A proof of concept study to identify Familial Hypercholesterolaemia in primary care

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Background

Atherosclerotic cardiovascular disease (ACVD) is still the leading cause of death in Australia and one of its contributing factors is Familial Hypercholesterolaemia (FH). FH is an autosomal dominant inherited condition that causes significantly raised total cholesterol and low-density lipoprotein cholesterol (LDL-c) levels which subsequently increase the chance of premature ACVD. When occurring in the heterozygous state, the prevalence of FH is 1 in 500 people[1, 2] and affected individuals have a 50% chance of passing the condition to their offspring.[3] For men with FH, the risk of developing coronary heart disease before the age of 50 is 50% while for women it is 30% at age 60 years. The genetic aspect of FH and its contribution to the marked acceleration of ACVD means that young adults have much to gain from early diagnosis and treatment. Effective treatment with statin therapy reduces the significant lifetime exposure to high cholesterol levels as seen with FH. This reduction in ACVD events will largely offset the cost of prolonged treatment.[4]

Most of the FH cases are caused by mutations in three identified genes generating countless number of gene variants. Hence, failure to detect a mutation does not exclude a diagnosis of FH. As a result, genetic testing for screening purposes becomes expensive and unfeasible. Under the current model of care (MoC) for FH in Australia, FH is diagnosed through a number of different routes[5, 6] and managed mainly through hospital-based lipid clinics undertaking genetic testing particularly if the clinical features (phenotype) are highly suggestive of FH. Diagnosis has been shown to prompt action by patients.[7] There are several tools for diagnosing FH clinically, with the Dutch Lipid Clinic Network Criteria Score (DLCNCS) being the tool of choice in Australia.[5] The fundamental step to FH care is the identification of the index case or first family individual with the diagnosed condition. This triggers the domino effect with the screening of first degree relatives of the index case for FH, a process known as cascade screening.

In Australia, over 80% of the population consult a GP at least once a year.[8, 9] Since GPs request 91.8% LDL-c tests through a community based pathology laboratory[10], and research has shown that it may be possible to use a serum LDL-c cut-off point alone to facilitate the detection of FH[10], GP consultations therefore offer a unique opportunity to help detect unknown index cases of FH in the community.[11] However, despite FH being easily detectable and its potential for early intervention, it is currently underdiagnosed and the 18- 40 year old target population in this study are amongst the least likely to be offered opportunistic lipid testing during routine primary care visits. This situation is unlikely to change unless the profile of the condition receives much greater prominence and the benefits and cost effectiveness of early intervention are brought to the attention of general practitioners (GPs) and practice nurses (PNs).

The effectiveness of minimally invasive Point-of-Care Testing (POCT) in GP settings has been proven.[12] POCT for lipids has considerable potential as an early detection test for FH in primary care.[13, 14] The quick and efficient nature of the test alleviates the resulting increase in workload and required resources. This study builds on the earlier UK research[15] and the experience gathered from our previous study whereby an electronic data extraction method was employed to retrospectively review patient records for possible FH among patients attending four Western Australian Primary Care practices.[16] Information from our retrospective study together with the one outlined in this report, will help optimise detection of FH patients and increase the efficiency of a primary care FH MoC.

Our aims for this study were (1) to trial the concept of opportunistic POCT for FH screening in 18-40 year old cohorts with a view to undertaking detection and management of index cases at the primary care level; (2) to assess the acceptability of POCT; (3) increase awareness of FH; and (4) assess the cost of proposed model of shared care. Through collaboration with a cardio-metabolic clinic, results from this study will feed into the processes and protocols for cascade screening, genetic testing and clinical services offered through the MoC in Australia.

Methods

TARGET POPULATION

A convenience sample of 18-40 year old patients attending two general practices in the Perth metropolitan area were recruited within a 6-month timeframe (4 May - 27 October 2015). Assuming that 30% of the target population will be eligible and consent to participant, and only one GP/practice will consent to participate, we aimed to recruit 500 patients over six months. Patients on cardiovascular medications were excluded from the study.

PROTOCOL

Patients presenting to GPs for any consultation were informed of the study and invited to participate. Upon written consent, patients were requested to provide some demographic information in a participant information sheet. The practice nurse (PN) or pathology phlebotomist (PP) then undertook a non-fasting finger-prick test (POCT) using the Cardiocheck® PA analyser[12] to measure the patient's lipid levels (Total cholesterol (TC), triglycerides (TG), high-density lipoprotein cholesterol (HDL-c), and low-density lipoprotein cholesterol (LDL-c)). If the LDL-c result was ≤ 4.9mmol/L, the PN or PP were requested to check with the GP to see if the patient required further advice. Patients with LDL-c level > 4.9mmol/L were requested to revisit their GP for advice and to have a confirmatory fasting blood lipid test at a standard diagnostic laboratory. The PN and PP were also informed to recall patients with TG levels above the accuracy range of the non-fasting POCT test for a fasting blood test to ensure optimal medical management.

