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Exploring the barriers and facilitators of implementing CanRisk in primary care: a qualitative thematic framework analysis.

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# Abstract

*Background:* The CanRisk tool enables the collection of risk factor information and calculation of estimated future breast cancer risks based on the multifactorial Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm (BOADICEA) model. Despite BOADICEA being recommended in NICE guidelines and CanRisk being freely available for use, the CanRisk tool has not yet been implemented widely in primary care

*Aim:* The aim of this study was to explore the barriers and facilitators to the implementation of the CanRisk tool in primary care.

Design and setting: A multi-methods study, conducted with primary care practitioners (PCPs) in the UK

*Methods:* Three methods were employed. Participants completed two vignette-based case studies, a semi-structured interview and a questionnaire.

*Results:* 16 PCPs completed the study. The main barriers to implementation were: the time needed to complete the tool, competing priorities, IT infrastructure, and PCPs' lack of confidence and knowledge to use the tool. The main facilitators included: easy navigation of the tool, its potential clinical impact, and the increasing availability of and expectation to use risk prediction tools.

*Conclusion*: This more developed understanding of the barriers and facilitators to the use of CanRisk in primary care highlights that future implementation activities should focus on reducing the time needed to complete a CanRisk calculation, integrating the CanRisk tool into existing IT infrastructure, and identifying appropriate contexts in which to conduct a CanRisk calculation. PCPs may also benefit from information about cancer risk assessment and CanRisk specific training.

Key Words: Primary Care, Breast Cancer, Multi-factorial Risk Prediction, Implementation, Qualitative

#### How this fits in

The CanRisk tool can help to identify women who are at increased risk of developing breast cancer.

Although the CanRisk tool is used widely in specialist genetics clinics, it is not frequently used in primary care.

By talking to General Practitioners and Nurses we now have a better understanding of the barriers and facilitators to using the CanRisk tool.

We can now plan how to better support General Practitioners and Nurses to use the CanRisk tool.

#### Introduction

Multifactorial cancer risk prediction models, such as the Breast and Ovarian Analysis of Disease Incidence and Carrier Estimation Algorithm (BOADICEA), have been shown to provide clinically valid risk estimates of developing breast cancer in the future <sup>1-4</sup> and their use is recommended in NICE guidelines <sup>5</sup>. The BOADICEA model calculates a patient's future risk of developing breast cancer by combining data on family history, demographic, lifestyle and hormonal risk factors, pathogenic genetic variants, common genetic susceptibility variants, and mammographic density <sup>1,4</sup>.

In primary care, the NICE guidelines (CG164 <sup>5</sup>) currently recommend that a risk assessment based on a first- and second-degree family history should be performed when women with no personal history of breast cancer present with breast symptoms or concerns about relatives with breast cancer and in other clinically relevant consultations, such as women older than age 35 years using an oral contraceptive pill, or women being considered for long-term HRT use. By using the BOADICEA model, the estimated risk of developing breast cancer - based on a multifactorial risk assessment can inform women of their risk and to identify those at above-population level risk who may benefit from referral to secondary care or to specialist genetics clinics.

In order to use the BOADICEA model in the clinical setting, a graphical user interface called the CanRisk tool (www.canrisk.org), has been developed to facilitate the collection of risk factor information (Figures 1 & 2) and provide healthcare practitioners with visual representations of risk to support effective communication (Figure 3) <sup>6</sup>. Developed for use by healthcare practitioners, the CanRisk tool has been shown to be both usable and acceptable in a variety of healthcare settings <sup>7</sup>.

