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Influence of payer coverage and out-of-pocket costs on ordering of NGS panel tests for hereditary cancer in diverse settings

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Abstract

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AUTHOR CONTRIBUTIONS

Grace Lin: Conceptualization, data curation, formal analysis, investigation, methodology, validation, writing - original draft, writing – review & editing. Julia Trosman: Conceptualization, data curation, formal analysis, investigation, methodology, validation, writing - original draft, writing – review & editing. Michael Douglas: Conceptualization, data curation, formal analysis, validation, project administration, writing – review & editing. Christine Weldon: Conceptualization, data curation, formal analysis, validation, writing – review & editing. Maren Scheuner: Conceptualization, formal analysis, validation, writing – review & editing. Allison Kurian: Conceptualization, formal analysis, validation, writing – review & editing. Kathryn Phillips: Conceptualization, data curation, formal analysis, funding acquisition, methodology, project administration, resources, supervision, validation, writing – review & editing. Drs. Lin and Trosman confirm that they had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. All of the authors gave final approval of this version to be published and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

CONFLICTS OF INTEREST

The authors report the following conflicts of interest: Grace Lin declares that she has no conflicts of interest. Julia Trosman: Not related to this manuscript, Dr. Trosman has received consulting income from Genentech, and research grant funding from The Merck Foundation and The Pfizer Foundation. Michael Douglas: Mr. Douglas has received consulting income from Illumina, Inc. Christine Weldon: Not related to this manuscript, Ms. Weldon has received consulting income from Genentech, and research grant funding from The Merck Foundation and The Pfizer Foundation. Maren Scheuner declares that she has no conflicts of interest. Allison Kurian: Not related to this manuscript, Dr. Kurian has received research funding to her institution from Myriad Genetics, 2017–2019. Kathryn Phillips: Dr. Phillips has received consulting income from Illumina, Inc.

HUMAN STUDIES AND INFORMED CONSENT

This study was reviewed and determined to be exempt by the UCSF Committee on Human Research. All procedures followed were in accordance with ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Verbal consent was obtained from all participants prior to the interviews.

ANIMAL STUDIES

No non-human animal studies were carried out by the authors for this article.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

The landscape of payment for genetic testing has been changing, with an increase in the number of laboratories offering testing, larger panel offerings, and lower prices. To determine the influence of payer coverage and out-of-pocket costs on the ordering of NGS panel tests for hereditary cancer in diverse settings, we conducted semi-structured interviews with providers who conduct genetic counseling and order next-generation sequencing (NGS) panels purposefully recruited from 11 safety-net clinics and academic medical centers (AMCs) in California and North Carolina, states with diverse populations and divergent Medicaid expansion policies. Thematic analysis was done to identify themes related to the impact of reimbursement and out-of-pocket expenses on test ordering. Specific focus was put on differences between settings. Respondents from both safety-net clinics and AMCs reported that they are increasingly ordering panels instead of single-gene tests, and tests were ordered primarily from a few commercial laboratories. Surprisingly, safety-net clinics reported few barriers to testing related to cost, largely due to laboratory assistance with prior authorization requests and patient payment assistance programs that result in little to no patient out-of-pocket expenses. AMCs reported greater challenges navigating insurance issues, particularly prior authorization. Both groups cited non-coverage of genetic counseling as a major barrier to testing. Difficulty of access to cascade testing, particularly for family members that do not live in the United States, was also of concern. Long-term sustainability of laboratory payment assistance programs was a major concern; safety-net clinics were particularly concerned about access to testing without such programs. There were few differences between states. In conclusion, the use of laboratories with payment assistance programs reduces barriers to NGS panel testing among diverse populations. Such programs represent a major change to the financing and affordability of genetic testing. However, access to genetic counseling is a barrier and must be addressed to ensure equity in testing.

Keywords

cost; decision-making; genetic testing; hereditary cancer panels; reimbursement; underrepresented populations

1 | INTRODUCTION

Approximately 30% of spending on genetic testing is now attributable to hereditary cancer panel tests (Phillips et al., 2018). Increased efficiency of testing multiple genes with next-generation sequencing (NGS) may result in an increased ability to identify individuals with pathogenic variants in hereditary cancer genes, rendering panel testing advantageous as compared to single-gene testing in many scenarios (Alvarado et al., 2020). For example, because as many as 50% of patients with hereditary breast and ovarian cancer may not be identified with *BRCA1/2* testing (Alvarado et al., 2020; LaDuca et al., 2020). NCCN guidelines suggest that patients who meet the criteria for genetic testing may benefit from NGS panel testing (Daly et al., 2020).

