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How can Australia integrate routine genetic sequencing in oncology: a qualitative study through an implementation science lens

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Purpose: This study sought to determine genetics and oncology specialists' views of integrating *BRCA1* and *BRCA2* testing in epithelial ovarian and breast cancer into routine practice.

Methods: Qualitative interviews were designed using the Consolidated Framework for Implementation Research. Questions included experiences or views of the *BRCA* testing processes, implementation needs of oncology health professionals, perceived challenges, and future ideas for interventions to integrate genetic testing into oncology.

Results: Twenty-two participants were interviewed from twelve health organizations and four themes were identified: (1) embracing the shift to mainstream genetic testing, with the majority of participants viewing *BRCA* testing as clinically useful and routine use important for maintaining a patient centered process; (2) the need for communication networks and role delineation to integrate routine genetic testing; (3) factors that influence sustaining routine genetic testing, including ongoing training, resources and funding, real-world adaptation, system complexity, and champions; and (4) variation in system interventions for integrating routine genetic testing align to organizational context.

Conclusion: Findings illustrate the need for integrating genetic testing into routine oncology, and that adaptation of interventions and processes is essential to sustain a feasible model. An understanding of individual and organizational implementation factors will help to prepare for future integration of routine genetic testing in other cancers.

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INTRODUCTION

Fifteen to twenty percent of high-grade serous ovarian cancers have been shown to harbor *BRCA* variants.[1] Recommendations made in the United States in 2007 allow for all epithelial ovarian cancer (EOC) patients to have *BRCA* testing regardless of age or family history.[2] In spite of this recommendation, a suboptimal referral rate to genetic counseling (GC) for women with EOC of 30% exists internationally.[3–6] In Australia, eviQ (a consensus evidence base for cancer treatment and information) recommends that *BRCA* testing be considered for patients with triple negative breast cancer under 50 years and EOC under 70 years or at any age with a significant family history of breast or ovarian cancer in a close relative or relapsed EOC.[7] The Australian government has publicly funded *BRCA1* and *2* testing of eligible candidates since November 2017[8] and this change in testing policy allows for multiple breast or ovarian cancer genes (*BRCA1*, *BRCA2*, *PALB2*, *STK11*, *PTEN*, *CDH1*, and *TP53*) to be tested[9] by any medical specialist—this is known as mainstreaming.[10] Mainstreaming of genetic testing requires a shift in practice from referral of patients to a specialist genetics service for GC and genetic testing to now be facilitated by their oncology health professional (OHP). The direct integration of genetic testing through the oncology setting has improved access to testing and increased the identification of *BRCA* individuals for effective cancer prevention to be promoted.[11–13] However, the implementation and contextual factors at an organizational and individual level that lead to successful *BRCA* test integration in some settings are unknown.

Integrating *BRCA* testing for EOC allows the targeting of therapy through the use of poly ADP ribose polymerase inhibitors (PARPi) in *BRCA* pathogenic variant positive EOC individuals. In 2017, PARPi were included on the Australian

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Register of Therapeutic Goods for patients with platinum-sensitive relapsed *BRCA* pathogenic variant high-grade serous EOC and Medical Benefit Scheme (MBS) funding for any medical specialist to order *BRCA* testing for these women. Additionally, women with EOC and a 10% probability of having a variant in *BRCA1*, *BRCA2*, *PALB2*, *STK11*, *PTEN*, *CDH1*, and *TP53* have access to testing funded under MBS[9] and this has led to a shift in pretest GC responsibilities onto the OHP, requiring the oncology workflow system to accommodate the process of genetic testing and delivery of results.

Genetic test integration into routine oncology practice assumes that the OHP will take on the role of pre-test information and informed consent for *BRCA* testing. *BRCA* mainstreaming programs introduced into the United Kingdom, United States, and Australia[11–13] have identified interventions that help to integrate genetic testing into oncology processes. Interventions such as the upskilling of nongenetics health professionals through cancer genetics education[11–13] and obtaining consent for genetic testing,[11] embedding a genetic counselor,[12] and use of the electronic system to streamline the process[13] were identified as important components of the mainstreaming toolkits. Specifically, these programs found an increase of *BRCA* testing completion rate from 27% to 82%[13] and 54% to 90% compared with baseline[12] and 100% testing completion rate.[11] The mainstreaming toolkit for piloting *BRCA* mainstreaming in various hospitals in Australia (Fig. S1) encompasses strategies such as education and obtaining consent with a standard form and pathology request. The assessment effect of these strategies at improving genetic testing access and completion is underway (manuscript under review); however, evaluation of contextual (organization culture, structure, and implementation climate) and individual provider issues (readiness to implement and individual needs) that impact on implementation efforts across multiple hospital sites was not included. This implementation science lens evaluation is required to inform strategy decisions to support future implementation efforts in *BRCA* mainstreaming. Another benefit of such evaluation gives generalizable lessons for wider integration of genetic testing in oncology.

