Genetic and genomic learning needs of oncologists and oncology nurses in the era of precision medicine: a scoping review

Abstract:

Genetic and genomic data are increasingly guiding clinical care for cancer patients. To meet the growing demand for precision medicine, patient-facing oncology staff will be a part of leading the provision of genomic testing. A scoping review was undertaken to identify the range of genetic and genomic learning needs of oncologists and oncology nurses. Learning needs were reported relating to interpretation of genomic data, clinical decision-making, patient communication and counselling, and fundamentals of genetics and genomics. There was a lack of empirical research specific to oncology nurses and their learning needs in tumour sequencing. Our findings suggest that oncologists and oncology nurses need tailored support, education and training to improve their confidence and skills in adopting genomic testing into clinical practice.

(Word count: 121)

Keywords:

Genetic testing, genomic testing, oncology, learning needs, precision medicine, oncologists, oncology nurses

Background

The rapid expansion of genetic and genomic testing over the past five years, driven by technological advances, decreasing costs and increasing demand, has seen genomics become incorporated into routine clinical care. Genomics is now being used to inform clinical diagnosis and treatment decision-making in oncology with the development of targeted therapies and a move towards a precision medicine approach to cancer treatment. Genetic testing typically refers to single- and multi-gene germline testing for inherited mutations, while genomic testing encompasses large-scale DNA sequencing, including whole exome and genome sequencing. In the context of oncology, genomic testing often involves sequencing of tumour tissue for somatic mutations, which may be undertaken with or without a matched normal DNA sample (paired testing).

Traditionally clinical genetics has largely operated as a distinct specialty. Genetic testing and/or counselling was typically provided by health professionals with specialist training and expertise in genetics, including clinical geneticists, genetic counsellors and nurses. However, the rapid growth of testing amongst cancer patients is beyond the capacity of the traditional clinical genetics workforce and care pathways. To meet this demand provision of genetic and/or genomic testing is increasingly initiated by health professionals external to clinical genetics and integrated into cancer care. In some cases formal ‘mainstreaming genetic testing’ programs, particularly in breast and/or ovarian cancer, have been adopted in some oncology settings [1-5].

The oncology workforce involved in face-to-face patient care encompasses a varied group of health professionals including nurses, surgeons, oncologists, pharmacists, pathologists, dieticians and psychologists. However, in terms of genetic or genomic testing for cancer patients, provision of testing is likely to fall to two key groups: nurses and oncologists – including surgeons, medical, radiation and clinical oncologists. This shift in how genomic testing is provided and by whom requires those involved to have sufficient knowledge, skills and confidence.

Worldwide, nurses form the largest group of health professionals. With their diverse roles supporting cancer patients from diagnosis, through treatment, recovery or palliation, nurses are ideally placed to facilitate the expansion of access to genetic testing [6]. In the United Kingdom (UK) some oncology centres have already moved to nurse-led services for providing BRCA germline testing in breast and ovarian cancers [2, 7]. In order to support this aspect of clinical practice, oncology nurses need strong foundations in genetics and genomics for their clinical practice. However, studies have reported low levels of genomic literacy and confidence in using genomics [8, 9].

While some oncologists may already be familiar with providing genomic testing, particularly in countries where tests can be ordered directly, a lack of confidence amongst oncologists about their knowledge of genomics, and ability to make treatment recommendations based on genomic data, has been reported [10, 11]. Furthermore, a survey of medical oncologists found a third did not feel confident communicating personalised genomic results to their patients [12]. A further study found that oncologists were most confident in using somatic single-gene tests, followed by multi-marker tumour panel tests, and least confident in using whole genome or exome sequencing to guide patient care [13].