Concomitant with the increased use of NGS panel tests are changes in the testing and payer landscape. There has been an increase in the number of laboratories offering testing, as well as the introduction of larger panels and an overall market reduction in pricing. State and federal policies may also play a role in test access and utilization. For example, the

Affordable Care Act (ACA) requires payers to cover genetic counseling and *BRCA1/2* testing for women at increased risk for breast cancer, and Medicaid expansion has been associated with a rise in multigene panel testing (Zhou et al., 2019). However, there is significant variation in coverage for NGS panel tests between commercial payers (Trosman et al., 2017).

Cost of testing and payer coverage have been described as major challenges to the adoption of new technologies, and willingness-to-pay for genetic testing varies greatly among patients (Guo et al., 2020). Furthermore, access to new technologies has traditionally lagged in underserved populations, so there may be differential access to NGS panel tests across populations (Kurian et al., 2019). For example, patients presenting to a comprehensive cancer center were more likely to undergo genetic testing compared with safety-net clinics (Huang et al., 2019), but the reasons for those disparities are not well-characterized. Understanding the impact of payer coverage and out-of-pocket (OOP) costs on genetic test ordering and patient uptake is critical to ensuring widespread and equitable access.

Little is known about how payer coverage and OOP costs impact provider ordering of NGS panels in the current clinical and reimbursement landscape. Provider decisions to order genetic testing may be affected by factors that are not well-captured in quantitative studies. In such situations, exploration via qualitative methods can provide in-depth information about attitudes, behaviors, and contextual factors that may influence the test ordering process (Pope & Mays, 1995). Because the influence of payer coverage and OOP costs may differ based on local regulations and settings, we sought to understand how these factors may affect ordering and uptake of NGS panels by interviewing providers who counsel patients about and order NGS panel tests at academic medical centers (AMCs, tertiary care hospital systems associated with medical schools) and safety-net clinics (hospitals and clinics that largely serve vulnerable populations) in California and North Carolina, two states with diverse populations and divergent Medicaid expansion policies under the ACA.

2 | MATERIALS AND METHODS

2.1 | Participants

The research protocol was reviewed and considered exempt by the UCSF Committee on Human Research. We sought to recruit key informants such as genetic counselors, clinical geneticists, and oncologists—henceforth referred to as a group as respondents—who had experience counseling patients about genetic testing and ordering NGS panel tests in two states, California and North Carolina, and two settings, AMCs and safety-net clinics. The two states were chosen based on state Medicaid policy differences, as California is a Medicaid expansion state while North Carolina declined Medicaid expansion under the ACA. Thus, access to and coverage of genetic testing may differ in these states. AMCs are tertiary care hospital systems associated with medical schools and have research and educational missions along with patient care. Safety-net clinics provide care to a substantial share of vulnerable populations, regardless of ability to pay, and generally have large Medicaid populations. Since the two settings serve different populations, the financial implications of genetic test ordering may differ.

2.2 | Instrumentation

A semi-structured interview guide, available in the Data S1, was developed based on a conceptual framework for the adoption of molecular genetic tests (Figure 1) (Trosman et al., 2020). Adoption factors such as the care delivery pathway, coverage, and cost, and role of actors such as clinicians, patients, health systems, and laboratories were considered when creating the interview guide. The guide was developed and reviewed by the study team who have expertise in medical genetics, oncology, health economics, precision medicine, and healthcare business models. The final guide included questions pertaining to the testing pathway, the impact of payer coverage and OOP expenses on testing decisions, clinician discussion about OOP costs, challenges, and potential solutions to help facilitate testing, and the role of direct-to-consumer and hybrid (laboratories that are consumer-facing but offer medical-grade testing ordered through the patient's or the laboratories' clinician (Phillips et al., 2019)) laboratories.

2.3 | Procedures

We conducted purposive sampling of providers who provided genetic counseling at AMCs and safety-net clinics in California and North Carolina. Initial institutions and contacts were identified in January 2020 through referrals from local and national oncologists, clinical geneticists, genetic counselors, and Medicaid policy experts. We reached out to contacts at 5 AMCs and 6 safety-net clinics we were referred to and requested the names of providers who had experience counseling patients and ordering HCP tests. E-mail invitations were sent in February and March 2020 to those informants, and at least one provider from each institution invited to participate was interviewed.

Interviews were conducted by two investigators (GL, a physician, and JT, a researcher with expertise in adoption and coverage of genetic testing) between February and April 2020. Verbal consent was obtained from all respondents prior to the interview. All interviews were recorded and transcribed verbatim.