The mainstreaming programs and strategies described above were not underpinned with an implementation science framework or lens to evaluate or guide the intervention design and implementation efforts taking into account the organizational context. Implementation frameworks enhance the translation of new evidence into clinical practice by giving a better understanding of how and why implementation succeeds or fails.[14] The Consolidated Framework for Implementation Research (CFIR) encompasses 39 constructs in five domains that address dissemination, innovation, organizational change, implementation, knowledge translation, and research uptake.[15] It has been widely used across various disciplines and health organizations to evaluate pre- and postimplementation efforts and implementation processes in real-world settings.[16] As various approaches are being trialed to integrate genetic testing into oncology, it is important to consider the implementation factors of GC pre-test role acquisition by OHP and to understand their service and support needs in the organizational context. In light of these developments, this study sought to determine genetics and oncology specialists' views of integrating *BRCA* testing in EOC and breast cancer into routine oncology practice using an implementation science framework to examine the successes and challenges in various Australian hospitals.

MATERIALS AND METHODS

Participants

Purposive sampling was used to gather evidence of implementation factors within different hospital organizations by sending email invitations to the heads of Australian Familial Cancer Clinics (FCC) and oncology, the Australian Genetic Testing Mainstreaming Collaborative Group, and trainee radiation and medical oncologists as part of the Basic Sciences in Oncology program in Australia to participate in a semistructured telephone interview. The invitation included a snowball sampling approach to forward the study invitation to potentially knowledgeable interviewees such as oncology or genetics colleagues who had experience or views about mainstreaming of genetic testing in ovarian and breast cancer either within or outside of their organization.

Procedure

The development of the interview guide was devised using CFIR's five domains: intervention characteristics, outer setting, inner setting, characteristics of the individuals involved, and the process of implementation. Intervention characteristics are key attributes of interventions that influence the success of implementation.[15] The outer and inner setting describe factors that influence implementation from an economic, political, and social context in the outer setting to structural, political, and cultural contexts within organizations in the inner setting.[15] The characteristics of individuals describes individuals involved with the intervention and/or implementation process.[15] The process of implementation connects an intervention with its setting to understand the process of effective implementation.[15] All CFIR domains and the associated 90 possible questions[15] were included in the initial draft of the interview guide. Each member of the Australian Genetic Testing Mainstreaming Collaborative Group (senior genetic counselors) were emailed the initial copy of the interview guide and asked which questions to include or not under the five CFIR domains. Their responses were compared with those of the study authors through Excel version 10 (2016), which led to refinement and selection of 24 qualitative questions. A consensus on the four key contextual implementation factors was reached through discussion and led to a further refinement of 17 questions to include and facilitate data collection on (1) oncology and genetic health professionals' (GHPs) views about the success and challenges of *BRCA* mainstreaming, (2) the support and education needs of OHPs

for sustaining mainstreaming of genetic testing, (3) the readiness of OHPs to implement mainstreaming genetic testing, and (4) organizational and individual factors that will facilitate or hinder implementing and sustaining mainstreaming. The final interview guide consisted of 17 questions across four CFIR domains (Supplementary Material), which elicit theoretically underpinned data on the key factors affecting the implementation process of *BRCA* mainstreaming. Email contact was initiated with all consenting participants to arrange a telephone interview and all interviews were conducted between March and September 2019 by a single researcher (R.O.S.). This study received ethics approval from the University of Sydney's Human Research Ethics Committee (approval number 2018/973).

Data analysis

Interviews were transcribed, de-identified, and coded in an iterative manner to identify common themes using a researcher-generated coding tree. The codes were created by analyzing the raw interview data and were developed (by R.O.S.) using the first interview transcript and mapped to the CFIR domains. The next two transcripts were independently coded by three researchers (R.O.S., N.T., N.M.R.) and checked for concordance. A consensus agreement on discordance codes was reached between the independent coders, giving an overall concordance rate of 80%. Refinement of the coding occurred at each of these discussions. Counting of codes allowed visualization of patterns and similarities in the data, leading to thematic characterizations.[17] The remaining transcripts were analyzed using the established codes and an inductive thematic approach[18] using the grounded theory methods of coding and constant comparison[19] to identify themes encompassed within the data. Final thematic consensus was reached through research team meetings.

