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ORIGINAL RESEARCH

Physician Experiences and Understanding of Genomic Sequencing in Oncology

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Abstract The amount of information produced by genomic sequencing is vast, technically complicated, and can be difficult to interpret. Appropriately tailoring genomic information for non-geneticists is an essential next step in the clinical use of genomic sequencing. To initiate development of a framework for genomic results communication, we conducted eighteen qualitative interviews with oncologists who had referred adult cancer patients to a matched tumor-normal tissue genomic sequencing study. In our qualitative analysis, we found varied levels of clinician knowledge relating to sequencing technology, the scope of the tumor genomic sequencing study, and incidental germline findings. Clinicians expressed a perceived need for more genetics education. Additionally, they had a variety of suggestions for improving results reports and possible resources to aid in results interpretation. Most clinicians felt genetic counselors were needed when incidental germline findings were identified. Our research suggests that more consistent genetics education is imperative in ensuring the proper utilization of genomic sequencing in cancer care. Clinician suggestions for results interpretation resources and results report modifications could be used to improve communication. Clinicians' perceived need to involve genetic counselors when incidental germline findings were found suggests genetic specialists could play a critical role in ensuring patients receive appropriate follow-up.

Keywords Genomics · Medical oncology · Cancer genomics · Physicians · Individualized medicine

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Introduction

The development of faster and less expensive whole genome and whole exome sequencing techniques allows for greater clinical integration of genomic testing. In oncology, sequencing of tumor tissue with the goal of identifying actionable mutations for personalized treatments is a part of clinical cancer care. Recent national attention driven by the Precision Medicine Initiative will likely continue to spur the expansion of this type of precision medicine (Le Tourneau et al. 2012; The White House 2015). The expanded use of genomic technologies in oncology brings with it several complex computational and evidentiary challenges, creating questions about how to properly incorporate genomic sequencing (GS) results into clinical practice (Bombard et al. 2013a, b).

The amount of information produced by GS is vast, technically complicated, and often difficult to interpret. Even highly specialized clinicians have difficulty translating the data for

medical decision-making (Meric-Bernstam et al. 2013). Numerous studies have demonstrated that non-geneticists ordering GS often have incomplete and/or inaccurate ideas regarding implications of results for a patient and his/her treatment (Frey et al. 2012; Haga et al. 2012; Houwink et al. 2012; Klitzman et al. 2013). Efforts to standardize return of results to patients and physicians – including which results to report and how to format the results report – raise ethical and legal questions (Dorschner et al. 2014; Garraway 2013; Van Allen et al. 2013). Understanding how to appropriately tailor genomic information to enable use by non-geneticists is an essential next step in the further integration of GS for clinical use (Green et al. 2011).

We conducted qualitative interviews with clinicians who had referred patients to a tissue based tumor/normal GS study (Robinson et al. 2013; Roychowdhury et al. 2011) in order to guide the development of a model for GS results communication that maximizes benefits to both the ordering clinician and the patient. Our aim was to explore clinicians' understanding of the tumor sequencing study, motivations for enrolling patients, and their perceived barriers to the successful integration of GS information into cancer treatment.

Materials and Methods

Study Population and Recruitment

Between May 2011 and September 2013, 58 physicians referred patients to the MI-ONCOSEQ (The Michigan Oncology Sequencing) Project at the University of Michigan Health System (UMHS) Comprehensive Cancer Center. This study provides comprehensive tumor GS analysis for adult patients with advanced or refractory cancer in order to identify genetic mutations that could inform future therapeutic choices. Tumor biopsy, along with matched normal tissue and blood samples, are subjected to whole-exome sequencing, transcriptome sequencing, and low-pass whole-genome sequencing as needed (Roychowdhury et al. 2011). We divided these providers into one of five possible "bins" in order to survey clinicians from a variety of backgrounds: Bin 1) Non-UMHS clinicians currently practicing at community institutions, Bin 2) Non-UMHS clinicians currently practicing at academic institutions, Bin 3) UMHS clinicians who had referred 1–2 patients into the GS study, Bin 4) UMHS clinicians who had referred 3–9 patients into the GS study, and Bin 5) UMHS clinicians who had referred 10+ patients into the GS study. We chose to classify clinicians into academic and community practice bins as we postulated that clinicians from these two populations would have differences in terms of their education and experience with clinical genetics in medicine. Additionally, we hypothesized that clinicians who had referred more patients to the study would have a more accurate understanding of the study aims. Our goal for this qualitative study was to interview a minimum of two physicians per bin to ensure representation from the various clinical backgrounds and experience.