2.4 | Data analysis

Transcripts were coded independently by two investigators with different backgrounds (GL, JT) using deductive thematic analyses (Braun & Clarke, 2006). Related codes were collapsed into key themes based on the interview guide in an iterative and consensus-based approach, and themes were also stratified based on settings and states. Codes and themes were also reviewed by experts in medical genetics (MS, AK), health economics (KP), insurance coverage (MD), and healthcare business models (CW) for triangulation and consensus regarding the identification of key themes.

3 | RESULTS

A total of 14 interviews from 11 cancer genetics or oncology clinics (3 AMCs and 4 safety-net clinics in California, 2 AMCs and 2 safety-net clinics in North Carolina) were conducted. Respondents were primarily genetic counselors (12), but also included an oncologist (1), and an oncology nurse practitioner trained in cancer genetic counseling (1).

The respondents were largely female (93%) and had a mean of 12.7 years in practice (range 1–35 years).

We identified the following two main areas of focus: the processes of ordering NGS panels and the challenges and potential solutions for NGS panel test ordering for hereditary cancer (Tables 1 and 2). The processes of ordering NGS panels were further organized into 4 themes: (1) Factors affecting laboratory choice and test ordering, (2) Experience with insurers, (3) Patient OOP costs, and (4) Alternate payment mechanisms for non-covered tests. We also compared our findings between states and settings (Table 3).

3.1 | Factors affecting test ordering and laboratory choice

All respondents reported that they usually worked with one or two specific commercial or hybrid laboratories to order NGS panel testing. Factors important in choosing laboratories included the availability of large panels, ease of working with the laboratories, transparent billing practices, and low OOP costs (Table 1). For AMCs, laboratories that accepted the patient's insurance and share data with ClinVar were also mentioned as selection factors. For safety-net clinics, laboratories contracted with Medicaid plans and those willing to offer testing with little or no OOP costs to patients were most often selected.

Respondents reported that their clinics increasingly order multigene panels rather than single-gene tests for hereditary cancer testing. They primarily relied on NCCN guidelines, patient history, clinical judgment, and test panel offerings from laboratories when deciding which tests to order. There were few clinic or institution-wide policies or protocols for ordering testing. Respondents also reported that insurance coverage of panels was less frequent than coverage of single-gene tests. However, the majority described little to no OOP expenses to the patient even if an insurer did not formally cover panel testing or the patient did not meet insurer criteria for panel testing, due to some laboratories absorbing the additional cost of panel testing, differential pricing for direct payment by patients, and laboratory payment assistance programs for patients unable to afford the cost.

3.2 | Experience with insurers

Almost all respondents relayed that insurance coverage was not a significant barrier to testing because of laboratory policies that cap patient OOP costs, assist with prior authorization and provide patient payment assistance programs for patients unable to afford testing. Figure 2 summarizes the most common coverage and payment pathways that respondents described. Laboratory payment assistance programs had the most impact on patients at safety-net clinics: the assistance offered with insurance authorization and waived fees allowed for test ordering with little concern for the patient's ability to pay.

Experience with insurers varied both by insurer and by setting (Tables 1 and 3). AMCs mainly served patients with commercial insurance or Medicare and reported that the burden of prior authorization constituted their most significant frustration, since many insurers only cover single-gene tests like BRCA, for example, and not larger panels. Some commercial insurers required clinicians themselves to file the prior authorization paperwork. On the other hand, respondents from safety-net clinics reported that they did not have many barriers with regard to prior authorization because they either worked with Medicaid contracted

laboratories or laboratories would manage the prior authorization process on behalf of their patients. Respondents from both AMCs and safety-net clinics also expressed frustration about the lack of insurance personnel with genetics expertise, which further complicated efforts to obtain prior authorization. Finally, some respondents reported frustration at having to spend additional time explaining that the explanation of benefit statement from insurance was not a bill in order to allay patient anxiety when such communications were received from insurance companies.

3.3 | Patient out-of-pocket expenses

Prior to ordering testing, respondents at both AMCs and safety-net clinics reported that genetics professionals routinely counseled their patients about potential OOP costs. However, OOP cost was almost never a barrier to testing. Respondents reported that laboratory direct pricing to patients capped OOP costs between $0–$250, depending on insurance coverage and financial need. As a result, very few patients declined testing due to cost considerations. For patients with insurance deductibles, the decision to bill insurance was largely dependent on whether the deductible had been met; patients whose deductible exceeded the laboratory OOP maximum often elected to pay the laboratories directly and not bill insurance for testing.

3.4 | Alternate payment mechanisms

The majority of respondents reported that while they were aware of alternate payment mechanisms such as research studies, charitable grants, or institutional fee waivers, such programs were used only occasionally since laboratories offer affordable pricing to patients.