Figure 1: Screenshot of the CanRisk tool showing how risk information is collected

<u>CanR<sup>®</sup>sk</u>	BOADICEA v6 Breast and Ovarian Analysis of Disease Inciden Welcome	ce and Carrier Estimation Algorithm
CanRisk Tool		
🛎 Load 🖺 Save 🤀 Reset 🔅	Preferences	
indicates completed stages	A indicates mandatory field	indicates hover information
Personal Details	In which country do you currently live?	0
Personal Details  Are you?   Formale  What is your date of birth?  Format dd/mm/www A	In which country do you currently live?     UK     How tall are you?     e g 123 5cm	What is your current weight?     e a 73 5kg
Personal Details  Are you?       ← Female  What is your date of birth? Format dd/mm/yyyy ▲      dd/mm/yyyy	In which country do you currently live?      UK      How tall are you?      e.g. 123.5cm      cm      cm	What is your current weight?         e.g. 73.5kg         kg

Figure 2: Screenshot of the CanRisk tool showing how family history is collected



Figure 3: Screenshot of the CanRisk tool showing how breast cancer risk is presented



Although the CanRisk tool is being increasingly used since it received its CE marking (a legal requirement for medical devices being used in the European Economic Area) in early 2020 (over 1,185,000 risk calculations have been conducted worldwide), the majority of users are based in clinical genetics services (~48%) or in secondary care (~35%). Despite primary care being the first point of contact for most women with concerns about their risk of breast cancer, <1% of CanRisk calculations in the UK are completed by General Practitioners (GPs) or Practice Nurses (PNs) even though they are well versed in discussing future risk of health conditions, and frequently use digital

risk prediction tools in a range of clinical areas <sup>8</sup>.

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Several published studies indicate why cancer based risk prediction tools may not be widely used in primary care. In a survey of 400 UK based GPs, over 85% of participants reported that they had not heard of the two clinical prediction tools cited in the clinical guidelines at that time <sup>8</sup>. Other studies have cited a range of personal and organisational barriers to the implementation of cancer risk assessment tools and cancer prevention more broadly <sup>9-13</sup>. Personal barriers include: the role of clinical experience and belief in clinical intuition <sup>11</sup>, a lack of knowledge of how to change patient behaviour around cancer prevention <sup>12,13</sup>, and a lack of confidence to provide risk-reducing medication <sup>9</sup>. Organisational barriers include: the need for additional funding <sup>10,13</sup>, a lack of time available within the consultation <sup>9-11,13</sup>, a lack of integration with the electronic health record <sup>11</sup>, and the need for training <sup>9-11,13</sup>.

Whilst many of these barriers may also apply to the implementation of the CanRisk tool, understanding the specific barriers and facilitators is important to i) inform further development of the CanRisk tool to increase its uptake in primary care, ii) inform the design of future CanRisk based primary care studies, and iii) focus implementation activities on a local and national level. This study therefore aimed to explore the barriers and facilitators to the implementation of the CanRisk tool in primary care and provide suggestions for future implementation activities.

#### Methods

# Design

This was a multi-methods study with three elements; (1) two clinical case studies, (2) a semistructured interview and (3) a questionnaire.

# Participants and recruitment

To gather the views of those most likely to use the CanRisk tool in clinical practice, GPs and nurses (including Practice Nurses (PNs), Nurse Practitioners (NPs) and Advanced Nurse Practitioners (ANPs)) from the East of England were invited to take part in the study by the local Clinical Research Network. Practices were chosen if they could recruit at least one GP and one nurse. Data were collected between July and September 2020, during the first COVID-19 national lockdown.

# Data collection

A testing/interview session was conducted online; it was arranged at the participant's convenience and lasted one hour. During the testing session, participants used the CanRisk tool to complete two clinical case studies presented in written vignettes (see Box 1). Following the testing session, participants were asked to share their thoughts and feedback and their screen was recorded. A semistructured interview with SA (a researcher with expertise in qualitative health services research) followed; as the interviews were designed to be short (<30 minutes) broad questions focused on i) general feedback about the CanRisk tool, ii) their views on when and how the tool might be used in clinical practice, and iii) what (if any) factors might influence this (see Supplementary file 1). Participants were also asked to complete a questionnaire to collect their demographic information and to provide details about the structural characteristics of their practice.