Learning needs of oncologists and cancer nurses in genetics/genomics

Learning needs refers to the gap between current skills and knowledge, and the level of skills and knowledge required to undertake a task. In the context of precision medicine and integrating genomic testing, the 'tasks' and corresponding abilities required are not only vast but increasingly complex. While there are likely to be shared learning needs about genomic testing amongst health professionals without specific genetics or genomics training, oncologists and oncology nurses may also have separate, specific learning needs relating to their clinical practice and the context of cancer genomic medicine. The scope of genomic testing in cancer includes germline testing for inherited cancers, tumour testing for somatic, non-inherited mutations and/or paired tumour and germline samples. Testing modalities vary from single gene testing, multi-gene panel tests, whole exome and genome sequencing, to novel genomic biomarkers such as mutation signatures and tumour mutational burden. Classifying and interpreting the clinical significance of genomic alterations identified from sequencing is key in determining eligibility for targeted therapies. Oncologists will increasingly face complex treatment decisions based on the actionability of genomic data [14]. Distilling and communicating relevant genomic information to patients likely to become a crucial part of oncology health professionals' roles.

In some cases recognition of the skills and knowledge needed for genomic testing across medical disciplines has been formalised as professional competencies; the European Society of Human Genetics has published suggested core competencies for health professionals from non-genetics specialties [15]. A set of core competencies in cancer genomics for clinicians and nurses has also been published recently, which were selected by identifying core competencies from the published literature and using a Delphi process to reach consensus [16]. However, whether, and how, oncology health professionals are able meet these recommended competencies is still unclear.

A systematic review identified 44 studies of existing genetics/genomics education programs across different specialties [17]. Despite the growing number of educational programs developed, the content and quality of such courses may vary between disciplines, providers, health services and

countries and lack clear learning objectives or evidence-based teaching [18]. A systematic review of genomic literacy and interventions reported overall low levels of oncogenomic knowledge amongst health professionals in cancer care, concluding that the reviewed educational interventions were limited in their ability to demonstrate sustained improvements in genomic knowledge and use of genomic services [19].

Understanding the learning needs required for adoption of genomics into clinical care is particularly pertinent in the context of integrating genomic testing in cancer where much of the 'up front' information and counselling will be led by oncologists and oncology nurses. This makes the need for further information about oncology health professionals' specific learning needs more urgent so as to develop relevant, tailored education and training.

Our aim in this scoping review is to identify the genetic and genomic learning needs of oncologists and oncology nurses in the context of cancer and precision medicine.

Methods

Design

A scoping review aims 'to identify key characteristics or factors related to a concept' (p2)[20], in this case specific learning needs for oncology health professionals. The scoping review methodology of Arksey and O'Malley (2005) was adopted for this review. This review also follows the Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) checklist (Supplementary materials) and the Johanna Briggs Institute (JBI) methodological guidance [21, 22]. The protocol for this scoping review has been published on the Open Science Framework (link here).

A competency framework in genomics has been developed by the Genomics Education Programme (GEP), part of the UK's National Health Service. Designed to be cross-disciplinary, the framework can be used on an individual level to highlight personal learning needs or by educators to identify training needs across groups of health professionals [23]. The framework captures eight areas of proficiency for clinicians facilitating genomic testing, shown in Table 1. We used this framework as a means to characterise the gaps in skills and knowledge in the delivery and utilisation of genomic testing amongst oncologists and oncology nurses.

[Insert here: Table 1 Framework competencies]

Search strategy

A systematic search was undertaken in key databases (Medline, EMBASE, CINAHL, SCOPUS) to identify relevant articles. A predefined list of keywords and MeSH terms relating to genetics, genomics, education, knowledge, skills and learning needs, and oncology health professional roles was used for the database search (see supplementary materials). The search strategy and keywords search was initially developed in Medline. Following review by an experienced research librarian, the search strategy was revised and then translated across the remaining databases. The reference lists of included articles were hand-searched to identify other potentially relevant publications. The database search was undertaken in April 2021.

Selection criteria

The eligibility criteria were developed following the JBI scoping review guidelines and population, concept and concept framework (Table 2). Only publications in English were included. Non-empirical research publications (e.g. guidelines, editorials, commentaries, case reports) were excluded. The screening and selection of records was undertaken in two stages using Covidence software [24]: (i) title and abstracts, (ii) full texts. During the first stage of screening, articles evaluating educational/training courses or tools that report baseline data in the abstract were included, as were relevant literature reviews for the purposes of reviewing references. To focus the study findings on literature about precision medicine, we further refined our search criteria after the title and abstract screen to exclude studies about referral to clinical genetics services and family history risk assessment. Articles published prior to 2010 were excluded to reflect this focus. At both stages, two reviewers (BR and CJ) screened 20% of records until good agreement was reached (Cohen's Kappa = 0.81) [25]; remaining records were screened by BR.