3.5 | Challenges and solutions related to payer coverage and out-of-pocket costs

Respondents reported few challenges to arranging for NGS panel testing for their patients. A substantial barrier to testing appears to be that visits for genetic counseling by a genetic counselor may not be covered by insurance. As a result, patients who cannot afford the fee for genetic counseling may not be able to access testing (Table 2). Furthermore, respondents at safety-net clinics perceived that some patients may not have followed up for genetic counseling because they believed that sophisticated genetic testing was out of their reach financially (Table 2). The logistics of arranging genetic counseling visits, particularly in rural areas, was also mentioned as a barrier to testing. For example, one respondent who practices in rural North Carolina felt that her inability to do telegenetic counseling due to lack of reimbursement for telephone visits and the need for physician supervision for all visits limited access to testing, as patients in rural counties may face difficulty traveling to the clinic.

Although respondents felt that laboratory payment assistance programs and expansion of coverage by many insurers facilitated testing, there remain some coverage-related challenges. Medicare's restrictive coverage policies, which largely do not cover testing for patients without a cancer history, and constant changes in coverage policies by commercial insurers that are not always in line with NCCN guidelines, were cited as significant concerns. Furthermore, many respondents were concerned that laboratory direct payment and patient assistance programs would not be sustainable in the long term, leaving large

gaps in the ability of clinicians to offer affordable testing to their patients. This was particularly true for safety-net clinics, as most of their patients would not be able to afford testing otherwise. Finally, although some laboratories offer no-cost cascade testing to family members, the logistics of cascade testing were cited as challenging. For example, for patients with families who live outside of the United States, access to testing may be limited by living in locations where testing and genetic counseling are not readily available.

3.6 | Solutions for payer coverage and out-of-pocket cost-related challenges

When queried about potential solutions to payer coverage or patient OOP cost-related challenges, respondents felt that helpful policies to improve access to NGS panel tests would be full reimbursement by insurers of both genetic counseling and testing in appropriate patients (Table 2). Eliminating the need for prior authorization for certain patients (e.g. those who meet NCCN criteria for testing) and having people at insurance companies who are more knowledgeable about the nuances of genetic testing during the prior authorization process were also suggested as potential ways to mitigate the challenges of ordering NGS panel tests. Finally, respondents at safety-net clinics suggested that better outreach efforts to underserved patients to help them understand that testing is available and affordable to them would be helpful in improving testing access.

3.7 | Comparisons between states and settings

There were no differences in NGS panel test ordering practices between clinics in California and North Carolina, even with differing Medicaid policies and different populations. This appears largely because clinics in both states used the same laboratories for testing. There were also few differences in NGS panel test ordering practices between AMCs and safety-net clinics (Table 3), as differences in socioeconomic status or insurance were superseded by laboratory payment assistance programs, making test access equitable for patients who were able to access clinical care. Respondents from AMCs tended to see more patients with commercial insurance and thus reported a greater burden of prior authorization paperwork. Respondents from safety-net clinics were concerned about their ability to offer counseling and testing to their patients due to barriers to accessing genetic counseling, particularly in more rural areas. Finally, respondents at both AMCs and safety-net clinics had significant concerns about what might happen to access and affordability of testing if laboratories ended their programs offering low-cost testing to patients.

4 | DISCUSSION

Our study examined the impact of payer reimbursement and out-of-pocket expenses on hereditary cancer panel test ordering in the academic and safety-net settings in two states with diverse populations and divergent state Medicaid policies. We found surprisingly few differences. Both AMCs and safety-net clinics largely worked with laboratories that offer testing for little to no OOP cost to patients, resulting in relatively few economic barriers to testing. Importantly, although multigene panels are not routinely reimbursed by some payers, laboratories either worked with payers directly to determine reimbursement, or offered patients testing at affordable or no cost.

Prior studies have documented differences in the utilization of genetic testing, particularly for Medicaid patients (Hall & Olopade, 2006; Kurian et al., 2017). Thus, an unexpected finding from our study is that Medicaid patients had few financial barriers to obtaining testing. Conversely, Medicare patients were less likely to have coverage for genetic counseling and testing, and patients with commercial insurance were more likely to have significant prior authorization hurdles and face higher OOP costs depending on their deductibles and benefit structure. Although historically cost concerns have been a strong determinant of willingness to undergo testing (Steffen et al., 2017), laboratory payment programs with capped OOP costs and patient assistance programs largely appear to mitigate this issue. However, even with laboratory payment assistance programs, respondents observed that some patients may not get tested due to lack of awareness that testing is accessible and affordable to them. Efforts to reach out to those patients are critical to achieving equitable genetic testing and treatment.