# Data analysis

Video data from the two vignette-based case studies was used to inform improvements to the tool. Qualitative data from the interviews were analysed using a deductive thematic framework approach <sup>14</sup> using the constructs from the 'Inner Setting' domain of Consolidated Framework for Implementation Research (CFIR) <sup>15</sup> (see box 2, for an overview). The main reasons for this were that i) the intervention characteristics had already been assessed as part of the development process <sup>7</sup>, ii) the semi-structured interview focused on barriers and facilitators to hypothetically implementing CanRisk in participants' specific practice, and iii) recruitment focused on two groups of clinical staff rather than other stakeholders (e.g. patients, clinical commissioners and policy makers).

Four of the five CFIR Inner Setting domain constructs and their original definitions were used as the basis for the analytical framework and codebook (networks and communication; culture; implementation climate; readiness for implementation). FSD and SA applied this framework to two transcripts and crosschecked the coding. Following this, FSD coded the remainder of the transcripts using NVivo <sup>16</sup> and further refined the framework by generating sub-categories. After completing the first round of coding, SA coded two transcripts with the revised framework to check for coding

consistency. Information concerning the fifth CFIR Inner Setting domain (structural characteristics) was summarised from the questionnaire.

As FSD had recently joined the CanRisk team, her distance from the project compared to SA (who has a long-standing investment in the overall CanRisk programme) was valuable when leading the analysis. In addition to this, FSD and SA held frequent discussions regarding the interpretation of data and received feedback from the wider team.

# Box 1 – example case study

# Summary:

Annabelle Bates, a white British woman, has come to see you today to ask about changing her contraception. She has been on the oral contraceptive pill for three years, but her mother was recently diagnosed with breast cancer. She would like to know whether she is at high risk of breast cancer.

Age: 32 DOB: 25/1/1990

Height: 1.63m Weight: 70kg

**Lifestyle** Does not drink alcohol.

# Women's Health

Had her first period when she was 9. Began taking the oral contraceptive pill 3 years ago.

**Children** Has 1 child, Amy – aged 3.

Breast Screening Has never had a mammogram.

Medical History Has no history of endometriosis. Has not had her tubes tied.

# **Family History**

**Mother**: Annabelle's mother is alive and is currently 48 years old. She was diagnosed with breast cancer last year, aged 47. Her cancer was oestrogen receptor positive, progesterone receptor positive and HER2 positive.

Father: Annabelle's father, who is 47, is well and has no history of cancer.

Box 2 – constructs and sub-constructs from the Inner setting domain of the Consolidated Framework for Implementation Research (CFIR) <sup>15</sup>.

**Structural characteristics** – The social architecture, age, maturity, and size of an organization.

**Networks and communications** - The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization.

Culture - Norms, values, and basic assumptions of a given organization

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**Implementation Climate** - The absorptive capacity for change, shared receptivity of involved individuals to an intervention, and the extent to which use of that intervention will be rewarded, supported, and expected within their organization. Sub-constructs include: 1) Tension for change, 2) Compatibility, 3) Relative Priority, 4) Organisational incentives and rewards, 5) Goals and feedback, and 5) Learning Climate.

**Readiness for Implementation** - Tangible and immediate indicators of organizational commitment to its decision to implement an intervention. Sub-constructs include: 1) Leadership engagement, 2) Available resources, and 3) Access to knowledge and Information.

# Results

# **Study Participants**

16 primary care practitioners (PCPs) (8 GPs and 8 nurses (6 PNs, 2 NPs)), from five general practices in the East of England took part in the study (see Table 1). Participants had a mean age of 42 (range 29-53) and 8 years of clinical practice experience (range 1-25). The majority of participants felt either confident or very confident using a computer in their clinical practice (94%), and used computer-based risk assessment tools in their patient consultations (81%). None of the participants had experience with electronic pedigree family history drawing.