[Insert here: Table 2 Inclusion/exclusion criteria]

Data extraction and synthesis

A data extraction form was developed based on the JBI instrument and pilot tested by two reviewers (BR and CJ). The form extracted relevant characteristics including: publication year, publication type, study design, participants, setting/context, study design, genetic/genomic testing type, and learning needs. A narrative synthesis was used to bring together findings from the included studies and described how the results relate to the scoping review's objectives and research question [26]. A quality assessment of included studies was undertaken using the Qualyst tools [27] to provide insight into the quality of the papers, rather than as a threshold for inclusion into this scoping review.

Results

Document characteristics

In total 22 publications describing 21 studies were included (Figure 1).

[Insert here: Figure 1 PRISMA flow diagram]

Included papers were published between 2010 and 2020, with the majority (n = 15) from the United States or Canada; one study recruited participants across 37 countries. Most studies sampled oncologists (n = 19), with only two studies focusing solely on oncology nurses. Two of the included papers were conference abstracts. Almost all studies used a quantitative study design of self-report surveys (n = 20), the majority of which were developed by the study authors. Most papers were in the context of genomic sequencing of tumour tissue (n = 13) of which two specifically reported using a paired tumour-germline testing strategy; three papers focused on pharmacogenomic testing in oncology. Two papers reported data from both somatic and germline testing scenarios. Eight papers reported a specific disease context, breast or ovarian cancer (n = 7) or colorectal and lung cancer (n = 1); the remaining studies were genomic sequencing for advanced cancer in adults. Two other papers focused on paediatric cancer. Study characteristics are presented in Table 3, with a more detailed description of included studies found in Table 4.

[Insert here: Table 3 Study characteristics]

[Insert here: Table 4 Description of included studies]

<u>Ongoing Care</u>

Learning needs in the context of continuing care post-genomic testing related mostly to interpretation of genomic data and use of data to make clinical decisions. Eleven papers highlighted learning needs in interpreting genomic data from sequencing results or reports [11, 12, 28-36]. More than 40% of oncologists from tumour sequencing clinical trials cited the need for further education or training to interpret genomic reports [28], or identified a lack of information and knowledge to interpret genomic results [12]. Amongst studies of oncologists, low confidence in interpreting results from somatic testing ranged from nearly two thirds to 20% of participants [11, 32, 34, 36]. In a national survey of cancer physicians in the USA, while half of respondents were confident in their ability to interpret results from next generation sequencing (NGS), the remainder reported this was often difficult (11%) or difficult some of the time (40%) [31]. Challenges with interpreting genomic results were also found in specific contexts of genomic testing. In a sample of breast cancer physicians, the majority (71%) were unsure or lacked the ability to interpret genomic

reports with variants of unknown significance [30]. In a comparison of genomic reports between traditional static documents and interactive web-based genomic reports, regardless of the type of report 28% physicians found genomic testing results difficult to understand [33]. Lack of confidence in interpreting results was also reported in the context of pharmacogenomics, with 36% of oncologists reporting discomfort in interpreting results from testing [29]. Determining actionability of reported genomic variants was also identified as a potential learning need [35].

Five studies highlighted difficulty in using genomic testing data to make clinical decisions amongst oncologists [10, 11, 28, 33, 34]. Nearly one quarter of oncologists (26%) [10] reported low confidence in their ability to make treatment recommendations based on tumour sequencing results; in another study 34% of oncologists found it often or sometimes difficult [33]. Oncologists also struggled with using genomic results in clinical care for germline testing results, with two studies reporting low confidence in making treatment recommendations for both somatic and germline testing [11, 34]. Nearly half of oncologists (48%) from a tumour profiling trial reported that they needed additional educational materials or training in order to use the results of tumour testing to guide treatment decisions [28].

