
<td>Informing family members</td>
<td>‘I tried to tell them how serious it is for the kids to get theirs checked. I might need a better letter so I can photocopy it for eight people.’ [Qld patient, regional]</td>
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<td></td>
<td>Family history</td>
<td>‘... when you ask them for a family history they say no; if you ask, “Have they got heart disease?”... they say no; if you say, “Have they had a heart attack?”... they say yeah. Some people think that once you are on treatment for hypertension, the hypertension is cured... They don’t realise it’s a diagnosis, and even though they’re on medications, they still have that diagnosis as past medical history...’ [WA GP, metro]</td>
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<tr>
<td>Cascade testing</td>
<td>GP contacting family members</td>
<td>‘I don’t feel I’ve got a relationship with those other family members, I have no right to contact them; I don’t know what the legality is, but didn’t feel I had the right, or felt awkward doing so.’ [NSW GP, regional]</td>
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<td></td>
<td>Family estrangement</td>
<td>‘Get them, push them to ring up the sister that they haven’t talked to for like 10 years and that’s what we find is the hardest, the extended family, the contact tracing.’ [WA GP, metro]</td>
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</tbody>
</table>

FH, familial hypercholesterolaemia; GP, general practitioner
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them information on the disease ...

[NSW GP, rural]

One GP noted the importance of resources being appropriate for lower literacy levels:

I was given some resources but it probably wasn’t that easily accessible… for someone with lower health literacy ...

[Tas GP, rural]

While some patients focused solely on addressing high cholesterol, others could understand the seriousness of the FH diagnosis:

It doesn’t matter how fit you are, you can just sort of like die at any time … you don’t know really how high your cholesterol is … until you go and have a blood test and you think ‘Oh what the hell’. [NSW patient, metro]

Some patients provided information to family members at risk of FH:

... my older brothers and parents had high cholesterol … said it was hereditary. I have tried to tell all the kids to get it done. [Qld patient, rural]

However,

It is up to them what they do with the information. [Vic patient, rural]

GPs need to provide ongoing patient education in terms of risk and management of the condition:

I am pretty sure I understood it … years before I threw all my pills away because I decided I didn’t like them … went off meat a few years ago so I threw them in the bin again, but when I had my next cholesterol test, it was way high again. [Qld patient, rural]

However, not all patients want active involvement in decision making:

It goes over my head really. I just take my pills and he tells me what to do. [Tas patient, rural]

Patient awareness of family history was often poor. For some, life circumstances may mean there is no connection to biological family:

This was brought up due to my situation of not knowing a lot about health history, being adopted. There was a lot of unknown factors. [Tas patient, rural]

For others, lack of knowledge can be due to poor health literacy and ability to understand the importance of family history in disease inheritance:

It is just getting me to understand it. [Qld patient, rural]

Many families don’t talk among themselves about their health-related history. Personal beliefs play a role, with some believing that individuals have personal responsibility for their own health:

There was an unexpected resistance to people putting much effort into it and I couldn’t really understand when you had the conversation about how much difference it would make to their management and preventive care. It was sort of like they were just taking responsibility for their own healthcare and expecting other people to have it themselves. [NSW GP, metro]

Cascade testing

GPs and general practice registrars were aware that cascade testing could involve close relatives attending other practices either locally, in nearby towns/cities, interstate or overseas:

They are all in New Zealand. [Qld patient, rural]

Cascade testing was challenging, especially when the FH patient’s relatives did not attend the practice. GPs didn’t feel comfortable contacting people who were not their patients, or at least patients of their practice. Family estrangement added an additional barrier to cascade testing:

Oh, my family is not really a family, you know what I mean? [NSW patient, metro]

Not all family members respond positively to suggestions about getting tested:

I contacted my siblings and my father. I will keep nagging. [Qld patient, rural]

Some GPs highlighted the need for an FH registry to assist with the contact tracing, with many feeling that general practices were time poor and lacking the necessary staff/infrastructure to follow up detailed family histories and pedigrees of FH index cases. They acknowledged that the patient needed to consent to being on a registry but wanted the process of contacting family members to be conducted by a third party:

If the rest of the family are your patients, that makes it easier. But then you have to get consent to talk to their relatives, that was a little more tricky. Having a registry would be a good way to help with that. [Vic GP, rural]

The development of a service where dedicated PNs or FH-trained personnel could visit the practice once an index case was diagnosed would be very welcome. [Tas GP, rural]

In some rural areas where kinship groups lived in close proximity, the opportunities were seen as potentially more fruitful. A general practice registrar felt that having a cascade testing professional within each state with an understanding of how practices work as well as a good knowledge of FH would be invaluable and help standardise the provision of information required.