Our respondents reported that access to genetic counseling is a significant barrier to accessing testing. This is in part due to lack of coverage of genetic counseling by some insurers. For example, Medicare only covers genetic counseling for specific situations and also does not allow for independent billing by certified genetic counselors or reimbursement for genetic counseling done solely by genetic counselors. Additionally, many insurers require genetic counseling as a pre-requisite for genetic testing (Stenehjem et al., 2018), and with the current shortages in both the clinical geneticist and genetic counselor workforces (Dragojlovic et al., 2020; Maiese et al., 2019), such policies present a barrier to genetic testing access. Additionally, there is an evidence that such requirements may prevent patients from receiving appropriate genetic testing (Stenehjem et al., 2018), as referring providers may lack the knowledge to help their patients obtain genetic testing through other pathways. Alternate models of care, such as direct-to-consumer testing or laboratory-employed genetic counselors that are available for consultation to patients and non-genetic professional clinicians (e.g. primary care physicians), could augment traditional genetic counseling visits (Phillips et al., 2019). However, given the complex nature of genetic testing results, including variants of uncertain significance and the potential need to test family members, models that do not ensure adequate pre- and post-counseling of patients undergoing NGS panel testing may result in inappropriate testing and harm to patients.(Roberts & Ostergren, 2013).

Policies of commercial testing laboratories have had an increasingly significant influence on the delivery of genetic testing services (Wolff & Wolff, 2018). Our study found that the clinics at AMCs and safety-net clinics represented by the respondents in our study utilized for-profit laboratories for NGS panel testing in part due to their pricing policies, which provide for no or low OOP costs if panel testing is not covered (which is the case for most insurers), no-cost cascade testing for family members, and financial assistance programs for low-income patients. However, a major concern amongst respondents was whether having laboratories subsidize testing is a sustainable model of care. Almost all respondents worried about what would happen if such programs were to end, since such programs offer an affordable testing option to patients, regardless of insurance coverage. This is a particular concern for safety-net clinics, where financial barriers would prevent a large proportion of patients from being able to afford testing, potentially opening up disparities in testing that

are minimized by the current payment model (Erwin et al., 2020). Additionally, bypassing insurance companies for payment may result in greater difficulties in convincing insurers to cover NGS panels in the future. Finally, some no-cost options may require that patients share their de-identified genetic information with a third party (and opting out of data sharing may increase the patient's costs), which may be one way that laboratories are able to minimize OOP costs to patients. Although data sharing can have substantial benefits to society in terms of increasing knowledge and ability to diagnose and treat diseases, it also presents privacy concerns and concerns about data ownership that may require navigation in the future as testing becomes more widespread and easily accessible.

4.1 | Study limitations

Typical of qualitative studies, our findings may not be generalizable to settings outside of the 11 clinics represented by the 14 respondents interviewed. Our findings were consistent across settings, making it more likely that our findings may be transferable to other settings; however, there is a need to confirm these findings in broader populations and a national survey of genetic counselors is ongoing. The majority of respondents who were referred to us and agreed to participate were genetic counselors; others who order NGS panel tests may have described different experiences, challenges, and solutions. The programs represented by the respondents ordered NGS panel tests largely from two laboratories, whose payment programs may differ from other laboratories. Finally, semi-structured interviews may miss topics related to payer reimbursement and OOP expenses. Our interview guide was based on a conceptual model of genetic test adoption and we used extensive triangulation for coding, making this less likely. However, future work is needed to investigate other topics related to reimbursement, such as insurer coverage of potential follow-up diagnostic testing resulting from NGS panel testing.

In conclusion, use of laboratories with payment assistance programs reduces barriers to NGS panel tests for hereditary cancer among diverse populations. However, we found that the main barriers to accessing testing are not the cost, or insurance coverage of the test itself, but the lack of insurance coverage for genetic counseling and the difficulty of cascade testing. These barriers need to be addressed to ensure testing equity. The current business model of commercial laboratories offering payment assistance programs represents a major change to the financing and affordability of genetic testing. Whether this model of payment is sustainable and how that impacts test access and equity remain to be evaluated.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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DATA AVAILABILITY STATEMENT

De-identified data are available for non-commercial purposes upon request.

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What is known about this topic

The use of NGS panel tests for hereditary cancer has been increasing, although use may be lagging in underserved populations. Little is known about how the changing laboratory, payer, and coverage landscape have affected the ordering of hereditary cancer panel tests in diverse settings.

What this paper adds to the topic

There are currently few financial barriers to access for NGS panel tests for hereditary cancer, largely due to laboratory patient payment assistance programs, though the sustainability of such programs is of concern. However, insurance non-coverage of genetic counseling and access to family cascade testing remain barriers to obtaining testing for many patients.