Purpose and Process

How to discuss or explain genomic sequencing tests, processes and outcomes with oncology patients emerged as a learning need in nine studies [10-12, 28, 34, 36-39]. In one study focusing on germline *BRCA1/2* testing amongst breast surgeons, nearly 12% of participants reported lacking confidence in providing appropriate pre- and post-testing counselling [37]. In the context of a tumour profiling clinical trial, more oncologists cited the need for further training or education in order to explain genomic testing results (40%), compared to purpose and concept of tumour profiling (37%), and genomic testing procedures (20%) to patients [28]. Explaining genomic concepts to patients was also identified as an area where oncologists' lacked confidence [10]. In the context of a targeted therapy and tumour testing trial, although participants were confident in their knowledge of genomic testing and ability to make treatment recommendations, only a minority discussed the possibility of germline findings with patients prior to testing [38].

In two studies of precision medicine trials, a third of oncologists reported a lack of confidence in communicating genomic results to patients [12, 34]. In a study of genomic sequencing in paediatric cancer, slightly more participants reported not being confident in discussing results with patients for germline testing (63%) compared to somatic testing (54%) [11]. Similarly, in a study of tumour molecular profiling, oncologists reported being less confident discussing germline findings and their implications [36]. A larger proportion of oncologists reported lacking confidence in providing

psychosocial support related to germline testing where an inherited cancer predisposition was identified (48%), compared to somatic testing with adverse prognostic implications (26%) [39].

Clinical Knowledge

In five studies, the need to improve knowledge and understanding of the fundamentals of genetics and genomics was reported [10, 40-43]. One study of oncologists found 22% reported being 'not very' or 'not confident at all' in their knowledge of genomics [10]. Using a validated measure of genetic knowledge, overall oncologists scored highly indicating good knowledge, although struggled with specific items related to inheritance of germline mutations [43]. The majority of oncology nurses self-reported poor knowledge of general genetic principles [40], with 69% reporting fair or poor genetic knowledge [41]. This was also reflected in objective knowledge measures with nurses scoring just over half of questions correctly [41, 42]. In the context of pharmacogenomics testing, 67% of nurses described their knowledge as poor or fair [41].

Learning needs associated with variants of unknown significance (VUS) were also reported in four studies [30, 34, 35, 44]. In the context of germline *BRCA1/2* testing for ovarian cancer, although oncology health professionals demonstrated good knowledge overall, more than 20% of participants answered items relating to VUS incorrectly including testing recommendations for unaffected relatives [44]. Amongst breast cancer physicians 42.6% did not fully understand VUS results, with 21.3% reporting no understanding or awareness of VUS [30]. From this study, only half of participants were able to appropriately interpret a genomics report where the result was reported as 'clinical significance unknown', in contrast to a report with a description of an 'unclassified variant' where almost all participants interpreted this correctly. In the context of tumour sequencing, including somatic and germline testing, 38.7% of oncologists reported poor or very poor knowledge of the meaning of a VUS [34]. Interpretation of tumour sequencing results was found to be more discrepant in cases with a VUS in an 'actionable' gene [35].

Test Factors

In a tumour genetic testing trial, oncologists reported uncertainty about which test to order as a barrier to testing use [38]. Two studies reported that participants lacked knowledge of genomic tests in terms of test capability, technology and processes [12, 45]. Oncologists had little knowledge of new genetic and genomic technologies, including the process of whole genome sequencing [12]. From a qualitative study of oncologists involved in a precision medicine clinical trial, five participants expressed a lack of understanding of genomic sequencing technology, with two participants expressing misconceptions related to its capabilities as a result [45].

Knowledge of genetic testing guidelines emerged from three studies [34, 37, 46]. In a survey of breast cancer surgeons, 61% of participants reported following national guidelines for *BRCA1/2* germline testing [37]. Two other studies reported some knowledge of national or professional guidelines for genetic testing as 73.2% [46] and 54.9% [34] amongst oncologists.