Once index cases had been identified, GPs had no issue with offering GP-based ongoing care for low- to intermediate-complexity patients with FH and a shared-care role with a lipid specialist for more complex cases. They saw the potential sustainability of undertaking cascade testing would involve developing chronic disease care plans? for the lifelong management of FH among index cases and close relatives. GPs felt such an approach could be built into routine general practice care, and they saw this as likely to be successful:
I was under the impression that I did have high cholesterol and that was it and [I] wasn’t really aware [about FH] until [the] doctor came in and ... yeah, it made sense. [Qld patient, rural]

Discussion

Undertaking change in any clinical setting can be challenging as it presents logistical problems in terms of additional work demands and suitable personnel to achieve the target goals. The 15 general practices undertaking the study used their existing clinical infrastructure. We showed that a pragmatic, general practice–based approach to detect and better manage FH is feasible with improved outcomes reflecting the intensity of follow-up care provided (Appendix 1; available online only).

This qualitative article reflects the views of GPs, general practice registrars, PNs and PMs as well as patients with FH themselves across the spectrum of screening, assessment, diagnosis and management. The training program delivered at the start of the study was generally well received and effective in increasing awareness and understanding of FH. However, heavy work demands in busy practices limited time available to participate in the study, highlighting the need to consider what mechanisms for training and ongoing support can be implemented in future.

Medical record reviews created a workflow challenge, especially among non-compliant patients who despite having a statin script issued failed either to keep taking the medication or to commence at all. The TARB-Ex algorithm was unable to decipher if the patient was taking the medications or not – hence medical record review was needed to monitor blood lipid levels as objective evidence. Falsely elevated DLCNC scores had to be discounted for such patients if their low-density lipoprotein cholesterol levels were not reflecting current lipid-lowering usage. While TARB-Ex was able to identify high-risk patients, it was not a pure diagnostic tool, suggesting a need for increased educational resources and practice-based supports to improve its early detection potential.

Most GPs responded positively to acquiring greater insight and confidence in using the DLCNC score to help establish a phenotypic FH diagnosis. While frustration with the lack of access to specialist lipid clinics remained, the potential of such a shared-care model was often appreciated, especially for patients with more complex conditions.

If the GP is not contacting family members, there is a need to empower patients to communicate the need for testing to their relatives. However, attempts at increasing patient and family awareness about FH was problematic, with poor health literacy, poor communications within families, and non-awareness of inheritance factors in diseases such as FH proving difficult barriers to overcome. Clear resources targeted to patients’ health literacy strengths and limitations would be beneficial to enhance understanding, self management and compliance with treatment, and to increase awareness among other family members. Education helped build patient capability, giving them ‘power’ to contribute to their role in shared decision making and management of their condition.

While the value of cascade testing was acknowledged, there were major barriers, including family communication and GP reluctance to contact relatives attending other practices. A more systemic approach involving an FH registry was seen to have potential. Further, a state-based cascade testing approach that could come into practices when index cases were identified, conduct the family pedigree development and pursue contact tracing with relatives, was supported. GPs were generally in favour of undertaking the management of new index cases diagnosed via contact tracing, and felt management was feasible and sustainable through use of chronic disease care plans in their own practices.

Limitations

Our study is limited as findings reflect the responses of the participating practice staff and patients, which may not be representative of other practice staff and health consumers across Australia. Not all potential participants could be interviewed, and their responses may differ from those who participated in the qualitative study component. The data extraction tool was sometimes overly sensitive and unable to capture the nuances of patient compliance.

Implications and conclusions

Our findings highlight the FH model of care supporting effective management in Australian primary care settings. Given the diversity of practices, there should be future consideration of how this approach can be implemented more broadly – for example, by using an established framework throughout the implementation phase across different settings.

Cascade testing is vital to allow for preventive management of FH, especially in younger people. However, our findings identified a number of barriers for cascade testing to occur in practices. A systematic, state-based approach may be more effective to support practices in this area.

Patient health literacy is an important factor for ongoing FH management, including the critical GP role in patient education. There is scope to consider the responsiveness of each practice to the variety of patient health needs and to increase patient compliance with FH treatment. The development of educational resources targeted at GPs, patients and families could improve the consistency of information about FH.

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