	Total	GP	PN/NP
Number of participants	16	8	8
Age (mean)	42.0	41.9	42.1
(SD, Range)	(7.0, 29-53)	(6.9, 32-53)	(7.7, 29-52)
Gender			
Male	4 (25%)	4 (50%)	0
Female	12 (75%)	4 (50%)	8 (100%)
Years of experience (mean)	7.9	10.0	5.9
(SD, Range)	(6.9, 1-25)	(8.8, 2-25)	(3.9, 1-13)
Level of confidence using computers in clinical practice			
Not very confident	1 (6%)	0	1 (13%)
Confident	7 (44%)	1 (13%)	6 (75%)
Very confident	8 (50%)	7 (88%)	1 (13%)
Current users of a computerised risk tool			
Yes	14 (88%)	8 (100%)	6 (75%)
No	2 (13%)	0	2 (25%)
Experience using an electronic tool to draw family histories			
Yes	0	0	0
No	16 (100%)	8 (100%)	8 (100%)

Table 1 – participant characteristics

In line with the constructs within the Inner Setting domain of CFIR, information on the *Structural characteristics* of the general practices are presented in Table 2. The data suggest that the practices were broadly comparable in terms of size, age, maturity and social architecture. Some relevant features across practices include regular online or in-person staff training and regular clinical and administrative coordination meetings.

# Table 2: Structural characteristics of research sites

\					
$\mathbf{i}$	1	2	3	4	5
Site No					
	[6 participants =	[3 participants =	[2 participants =	[2 participants =	[3 participants =
$\backslash$	37.5% of	18.75% of	12.5% of	12.5% of	18.75%of
$\langle \rangle$	sample]	sample]	sample]	sample]	sample]
Characteristics					
Number of patients	17,000	13,000	19,000	7,000	9,500
registered					0
Number of clinical	30	11	22	14	21
staff					
Number of non-	32	22	48	26	9
clinical staff					
Practice opened for	Over 55 years	Over 40 years	Over 25 years	Over 30 years	Over 30 years
Electronic Record	SystmOne	SystmOne	SystmOne	SystmOne	EMIS
System					
Staff training	Training	Staff have	Regular training.	Training	Monthly
	available	mandatory	Much of it	available	Training Session
	through	training via	online via	through	for Doctors
	"Clarity"	website	"Bluestream"	"Bluestream"	
				and the Clinical	Annual
		Oran antun iti aa		Commissioning	Annual
		Opportunities		Group	mandatory
		for external			training
		training via	2		
		monthly circular			
	Frank frank	Deutsin	Marah hulumah	N a sa tha bas	Diverse the staff
Clinical coordination	Face-to-face	Partners	weekiy lunch-	wonthly	Bimonthly staff
meetings	weekiy	thetaware ear	time meeting	multidisciplinary	meeting for all
	meetings	chat hurses can		ledin dhu	Monthly doctors
	L C	ask to attend if		clinical team	wonthly doctors
	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~			nercon and	ineeting
		business		person and	
		Ri monthly			
1	V.Cr.			reallis)	
	J.Y	nuise meetings			
	/				
Admin organisation	Weekly	Regular	At least once a	Regularly in	Bimonthly staff
meetings	meetings at	reception	month	person and	meeting for all
	practice level	meetings with		online (MS	
	and monthly	practice		Teams)	Weekly Meeting
	at Primarv	manager and			with PM.
	Care Network	reception			Assistant PM
	level (3	manager with			and Senior
	practices)	nurse/and or			Partner
	practices	general			discussing
			i i i i i i i i i i i i i i i i i i i	1	
		nractitioner			finance and
		practitioner			finance and
		practitioner input.			finance and human resource

		Daily huddle (15
		minutes long)
		for all working
		that day to
		discuss staffing,
		workload
		distribution
		across clinical
		and admin
		teams plus any
		other relevant
		issues

# Qualitative data analysis

The interview data mainly informed the constructs of *Implementation climate* (59%) and *Readiness for implementation* (42%). *Networks and communication* only gathered a small amount of data (<1%), and no data was coded under *Culture*. Supplementary file 1 presents the distribution of references across constructs and sub-constructs.