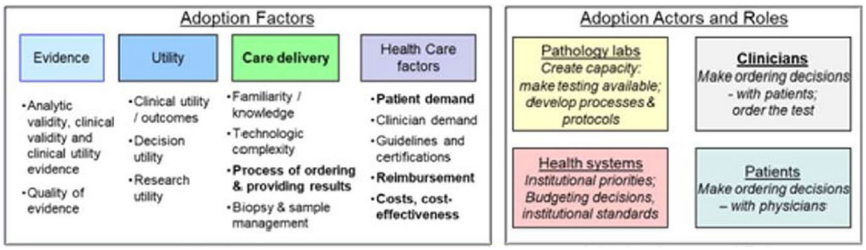

FIGURE 1. Conceptual Framework for Adoption of Genomic and Molecular Tests.

Schematic showing the potential factors and actors that could contribute to the adoption of genomic and molecular tests. Factors that were investigated in our study are in bold

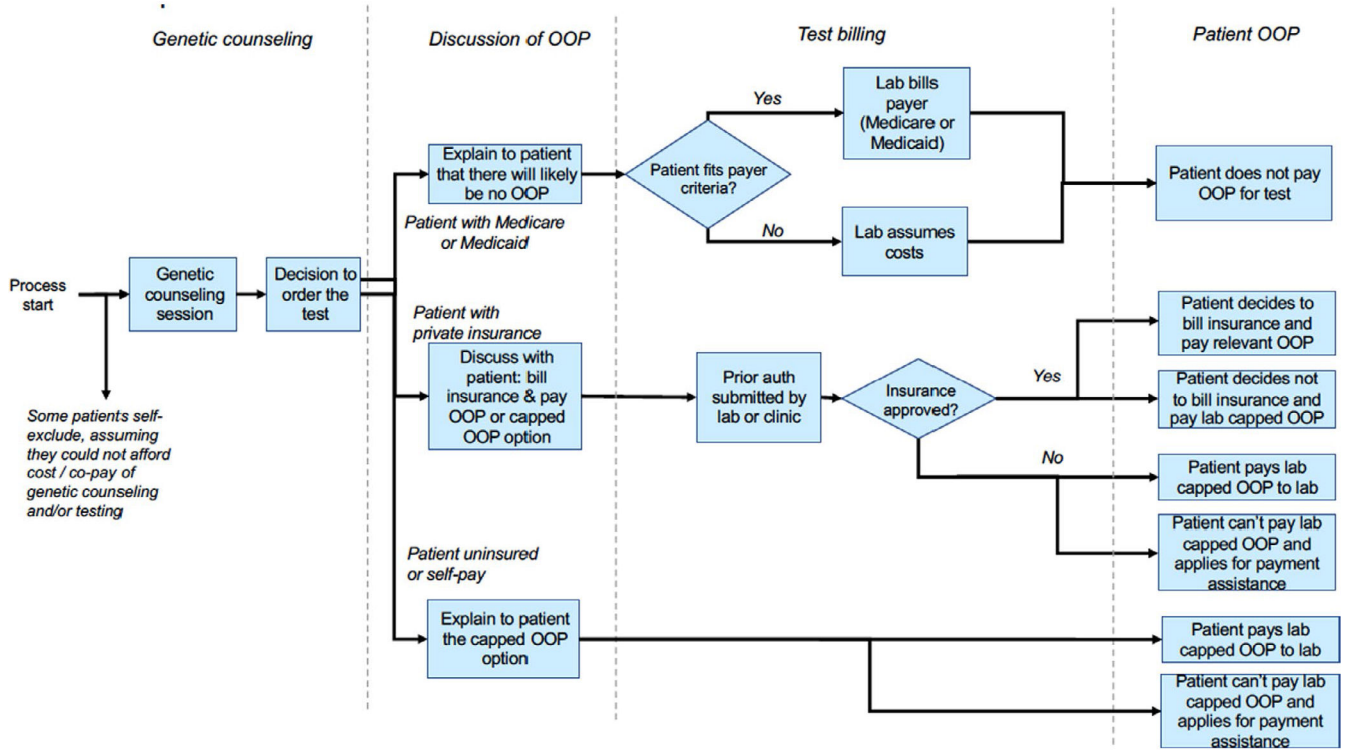

FIGURE 2. Schematic Representation of Payment Pathways for NGS Panel Tests for Hereditary Cancer.