RESULTS

Twenty-four participants consented and 22 were interviewed and two indicated they were no longer available. Participation represented all the Australian states with the exception of Tasmania (Table 1). Participants included genetic counselors and clinical geneticists (GHPs), nurses, a surgeon, and oncologists (OHPs). The majority of participants (91%; 20/22) had more than 5 years' experience in practice and 9% (2/22) had 1–5 years in practice with five GHPs and OHPs holding senior or leadership positions, respectively.

Table 1 Participant demographics and characteristics.

Gender	Female	18
	Male	4
Age range		29–65
Profession	Genetic counselor (GC)	6
	Clinical geneticist (CG)	2
	Medical oncologist (MO)	6
	Surgeon (S)	1
	Nurse (N)	7
Mainstreaming role	Direct involvement, active role in *BRCA* mainstreaming process	16
	Not directly involved, exposed to *BRCA* mainstreaming process	6
Hospital site	Metropolitan	18
	Rural	2
	Statewide system	2
States represented		5

Implementation influences of inner, outer setting and implementation process

Embracing the shift to mainstreaming of genetic testing

The majority of participants (18/22; 8 GHPs and 10 OHPs) indicated that they value mainstreaming the genetic testing process to give patients further options in their treatment for EOC (clinical utility) and facilitate a streamlined process. Public and private metropolitan hospital based (13/18) genetic counselors (3/6), consultant geneticists (2/2), oncologists (5/7), and nurses (3/7) expressed clinical utility as important (Table S5). Although many participants reported that current mainstreaming processes are streamlined and provide better access for patients, there was a recognized need for optimization, especially in regard to results delivery and follow up (14/22; 7 GHPs and 7 OHPs). This subtheme was expressed by genetic counselors (5/6) from metropolitan, statewide, and regional services and oncologists (6/7) and nurses (5/7) in public metropolitan and regional or community hospital settings (Table S5). Most participants (12/22; 5 GHPs and 7 OHPs) expressed the importance of a patient centered process through continued contact with the OHP and understanding the right time to introduce genetic testing into the EOC care process. Public metropolitan hospital based (8/18) genetic counselors (2/6), consultant geneticists (1/2), oncologists (3/7), and nurses (2/7) and all genetic counselors (2/2) and oncologists (2/2) in a regional and statewide setting viewed the patient centered process as important (Table S5). OHPs were viewed as the most appropriate to facilitate routine genetic testing in a patient centered manner. Illustrative quotes in Tables 2 and S1 relate to the various subthemes and map to either the inner (relative priority construct) or outer setting (patient needs) and implementation process (executing) domains of CFIR.

Implementation influences of inner setting and individuals

Communication networks and role delineation needed to integrate genetic testing

Most participants (12/22; 8 GHPs and 6 OHPs)—mainly genetic counselors (3/6), consultant geneticists (2/6), oncologists (3/7), and nurses (3/7) based in metropolitan public and private hospitals (11/18) with a smaller number in statewide and regional settings (3/6 genetic counselors and 1/7 oncologists) (Table S5)—expressed the importance of good communication between genetics and oncology. Communication networks and collaboration to ensure

Table 2 Illustrative quotes for subthemes of embracing the shift to mainstream genetic testing.

CFIR (domain—construct)	Illustrative quote
Inner setting—implementation climate—relative priority Individuals' shared perception of the importance of the implementation within the organization[15]	**Clinical utility** "I guess it's reassuring, I suppose, to know that yes we have tested and having that result on hand and so then advising about chemo choices. I've also been able to go back and test historical patients that might not have met eligibility when we first met and now can be tested, so some retrospective test as well to sort of know, yes okay we've done that and I now know that a PARP inhibitor is not in your treatment paradigm" (P08, OHP) "I think in the gynae space they see it as important. But probably in a different way to us obviously because the PARP inhibitors and treatment option for those women, they see it important for that woman's care, whereas we see it as important for the rest of the family" (P16, GHP)
Implementation process—executing Carrying out or accomplishing the implementation according to plan[15]	**Current mainstream process and future adaptation** "I think one of our key concerns is making sure that results get to where they need to go and are acted upon appropriately, making sure that these people are found to have variants, that they then subsequently get referred to the familial cancer center to for a proper assessment and discussion" (P7, OHP) "Although there was a pathway that was part of the training module, there was a lot of kinks to work out, particularly in terms of results delivery and also in terms of who felt responsible for ordering the testing" (P3, GHP)
Outer setting—patients' needs The extent to which patient needs, as well as barriers and facilitators to meet those needs, are accurately known and prioritized by the organization[15]	**Importance of maintaining a patient centered process** "I think case by case really and just feeling out how the patient's traveling with information load, but we would have it on the initial consultation, we'd have it on the to-do list at the first consultation and sometimes they're keen to discuss that at first consultation or it might be subsequent consultations" (P12, OHP) "They knew the patients well and had that regular contact with them, so they could just work out the right timing to raise it and also knowing where their treatment was at, knowing when it's going to benefit the treatment decisions" (P01, GHP)