# Implementation climate: Compatibility

Interviewees reported that the integration of CanRisk into electronic health records (EHRs) would simplify access and could facilitate the addition of results to patients' records. Although full integration would be ideal to allow for data already recorded in the EHR to prepopulate the CanRisk tool, participants described accessing CanRisk via an external link as acceptable:

"But, as long as it's integrated into SystmOne and can be saved in the notes that's, honestly, the main thing, so as long as that happens it's fine. And, as long as we can open it from SystmOne, like all the other tools we use, that's fine, as well. So, as long as those two things apply the rest of it we can use as is" (Male, GP, 15 years of experience, research site 2).

There was a general preference to collect the data required for the CanRisk calculation during patient consultations, but in order to save time, participants thought it would be helpful if patients could complete some information beforehand. Participants were aware of women's potential emotional reactions to the risk information and saw consultations as the appropriate context to answer questions and offer support. As such, they expressed a preference for risk outcomes and management options being discussed in a consultation.

Appointments about oral contraception were cited as the most appropriate and relevant to complete CanRisk, followed by those on hormone replacement therapy (HRT), as breast cancer risk information is already part of these consultations. Attaching CanRisk to existing cervical screening ('smear') appointments was also suggested, although some had concerns:

"Women are already often quite stressed when they come in for their smear and then to then without a warning shot say, oh, they leave the consultation saying, why did the nurse say that? Does that mean that I've got cancer...?" (Female, GP, 3 years of experience, research site 1). Most participants reported that all clinical staff would be able to collect the data to complete a CanRisk calculation due to its usability. Furthermore, many reported that those who are directly involved with appointments about women's health (e.g. contraceptive and HRT appointments) would be able to communicate the risk result. However, there was some uncertainty as to who would be best-suited to give management recommendations:

"I think in terms of the actual counselling element of it [...] I think that our nurses who do contraceptive counselling should feel confident using this information. I suspect that most of them would then defer to a GP for [a] final decision, particularly regarding contraceptive changes" (Female, GP, 3 years of experience, research site 1).

# Implementation climate: tension for change

Participants expressed that CanRisk would be a valuable tool in primary care. In particular, CanRisk was considered relatively easy to use, was similar to other computer-based risk assessment tools, and provided systematic/tangible information to reassure patients regarding their risk and offer them appropriate advice or management options:

"To just have something that you can just put in all the data and the figures, and come up with solid, sort of, evidence, and be able to say to the patient, well your risk is actually no greater than the general population. Again, that's really useful, and I think that will be really reassuring for a lot of the patients that we see" (Female, GP, 4 years of experience, research site 1).

Participants could see benefits in using CanRisk in the decision-making process for specialist services referrals of women who are worried about their breast cancer risk, or have a relevant family history of breast cancer:

Because when we're referring to genetics, a lot of the time we'll be going: well, it sounds a bit farfetched and I'm sure it's probably not necessarily an issue at all. But you are concerned, I don't have the answer, therefore off you go (Male, GP, 7 years of experience, research site 1).

Despite the potential benefits of using CanRisk, participants also expressed worries about not all healthcare practitioners being as keen on using computer-based risk assessment tools and about the psychological impact that risk assessments can have on different patients:

"If the patient is a high risk and, you know, they've got all this medical diagnosis of anxiety, depression, panic attacks, I'll be less inclined to be using this because even though it is clinically helpful and it will help them understand the risk, I feel like there's still this other risk where they'll take this home and then look at it and then be constantly worried about it" (Female, GP, 2 years of experience, research site 1).

#### Implementation climate: organisational incentives and rewards

Many participants described the importance of the tool being endorsed by the CCG and/or included in practice performance measures. Most of the participants who talked about this expressed that for PCPs to use CanRisk proactively, *and not just in place of current discussions about family history of* 

*breast cancer,* it would need to have funding attached and be somehow reimbursed. Examples of how this could be achieved are for CanRisk to be included in the Commissioning for Quality and Innovation (CQUIN) goals or the Quality of Outcomes Framework (QOF):

"Time, time is money, unfortunately. Which is very different for me coming from a background of secondary care then into primary care, where it's, you know, it's a business. I think, if there's some incentive for it to be used, so whether it's involved in some kind of QOF points or quality [...] that would definitely, 100%, make it different" (Female, NP, 3 years of experience, research site 5).