Typical test ordering and coverage/patient out-of-pocket cost scenarios. Example of lab with programs for assuming costs for Medicare and Medicaid patients

TABLE 1

Respondents' experiences with the process of ordering NGS panels for hereditary cancer

Topic	Themes	Example quotes
Factors affecting test ordering and laboratory choice	Good customer service	*[Genetic testing laboratory]…helped us with a grant to provide testing for people who would benefit who didn't have insurance, they were just really easy to work with…it's always easy to reach out to a genetic counselor if I have questions because when I was doing it, I was the only genetic counselor for a million people.* (Participant 6, Genetic counselor, safety-net)
	Transparent billing practices	*We like [genetic testing laboratory] - they have a standard billing practice and are more transparent.* (Participant 11, Genetic counselor, AMC)
	Low patient out-of-pocket cost	*I don't have to really decide and use cost as a decision-making factor when I'm ordering a test…I think it's about no more than 250 at the most dollars for the testing and then they can subsidize it depending on their income and their financial situation.* (Participant 3, Genetic counselor, safety-net)
	Patient's insurance coverage	*We review the insurance benefits even before the appointment to see what is covered and how. That is a consideration for where to send the test.* (Participant 11, Genetic counselor, AMC)
Experience with Insurers	Laboratories do much of the prior authorization work	*I haven't had to do a prior authorization for cancer genetic testing in a long time. Usually the laboratory…they will be the ones who will try to do the prior auth.* (Participant 5, Genetic counselor, safety-net)
	Medicare has the most restrictive policies, only patients with cancer are covered	*Medicare criteria are frustrating - they only cover patients with cancer.* (Participant 10, Genetic counselor, AMC) *Many laboratories absorb the cost of tests for [Medicare] patients who meet NCCN guidelines, even if they don't meet Medicare criteria.* (Participant 13, Genetic counselor, AMC)
	Very few barriers to test ordering in patients with Medicaid	*Most patients that meet NCCN guidelines will meet Medicaid criteria for genetic testing. So, as long as I can document that, then their Medicaid or managed Medicaid…will generally cover testing.* (Participant 1, Genetic counselor, safety-net) *Payment for tests for our Medicaid patients is the easiest. Medicaid doesn't cover these tests, so they qualify for financial assistance by laboratories. That is paid at 100%.* (Participant 12, Genetic counselor, AMC)
	Prior authorization is most complicated and frustrating with commercial insurers	*Now laboratories have established contracts with insurers, and we have to do more for prior auth. For [insurer X and insurer Y], I have to fill out forms - they are all different and very long. Others have portals - they have multiple sign-on's you have to go through and it's a pain. It's not always clear who has portal who doesn't. So now this is getting more and more frustrating.* (Participant 13, Genetic counselor, AMC) *For private insurance, we typically do prior auth for BRCA or Lynch genes only…as these plans don't cover large panels.* (Participant 12, Genetic counselor, AMC)
	Patient's deductible affects whether tests are billed to insurance	*Patients usually choose the $250 option, unless they have cancer diagnoses and will meet their deductible, or they have other conditions for which they will meet their deductible.* (Participant 12, Genetic counselor, AMC)
	Patients are sometimes sent Explanation of Benefit statement that causes significant anxiety	*Frustrating to have to deal with situations when the patient freaks out about an EOB [Explanation of Benefits] for thousands of dollars they get and they think it's a bill.* (Participant 14, Genetic counselor, AMC)
Patient out-of-pocket costs	Laboratories largely underwrite testing costs, particularly in low-income patients	*I'm always very confident…that there won't be any out-of-pocket pay, any bill for them; if a test is not covered…this particular laboratory has an out-of-pocket flat rate for patients to pay; at a low income, then there's no charge.* (Participant 1, Genetic counselor, safety-net)
	Very few patients decline testing due to cost	*Pretty rare for someone to say they don't want to do testing because of the price. Once test is ordered, nobody cancels either because of the cost.* (Participant 11, Genetic counselor, AMC)
	Very little use of direct-to-consumer laboratories	*Rarely use [direct-to-consumer testing laboratory]. Only when patient's family members who live internationally want to get tested, if the proband tested positive.* (Participant 10, Genetic counselor, AMC)

Topic	Themes	Example quotes
Alternate payment mechanisms	Uncovered test costs largely covered by laboratories	*Our patients have no money, so we just assume that [genetic testing laboratory] will take whatever they can get from the insurance company for our patients…the genetic testing companies I think are more in the mindset of writing off the cost for our clinics and getting their money from [Hospital X or Hospital Y] or other places that take care of wealthier patients on the average.* (Participant 2, Oncologist, safety-net)

TABLE 2

Challenges and potential solutions for NGS panel test ordering for hereditary cancer

