Title: Factors influencing medical practitioner participation in population carrier screening for cystic fibrosis

Running Title: Providers' experiences of CF carrier screening

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Conflicts of Interest statement:

The authors have no conflict of interest to declare.

Unblinded sentences**Materials and Methods:**

- Potential participants were identified, through the Maternal Serum Screening database at VCGS.
- Study data were collected and managed using REDCap electronic data capture tools hosted at Murdoch Children's Research Institute.

Supporting Information Table S1

- "If it's a negative result they get a letter within twenty-four hours if it's a positive result then [the VCGS] counsellor will contact them and organise partner testing"
- "Information on [the VCGS web]site is very easily accessed and downloadable and printable and that helps very much"
- Table legend *[organisation blinded for review]*: VCGS = Victorian Clinical Genetic Services

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Abstract:

Background: Cystic fibrosis (CF) carrier screening should be offered to people planning a pregnancy or in early pregnancy, according to current recommendations. However, research indicates rates of

offering CF carrier screening are low. Health professionals (HPs) play an important role in offering population carrier screening

Aims: To determine the opinions, knowledge and practice patterns of HPs with regard to the routine offering of population carrier screening for CF.

Materials and Methods: Five key informant interviews informed the development of an online questionnaire which was distributed to a select group of HPs involved in prenatal care in Victoria, Australia.

Results: Of the participants who completed the questionnaire (n=87), 35.6% reported offering CF carrier screening to all patients attending for preconception or early pregnancy consultations. High referrers of CF carrier screening were more likely to be female, work in the private sector, in metropolitan areas and specialise as an obstetrician. High referrers demonstrated a greater level of knowledge of CF and carrier screening than low referrers ($t = -3.779$, $p = < 0.001$). Low referrers perceived more barriers to offering carrier screening than high referrers ($t = 2.125$, $p = 0.037$). Low referrers were more likely to perceive lack of community awareness and HP knowledge as a barrier to offering CF carrier screening, compared to high referrers, who were more likely to perceive time constraints as a barrier.

Conclusions: To promote routine offering of population CF carrier screening, resources are needed to improve knowledge and provide clinical support thereby reducing perceived barriers.

Introduction:

Cystic fibrosis (CF) is the most prevalent life-shortening, autosomal recessive condition in the Australian Caucasian population. Approximately 1 in 25 Caucasians is a carrier of CF,¹ and therefore at risk of having a child with CF. Of children born with CF, 94% do not have a family history of the condition.²

Population carrier screening is performed to identify carrier status in an individual with no known family history. It aims to identify carrier couples who are at increased risk of having an affected child and promote reproductive autonomy,³ including the options of prenatal and preimplantation genetic testing. Due to the implications for reproductive decision-making, population carrier screening is most relevant for women and couples planning a pregnancy or in the early stages of pregnancy.^{3,4}

The Royal Australian College of General Practitioners (RACGP) has released guidelines supporting the offer of CF carrier screening to women or couples planning a pregnancy or during early pregnancy,⁵ whilst the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) recommends that all women planning a pregnancy or in early pregnancy be offered CF carrier screening.⁶ In Australia, carrier screening is provided as a fee-for-service test, but recently, a Government-funded Australian reproductive carrier screening project,

Mackenzie's Mission, was launched to investigate how to make carrier screening more accessible as a national program.⁷

Since 2006, a population CF carrier screening program has been available in Victoria, Australia by Victorian Clinical Genetic Services (VCGS)^{8,9} and is offered by general practitioners (GPs), obstetricians and fertility specialists. During the first seven years of the program 10,489 individuals with no family history of CF were screened.⁹ Of these, 320 were identified as carriers of CF, including 15 carrier couples. Follow up revealed that all carrier couples used information received through screening to inform their reproductive decisions.^{8,9}

In addition to being recommended by professional bodies, population carrier screening for CF is supported by the target population,¹⁰⁻¹² and by people with CF and their families.¹³⁻¹⁵ Despite recommendations of professional bodies, community support, and the availability of a carrier screening program, the frequency of offering CF carrier screening is low.¹⁶ Health professionals (HPs), in particular GPs, obstetricians, and fertility specialists, are gatekeepers of patient access to carrier screening. In addition to offering population carrier screening, HPs may also provide pre-test and post-result information, as well as referring carrier couples for genetic counselling. Given the crucial role HPs play in patients' access to carrier screening, it is important to understand their opinions and perceived barriers to offering CF carrier screening routinely.

Given the gap between organisational guidelines and routine practice, this study aimed to explore the opinions, knowledge and practice patterns of GPs, obstetricians and fertility specialists in Victoria, Australia.