Furthermore, and although CanRisk is currently free to use, any requirement for GP surgeries to pay for a licence to use it would negatively impact on its implementation.

# Implementation climate: goals and feedback

Beyond the financial aspects, participants also described the importance of giving visibility and support to new interventions for their uptake among PCPs:

"It's just making sure people are aware of it I think, so cascading it and showing it to members of staff." (Female, NP, 8 years of experience, research site 3).

Having the endorsement and promotion from commissioning services could help achieve this goal.

# Implementation climate: learning climate

Participants described already having dedicated time to learn about new interventions available and receive training on how to use them to increase their uptake:

"We have these clinical meetings on Tuesday afternoons [...] if we are launching this, we've got this access to this then I'd probably take it in that meeting and show it to everyone how it's used and then we just hope that everybody will use it" (Female, GP, 20 years of experience, research site 3).

# Implementation climate: relative priority

Participants described how taking on new interventions and their associated training while continuing to deliver routine care can be overwhelming for PCPs, and even more so while adjusting and responding to the COVID-19 pandemic emergency:

"I think your biggest difficulty at the moment is, information overload. COVID has brought so many changes [...], so much is coming, that I'm thinking, before, I'd love all this free education, but there's only so much I can do" (Male, GP, 25 years of experience, research site 4).

Still, participants thought that highlighting the potential clinical benefits of using CanRisk would help increase its relative priority:

"Rather than just sending patients to hospital, it's like [...] a very expensive service so if we can do something like that [CanRisk], that will definitely help, yes, and it's just, you can reassure the patient" (Female, GP, 20 years of experience, research site 3).

# Readiness for implementation: available resources

As appointment length in UK primary care is limited (approximately 10 minutes), participants were concerned that they would need longer to complete CanRisk (which takes approximately 15 minutes to complete) and discuss the outcomes with patients:

"Definitely have to extend the normal clinic time. I mean, if you could, you know, if you know the lady's going to be low risk then that's fine, isn't it, you could quickly do it but I think you always have to account for a degree of counselling with the results so I'd definitely need to have extra appointment time" (Female, PN, 6 years of experience, research site 5).

# Readiness for implementation: access to knowledge and information

Participants faced challenges when completing the family history section. They reported finding it difficult and time consuming to complete as they had little experience of using pedigree drawing software. Participants expressed a desire for a simplified process with more prompts:

"So you just need to keep it as quick and as simple as possible if you like. That bit at the end with the family history was tricky, I didn't find that easy at all [...] ...doesn't always make it obvious where you have to click on things" (Female, PN, 13 years of experience, research site 2).

Despite their experience completing risk assessment tools and discussing risk information with patients, both GPs and PN/NPs lacked confidence regarding their general breast cancer knowledge to discuss CanRisk outcomes and management options with patients:

"In terms of confidence, I wouldn't say I'm very high up confident on that, but I think the good thing about being a GP is you can always say [...] to the patient, I'm not sure, I'll do my research and I'll come back to you in a bit" (Female, GP, 2 years of clinical experience, research site 1).

When thinking about how and when they might offer risk management options to women who are at moderate risk in the future, participants reported that they would lack the experience and confidence to prescribe risk-reducing medication, as this is currently initiated in secondary care and/or specialist genetics clinics:

"If a tool like this said so, I might do [prescribe risk-reducing medication], yeah. [...] ...had that situation been presented in real life, I might send an advice and guidance request to genetics or the breast clinic [...] But no, I've never prescribed that before" (Male, GP, 4 years of experience, research site 1).

Therefore, beyond learning about the CanRisk tool and how to navigate it, support on how to interpret and deliver CanRisk outcomes seems necessary for its implementation in primary care:

"I think to have some training to interpret the information would be good and because obviously it's a really sensitive subject that you're discussing, if somebody comes out at a really high risk and then to try to then explain it to them, that's quite hard if you haven't had any kind of training" (Female, PN, 2 years of experience, research site 4).