Topic	Themes	Example quotes
Challenges related to payer coverage and out-of-pocket costs	Patients who are concerned about cost do not come for testing	*We do have patients who call in advance and ask about the cost and coverage. Our coordinators tell them about the $250 option. Some patients probably decide it's too expansive and don't even come in.* (Participant 11, Genetic counselor, AMC) *The socioeconomic status is a huge factor for a lot of these families. So, there's a huge gap in care…coming from the other side and seeing this and saying, Wait a second, I really want you to make sure that you can get the same care. But they don't even know that they could have it.* (Participant 3, Genetic counselor, safety-net)
	Lack of coverage for genetic counseling	*…genetic counseling is really hard to get covered, but genetic testing isn't, which is also very ironic, that the laboratory have programs for people who are low income, but the university doesn't really have programs for genetic counseling for people who are low income. And so, for many cases that's where our biggest gap is.* (Participant 1, Genetic counselor, safety-net)
	Getting coverage is not an issue, but prior authorization is frustrating	*Getting test reimbursed one way or another is not a challenge for us anymore. It used to be.* (Participant 8, Genetic counselor, AMC) *Many times, when I speak with an insurance company about covering a test, I talk to a utilization review nurse. They don't have the knowledge of genetics and it's hard for them to understand why they need to cover.* (Participant 13, Genetic counselor, AMC)
	Concern that laboratory practice of underwriting tests is not sustainable	*The biggest concern is knowing that the patient guarantee practices by laboratories are not a lasting solution to this problem. I don't know how much longer the laboratories can afford doing this. The minute they decide not to, we will have a huge problem.* (Participant 12, Genetic counselor, AMC) *It's wonderful that the laboratories are offering low prices, but I definitely question if this is sustainable. How are they able to offer this? I don't know how this works and that makes me worry.* (Participant 14, Genetic counselor, AMC)
	Lack of Medicare coverage for non-cancer patients	*We need to get coverage for genetic counseling for Medicare, which we don't have, and genetic testing for Medicare needs to be more akin with the NCCN guidelines.* (Participant 1, Genetic counselor, safety-net)
	Insurer policies are not up-to-date with NCCN guidelines	*Staying on top of all changes in coverage policies by payers. They don't follow NCCN guidelines and change their policies frequently. This is very frustrating.* (Participant 11, Genetic counselor, AMC)
Potential solutions suggested	Universal coverage of indicated genetic testing and genetic counseling	*I hope that the Medicare criteria get amended to reflect guidelines, then we won't need subsidies.* (Participant 10, Genetic counselor, AMC) *What I'd like to see is the payers come in and say, "Well, we're only going to pay for genetic testing when it makes sense, and so we're going have you go into a certified genetic counselor and get the genetic counselors involved in this."* (Participant 2, Oncologist, safety-net)
	Education of insurers on importance of genetic testing	*I am trying to figure out a way to maybe educate the people who review the tests, the prior authorizations to give them some information about the rationale for tests, why this is a good idea and ask them to what they need to be able to trust me to order the right test.* (Participant 4, Oncology nurse practitioner, safety-net)
	Eliminate need for prior authorization for patients meeting NCCN criteria	*My hope is that in the future there is no prior auth and that these are reimbursed based on NCCN criteria.* (Participant 7, Genetic counselor, AMC)

TABLE 3

Comparing insights about ordering NGS panel tests for hereditary cancer from AMCs and safety-net clinics

Topic	Themes from AMCs	Themes from Safety-net clinics
Populations served	Serve a mixed population, including Medicare, Medicaid, and commercial insurance	Serve primarily minority populations who are low-income with Medicaid.
Administrative support	Genetic counselors are largely responsible for test ordering, prior authorizations, and managing results	Genetic counselors order tests but either the laboratories or other administrative support is generally available for prior authorization
Factors affecting test ordering and laboratory choice	Laboratories that cover testing or offer low out-of-pocket costs to patients	Laboratories that cover testing at no cost to patient
	Transparent billing practices	Laboratories contracted with Medicaid
	Patient's insurance	
Experience with insurers	Prior authorization takes the most time with commercial insurers	Safety-net clinics largely do not do prior authorization – the laboratory files paperwork
	Patients are very anxious when they receive Evidence of Benefit statements and providers are frustrated to spend time to explain to them	
Patient out-of-pocket expenses	Low out-of-pocket costs mean that testing is rarely declined because of cost	Very few patients have out-of-pocket costs for testing
	Whether to bill insurance often depends on if patient has met deductible	
Alternate payment mechanisms for non-covered tests	Laboratory offers low out-of-pocket test option	Either laboratory or institution covers cost
Challenges related to payer coverage and out-of-pocket costs	Concern that laboratory underwriting of costs is not sustainable	Concerned about patient access if laboratories stop underwriting cost of testing
	Lack of coverage for genetic counseling services	Lack of genetic counselors available to counsel patients, particularly in more rural areas
		Need to educate patients that testing is available and affordable

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