We sent a single recruitment e-mail containing the informed consent document to eligible clinicians for whom e-mail addresses could be located (n = 52). Interviews were conducted by a single investigator (CMW) between November 2013 and June 2014 and were in-person (UMHS clinicians) or by telephone (non-UMHS clinicians).

Study Design

Interviews focused on three topics: 1) cancer treatment decisions; 2) gene mutations, GS, and their relationship to cancer; and 3) expectations for, and communication of, GS results. The interview guide (see Appendix 1 in Supplementary Material) was structured using elements of the "mental models" approach. This approach has been used by public health researchers and involves semi-structured interviews to explore the conceptual models that patients and providers use to make sense of information about health risks (Downs et al. 2008; Morgan and Millett 2002; Zikmund-Fisher et al. 2013). Piloting of the interview guide took place in the summer of 2013, and revisions were made based on feedback from practicing clinical cancer geneticists and cancer genetic counselors. This study was judged exempt by the institutional review board at the University of Michigan in August 2013 (HUM00078489).

Analysis

Each interview was recorded and transcribed (CMW). Clinicians were asked to avoid identifying themselves or their patients during the interview. To further ensure confidentiality, all transcripts were de-identified. In order to ensure the accuracy of the transcripts, a team member (CMW) checked each one for fidelity with the recordings. Following a phenomenographic framework, we began our analysis by reading through the transcripts and identifying global themes (Larsson and Holmström 2007). These themes became the core codes. Using the core codes as a framework, two study team members (CMW, KAR) coded two transcripts in parallel to identify further trends and patterns existing within the core codes and created the initial draft of the codebook. All study team members reviewed and edited the initial draft of the codebook to create the finalized version, which was then used to code all transcripts (CMW). All coding was performed using Dedoose data analysis software v.5.1 (www.dedoose.com).

Results

Fifty-two of 58 (89.7%) eligible clinicians were e-mailed a study invitation. Six eligible clinicians were not contacted because email addresses were not available. Nineteen clinicians

Table 1 Study population and response rate

Bin	Total number of clinicians	Total number of clinicians contacted	Number of clinicians interviewed	Response rate
Bin 1 (Non-UMHS[a] physician working in community hospital)	4	2	2	100%
Bin 2 (Non-UMHS physician working in an academic hospital)	13	12	3	25%
Bin 3 (UMHS physician, referred 1–2 patients)	24	21	7	33%
Bin 4 (UMHS physician, referred 3–9 patients)	9	9	4	44%
Bin 5 (UMHS physician, referred 10+ patients)	9	8	2	25%
Total	58	52	18	35%

[a] UMHS = University of Michigan Health System

responded to the study invitation (36.5%), and 18 (34.6%) were interviewed. One respondent was not interviewed due to scheduling conflicts. We achieved our goal of interviewing at least two clinicians from each of the five bins (Table 1). Of physicians interviewed, 16/18 (89%) worked at academic centers; 6/18 (33%) held MD/PhDs; and 10/18 (56%) finished medical school more than 20 years ago (Table 2).

Following iterative analysis of all transcripts, the finalized draft of the codebook included 27 core codes, with five key emerging themes: comprehension of genomic technology, conflicting goals, results reporting, education, and interpretation. For additional representative quotes for each theme see Supplemental Table 1.

Theme 1*:* Comprehension of Genomic Technology

Of clinicians who discussed the genome sequencing technology utilized within the MI-ONCOSEQ GS study (n = 10), half exhibited a high level of understanding of the study's sequencing technology (n = 5), while half (n = 5) expressed a lack of understanding. Clinicians who expressed a lack of understanding felt they did not have enough education about the technology to fully understand it, which at times impeded their ability to fully comprehend and communicate the results.