CFIR Consolidated Framework for Implementation Research, *GHP* genetic health professionals, *OHP* oncology health professionals, *PARP* poly ADP ribose polymerase.

continued support for integrating genetic testing through a point of contact in genetics (15/22; 7 GHPs and 8 OHPs) were mentioned by genetic counselors (3/6), consultant geneticists (2/2), oncologists (4/7), and nurses (2/7) based in metropolitan public and private hospitals (11/18) and genetic counselors (2/2) and oncologists (2/2) in statewide and regional settings (4/4) (Table S5). Both oncology and genetics participants indicated the need for role delineation (15/22; 8 GHPs and 7 OHPs) and to have a clearer pathway of responsibility for different aspects of the patient's care continuum. Genetic counselors (3/6), consultant geneticists (2/2), oncologists (3/7), and nurses (3/7) based in metropolitan public and private hospitals (11/18) and all genetic counselors and oncologists in statewide and regional settings (2/2) viewed role delineation as important (Table S5). Illustrative quotes in Tables **3** and S2 relate to the various subthemes and map to either the inner setting (networks and communication) or individuals involved (other personal attributes) domains of CFIR.

Implementation influences of inner setting, intervention characteristics, and process

Influencing factors on sustaining routine genetic testing

Almost all participants (18/22; 8 GHPs and 10 OHPs) had views on ongoing training in genetics to sustain mainstreaming in practice and enabling upskilling to increase comfort levels with the pre-test GC role. Public and private hospital based metropolitan (13/18) genetic counselors (3/6) and consultant geneticists (2/2), oncologists (5/7), and nurses (3/7) and all regional and statewide participants expressed ongoing training as important (Table S5). Some highlighted the need for training in genetics to be a core component of the university curricula of nursing and oncology trainees (7/22; 4 GHPs and 3 OHPs). Most participants (13/22; 6 GHPs and 7 OHPs) identified sufficient resources and funding as a barrier to sustaining mainstreaming in public and private hospital based metropolitan (11/18) settings, with genetic counselors (3/6) and consultant geneticists (2/2), oncologists (4/7) and nurses (2/7), and some in regional and statewide

Table 3 Illustrative quotes for subthemes of communication networks and role delineation for mainstreaming genetic testing.

CFIR (domain—construct)	Illustrative quote
Inner setting—networks and communication The nature and quality of webs of social networks and the nature and quality of formal and informal communications within an organization[15]	**Communication networks and collaboration** "I think making sure that genetic counselors build up a relationship with oncology services, we're lucky here in that we're closely linked with a number of the familial cancer centers, but there would be other hospitals where that isn't the case" (P17, OHP) "I guess because we're still in the infancy with breast cancer, I think that having the doctors knowing where they can contact, I think that is certainly—having that, I guess, relationship between genetics and that specialty, I think that that is probably integral so the nongenetic specialist has a resource to go to" (P01, GHP) **Genetics point of contact** "So having a dedicated person, especially as a go-to person, because I'm not a genetic counselor, my knowledge is very simple. I think that's sufficient, but you do need to network with people who have a greater knowledge and they keep up with it" (P18, OHP)
Individuals involved—other personal attributes A broad construct to include other personal traits such as tolerance of ambiguity, intellectual ability, motivation, values, competence, capacity, and learning style[15]	**Role delineation** "I think everybody knows that it's becoming more integrated into what we do and how we do it, but I don't think they are clear about their role in it" (P08, OHP) "I think it's just respecting each other's different roles. I don't think we can expect a medical oncologist to do a full…genetic counseling discussion and find out about all the people" (P05, GHP)

GHP genetic health professional, *OHP* oncology health professional.

participants raising this as a barrier (Table S5). Many participants (12/22; 6 GHPs and 6 OHPs) talked about the real-world adaptation of the pilot research mainstreaming project (Fig. S1) with varying degrees of success and challenges to embed mainstreaming into routine practice in public and private metropolitan hospital based (7/18) settings, with genetic counselors (1/6) and consultant geneticists (2/2), oncologists (2/7), and nurses (2/7) and all participants in regional and statewide settings indicating that testing was in routine practice or still being piloted (Table S5). Illustrative quotes in Tables **4** and S3 relate to the various subthemes and map to either the inner setting (readiness for implementation—access to knowledge and information or available resources) or intervention characteristics (adaptability) domains of CFIR.