# Networks and communication

Participants suggested that good team communication and wider networks would enable primary care users to support each other and increase their confidence:

sr s or an, e, then obvic sperience, reserved the second s "We have a very supportive sort of team as well, so if there's something that I wasn't sure then we have all the GPs and things here that we could sort of flag up concerns or anything.

# Discussion

# Summary

The majority of barriers and facilitators to the implementation of the CanRisk tool in primary care clustered around the time needed to complete the CanRisk tool, the CanRisk tool's compatibility and integration with existing primary care IT systems and ways of working, competing priorities, and the need for training and capacity building within healthcare teams (see Table 3).

Table 3: Clusters arising from the barriers and facilitators to implementation

Cluster	Barriers	Facilitators
Time taken to complete	• Amount of time required to	• The tool is easy to navigate
the tool	complete a CanRisk assessment,	by GPs and PN/NPs.
	communicate the outcomes and	• A patient facing version of
	discuss management options.	the CanRisk tool could
		facilitate risk factor and
		family history data capture
		0
		$\mathbf{\vee}$
Compatibility and	• Lack of integration of the CanRisk	Professionals are already
integration with existing	tool into the EHR.	used to similar risk
primary care IT systems	Individual resistance to electronic	assessments tools.
and ways of working	risk assessment tools.	
	script	
Opportunities for use	• The competing priorities within	<ul> <li>The potential clinical impact</li> </ul>
within primary care	primary care.	of the CanRisk tool in general
A Least	<ul> <li>Causing anxiety to patients</li> </ul>	and its potential value in
0		appointments (e.g. pill
~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~		checks, HRT and smear tests)
R		breast cancer rick bappen
~0~ /		• The notential benefit of
		reassuring women in the
7		population risk category.

Need for training and	Professionals' lack of confidence	<ul> <li>General practices having</li> </ul>
capacity building within	regarding their knowledge about	protected training time to
healthcare teams	breast cancer.	learn about new
	Professionals' lack of experience	interventions such as the
	using electronic pedigree family	CanRisk tool.
	history drawing tools.	<ul> <li>Relationships of trust and</li> </ul>
	• Time-consuming and complicated	support among professionals
	family history section in the	within a given setting.
	current version of the CanRisk	
	tool.	0
	Professionals' lack of knowledge	0.2
	and experience prescribing risk-	O.V
	reducing medication.	

# Comparison with existing literature

Whilst the data from the interviews (further supported by videos from the vignette-based case studies) indicate that the CanRisk tool was considered accessible and easy to navigate, there were concerns about whether PCPs could complete a risk calculation and offer appropriate counselling to the patient within a typical UK primary care appointment (an average of 10.9 minutes <sup>17</sup>). This is consistent with our previous work exploring the acceptability of the CanRisk tool in multiple settings and countries <sup>7</sup> as well as the broader body of literature around incorporating cancer risk assessment into practice <sup>9,10,18,19</sup>. As a way of reducing the amount of time needed to complete a CanRisk calculation in clinic, the development of a patient facing version of the tool received broad support.

Whilst some of the data required to complete the CanRisk tool (e.g. BMI and contraceptive use) may be easily entered into a patient facing version of the tool, collecting information on family history is more challenging. Despite an established need for family history data collection tools <sup>20,21</sup> and several having been designed specifically for use in primary care <sup>22</sup> and/or cancer <sup>23</sup>, even highly promising tools <sup>24-30</sup> are not currently routinely used in UK primary care due to the time they take to complete, the accuracy of information collected and the need to update them over time. With these points in mind, any development of a patient facing version of the CanRisk tool that includes family history should use the gold standard of user centred design <sup>31,32</sup>, take into account the elements of existing designs that have already been tested, and undertake appropriate evaluation and validation studies.