> "*... you start to read the statistics section and/or the methods section of a lot of the manuscripts that utilize the same techniques or technology and after the first sentence you're lost…I mean, I have a PhD and I don't understand a lot of the biology behind how the DNA is captured and how the actual sequencing works and how the statistics are used to determine biologically important versus a biologically irrelevant abnormality that was identified…we're not educated enough to understand that.*" SUBJECT 2, BIN 4

Of the five clinicians lacking understanding of the technology, two expressed misconceptions related to what the technology was capable of detecting, and these misconceptions led to overestimates about the scope of the GS study and the types of results that could be returned. The quotation below illustrates how a clinician has overestimated the ability of the study to screen and identify clinical trials that may be appropriate for the patient.

> "*…we can refer them other places for other trials, but again, the trial is only as good as this [study]. This [study] hopefully would encompass all trials, or that's the idea… you may have a thousand druggable targets, but each individual trial I could send someone to would only test one of those drugs. This [study] should be able to figure out…everything about the patient.*" SUBJECT 10, BIN 3

Theme 2: Conflicting Goals

Some clinicians (n = 3) perceived discordance between the goals of the GS study's basic scientists and the

Table 2 Demographic information of clinicians interviewed

Clinician characteristics	Proportion of interviewed clinicians (n = 18)	Percentage
Educational background		
Doctor of medicine (MD)	18	100%
Additional advanced degrees	6	33%
Years since medical school		
< 5	0	0%
5–10	3	17%
11–20	5	28%
21–30	4	22%
31+	6	33%
Specialty		
Medical oncology	12	67%
Hematology/oncology fellow	2	11%
Other	4	22%

referring clinicians, mainly related to differing expectations regarding translation of results into clinical care, with clinicians having lower expectations about the likelihood of GS results impacting patient care. These clinicians acknowledged that decreasing this discordance could positively impact the translation of the sequencing results for clinicians in the results report.

> "*…I want to comment that the sequencing side of it or the lab side of it… does a wonderful job of looking at the literature but they have no concept of how this might be used or useable in the patient. So there's this gulf even with that attempt at communication from both sides…the basic scientists have no concept of what it takes to put a drug into a person. And the clinician struggles a little bit with trying to understand some of the gobbly-goo that the scientists talk about.*" SUBJECT 8, BIN 5

Theme 3: Results Reporting

Clinicians had variable views on the best structure for the results report (Mody et al. 2015; Roychowdhury et al. 2011). Multiple clinicians (n = 6) expressed a desire for the results report to include more detailed information regarding the specific genetic mutations identified and their potential involvement in the patient's cancer development.

> "*So the fact is, it's too hard for me, if they basically say, 'Well, here's the mutations, good luck'. Realistically, physicians are going to be more reluctant to refer patients if it just creates lots of work for them to try and figure out okay, where on God's green earth am I going to get this drug?*" SUBJECT 1, BIN 3

Some clinicians (n = 4) expressed a desire for more detailed and specific information linking potentially actionable mutations with specific clinical trials. However, one clinician worried about the reports including too much clinical advice.

> "*The report sometimes goes a little too far in trying to suggest clinical approaches to the patient's management given that it's not really written by oncologists with any expertise in the particular disease…It worries me a little bit that reports like that may get out…to the general public…or even the patient who may say, 'Well, why didn't you treat me with this drug that this says it should work?' and then having to explain that I don't necessarily agree with the report.*" SUBJECT 4, BIN 4

Theme 4: Genomics Education

When asked what resources could be used to help clinicians understand and properly interpret GS results, some clinicians (n = 6) indicated a need for education regarding genetics/genomics. Other resources clinicians suggested could be useful included access to the study team (n = 6), links to online resources (n = 4), resources to help match/facilitate patient enrollment in clinical trials (n = 2), and access to genetic counselors (n = 3) and other specialists (n = 2) as needed based on the results of the testing (Fig. 1). Several clinicians (n = 8) stated that they expected oncologists working in an academic setting to have a higher degree of exposure and understanding of cancer genomics, but were less confident in the abilities of clinicians working in non-academic settings.

> "*I would see it as a problem if this becomes more of a standard for [the] wide oncology community because … frankly, I would not trust a community oncologist to order this test or to interpret it because… they are not there. This is something that they had in their…cancer bio or molecular biology or pathology in med school but they are so far out….*" SUBJECT 5, BIN 3

Another clinician pointed out the challenges of translating GS findings for patients and avoiding potential misconceptions.