Some participants (7/22; 5 GHPs and 2 OHPs) commented on the complexities of private and public hospital processes for follow up and tracking of results due to the lack of a shared information system. Public and private hospital based metropolitan (4/18) genetic counselors (2/6), consultant geneticists (1/2), and nurses (1/7), as well as genetic counselors (1/2) and oncologists (2/2) in regional and statewide settings, expressed challenges with integrating public and private systems for sharing genetic information (Table S5). Some participants (5/22; 3 GHPs and 2 OHPs) raised concerns due to complications of genetics not being integrated into the main hospital public setting—genetic counselors (1/6), consultant geneticists (1/2), and oncologists (2/7) and a genetic counselor (1/2) in the statewide system (Table S5)—with concerns regarding privacy of genetic information noted. Most participants (13/22; 7 GHPs and 6 OHPs) spoke about the importance of having a genomics "champion" within the oncology team or department. Public and private hospital based metropolitan genetic counselors (3/6), consultant geneticists (2/2), oncologists (3/7) and nurses (2/7) and genetic counselors (2/2) and one oncologist in the statewide and regional setting expressed the importance of champions to maintain routine use of genetic testing within the oncology service. In settings where there was no existing champion to influence oncology practices, there were challenges to implementation and other system structures limiting the generalizability of integrating a genetic testing pathway. Illustrative quotes in Tables **4** and S3 relate to the various subthemes and map to either the inner setting (readiness for implementation and implementation climate) or intervention characteristics (adaptability) or process (engaging champions) domains of CFIR.

Implementation influences of intervention characteristics

System interventions for integration of genetic testing

Most participants (14/22; 7 GHPs and 7 OHPs) were supportive of having a genetic counselor embedded in an oncology clinic as a version of mainstreaming. Public and private hospital based metropolitan (10/18) genetic counselors (2/6) consultant geneticists (2/2), oncologists (3/7), and nurses (3/7) and all regional and statewide participants

Table 4 Illustrative quotes for subthemes of influencing factors on sustaining mainstreaming.

CFIR (domain—construct)	Illustrative quote
Inner setting—readiness for implementation—access to knowledge and information Ease of access to digestible information and knowledge about the intervention and how to incorporate it into work tasks[15]	**Ongoing training** "Ongoing training and updates...and ongoing training when staff change all the time, which they do" (P18, OHP) "I think we should be targeting trainees and the course curriculum at the college and make knowledge of genetics and experience with a range of administering testing part of the training curriculum" (P21, GHP)
Inner setting—readiness for implementation—available resources The level of resources dedicated for implementation and ongoing operations, including money, training, education, physical space, and time[15]	**Resources and funding** "It's very hard and I've been trying on other fronts to make a change in practice, unless you put in something and an extra FTE to embed that into practice. For the existing staff to take it on as one more thing when they're already really struggling with what's required, it's just not reasonable" (P18, OHP) "More public FTEs for the medical oncologist, more critical mass of clinical oncologists who've come through the clinic to learn, who've sat in when we've done testing" (P05, GHP)
Intervention characteristics—adaptability The degree to which an intervention can be adapted, tailored, refined, or reinvented to meet local needs[15]	**Real-world adaptation to mainstreaming** "What we have been doing or what we have got gynecologic nurses to do, is to actually organize the testing before the patients go home after their surgery…on the whole it's now done pretty much automatically straight away" (P13, OHP) "I would say piloting probably. So basically genetics is still babysitting the whole lot and developing request forms and that kind of thing and I know they've started a bit of a foray into the breast sphere as well" (P03, GHP)
Inner setting—implementation climate—compatibility The degree of tangible fit between meaning and values attached to the intervention by how the intervention fits with existing workflows and systems[15]	**System complications** "I guess our setting is a private practice, so if it went through the public hospital EMR whether other people may have access or they've had testing, that's interesting, I know Aunty So-and-So" (P12, OHP) "There's a big private presence in gynae as well, so a lot of patients are being seen privately with their gynae oncology stuff and I do know of the private gynae-oncs who are mainstreaming, but they aren't sending the tests to [pathology name] for example, where we can see those tests" (P16, GHP)
Process—engaging—champions Individuals who dedicate themselves to supporting, marketing, and "driving through" an implementation overcoming indifference or resistance that the intervention may provoke in an organization[15]	**Genomics champions to sustain mainstreaming** "I think that's the only way that mainstream genetic testing across multiple different disciplines. it's really only going to happen if the hospitals move to a model where we have a genomics champion within individual services" (P21, GHP) "So clearly you need buy-in from the clinicians at the local level. So if they're willing and interested to do it, it will work and if they're not, there's no chance in the world" (P07, OHP)