Materials and Methods:

Ethics approval was obtained from the Royal Children's Hospital, Human Ethics Committee (HREC 34281D).

Questionnaire development

Key informant interviews were conducted via telephone between March and April 2015. The interviews were recorded, transcribed and analysed using content analysis. Domains from the interview data (Supporting Information Table S1) and existing literature^{10,16-18} informed the development of an online questionnaire. Knowledge questions were sourced from previous studies surveying pregnant women's attitudes towards population CF carrier screening.¹⁰⁻¹² Study data were collected and managed using REDCap electronic data capture tools hosted at Murdoch Children's Research Institute.^{19,20}

Recruitment

Potential participants were identified, through the Maternal Serum Screening database at VCGS. This recruitment source allowed for recruitment of HPs who did, and did not, offer CF carrier screening.

Recruitment was limited to HPs practicing in Victoria, Australia. Two rounds of recruitment were conducted between July and August 2015, and September 2016 and January 2017. A second round of recruitment was performed to reach the desired survey sample size. Potential participants who had ordered maternal serum screening within three months (first round) or 30-days (second round) prior to recruitment, were sent invitations containing a link to the online survey via email (first round) or post (second round). For both rounds of recruitment, potential participants who had email addresses available were sent at least one reminder email. Participants who completed the questionnaire during the first round of recruitment were asked not to complete it again in the second round.

Analysis

Partially completed or unfinished questionnaires were excluded from the analysis to avoid the potential of double entries from participants who may have experienced technological issues. Data analysis was performed using IBM SPSS Statistics for Windows (Version 26.0). Frequency of offering population CF carrier screening was measured on a Likert scale. Points '1', '2' and '3' formed the category 'low referrer' and points '4' and '5' formed the category 'high referrer'. Categorical variables were compared using Chi square (χ^2) and Fisher's exact tests. Means of continuous variables were compared using t-tests.

Results

Participant demographics

Eighty-seven participants completed the online questionnaire. High referrers were more likely to be female ($\chi^2 (1) = 4.243$, $p = 0.039$), work in the private sector (*Fisher's exact test* = 12.982, $p = 0.001$), have been practicing for 10-20 years ($\chi^2 (3) = 8.123$, $p = 0.044$), specialise as an obstetrician or fertility specialist ($\chi^2 (1) = 25.277$, $p < 0.001$), and work in a metropolitan area ($\chi^2 (1) = 9.440$, $p = 0.002$) (Table 1).

Practice of offering CF carrier screening

Thirty-one participants (35.6%) reported offering CF carrier screening routinely to all patients they see for preconception and early pregnancy appointments. Twenty participants (23.0%) responded that they did not offer CF carrier screening to their patients. Thirty-six participants (42.4%) responded they only offer CF carrier screening in certain clinical situations. Participants could clarify responses by selecting one or more clinical situations from a provided list or enter individual responses (Supporting Information Table S2). The most common reason provided was if there was a personal or family history of CF in patient or partner.

Attitudes towards population CF carrier screening

Most participants (n = 83, 95.4%) agreed that patients have a right to know CF carrier screening is available, and that the decision to have CF carrier screening is a patient choice (n = 76, 87.4%). Eighty participants (92.0%) agreed that there is a lack of community awareness regarding CF carrier screening. Low referrers were more likely to agree that there is a lack of awareness of CF carrier screening among HPs ($\chi^2(2) = 14.654$, $p = 0.001$). High referrers were more likely to agree that population carrier screening would increase in the future ($p = 0.002$, *Fisher's exact test*), and that they perceived CF carrier screening as a routine test ($\chi^2(2) = 7.637$, $p = 0.022$) (Figure 1).

Knowledge of CF and carrier screening

Seven true or false questions evaluated participants' knowledge of CF and carrier screening. Responses of 'unsure' was categorised as incorrect. Thirty-two participants (36.8%) answered all seven questions correctly, and 64 participants (73.5%) answered at least five correctly. Overall, high referrers had greater knowledge of CF and carrier screening than low referrers ($t(63) = -3.779$, $p \leq 0.001$). The three most poorly answered questions were: (a) cystic fibrosis affects more males than females (false), n = 52 (59.8%), (b) if only one partner of a couple is a carrier of the cystic fibrosis mutation there is still a small chance of the couple having a child with cystic fibrosis (true), n = 52 (59.8%) and (c) if no gene change is found the person cannot be a carrier of cystic fibrosis (false), n = 55 (63.2%). Low referrers were more likely to answer these questions incorrectly, compared to high referrers ((a) $\chi^2(1, n = 87) = 6.800$, $p = 0.009$; (b) $\chi^2(1, n = 87) = 4.537$, $p = 0.033$, (c) $\chi^2(1, n = 87) = 10.162$, $p = 0.001$) (Figure 2).