> "*… I've had a number of questions from patients, especially after the Angelina Jolie thing…I start talking about EGFR mutations and ALK mutations and your tumor has an EGFR mutation they look at their daughter… in the room. I say, 'This is not something that you passed on to your daughter… this is only in your cancer.*

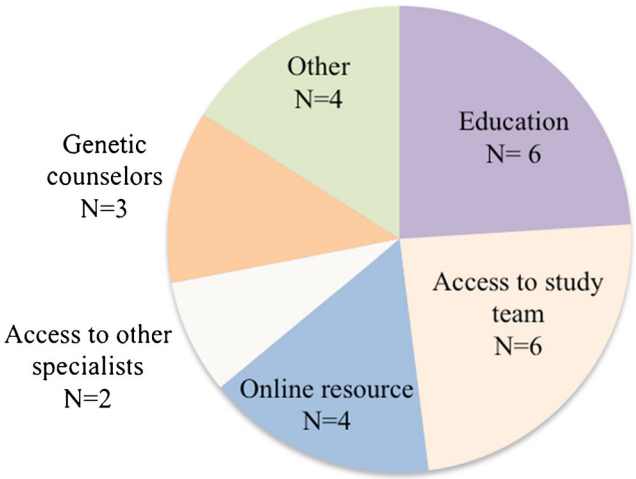

Fig. 1 Number of clinicians who suggested each resource when asked what resources could aid clinicians in the interpretation and disclosure of genome sequencing results

It's not heritable.' And you have to make sure that you use the right words because people don't understand a lot of this stuff… and I don't have a lot of training in that…and so how do I talk to patients about that is becoming an important issue, but I kind of figured out how to get them clear on that fact…it's important for people to understand that issue, germline versus somatic mutations." SUBJECT 3, BIN 4

Theme 5: Germline Results Interpretation

Clinicians recognized the potential complications associated with identification of incidental germline findings (IGFs). Many (n = 6) expressed a lack of clarity related to the types of IGFs that could be returned. Others (n = 11) expressed discomfort in communication of those results to patients, especially in regards to germline mutations related to non-cancer conditions. When asked if there are any results that clinicians would prefer not to receive, one respondent stated:

'I don't think so. Well I think some… if we are just talking about the cancer side, I don't think so. I think some clinicians may… not want to deal with the non-cancer genetic information.'" SUBJECT 13, BIN 2

Most of the clinicians interviewed acknowledged the need for genetic counselor (GC) involvement when IGFs were identified (n = 12).

"*… if I were to order the test I would probably need to talk to somebody like you [a genetic counselor] before… I convey the message because… there are undoubtedly going to be results that I don't know the implication of… I'm not saying that because I ordered the test I should be the one explaining it…I guess actually as I'm thinking about this, the results as a whole, when you start thinking about germline mutations, probably are best discussed by a genetic counselor who can talk about all the results and not just something specific to the cancer. I actually hadn't thought about that.*" SUBJECT 11, BIN 3

Discussion

Our qualitative study examined the understanding and expectations related to genomic sequencing (GS) among clinicians referring patients with cancer to a tissue tumor/normal GS study. One of the most challenging aspects of incorporating GS into clinical practice is effective results interpretation and disclosure, which can be confounded by many factors. These interviews offer valuable insight on a number of key issues that can be used to further develop the model of GS results communication in a precision medicine context. Since the time these interviews were conducted (November 2013 through June 2014) the use of somatic tumor testing with the goal of identifying therapeutic targets specific to a patient's unique tumor profile has become much more widespread. In a recent study of cancer genetic counselors examining their current practices with regards to tumor testing, 87.6% reported that their institutions were using tumor testing, though only 6.7% did this routinely (Goedde et al. 2017). While the current study conducted interviews in the context of examining clinician understanding and experiences within a specific research study, the overall objectives of both the research study and the clinical tumor testing taking place today overlap significantly. For example, the FoundationOne website states that "The test is designed to provide physicians with clinically actionable information to guide treatment decisions for patients based on the genomic profile of their disease" (https://www.foundationmedicine.com/genomic-testing/foundation-one). Thus, we believe that many of the opinions and suggestions of the clinicians interviewed as a part of this study are applicable to the wider context of the clinical somatic tumor testing that is currently being utilized.