Amongst the studies included in this review, no learning needs were identified for the GEP framework competencies of Recording Consent, Consent Conversations or Support Routes.

Discussion

The purpose of this scoping review was to identify key characteristics of genomic testing learning needs for oncologists and oncology nurses. In this review, 22 papers which reported data or outcomes related to learning needs in this participant cohort were included. 'Learning needs' – areas where oncologists or oncology nurses were found to lack ability or confidence in specific knowledge and/or skills related to genetic and/or genomic testing – were identified across four of the framework competencies: Ongoing Care, Purpose and Process, Clinical Knowledge and Test Factors.

As testing expands beyond a single gene approach for inherited cancers to genomic testing for somatic mutations, so too do the skills and knowledge needed to deliver testing in the context of precision medicine. Previously these skills related to assessing and recording family history, recognising features of hereditary cancers, determining eligibility for genetic testing and making referrals to clinical genetics services. With testing now focusing on identifying genomic changes which can be targeted with novel treatments, not surprisingly, the most frequently reported learning needs from this scoping review related to specific clinical skills after genomic testing, such as interpretation of genomic data and use of genomic data for making treatment decisions.

Overall, there was uncertainty amongst oncologists about their ability or confidence to interpret sequencing results from genomic testing. This may ultimately have potential clinical implications as noted by Brusco et al (2018), 'The clinical impact of genomic testing may be limited by clinicians' ability to appropriately order testing and correctly interpret results' [47]. Genomic testing results and their accompanying reports are complex and can vary significantly between institutions. Despite the challenges associated with genomic results interpretation, there are data to suggest that oncologists do not want simplified reports; instead expressing a preference for more detailed information to link reported mutations with patient carcinogenesis or actionable mutations with relevant clinical trials [45].

The lack of confidence amongst oncologists in making clinical decisions and recommendations from genomic data may also be attributed to uncertainty surrounding the clinical utility of genomic testing. Studies have reported that oncologists have little confidence that tumour profiling guides useful treatment decisions [36], or that it factored little into treatment decision-making [48]. The ability to identify therapeutic targets from genomic testing is still emerging, with a small but growing number of targeted therapies for a range of tumour types including metastatic colorectal cancer, serous ovarian cancer, non-small cell lung cancer and melanoma [49]. The impetus to develop skills to use genomic data for patient management needs to be founded upon robust clinical evidence. Clinicians are unlikely to embrace genomic testing in the absence of clinical impact [50].
In the context of cancer genomic testing, oncologists may undertake the bulk of the testing process, including providing pre- and post-test counselling for patients and disclosing results. This review identified that oncologists' lacked confidence or self-perceived ability in communicating results of testing to patients and providing psychosocial support post-testing. Oncologists appeared to report more difficulty with patient communication in relation to germline testing and its implications, perhaps indicating better understanding and/or increased familiarity with discussing and managing somatic testing. This was also reflected in poorer knowledge regarding inheritance patterns of germline mutations [43], and failure to discuss the potential of germline mutations from tumour sequencing with patients [38]. As up to 12% of patients will have germline mutation identified as a result of tumour sequencing [51], oncologists need to have the skills and confidence to initially disclose and discuss these results with their patients and a clear and accessible referral pathway to clinical genetics services.

This scoping review identified a paucity of research studies specific to oncology nurses and their genomic learning needs. Despite a growing number of published commentaries and editorials describing the crucial role oncology nurses will play in genomic testing for cancer care, there is a lack of empirical research regarding their knowledge and skills; in particular no studies were identified in the context of tumour sequencing and learning needs for oncology nurses. Oncology nurses care for cancer patients through diagnosis and treatment, providing support, education and information. In the context of precision medicine nurses need to have sufficient knowledge of current clinical evidence [52]. Two studies of oncology nurses found poor self-reported and objective knowledge of the fundamentals of genetics and genomics and pharmacogenomics. These studies however did not address the many other skills and knowledge oncology nurses may require in the context of precision medicine.