Consistent with previous research <sup>9,10</sup>, our study shows that integrating the CanRisk tool with existing NHS IT infrastructure is essential for successful implementation in primary care. There are significant issues for complex digital multifactorial risk prediction tools such as CanRisk, as the fragmented local governance structure would require the CanRisk tool to be approved and adopted by governance and IT teams service by service basis, or the BOADICEA model becoming integrated within existing EHRs (e.g. EMIS/TTP) or via third party providers (e.g. Ardens <sup>33</sup>). The integration and implementation of new technology within the NHS has traditionally been a complex and lengthy process. However, the transformation of digital services following the unprecedented need to adapt during the COVID-19 pandemic may be of benefit in facilitating the use of the CanRisk tool in primary care and sharing/updating the results within a range of services within the NHS <sup>34-36</sup>.

As in other studies, our participants described that primary care presents a clear opportunity for CanRisk to identify patients at increased risk of cancer who would benefit from interventions focusing on early detection and prevention <sup>10,37</sup>. However, the potential benefits of using the CanRisk tool were juxtaposed to the increased effort in conducting the risk assessment, and receiving training on how to do so, in a setting where there appears to be an ever increasing workload and rapidly dwindling resources <sup>38-40</sup>. Several suggestions were put forward that focused on regular women's health appointments (e.g contraceptive pill checks and HRT appointments) which may be suitable as they provide opportunities to a) approach the topic of risk assessment as part of a wider conversation on cancer risks and b) easily talk about hormonal and lifestyle risk factors which may contribute to their risk score <sup>41</sup>.

Our study identified that training and capacity building within healthcare teams is likely to have a significant role in the implementation of the CanRisk tool. The development of bespoke training resources around CanRisk is required, but for now centralised genetics focused training initiatives (.e.g GeNotes <sup>42</sup> and QGenome <sup>43</sup>), may be helpful in improving knowledge, skills and attitudes around taking and understanding family histories. A lack of knowledge around breast cancer and knowledge and experience of risk-reducing medication were also cited as potential barriers to implementation. Whilst training on these topics was highly desirable, our participants were concerned about the competing demands in clinical practice, particularly following the COVID-19 pandemic. As such, any educational intervention designed to provide PCPs with the knowledge and skills to use the CanRisk tool should consider the best mode of delivery <sup>44,45</sup> and if protected learning time is required.

#### Strengths and limitations

We interviewed equal numbers of GPs and PN/NPs who ranged in age and experience of clinical practice. As many of the structural characteristics of the practices were similar and practices consenting to take part may have been more research active or have a particular interest in cancer, greater diversity in terms of location, practice size and practice organisation, as well as sites that are non-research active, may add additional depth to the results in future studies. The interview schedule was very broad and not based on the CFIR constructs as the interviews focused on participants' experiences of using the tool through case studies and their general views on implementation based in their clinical experience. A greater focus on CFIR during the data collection stage may have resulted in a more nuanced discussion of specific elements. Whilst we focused this study on GPs and nurses as they are the healthcare practitioners most likely to use the tool in clinical practice, we did not collect data from other allied healthcare professionals (e.g. healthcare assistants and practice pharmacists) or key stakeholders (e.g. patients, commissioners and policy makers) who would be able to give insight into other domains of CFIR.

# Implications for research and/or practice

Based on the findings from this study, future work to facilitate the implementation of the CanRisk tool in primary care should focus on four main areas. First, developing a user friendly interface that allows patients to enter some of the risk factor information before a clinical appointment. Second, establishing a mechanism for the integration of the CanRisk tool within the EHRs used in the primary care setting. Third, exploring and testing which clinical appointments might be most appropriate for introducing and performing a CanRisk calculation. Finally, developing a training package to support

healthcare practitioners to use the tool, interpret the findings and make choices about the next steps following the risk assessment.

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#### Conclusion

A range of barriers to the implementation of the CanRisk tool in primary care exist, predominantly , sr focusing on the amount of time needed to complete the assessment using the tool, the need for

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# **Ethical approval**

Research Ethics approval was granted by the Health Research Authority prior to commencing the study (Ref No: 18/HRA/1094).

# **Competing interests**

The BOADICEA model has been licensed to Cambridge Enterprise for commercialization, with the authors D.F.E., A.C.A., A.P.C., and T.C. listed as its inventors. These authors may receive royalties in the future if commercialization is realized.

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