If the fasting laboratory LDL-c result was ≤ 4.9mmol/L, the GP was requested to see the patient for general advice on how to maintain a low lipid level. If the fasting laboratory LDL-c result was > 4.9mmol/L, the patient would be assessed using the Dutch Lipid Clinic Network Criteria Score (DLCNCS) for FH. A DLCNCS of ≤5 classifies patients in the possible/unlikely FH category and a DLCNCS >5 classifies patients in the probable/definite FH category. Patients with LDL-c levels >4.9mmol/L and DLCNCS ≤5 would be managed at the discretion of their GP. Patients with LDL-c levels >4.9mmol/L and DLCNCS >5 (probable/definite FH) would be managed in a shared care model mainly by the GP with advice from the specialist. If high complexity FH patients (i.e. those with multiple uncontrolled risk factors, symptomatic CVD, pregnant or severe statin intolerance) were recruited, they would be managed through the specialist hospital care with feedback to their GP. As part of clinical care, first degree relatives (parents, siblings and offspring) of a screened FH index case would be contacted and offered FH screening.

Staff at the two participating general practices were also informed of the study and invited to participate. At the end of the study, semi-structured interviews (face-to-face and telephone) were conducted with a subset of the patients recruited and all staff of the two participating general practices. Feedback sessions reporting the findings of the study to practice staff at both participating practices took place in early March 2016. A feedback letter and acknowledgement will be sent to all participating patients.

The cost of the GP consultations and pathological laboratory test were Medicare billed as this is part of clinical management. There were no specialist costs as the GP did not use this service. All other POCT costs were funded by the study. Patients had no out-of-pocket expenses for the study purposes.

This study was approved by the Human Research Ethics Committee at The University of Notre Dame Australia (approval number 015024F) and registered in the Australian New Zealand Clinical Trials registry (Registration number ACTRN12615000153516).

Results

PATIENT CHARACTERISTICS

A total of 201 participants (66 males and 135 females) were recruited within the 6-month timeframe and completed the POCT finger-prick test. Two of these participants (1 male and 1 female) were excluded as they fell outside the age range. Therefore this report will include data of only 199 participants (65 males and 134 females) and their demographic characteristics, as per the self-reported questionnaire, are listed in Table 1.

Table 1: Self-reported demographic characteristics of participants who completed the POCT finger-prick test

Self-reported demographics of participants	
Total number of participants	n = 199
Age	29 ± 6 y (min:18y, max: 40y)
Gender	65 Males 134 Females
Index of relative socio-economic advantage and disadvantage, IRSAD > Lowest statistical area1 (SA1) range recruited > Highest SA1 range recruited	 SA1 min: 650, SA1 max: 1073 SA1 min:1087, SA1 max: 1188
Smoking status > Never smoked > Smoked but stopped > 10y ago > Smoked but stopped 5-10y ago > Smoked but stopped >1 but <5y ago > Smoked but stopped <12m ago > Smoker <1 packet/week > Smoker >1 packet/week	 n =124 (62.3%) n = 9 (4.5%) n = 6 (3.0%) n = 14 (7%) n = 11 (5.5%) n = 17 (8.5%) n = 18 (9.0%)
Frequency of alcohol consumption in past year > Never > Monthly or less > 2-4 times per month > 2-3 times per week > >6 times per week	 n = 11 (5.5%) n = 40 (20.1%) n = 69 (34.7%) n = 67 (33.7%) n = 12 (6.0%)
Number of drinks on a typical drinking day > None > 1-2 drinks > 3-4 drinks > 5-6 drinks > 7-9 drinks > >10 drinks	 n = 14 (7%) n = 92 (46.2%) n = 57 (28.6%) n = 22 (11.1%) n = 8 (4%) n = 6 (3%)

Self-reported demographics of participants	
Frequency of having >6 standard drinks on one occasion in past year > Never > < Once/Month > Monthly > Weekly > Almost daily	 n = 56 (28.1%) n = 86 (43.2 %) n = 39 (19.6%) n = 17 (8.5 %) n = 1 (0.5%)
Family history of high cholesterol > Paternal side > Maternal side > Unspecified	 n = 2 n = 2 n = 3
Patients on cardiovascular medication	n = 0
Weight (kg, n = 197), Mean ± SD (min : max)	71.15 ± 15.6 (46.0 : 130.0)
Height (m, n =192), Mean ± SD (min : max)	1.71 ± 0.94 (1.5 : 1.95)
Body mass index, BMI (kg/m^2, n = 192), Mean ± SD (min : max)	24.17 ± 4.09 (16.46 : 38.37)

POINT OF CARE TESTING (POCT)

As a result of technical difficulties with the CardioCheck® machine and capillary tube, lipid levels were not obtained from all participants. Table 2 depicts the lipid profile of the patients tested.