EMR electronic medical record, *FTE* full-time equivalent, *GHP* genetic health professional, *OHP* oncology health professional.

expressed embedding a genetic counselor into the oncology setting as a potential intervention to support mainstreaming (Table S5). However, a few participants (3/22; 1 GHPs and 2 OHPs) felt that the funding and structure of certain state health systems would limit it as a generalizable intervention. Some participants (7/22; 1 GHPs and 6 OHPs) viewed multi disciplinary team (MDT) meetings with documentation and tracking of genetic testing outcomes in the existing template within the public hospital metropolitan setting (6/18) from the oncologist (3/7), nursing (2/7), and genetic counselor (1/6) perspective (Table S5) as a suitable intervention for their system. Others (9/22; 3 GHPs and 6 OHPs) expressed that a centralized or main electronic tracking system in the medical record would be a more suitable system intervention for public hospital metropolitan (8/18) based genetic counselors (2/6) and consultant geneticists (1/2), as well as from the oncologist (4/7) and nursing perspective (1/7). Some participants (6/22; 2 GHPs and 4 OHPs) suggested a

Table 5 Illustrative quotes for suggested systems interventions for integrating genetic testing into routine practice.

CFIR (domain—construct)	Illustrative quote
Intervention characteristics	**Embedded GC in oncology**
Key attributes of interventions that influence the success of implementation	"I'd love a counselor to actually be in the clinic and certainly coming to like a clinic that does breast and ovarian, because at the moment they have a separate clinic, they have no space, they need space to be able to sit down and talk to people as well" (P08, OHP)
	MDT and patient tracking systems
	"It could certainly be added to the MDT, the template of the MDT, that would make sense and it just gives us another flag, this one we have to follow through with it" (P18, OHP)
	"It would be great to have all of that in one place where you could go into a certain application for all the consent forms to be there, then linked with the results, that would be really helpful…. Because doing it by email is fine, but obviously having a specific area or specific tool would be...ideal" (P17, OHP)
	Flowchart of process for a standard of care pathway
	"All that sort of navigating that and having possibly another flowchart or another way of processing that would be really helpful" (P19, OHP)
	"So I think that having that in the flowchart—it's possibly helpful…. Certainly incorporating [it] into the process" (P01, GHP)

CFIR Consolidated Framework for Implementation Research, *GC* genetic counselor, *GHP* genetic health professional, *MDT* multi disciplinary team, *OHP oncology* health professional.

flowchart or checklist intervention to ensure that there is an understandable pathway for OHPs to follow for incorporating genetic testing into their routine practice from the public hospital metropolitan (5/18) based genetic counselor (1/6), consultant geneticist (1/2), oncologist (1/7), and nursing perspective (2/7). Online training, automatic or email reminders, information provision, applications, and telehealth (1–3 participants) were other suggested interventions to facilitate mainstreaming within various hospital settings per role of the participant (Table S5). Illustrative quotes for each intervention are provided in Tables **5** and S4 and relate to the intervention characteristics domain of CFIR.

DISCUSSION

This study explored current and emerging integration of *BRCA* germline genetic testing for EOC and subsets of breast cancer in various health settings in Australia. Overall, both OHP and GHP recognize the value of routine *BRCA* testing to inform treatment management decisions and to maintain patient centered care through the ongoing relationship with the OHP. Most organizations had to adapt their processes to ensure incorporating *BRCA* testing was a suitable fit with their patients and systems. Collaboration, communication, and role delineation between OHP and GHP and departments were viewed as important in initiating and sustaining routine testing. Ongoing training, additional resources, funding, and mainstreaming champions, especially in settings where genetic testing was not wholly integrated into routine practice, were recognized modes of facilitating or sustaining the integration of *BRCA* testing. Generalizable interventions to facilitate routine genetic testing were accepted as positive practice, such as embedding genetic counselors into oncology departments, working better with MDT, and electronic patient tracking through medical records to ensure results were followed up. However, organizational variation existed as to what intervention would suit particular systems to facilitate and sustain a future model for genetic test adoption.