Barriers to CF carrier screening

Low referrers perceived more barriers to offering CF carrier screening than high referrers ($t(85) = 2.125$, $p = 0.037$). The majority of both low and high referrers indicated that costs associated with testing (89% and 69% respectively), and the consideration of CF being a low priority in a preconception or early pregnancy appointment (73% and 58% respectively) were barriers. Time constraints were the greatest barrier for high referrers with most (80.8%) considering it a barrier; however, only 45.9% of low referrers identified this as a barrier. This difference was significant ($\chi^2(1) = 9.009$, $p = 0.003$). Both patient knowledge ($\chi^2(1) = 4.644$, $p = 0.031$) and participant knowledge ($\chi^2(1) = 12.067$, $p = 0.001$) of CF and carrier screening were more likely to be considered barriers by low referrers, compared with high referrers (Figure 3).

Discussion

General practitioners, obstetricians and fertility specialists are crucial to the offering of population CF carrier screening to preconception and early pregnancy patients. This is a unique study, utilising a

questionnaire informed by key informant interviews to compare differences between the opinions, knowledge and perceived barriers of high and low referrers of CF carrier screening. Only slightly more than a third of participants offered CF carrier screening routinely to patients they saw for preconception and early pregnancy appointments. Overall, low referrers had lower knowledge and perceived more barriers than high referrers. Low referrers were more likely to agree that there was a lack of awareness of CF carrier screening among HPs and were more likely to perceive their lack of knowledge as a barrier to offering CF carrier screening, compared to high referrers. These findings suggest that HPs' lack of knowledge of CF and carrier screening may influence their practice, resulting in them offering screening less frequently.

The findings of this study suggest the rate of offering population CF carrier screening is low, despite recommendations. Since March 2015, RANZCOG have recommended that carrier screening for more common genetic conditions, including CF, be offered to patients seen preconception or in early pregnancy.^{6,21} Participants' knowledge of population carrier screening guidelines and its impact on their practice were not explored in this study; however, Darcy et al. showed that obstetricians who were aware of the similar guidelines released by the American College of Obstetricians and Gynecologists were more likely to offer CF carrier screening to all patients than those who were unaware.²²

Independent of whether they were a high or low referrer, HPs surveyed in this study hold positive attitudes towards population CF carrier screening. Most participants agreed that patients have a right to know that CF carrier screening is available. Therefore, there appears to be a high level of support for offering CF carrier screening regardless of participants' own practice. These findings are consistent with previous studies reporting that HPs have positive attitudes towards population CF carrier screening.^{15,16,23-25} These positive attitudes suggest there are other factors which influence HPs' practice of offering CF carrier screening routinely.

High referrers were more likely to be obstetricians or fertility specialists and work in private practice in metropolitan areas. This supports data showing that carrier screening is taken up predominantly by pregnant women in the private health sector, living in metropolitan areas.²⁶ Therefore access to carrier screening is likely to be inequitable, with public and regional patients less likely to be aware of its availability. In Australia, uptake of carrier screening is higher in women of higher socioeconomic status.²⁷ Given that 83% of participants perceived the cost of testing a barrier to offering CF carrier screening, this suggests that HPs may be uncomfortable raising carrier screening with patients they think may not be able to afford it.

Participants' overall knowledge of CF and carrier screening was higher in high referrers compared to low referrers and a lack of knowledge was more likely to be perceived as a barrier to offering CF carrier screening for low referrers. This supports previous studies that have identified HPs' lack of knowledge of CF and carrier screening as a barrier to offering screening.^{18,28,29} It appears knowledge is a significant factor in influencing a HP's practice of offering CF carrier screening. Low

referrers seem to be aware of their lack of knowledge and this appears to reduce their confidence to offer screening.

Low referrers had a specific knowledge gap in relation to inheritance and residual risk. Rowley et al. demonstrated a similar gap in knowledge regarding CF inheritance in obstetricians²³ and Darcy et al. found that 43% of surveyed obstetricians lacked knowledge about carrier rates, screening sensitivity and residual risk.²² These knowledge gaps impact on HPs' ability to interpret results as well as providing accurate pre-test counselling. This likely impacts their confidence to offer carrier screening.