Table 2: Non-fasting lipid profile of POCT participants

	Mean ± SD (min : max)
POCT-LDL, mmol/L	2.096 ± 0.797 (0.21 : 4.30)
POCT-TC, mmol/L	4.271 ± 0.872 (2.59 : 6.62)
POCT-HDL, mmol/L	1.60 ± 0.475 (0.39 ± 2.59)
POCT-TG, mmol/L	1.293 ± 0.709 (0.57 : 4.36)

Recruitment Rate

The total number of patients age 18 – 40y who visited the two participating medical centres during the study period was used as denominator to calculate the recruitment rate. A breakdown by gender is shown in table 3.

Table 3: Recruitment rate by gender during a 6-month period

Medical Centre	Gender	No recruited	No visited practice	% recruited
1	Male Female Total	41 72 113	441 711 1152	9.3 10.1 9.8
2	Male Female Total	24 62 86	1777 2853 4630	1.4 2.2 1.9
Overall		199	5782	3.4

Technical Issues

One major technical difficulty encountered during the study was a problem with the first batch of lancets supplied with the testing kits. This resulted in blood collection difficulties and many patients had to have a few attempts with finger prick testing before an adequate sample was obtained. This problem proved to be frustrating not just for the patient but also for the PN/Phlebotomist and GP involved and probably accounted for some loss of momentum at the commencement of the study.

The problem was rectified after consultations with the kit supplier who acknowledged that the original lancets supplied were not adequate for the amount of blood required. A replacement batch of lancets rectified the problem but some patients were undoubtedly lost to the study as a result. In addition, the confidence of staff undertaking the process was hampered in the early phase of the study and could have contributed to lower than expected numbers being recruited. PNs compared this phase unfavourably with POCT for blood sugars levels and International Normalised Ratio (INR) in Warfarin management. Hopefully, lessons learned for future work.

PATIENTS' PERCEPTIONS OF THE POCT PROCESS

A subset of 34 participants was systematically selected for the semi-structured telephone interview. Table 4 shows the characteristics of the subset of participants attending the two medical centres.

Table 4: Characteristics of the subset of participants attending the two medical centres

	Number of Participant	% of total respondents
Patient Visit Type: • First time visits • < 1 year • >1 and <10 years • >10 years	 4 3 18 9	 11.76 8.82 52.94 26.47
Choice of GP: • Whoever is available • Same GP all the time • 2 GPs • First time at practice	 9 16 5 4	 26.47 47.06 14.71 11.76

Participants' perspectives on the opportunistic nature of the test

Key Findings:

- Patients were not bothered about being asked to do the POCT test even if they came to the practice with a different issue
- Patients were happy to help research and the University and were keener on the study when a close family member had known high cholesterol levels.

Overall, participants were not averse to being asked to participate in the study (Table 5). Participants thought it was fine and were not bothered to have their cholesterol levels opportunistically tested. Comments such as "Happy to do it as was already at the practice" (Patient 17), "Father has high cholesterol, I have Hashimoto's, so wanted to know if T3 was working effectively in keeping my cholesterol level down" (Patient 14) and "was going for a skin check, so was fine" (Patient 107) were noted by the respondents.

Four out of 34 participants (12% of sub-group) also mentioned that they were "happy to help" since it was a university research project.

A couple of respondents (6% of sub-group) had mixed feelings about the test. One participant had agreed to participate for altruistic reasons and explained, "I would rather not do the test but I was happy to help" (Patient 59) and another one mentioned that they "…did not know what [I] was agreeing to at the time, but was ok with it" (Patient 65).

Table 5: Breakdown of the participants' perspectives on the opportunistic nature of the test

Responses	Number	Percentage of total respondents (5)
No issues	29	85.3
Willing to help	9	26.5
Other*	6	17.7

**Other includes: motivated to do test due to family history of high cholesterol, convenience of already being at the practice, and reluctance to do test*

Participants' perspectives on the process of POCT

Key findings:

- Participants felt that the process was easy and quick
- Issues with wait time and test were due to glitches with the blood capillary tube
- Participants were not always referred back to their GP to have their results explained

Overall, participants acknowledged that the process was easy and not a burden to them. They described it as being quite efficient, easy, fine and simple and professional.