The survival advantage of those with EOC pathogenic variants targeted with PARPi[20] drives the initiation of routine *BRCA* testing, improving access and personalized medicine approaches. Our findings show both OHP and GHP view routine *BRCA* testing for EOC clinically useful in that testing was streamlined and delivered further treatment options while maintaining personalized care for their patients. Oncologists viewed the perceived relative advantage and clinical utility of routine *BRCA* testing as important in their practice for treatment options in other *BRCA* mainstreaming programs.[11,12,21] Clinical utility in oncology and neurology in the United States allowed a streamlined approach and was preferred in all specialties.[22] Surgeons and oncologists in the United Kingdom viewed a simplified pathway for mainstreaming as efficient for turnaround and expediting treatment decisions.[23] Our study found that OHPs were viewed as the most appropriate professional to take on the role of pretest GC for routine *BRCA* testing and adhere to a patient centered process. Similarly, the oncologist was viewed as key to providing patient follow up for integrating universal tumor screening (UTS) in colorectal cancers and in routine genetic testing for women with breast cancer due to the ongoing patient–practitioner relationship.[23,24] Our findings support previous research and show that implementation factors in the inner, outer, and process domains such as relative priority, executing, and patients' needs appear to drive the uptake and sustainability of integrating genetic testing into routine care.

The adoption of genomics is an acknowledged challenge in health systems due to the gap between the fast pace of genomic discoveries and their translation into clinical care,

even when there is proven validity and utility.[25,26] In view of the recognized challenges, our results indicate that role delineation, collaboration, and communication are important implementation factors for ensuring OHPs feel supported in taking on the role of pretest GC. The Implementing Genomics in Practice (IGNITE) Network in the United States showed that effective communication and collaboration factor into the successful integration of genomics across specialities.[27] Successful implementation factors such as educational support and pathways to routine genetic testing with partnership from genetics and oncology are highlighted in EOC mainstreaming programs internationally.[11–13] Delineating clinical responsibility with OHPs responsible for pathology evaluation and treatment management decisions and embedding a genetic counselor responsible for pre-test GC during chemotherapy sessions and genetic test result follow up in the oncology workflow were described as success factors in one approach to integrating *BRCA* testing into oncology in Australia.[12] Our findings support previous research and illustrate that implementation factors in the inner and individual domains such as collaboration, role delineation and, good communication between OHP and GHP influence implementation success in the adoption of routine genetic testing.

Mainstreaming is challenged by the recognized need to upskill medical specialists with the relevant capability to take on the new role of pre-test GC.[28] The most common barrier to access to genetic testing identified by patients was that their doctor did not recommend it or physicians felt unprepared to use genetic information in their practice.[29,30] Most participants in our study recognized the need for ongoing training to support OHPs in adopting the role of pre-test GC and some indicated that for long-term sustainability, genetics education needs to be part of university training curricula for doctors and nurses. The need to keep abreast of the evolution of knowledge in genomics and oncology due to new treatments and testing regimes requires the cancer workforce to be continually updated as new genes are discovered, variants are interpreted, and tumor testing evolves.[31] Our results indicate that the integration of genetic testing would be influenced by an inner setting implementation factor in the organization's readiness for implementation through long-term access to knowledge and information to upskill in genetics.

Additional issues were found that highlight implementation factors that extend beyond ongoing training and upskilling of OHPs in cancer genetics. These issues that would impact sustainability of mainstreaming include ensuring the availability of sufficient infrastructure resources and funding for personnel, and managing the differing needs of public and private information systems to store and allow access to genetic information in the main health record. Additional infrastructural resources, staff capacity, and time commitment are also seen as barriers in other studies.[23] Systems infrastructure with lack of a tracking system for genetic referrals and patient follow up in 33% of community based hospitals incorporating UTS[32] and laboratory processing and systems for electronic ordering and tracking for UTS[33] were identified as key implementation success factors. Our findings support previous research and illustrate that implementation factors such as readiness for implementation through available resources, infrastructure, and funding influence sustainability, and that the mainstreaming interventions adaptability and compatibility impact the real-world adoption of routine genetic testing.