The findings of this scoping review suggest a need for greater understanding of both objective and self-perceived learning needs in tumour sequencing for oncology nurses. In a recent publication of core curriculum in cancer genomics for health professionals, the knowledge and abilities competencies for nurses related primarily to inherited cancer predispositions testing [16]. In

contrast, physician competencies included competencies specific to somatic testing such as 'Knowledge of the concept of somatic genetic change' and 'Awareness of incidental and secondary findings from somatic tumor profiling'.

The GEP competency framework is a useful tool developed in the context of a national genomic testing program and designed to be cross-disciplinary. Education and training strategies could be tailored to address learning needs of key competencies, facilitating the utilisation and delivery of genomic testing in the context of cancer care and precision medicine. The absence of identifiable learning needs for three framework competencies – Recording Consent, Consent Conversations and Support Roles – likely reflects that oncologists and oncology nurses may already be familiar with complex consent conversations, for example consenting patients for clinical trial participation. In some contexts tumour analysis is undertaken as part of standard care and diagnostic work-up and may not require explicit consent. However genomic testing of tumour has the potential to identify germline mutations; patients need to be informed of this and provide consent to testing as well as indicate their preferences to receive such findings [53]. Management of germline findings should also be supported by knowledge of and access to hereditary cancer services; in the context of germline testing, data has shown variable referral rates amongst oncologists both pre- and post-testing ranging from 7-100% [4, 54].

In general, the papers included in this review were not designed to specifically measure learning needs or gaps in participants' skills and knowledge. Only a minority of papers used objective measures of knowledge, with most papers relying on self-report measures of confidence or ability related to specific genomic testing topics. There was a lack of clarity of the genomic knowledge or skills measured due to the use of general terms such as 'genomic literacy' or 'genomic concepts'. Thus it is difficult to establish whether reported self-confidence and understanding is reflective of actual abilities amongst oncologists and oncology nurses [11]. Excluding studies where participants were physicians treating cancer patients, but not explicitly described as oncologists, may have meant some relevant publications were missed. There was some lack of clarity in the reporting of the genomic testing mode undertaken, with only two studies specifically reporting paired tumour-germline testing strategies. While a quality assessment of included papers was undertaken, it was not used as a means to reject studies of lower quality.

Future perspectives

In this era of cancer precision medicine, genomic testing is likely to become standard of care for cancer patients, utilised by oncology clinicians to inform treatment decisions. Harnessing the potential of genomic cancer will not only depend on treatment and technological advances, but also on the skills and knowledge of the health professionals involved [55]. Recently published

competencies are an important step in defining relevant cancer genomic skills and knowledge, however further research is needed to determine how these competencies will be met. Tailored educational interventions with a shift away from self-perceived measures of ability to objective measures and outcomes are also needed. Oncology nurses play a significant role in the care of cancer patients and their capacity in the provision of somatic testing should not be neglected.

Word count: 4199

Executive summary

- Using the Genomics Education Programme (GEP) framework of proficiency in genomic testing identified learning needs in four areas: Ongoing Care, Purpose and Process, Clinical Knowledge and Test Factors
- The most cited learning needs for oncologists related to interpretation of genomic data, patient communication and counselling, use of genomic data to make clinical decisions and knowledge of fundamentals of genetics and genomics
- Most research was conducted in the context of somatic testing for molecular tumour profiling, reflecting a shift in testing mode in the clinical setting
- There is a dearth of empirical research focusing on oncology nurses and knowledge of tumour profiling
- Tailored education interventions specific to the learning needs of oncology clinicians is needed
- Objective measures of genetic and genomic skills and knowledge are key to ensure professional competencies are met

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Table legends

Table 1 Genomics Education Programme cross-disciplinary competency framework for genomic testing and corresponding learning needs

Table 2 Inclusion and exclusion criteria used for screening articles

Table 3 Study characteristics in alphabetical order (n=22)

Table 4 Details of included studies

Figure legends

Figure 1 PRISMA flow diagram

Supplementary materials

Table 1 Medline search terms and search strategy

Table 2 PRISMA-ScR Checklist