Participants particularly liked the fact that having the test done was made easier by them already having an appointment to see the GP. As some explained, "I did the test and then went to see the doctor for the rest of my appointment" (Patients 20 and 32) and "the doctor was running late and so I did the test first and did not wait any longer" (Patient 98).

The majority of the participants also thought that the test was quick and easy. Some even mentioned that it was an "in and out job" or "really quick test". However, the process did not

go smoothly for all. A few participants mentioned that “the paperwork took a bit of time”, that “the test was supposed to be fast, but was late”, and that they had to wait for a long time, “an extra 30-45 minutes instead of the five minutes as was told” (Patient 21).

The disappointment and frustration were due to difficulties in drawing blood. As one patient said, “it took 30 minutes as they could not get blood off my finger. Then they finally got it” (Patient 4).

Another mentioned that “it was a bit of a pain as it was hard to get blood. They had two to three attempts before they could fill up the capillary tube” (Patient 6). Two (out of 34) participants explained that they were disappointed as despite the multiple attempts, they still did not get enough blood for analysis and thus no results.

Several participants (26% of sub-group) highlighted a few issues with the process of testing. They would have preferred the finger-prick test to be more straight forward instead of milking the finger. One participant (Patient 31) explained that he “had to run his hand under hot water, then it was fine”. Another felt that they should have been given more information on the results and commented that “the test was easy but I did not know what was going on. I did not know what the results meant. I had seen the GP then got the test done” (Patient 146).

Participants’ perception on the adequacy of information received

Key findings:

- Mostly nurses and the phlebotomist explained the study
- Some patients would have preferred the GP to explain the results

In general, nurses and the phlebotomist were the ones who explained the study to the participants before carrying out the finger-prick test. In one of the participating practices, nurses were in charge of the finger-prick test, while in the other, a phlebotomist was in charge.

Overall, patients had their questions answered. Only one patient who got their test done close to closing time did not get to ask questions nor had the study explained to them. Only a few patients did not have many questions or did not remember much of the test. Patients were urged to go back to their GPs to have their results explained; however, we had no control on information given to patients by the nurses or the phlebotomist. One patient (Patient 167) in particular did not find the phlebotomist’s explanation adequate: “I did have a slice so it was a non-fasting test. I was worried as the phlebotomist told me that my cholesterol level was really high. So I had my GP to check it. I did a fasting [blood] and was all good. I have high HDL, so overall fasting cholesterol was high. But I would have preferred if the GP did the explanation not the phlebotomist, as the GP would know more”.

Participants’ suggestions on how to improve the process in the future

Key findings:

- Participants in general were happy about the process and had no further suggestions
- Some of the suggestions put forward included having an explanation sheet for the results, using better equipment, and getting more staff on-board for the finger-prick test

The majority of the participants had no suggestions as to how to improve the point of care testing. But if they did comment, participants gave good feedback about the process. They thought it was quick, very streamlined, and all handled as expected. Only a few gave

negative feedback about the test. A couple of participants (6% of sub-group) suggested having a sheet explaining the results and a process guiding who explains the results to the participant, while others commented on the difficulties experienced in having the test done, with comments such as: “I seem to have been the first patient. I just had issues getting blood from my finger” (Patient 8) and “get another staff on it to speed up the process as was told it would take only five minutes but it took much longer” (Patient 65). Another two participants (6% of sub-group) felt that the tests could be done by venipuncture on people who already have a referral for blood tests or on those who come for injections.

Participants’ perceptions on the benefits of the study

Key findings:

- Overall, participants thought that the study was beneficial
- The reasons stated by participants to justify the value of the study could be grouped in four categories: Opportunistic, age, on the spot results, and family history of high cholesterol levels.

All but three of the participants (n = 31) interviewed thought that the study was beneficial. The three differing participants thought that the study was not beneficial at this point in time as their test showed normal cholesterol levels.

The reasons stated by participants to justify the value of the study can be grouped in the four categories as follows:

1. Opportunistic – Participants liked the fact that they were asked to have their cholesterol tested opportunistically and that getting the test done made them more aware of their health. One participant even said he was “happy with the test, and would come again” (Patient 8), and another said “I think more people should do it” (Patient 65)
2. Age – A few participants understood that their age group did not routinely get asked to do blood tests and that it was good to be able to get tested
3. On-the-spot results – Participants liked the fact that they could get their results instantly.
4. Family history of high cholesterol levels – A few participants had a family history of cholesterol and therefore were pleased to have their cholesterol levels tested. One participant said “I have a history of high cholesterol in the family. I’m happy to have current results. Very pleased” (Patient 47). Another said “Mum has high cholesterol. It was good to find out about my own levels” (Patient 137).