Many of our clinicians expressed a need for increased genomics education, and many also expected academic oncologists to have higher levels of genomic knowledge than oncologists working in community settings. This variability in knowledge concerning genomic technology, even within an academic cancer center, aligns with previous findings and indicates this lack of knowledge is not unique to community oncologists (Gray et al. 2014). Perhaps more importantly, misconceptions related to the technology led to misunderstandings about potential results and inaccurate ideas about the scope of research. A lack of genomics knowledge has been consistently identified as a barrier to the adoption and use of genetic/genomic testing, and thus could lead to provider-based variation in the use of clinical GS (Cox et al. 2012; Delikurt et al. 2015; Freedman et al. 2003; Hamilton et al. 2014; Khoury et al. 2012; Scheuner et al. 2008). While it is possible that the clinicians' apparent misunderstanding of the GS technology and goals of the GS study could be unique to this particular study, we believe a more likely explanation is that many of the misunderstandings clinicians expressed are tied to the deeper and more widespread problems relating to clinician misunderstanding of genetics in general. Significant work has been done in attempts to examine different educational programs aiming to increase clinician knowledge about genetics, however, it is clear that this is an area that remains a large challenge across disciplines (Bell et al. 2015). While an in-depth review of different educational strategies that have been employed to enhance clinician understanding of genetics is beyond the

scope of this research, we did ask clinicians what resources they thought would be helpful in increasing study comprehension and results interpretation. Their recommendations included online resources (e.g. linking mutation information directly to online data), direct access to the study team, and access to genetic counselors/other specialists in the event of an IGF.

Of note, at the time these interviews were conducted, a total of four clinicians practicing in the community setting had referred patients to the research study, and of those, email addresses were available for two. Both of these clinicians agreed to be interviewed. The paucity of community physicians available for interview is therefore reflective of the makeup of clinicians referring patients to this research study within an academic medical center and speaks towards a broader inequality in terms of patients treated in academic versus community settings and enrollment in clinical trials. Significant research has been done examining clinical trial enrollment and factors such as race, age, socioeconomic status, and treatment setting have all been shown to impact levels of clinical trial enrollment (Behrendt et al. 2014; Goss et al. 2009; Sateren et al. 2002). In 2007 the National Cancer Institute (NCI) created a program, the NCI Community Cancer Centers Program (NCCCP), with the aim of improving patient access to state-of-the-art care in community settings (Clauser et al. 2009; Copur et al. 2016; Hirsch et al. 2016). Previous studies, focused on genetics services, have found that clinicians working in rural settings may be more likely to lack awareness regarding the availability of genetic services. In one study, only 1% of patient referrals to a hereditary breast cancer program came from rural areas (Delikurt et al. 2015; Koil et al. 2003). This speaks to a larger issue regarding disparities in access to genetics services between patients living in urban/suburban settings compared with those in rural settings, which we discuss in further details below.

There is no consensus about which GS results to report and how reports should be formatted (Van Allen et al. 2013). Our study found that many clinicians expressed a desire for the results report to contain detailed information regarding the specific mutations identified, their potential involvement in the patient's cancer development, and suggestions for therapies/clinical trials. Clinicians also raised the concern that reports should not be too prescriptive in their interpretation and recommendation. Many clinicians associated a desire for a more detailed report with a high level of personal interest in the underlying genetics/genomics, however this may be unique to our study population of first adopters in a novel GS study in an academic institution. Interviewees acknowledged that many clinicians would likely prefer a one-page report outlining major findings, an idea consistent with other studies examining the format of genomic reports (Dorschner et al. 2014).

Clinicians felt the basic scientists on the MI-ONCOSEQ project were largely focused on identification of targetable mutations that could alter a patient's clinical management and failed to understand the practicalities involved in getting a particular drug to a specific patient (e.g., access and availability of suggested treatments), leading to frustration about the lack of translation of the GS results. Better alignment of the goals of basic scientists and referring physicians on GS studies is an integral step in developing the proper framework for the return of results necessary for the successful translation of GS for clinical care. Of note, all clinicians who referred a patient to this sequencing study were invited to attend a Precision Medicine Tumor Board, consisting of a multidisciplinary team of oncologists, molecular and clinical geneticists, genetic counselors, bioinformaticians, pathologists, and bioethicists (Everett et al. 2014). Other centers have also begun to develop similar precision medicine-focused tumor boards to specifically review tumor testing results (Gunderson et al. 2016; McGowan et al. 2016; Schwaederle et al. 2014). These types of multidisciplinary conferences may present another opportunity for clinicians to increase their education about tumor testing and increase direct interactions between basic scientists and clinicians, which could aid in improved communication and alignment in the perceived goals and outcomes of tumor testing. Additionally, in an effort to improve clinician knowledge at academic and community centers alike, we suggest that it may also be useful for hospitals that have active molecular tumor boards to open up these discussions to clinicians at other institutions (e.g. via teleconference or web conference) and allow these clinicians to submit their own cases for discussion. Further development of web-based tumor boards, like the series of "Virtual Molecular Tumor Boards" webinars currently being broadcast by the Association of Community Cancer Centers, also represent additional areas of growth that could allow for further dissemination of education about molecular tumor testing (http://accc-cancer.org/resources/virtual-tumor-boards.asp). Future research could examine the perceived utility of providing detailed clinical management suggestions on reports, most specifically in situations where the laboratories writing the reports may have no or very little clinical information about the patient.