The importance of identifying champions to influence adoption of interventions and innovations in health systems is recognized as an important implementation science factor.[34] Our findings suggest the need for genomics champions to push for routine incorporation of genomics into oncology. This is echoed in other studies that identified the need to have local champions to influence adoption of UTS in colorectal cancer and incorporate treatment focused genetic testing in routine oncology for breast cancer,[23,24,33] along with the need for mainstreaming champions to provide leadership to influence the adoption of genomics.[23,35] Due to the ongoing need for education and champions, suitable health professionals with specialist genetic knowledge such as genetic counselors or OHP genomics champions are required to ensure that evolving evidence is translated into clinical practice. Our findings on suitable interventions for integrating genomics in oncology suggest that genetic counselors could facilitate the role of mainstreaming champions to allow for real-world adoption of genomics in cancer care.

Some participants suggested that embedding a genetic counselor (either for a transitional period or more long-term if funding resources allow) as an intervention would be useful for future sustainability to support routine integration of genetic testing into oncology, which was an approach employed in one Australian program.[13] However, this approach is demanding on the resources of genetic services, and would not be an option for some service structures (including some statewide or smaller rural services) and may limit the upskilling of OHPs to take on the role of pretest GC. Some strategies to consider these demands for future integration of testing could include different models of GC that move away from the traditional face-to-face hospital based model to alternatives such as telephone or telemedicine GC[36,37] or pretest education provision through written (pamphlets, booklets) and online platforms (websites, decision aids).[38,39]

The other suggested interventions varied between organizations such as MDT meetings and template documents to include tracking of patients who had *BRCA* testing, a centralized or main electronic tracking system in the medical record, a flowchart or checklist intervention to ensure that there is an understandable mainstreaming pathway, online training, automatic or email reminders, information provision, electronic applications, and telehealth to facilitate integrating routine genetic testing within different hospital settings. Successful international health system interventions to date include online education and upskilling of nongenetics health professionals in cancer genetics and consenting for GT,

the development and testing of a care and referral pathway for the collaborative working of the oncology and genetic specialist, utilization of the electronic health record, and streamlined patient appointment services for universal referral to GC.[11–13] The varied views on intervention characteristics' suitability and need for adaptation to the *BRCA* mainstreaming EOC intervention provided (Fig. S1) suggest that preimplementation research and evaluation of implementation is required to allow for ease of adoption and sustainability of *BRCA* mainstreaming intervention. Our findings suggest that the key attributes of the *BRCA* mainstreaming intervention characteristics are important to evaluate in pre-implementation research to ensure compatibility of the interventions at the individual organizational level.

It is broadly recognized that pre-implementation research, to examine the chances of an intervention working in real-world settings, does not always occur.[40] As *BRCA* and other genetic testing integrates into routine oncology care, pre-implementation research to evaluate the organization context and process to suitably design and adapt multiple hospital system interventions before implementation would aid the effectiveness and sustainability of integrating routine genetic testing in other cancer types and across a diverse set of organizations and structures.

This study has a number of strengths and limitations. We were able to collect data from health-care professionals from all Australian states involved in mainstreaming. Not all professional groups were represented, with a lack of breast surgeons' involvement; however, an equal number of genetics and oncology professionals were represented. Most participants had considerable experience in health-care practice and had or were in a variety of roles in the mainstreaming process; however, as not all participants had direct experience of current mainstreaming pathways, their views may not be representative of all GHPs and OHPs in Australia. A diverse set of health organizations and systems were included, leading to generalizable genomics implementation lessons for metropolitan, rural, and statewide health systems. R.O.S. was the sole interviewer and is a qualified genetic counselor, leading to consistency in data collection and interpretation. To overcome any bias of data analysis and reporting due to one genetic counselor's perspective, the data were independently assessed by implementation scientists (N.T. and N.M.R.) to ensure objectivity in reporting. The use of CFIR underpinned the collection of data and facilitated the interpretation of our findings to identify lessons and gaps in the needs of individuals and organizations in the implementation of routine oncology *BRCA* testing. Understanding the implementation factors that affect the adoption of routine *BRCA* testing across hospital organizations provides important information for future implementation research to guide and tailor implementation strategies for health-care organizations seeking to sustain models for integrating routine genetic testing in other cancer types.

SUPPLEMENTARY INFORMATION

The online version of this article (https://doi.org/10.1038/s41436-020-0838-x) contains supplementary material, which is available to authorized users.

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DISCLOSURE

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