Two of the 34 participants interviewed did not get their test results as their blood sample quantities were insufficient. However, they still reported that the study was beneficial.

GENERAL PRACTITIONERS’ PERCEPTION OF THE POCT PROCESS

Sixteen of the 18 participating general practitioners (GPs) were interviewed. One GP had a conflict of interest and was therefore excluded from the interviews and the other GP could not be reached. Since no index cases were identified, questions regarding family tracing were omitted from the interviews.

General Practitioners' perspectives on the process of POCT

Key findings:
GPs reported that

- the process was straight forward and easy to implement
- it was hard to remember to enroll patients
- the study was well received and patients would only decline if they recently had a blood test or if the wait time for the finger-prick test was too long

Eighty seven percent of the general practitioners interviewed reported that the process was fine, straight forward and easy to implement. One doctor mentioned "I think the process was good…It is a new thing to do as a practice for us… It was a learning curve" (GP 15) and another agreed that "most people who got the test done were younger people whom I would not have been too concerned about high cholesterol; but I guess they are the people we want to target" (GP 10). Thirty one percent of the GPs interviewed also thought that the process was well received and that patients "were really interested in finding out their cholesterol levels" (GP 7).

However, 19% of the GPs interviewed did admit that it was hard to remember to enrol patients in the study. One said "I must be honest. At the start, I kept forgetting to do it" (GP 12) and another GP mentioned "Good test to do, no extra time; it is the process of remembering to enrol them in the study" (GP 7).

Three of the 16 GPs interviewed agreed that the nurses and the phlebotomist had some technical difficulties at the start of the study. "The machine and pipettes were difficult to use and were not as user friendly as thought" was the general comment and one GP also said that "the paperwork took time" (GP 5).

GPs observed that only a few patients declined to participate and that it was either because they recently had their cholesterol levels tested or the wait time for the blood test was too long.

Two of the 16 GPs interviewed had little involvement with the study.

Impact of the study on the general practitioners' consultation time

Key findings:

- All but two doctors felt that the study did not prolong their consultation time
- On average it took two minutes to explain the study

All but two of the general practitioners interviewed (88% of sub-group) reported that the study did not prolong their consultation time. "On average took two minutes", or "not much time", or "quite easy to do in terms of squeezing the POCT in an appointment time slot" were mentioned. Five of 16 GPs (31% of sub-group) also remarked that the POCT mostly impacted on reception staff and the nurse time.

Only two doctors felt that the study took some time. One said that "nurses often would knack patients from me [the doctor] at the time I would call to see them. So I got behind [with my work]" (GP 4).

General Practitioners' perspectives on the addition of POCT to their role

Key findings:

- No unanimous answer. Some were for and others against the concept
- Decision will depend on the medical circumstances of the patient

There was no unanimous answer to this question. While many general practitioners (56% of the sub-group) stated that the POCT can be part of their role, 50% of those interviewed said that it was not a straight forward decision and would depend largely on the medical circumstances of the patient or whether they were regular patients as opposed to one-off visit patients.

"We cannot overburden people. We are already opportunistically asking people about their Pap smear and blood pressure. Adults do not come to GPs often. We do not want to harass them. We need to pick up what is important" (GP 1).

"I will take into context if people came with a history of FH, then I would do it. Otherwise I will take into context. I will not inject it [POCT] unless there is some peripheral condition and the patient is worried about it" [*sic*] (GP 6).

Two of the doctors interviewed were not in favour of the POCT. One said that "there are so many things to negotiate in a consult that it will not be feasible to do point of care testing as a GP in a consult" (GP 10). The other affirmed that "[they are] not particularly looking into doing it unless has a good reason to do it. Certainly not if just financial benefit from doing it. As often point of care testing has been done because there's been financial reward attached to it" (GP8).

General practitioners' thoughts on whether Familial Hypercholesterolaemia should be managed in general practice and its associated benefits and challenges

Key findings:

- FH could and should be managed in general practice provided clear guidelines are set and GPs are educated on the topic
- GPs agree that resistant cases should be sent to the FH clinic
- If managed in general practice, it will be easier to follow up patients and their families
- Genetic counselling should be available at the practice should the POCT process be rolled out
- Time factor and lack of experience on FH were mentioned as challenges

Only one general practitioner thought that managing FH in general practice would be difficult. Eighty eight percent of the doctors interviewed stated that FH could and should be managed in general practice provided clear guidelines are set and GPs are educated on the topic. However, they would still send the patient to the FH clinic should they encounter a resistant case. One GP said:

"If have good, clear guidelines for how things are best managed, when do people have to see a specialist and what the current recommendations are [then FH could be managed in general practice]" (GP 2)

Others have said:

"Needs to have clear guidelines of what test needs to be done…. Guidelines on family tracing, how to go about that, how to encourage people to do it" (GP 7)

"The more information you get, the more confident you become. Recording materials,

talks/presentations to educate GPs on FH is needed. Fortnightly magazines, with updates and references will evoke passive learning" (GP 12).