Mandating the involvement of genetics specialists when ordering germline testing for hereditary cancer syndromes has generated controversy, with the American Society of Clinical Oncology positing that requiring genetic specialist involvement would limit the ability of oncologists to deliver proper care to their patients (American Society of Clinical Oncology 2013; Cigna 2017). Though there certainly are non-genetic specialists capable of providing high-quality care in relation to discussions of hereditary cancer, recent studies have demonstrated differences in the quality of services delivered by clinicians who are genetics specialists versus those who are not (Armstrong et al. 2015; Cragun et al. 2015). When discussing the possible results that could be produced by tumor GS, our participants expressed discomfort in communicating IGFs to patients. Though the MI-ONCOSEQ project is only returning pathogenic germline mutations identified in known cancer predisposing genes,

clinicians discussed the potential complexities involved in the incidental discovery of conditions such as sickle cell anemia, Huntington's disease, or issues such as non-paternity (Everett et al. 2014). Some clinicians said they would prefer not to receive incidental results that did not relate to hereditary cancer predisposition, while others stated they would be willing to disclose those results to patients, but would then refer them to the necessary specialist. They acknowledged the need for genetic counselor involvement when IGFs were identified in order to aid clinicians in properly communicating results to patients and to help ensure appropriate follow-up testing. Some clinicians admitted that they had not associated the GS study with the identification of germline variants, although these findings are possible through both tumor/matched normal tissue GS (as in this study) or indirectly through somatic mutation testing of tumor tissue (Bombard, Robson, et al. 2013; Raymond et al. 2016). This is an important finding as a recent American Society of Clinical Oncology policy statement advocates for a pre-test discussion on the potential risks of identifying incidental and secondary germline information in tumor sequencing (Robson et al. 2015). Additionally, one of the recommendations within the recently released Cancer Moonshot Blue Ribbon Panel Report related to prevention and early detection of cancer emphasized the importance of identifying individuals with a genetic predisposition to cancer (National Cancer Institute 2016). Recognizing individuals whose tumor sequencing results could indicate a possible germline mutation related to a hereditary cancer syndrome may serve as an important channel for identifying these patients and allowing for more personalized cancer risk estimates and screening/surveillance recommendations for them and their family members.

The findings of this study suggest that involvement of a genetics specialist benefits both clinicians and patients and thus serves an important role in GS results communication (see Everett et al. for a review of genetic counselors' work within the MI-ONCOSEQ project)(Everett et al. 2014). We acknowledge that the limited number of genetic specialists means it is unrealistic to mandate their direct involvement on all GS projects. We suggest the involvement of genetic counselors in the project development plan to specifically address how patients should be informed of the potential to identify incidental and secondary results, and that in situations where genetic counselors cannot be directly involved in GS projects, steps should be taken to ensure that all patients found to have actionable IGFs receive the proper follow-up and a referral to an appropriate genetics clinic. As noted above, there are known disparities in terms of access to genetic services between patients in rural versus urban/suburban settings, and overall the demand for genetic counseling services may soon exceed the current supply of genetic counselors. While the genetic counseling community is attempting to combat this workforce issue in numerous ways, including the development of more genetic counseling programs and expansion of current programs, it seems likely that other innovations will be needed to ensure that patients in need of genetic counseling have access (Pan et al. 2016). For example, tumor testing companies may consider hiring genetic counselors who can be available to clinicians to answer questions regarding their patient's results specifically as it relates to germline findings. Additionally, given that the lack of awareness of the availability of genetic specialists has been shown to be a barrier to referral, these company-based genetic counselors could also aid clinicians in identifying genetic specialists in their area who they could refer their patient to. Consideration for alternative genetic counseling delivery models, such as telemedicine, could also provide a possible option for patients who may not have direct access to a genetic counselor. Early research on telegenetic counseling models have shown similar results in terms of psychosocial outcomes and patient satisfaction between patients receiving telephone counseling versus those receiving in-person counseling, and thus represents a promising alternative for patients (Buchanan et al. 2015, 2016). It is also important to note that additional education regarding tumor testing may be beneficial to both practicing genetic counselors, as well as for students who are currently in genetic counseling graduate programs. In the study by Goedde et al. 63.7% of cancer genetic counselors reported being personally involved in tumor testing in some capacity, though notably "only 16.5% (16/97) of genetic counselors felt their institution was completely prepared to handle tumor profiling results, and only 5.2% (5/97) felt they were personally completely prepared" (Goedde et al. 2017). This speaks towards an urgent need within the cancer genetic counseling community for increased education regarding tumor sequencing to ensure that our workforce is prepared to handle these types of referrals when they arrive.