More than 80% of high referrers considered time a barrier, supporting previous research;^{16,28} however, over half of low referrers did not agree. This suggests that time constraints impact those who offer screening routinely, whereas low referrers perceive other barriers, reducing the frequency with which screening is offered, making time constraints less significant. The perception that CF carrier screening is a low priority, due to the many other aspects to be covered during preconception and early pregnancy consultations, was also identified as a barrier by just over half of the high referrers and majority of the low referrers. In contrast, Morgan et al. demonstrated that the low disease incidence of CF compared to other obstetric problems was only a concern for less than half of participating obstetricians, with regards to offering carrier screening.¹⁸

Most participants agreed that population carrier screening is likely to increase in the future. Patient knowledge has been shown to decrease with an increase in the number of conditions included in carrier screening,³⁰ highlighting the need for pre and post-test counselling. This will likely impact on genetic counsellor resources, both with regards to their workload, as well as the urgent need to provide additional support, training and information resources for HPs involved in offering screening.³¹

This study was limited by its small sample size and therefore care should be given to generalising the findings. Calculating a response rate was not possible as invitation letters were either posted to the doctor's practice or emailed to (in most cases) a generic clinic email address. Therefore, it is unclear how many study invitations reached the intended recipient. It is possible that screening practice and HPs' knowledge has shifted since the questionnaires were distributed (between 2015 and 2017). However, recent Australian data demonstrates that it is still the case that only a small proportion of pregnant couples are offered carrier screening before or in early pregnancy, with only 1.36% of couples being tested.²⁷ While there is growing availability of expanded carrier screening in clinical practice,³² HPs remain less likely to offer carrier screening in the absence of identified risk, such as at-risk ethnic background or family history.³³ Therefore, identifying key barriers and enablers to offering population-based carrier screening, even in the context of a single condition, contributes knowledge to improve accessibility of carrier screening.

In conclusion, the majority of participating HPs did not offer CF carrier screening routinely to patients seen for preconception and early pregnancy consultations. This practice is contrary to current

guidelines and to their own opinion that patients have a right to be offered screening. Low knowledge of CF and carrier screening appears to negatively impact on HPs' practice of offering screening, whilst other barriers to offering CF carrier screening included knowledge, time constraints, the cost of screening and the perception that it is a low priority. With peak bodies recommending carrier screening, more resources are required to promote carrier screening and improve HP knowledge through education and information materials. This would improve accessibility of CF carrier screening as HP confidence in, and frequency of, offering screening increases.

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Table 1. Comparison of demographic variables between high and low referrers

Demographic	Categories	No. of participants (%)			p-value
		Total (n=87)	High Referrers (n=26)	Low Referrers (n=61)	
Sex	Male	27 (31.0)	4 (15.4)	23 (37.7)	0.039*
	Female	60 (69.0)	22 (84.6)	38 (62.3)	
Area of practice	General Practice	60 (69.0)	8 (30.8)	52 (85.2)	<0.001*
	Obstetrics/IVF	27 (31.0)	18 (69.2)	9 (14.8)	
Years of practice	<10	27 (31.0)	6 (23.1)	21 (34.4)	0.044*
	10-20	26 (29.9)	13 (50)	13 (21.3)	
	20-30	18 (20.7)	5 (19.2)	13 (21.3)	

	>30	16 (18.4)	2 (7.7)	14 (23.0)	
Practice demographics	Private	60 (69.0)	23 (88.5)	37 (60.7)	0.001*
	Public / bulk-billing	24 (27.6)	1 (3.8)	23 (37.7)	
	Mixed billing	3 (3.4)	2 (7.7)	1 (1.6)	
	Metropolitan	60 (69.0)	24 (92.3)	36 (59.0)	0.002*
	Rural/regional	27 (31.0)	2 (7.7)	25 (41.0)	
Involved in pregnancy care	Yes	82 (94.3)	25 (96.2)	57 (93.4)	1.000
	No	5 (5.7)	1 (3.8)	4 (6.6)	

*p<0.05 for comparison of high versus low referrers using χ^2 or Fisher's exact test

Figure Legends

Figure 1. Comparison of agreement with statements related to CF carrier screening between high and low referrers. *p<0.05 for comparison of proportions of high versus low referrers using χ^2 or Fisher's exact tests.

Figure 2. Comparison of percent of high referrers versus low referrers who answered knowledge questions correctly. The correct answer is provided in parentheses (T = true, F = false). *p<0.05 for comparison of proportions of high versus low referrers using χ^2 tests.

Figure 3. Comparison of percent of high referrers versus low referrers who rated the following factors as barriers (3–5 on a scale of 1 = not a barrier to 5 = a very high barrier) to offering population CF carrier screening. *p<0.05 for comparison of proportions of high versus low referrers using χ^2 tests.

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