And,

"If ought to be managed in GP land, would have to be something GPs are educated about" (GP 10)

One GP (GP 8) also mentioned that it was important to make genetic counselling available at the practice should the POCT process be rolled out.

Apart from taking the pressure off the tertiary system, doctors agreed that benefits revolve mostly around the ease of patients visiting and the holistic approach, and better continuity that general practitioners provide. One doctor mentioned: "We would be seeing them [patients] otherwise, so it could be opportunistic. If they are not being followed up or if they have not attended an appointment, we could say 'by the way, we have not checked you; we have not seen you for ages'. Also you might know the family members, so you might treat the whole family. Also, it is easier for the patient [to go to their GP] than going to a new place" (GP 16).

Another GP mentioned: "We like to look after families, it [FH] is related to families. We want people to see general practice as their medical home, so therefore they should identify all their problems that they can with general practice. There are a lot of advantages to do it" (GP 15).

In terms of challenges, doctors mentioned the time factor and their lack of experience with FH. As one doctor pointed out:

"It is purely a time factor. Patients come and see well-established doctors with a list of things they want dealt with. It is often in 15 minutes. The reason you do not have time in the 15 minutes, the list that they have got, let alone the point of care testing" (GP15).

Other similar comments included "challenges will be the increase in workload", "when the nurse was not familiar at the beginning, it took longer. We needed the nurse with other things and there was a conflict of time", "Challenges will be the increase in workload". They agreed that if POCT were to roll out in general practice, they would need more support.

In addition to the above challenges, two of the 16 doctors interviewed felt that for those patients who have just moved to Perth, it would be difficult to get a background picture to compute their Dutch lipid profile. Another GP (GP 11) also mentioned that since most FH cases are asymptomatic, it will be harder for doctors to convince patients to go on medications.

General practitioners' perspectives on working with other practice staff

Key findings:

- GPs agree that working on the POCT with other practice staff was no different to the other day-to-day activities
- POCT needs ease of implementation and good leadership

Sixty nine percent of the doctors interviewed thought that working with the other practice staff for this study was no different to their other day-to-day activities. Twenty five percent of the GPs interviewed did mention that the receptionists, nurses and the phlebotomist did the bulk of the work and did not have to rely on the doctors. One even said that "if it was harder, I will not do it as it feels like I am running out of time" (GP 6). Another mentioned that POCT "needs ease of implementation, or else it will not work" (GP 3).

However, 25% of the doctors interviewed still felt that the POCT process did not work well as it was too time consuming and needed better leadership in the practice. One doctor said that "'it held up the treatment room at times. Nurses would be busy doing this and I would want the nurse for something else… More occasionally patients were with the nurse and not

ready” (GP 4). Another said “I think the reasons why it did not work so well in our practice was mostly to do with not having good leadership within the practice for it. I do not think it was anything to do with the design of the study, the research at the University, the researcher or our staff. I think it was just lack of leadership in our practice” (GP 15).

Getting a GP champion was also suggested:

“In everything that you roll out in general practice, you need a GP champion in the practice. That is what we found with everything and whenever, I have thought 'let's just see how it runs with this person, that person taking over’, somehow it might work for a day or two when it is on people's mind, but it doesn't stay without a GP champion. For example in our practice, we have a GP champion for diabetes. That works when the person is there and when the person is not there; it starts to fade away again” (GP15).

NURSES’ PERCEPTIONS OF THE POCT PROCESS

Five nurses and one phlebotomist completed the semi structured interviews. Since no index cases were identified, questions regarding family tracing were omitted from the interviews. The nurses and the phlebotomist will be referred to as PN in this report.

Nurses’ perspectives on the process of POCT

The nurses and the phlebotomist working on the study were not unanimously in favour of the process for the POCT. Half of the group interviewed thought it was a good and straight forward process while the other half felt it was lengthy and fiddly. One of the nurses said: “It was a pain in the bum. It started badly when it was introduced, the timing of it (flu season)”. However, most of the antagonisms were due to internal politics at the practice and getting to know how to use the machine and implement a recruitment process.