Study Limitations

The current study is not without limitations, the most significant of which is the small sample size. The views expressed by the interviewed clinicians may not reflect those of all clinicians currently using GS in their clinical practice or intending to use it in the future. Clinicians with a variety of institutional and educational backgrounds were interviewed; however, the majority of clinicians were practicing within an academic center. As noted above, the small number of clinicians interviewed within the community setting is reflective of the population of clinicians who had referred patients to the study at the time interviews were conducted, though certainly does indicate that the views of community clinicians are likely underrepresented by this analysis. Additionally, because the tumor sequencing study is a pilot, it is expected that the referring clinicians who were interviewed may be more interested in the integration of GS into clinical practice than non-referring clinicians. This self-selection may

be even more pronounced among the clinicians who agreed to be interviewed.

Policy Implications and Research Recommendations

In summary, through iterative analysis of interviews conducted with clinicians who referred patients to a tumor sequencing study, we gained valuable insight on a number of key issues related to the use of GS that could be used to further develop a model of GS results communication. Variable levels of clinician knowledge suggest that the development of accessible educational programs focused on genomics for clinicians is an imperative step in ensuring the proper utilization of GS in cancer care. In general, clinicians desired more in-depth interpretation of the mutation data, and more specific, detailed information linking specific mutations with appropriate clinical trials (with practical assistance as necessary in facilitating patient enrollment in trials for which they are putatively eligible). Further research on refining the depth and detail in tumor testing reports to facilitate clinician understanding and ensure clear communication of results is essential, especially as tumor testing becomes more widespread. Finally, clinicians recognized the specialized communication skills required for discussions of IGFs, and we would suggest that the involvement of genetics specialists, when augmented with both in-person and online educational resources will help ensure the accurate and judicious integration of GS results into clinical practice. Genetic counselors should anticipate receiving increasing numbers of referrals based on findings from tumor testing, and educational opportunities to allow genetic counselors to increase their knowledge in this area represents an urgent need within our community. This represents a possible area of growth for the genetic counseling field, and learning how to decipher tumor sequencing reports and identify mutations found in tumors that could represent germline mutations will be integral skills for counselors moving forward. Genetic counselors have an opportunity, working alongside the oncologists and laboratory scientists at their institutions, to play a key role in establishing a pipeline to allow for identification of patients who may benefit from follow-up germline testing.

Compliance with Ethical Standards

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Arul M. Chinnaiyan: Stock in Oncofusion Therapeutics, Armune Bioscience; Consulting/Advisory role: Oncofusion Therapeutics, Tempus, Armune; Patent/IP with University of Michigan.

Conflict of Interest Caroline M. Weipert, Kerry A. Ryan, Jessica N. Everett, Beverly M. Yashar, Arul M. Chinnaiyan, J. Scott Roberts, Raymond De Vries, Brian J. Zikmund-Fisher, and Victoria M. Raymond declare no conflict of interest.

Human Studies and Informed Consent All procedures performed in studies involved human participants were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. This study was deemed exempt from federal regulations by the University of Michigan's Institutional Review Board.

Animal Studies No animal studies were carried out by the authors for this article.

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