Impact of the study on the nurses’ consultation time

Some nurses admitted that they were not directly involved. For those who were involved in the recruitment of patients and their finger-prick test, the time it took per patient depended on whether the patient had filled out the forms and whether they were an easy bleed. The lancets and capillary tube used were a challenge and contributed to the lengthy blood test. But on average, nurses and phlebotomist said it only took about five minutes.

While the study plan was to have reception staff identify and invite patients to participate in the study, one nurse, however, was more involved with patient recruitment and was not impressed with the increased workload. They said that “it came back to the nurses. If the nurses did not do anything, nothing happened. A lot of it just was unrealistic for reception staff to be able to ask patients because of what they need to do out there” (PN 1).

Nurses’ perspectives on the addition of POCT to their role

Two nurses out of six said that they do not see the point of care testing being included in their role as practice nurses. While one thought that there were too many things already being done opportunistically in general practice, the other did not feel it was something worthwhile to conduct in the selected age group.

“Not role as a nurse, not in this practice…Through reading, I did not see anyone would fit the criteria, so did not think ‘wow’ ” (PN 1).

Others felt that the finger-prick test is an easy test and thus would be manageable to include in their role. One nurse said “if the test [lancet and capillary tube] was perfected, it would be better” (PN 3), and another mentioned “it is about putting it in one’s timeframe and workload”

(PN 6).

Nurses' thoughts on whether Familial Hypercholesterolaemia should be managed in general practice and its associated benefits and challenges

Key findings:

- All (83%) but one nurse were in favour of FH being managed in general practice
- Nurses felt that it would benefit patients by providing a more accessible atmosphere
- Time constraint and educating nurses on the topic were the foreseen challenges

Nurses thought that it was a good idea to have FH managed in general practice. They felt it would greatly benefit patients by providing a more accessible and relaxed atmosphere as well as more opportunities to see different age groups.

However, they felt that nurses need to be educated if they were to doing the POCT. One even said that a participating phlebotomist or nurse would be needed for it to work. Only one nurse opposed to the idea and felt that "the survey failed to grab me in the first place" (PN 1), and another felt it should be treated at both general practice clinics and primary health care settings. Time constraint was the general challenge foreseen and one nurse felt the onus is on the GP to recruit patients.

Nurses' perspectives on working with other practice staff

There was no consensus to this question. Two of the six participating PN thought that working with GPs and other staff for this study was no different than usual. It worked fine and just needed to encourage the receptionists who were busy to identify patients.

Two did not give answers applicable to the question and the others felt that it did not work smoothly.

One said that "we need to convince whoever owns the practice that the study is worth doing" (PN 1), another said "some GPs were already doing other studies and thus were not as keen" (PN 2).

Nurses' suggestions to improve the process in the future

Nurses and the phlebotomist gave a few suggestions to improve the process. These included:

- Preventative health education for the patients. For example leaflets to explain what the cholesterol levels meant.
- Education package for the staff – Cheat sheets and other materials to allow staff to refer back to
- Better way to invite patients to have their cholesterol tested opportunistically
- Factor the test into staff day to day work
- Have a better capillary tube

NON-MEDICAL STAFF (RECEPTIONISTS) PERCEPTIONS OF THE POCT PROCESS

Eight receptionists (RC) completed the semi structured interview.

Receptionists' perceived degree of difficulty to target patients

Half of the reception staff interviewed felt that it was easy to remember to target patients from the specified age group. They used the booking system to check the patient's age and to put alerts to remind themselves.

One said "Was easy as need to check patient's details anyway, so was easy for us to do" (RC 1).

Another said "I kind of put little notes/alerts for me in the morning that this person might be the right age" (RC 6).

The other staff on the other hand, felt it was difficult to remember especially when working part-time or when busy at the practice. One staff mentioned that "some days were a bit challenging because of the nature of our business… we are quite busy and it was hard to remember, in a professional way, to offer people the form" (RC 8).

Another said "because I am part-time, am not here all the time. It was not easy to remember. Sometimes got busy with files and things and last thing on your mind is to do a survey" (RC 2).

Receptionists' perceived degree of difficulty to get patients to read the information

Seventy five percent of the reception staff said that it was difficult to get patients to read the information due to the combined length of the information sheet, consent form and participation form:

"Long form. Lots of patients found that" (RC 6).

"A lot of them looked and said 'do I really need to read all of that?' and I said 'it is advisable, it will give you some knowledge on why it's being done'. But told them it is optional if they want to participate or not. A lot of them pushed it aside and said no. As soon as they saw they had all that to read, they went 'nah, I haven't got the time' " (RC 3).

Some staff said that it was OK to get patients to read the information. One said "pretty good. They would read it" (RC 7), one other mentioned that it all depended on whether the patient had time, and another said it was "50/50" (RC 4).

Impact of the study on the receptionists' time

The majority of the staff (88%) felt that the process did not take much time. One mentioned that the patients just took the form and read. However, this was not always the case and a few staff said that it did take some time to explain the study to patients and also to remember who should be given the form.

One receptionist explicitly said "Yes, because you have to try to explain it and when you don't have a medical background, it is a bit hard to ask somebody to do something" (RC 2).

Receptionists' suggestions to improve the POCT process

Key findings:

- Have GPs more involved in the study and having a dedicated person to do the POCT were mentioned by more than one staff (63% of sub-group)

A few suggestions were given to help improve recruitment for future studies. “To increase doctors’ involvement” and “to have a dedicated person to do the Point of Care Testing” were the only suggestions mentioned by more than one staff (63% of sub-group).

Other suggestions were:

- Targeting specific gender
- Having a pop up system to remind staff of the suitability of patients for the study
- Make the forms shorter
- Recruit from other locations such as pharmacies
- Recruit from practices that see more patients of the specified age group

Other issues raised by receptionists

Two reception staff reiterated the fact that receptionists were not well placed to recruit patients.

One mentioned: “It was not always easy to target this age group. Don’t think reception should do this. Maybe the nurse as they have more access to the patient’s file” (RC 2).

Another said: “The way it has been tried at the front desk of a doctor’s surgery is not the best way. Eighty percent of people coming are unwell, grumpy and not accommodating” (RC 3).

Discussion

The overarching aim (Aim 1) of the study was to assess feasibility of identifying incident index cases of familial hypercholesterolaemia (FH) in younger patients presenting routinely to GP using opportunistic screening and point-of-care testing (POCT). Only 3.4% of the age group presenting was captured for screening with a sample size of 199 instead of the 500 required. It was not unexpected therefore that no cases of FH were identifiable in the period of the study. Patients who participated provided useful feedback in regard to Aims 2 and 3.

With regard to assessment of acceptability of POCT (Aim 2), GPs felt overall it was a straight forward process which could be implemented into usual practice. However, the medical circumstances of the patient or whether they were regular or one-off patients would determine the ease with which this was done. PNs felt similarly that POCT was not overly time consuming but felt it added to their already busy workload. One limiting factor that had a negative impact in the early phase of the study was the supply of equipment not suitable for purpose. Both GPs and PNs said the team approach adopted with other practice staff was no different to their day-to-day activities. Other practice staff felt the research process i.e. number of forms to read and sign made it difficult to recruit patients. Identifying patients was not difficult. This could be done through practice software. Overall, patients acknowledged that the process was easy and not a burden to them. Patients were accepting and satisfied with explanations given to them about the point of the study and process. They liked the fact that the results were given to them immediately.

With regard to awareness of FH (Aim 3), the majority of the doctors thought that FH could and should be managed in general practice provided clear guidelines are set and GPs are educated on the topic. If they encounter a hard to manage (resistant) case, they would still send the patient to the specialist clinic. Like GPs the PNs believed FH should be managed in general practice. They also believed that better clinical and patient education of the problem would help increase identification and awareness of FH. The fact that patients were asked to have their cholesterol tested opportunistically made them more aware of their health. It also brought home the fact that that the targeted age group does not routinely get asked to do blood tests and patients felt that it was good to be offered the opportunity. A few participants had a family history of cholesterol and therefore were pleased to have their blood tested.

No FH cases were detected hence there were no patients referred for shared care. Resource use / costings were not undertaken (Aim 4).

KEY FINDINGS

- POCT is feasible in implementation and acceptable within a GP setting provided there is good engagement among practice staff (reception staff, practice nurses, GPs)
- Increasing awareness of the FH in the community will be a key factor in improving detection and management
- Encourage younger age group blood testing in patients with a family history of premature coronary artery disease
- For undertaking research, it is important to:
  - Have a dedicated research person to work with practice staff
  - Have a research study champion from within the practice
  - Ensure research protocol fits with day-to-day running of the practice
  - Minimise paperwork and not overly burden participants

FOLLOW-ON FUTURE PLANS

A larger FH study looking at implementing a method of care in general practice is being undertaken within Western Australia with a plan to extend to other States through NHMRC

funding. Following on from the lessons learned in this proof of concept study we are holding community conversations hosted through the Consumer and Community involvement program (http://www.involvingpeopleinresearch.org.au/) to determine how best to implement the study in the general practice setting.

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