Patient Assistance Programs for Genetic Testing: Closing the Underinsurance Gap or Widening Disparities?

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BACKGROUND

Genetic testing has become more efficient and cost-effective, but the cost of genetic services remains a barrier for many patients and contributes to access disparities[1]. In the U.S., coverage and reimbursement barriers to genetic testing are partly due to uneven insurance coverage across health payers and plans[2-3]. Biomedical manufacturers and charitable patient advocacy programs administer patient assistance programs (PAPs) to help patients pay for higher-priced medical care, including genetic tests[4]. However, there is limited research on the effectiveness of PAPs in reaching patients most in need of financial assistance. This study addresses this research gap by examining how individuals referred for genetic testing interacted with PAPs; results identify key facilitators and barriers to assistance programs.

OBJECTIVE

This study is among the first to examine how individuals without adequate insurance coverage or financial capability to pay for testing can access assistance programs.

METHODS

- Data Source: In-depth, 1 to 2-hour interviews were conducted with individuals who met the inclusion criteria.
- Inclusion and eligibility criteria: (a) personal history of breast cancer, (b) diagnosis of breast cancer between 2009 and 2016, (c) health insurance coverage at the time of diagnosis, and (d) experienced guideline-recommended germline testing following a breast cancer diagnosis.
- Interviews were conducted using an interview guide developed for the study based on the author's previous research and experience.
- Interviews were transcribed verbatim; transcripts were uploaded to Atlas.ti software to facilitate data organization and more intensive data analysis.
- Data were coded first by *a priori* themes related to an individual's experience with PAPs; next, a more intensive abductive analysis approach used iterative engagement with existing theory alongside tools of ground theory to identify emergent themes and generate more meaningful theory.

RESULTS

- Total of twenty-one participants (N=21), women with a breast cancer diagnosis, experienced guideline-directed genetic testing after being diagnosed.
- The median age of participants at the time of the interview was 58 years of age (table 1); this is slightly lower than the median age at diagnosis for breast cancer; however, this is consistent with the increased likelihood of genetic testing referral among people diagnosed at younger ages[5].
- Interviews indicate three primary themes associated with the patient burden seeking access to PAP: navigating the application process, the time required to apply, and the psychological burden (i.e., stress) associated with the application process (table 2).
- Participants detailed how the PAP application process imposed similar burdens on providers, including genetic counselors and physicians (table 3).
- Participants receiving treatment at academic medical centers and/or specialty care centers with more resources and familiarity with PAPs and similar assistance programs often reported fewer impediments and higher levels of support in seeking and applying to PAPs.
- Across all clinical care settings – patient experiences reflect how patient navigators, social workers, and/or financial assistance staff who often are tasked with supporting patients with the PAP application process are overwhelmed – consequently, some participants felt they did not get the support needed to navigate challenges with the PAP application process.
- Results also indicate themes related to the socioeconomic status (SES) of patients accessing an assistance program, including individuals' formal and informal education, activation, engagement, and social network (table 4).
- The considerable time spent by participants in seeking out and applying for a PAP required persistence and higher levels of self-efficacy, which are factors associated with SES-level and health information-seeking behavior.

Table 1. Characteristics of Participants (N=21)

Age at Interview	
Median	58 years
Range	32 - 71 years
Marital Status	
Married/Partnered	61.9% (13)
Widowed/Divorced	33.3% (7)
Single	4.8% (1)
Type of Health Insurance Coverage	
Health Maintanence Organization (HMO)	38.1% (8)
Preferred Provider Organization	28.6% (6)
Point of Service (POS)	14.2% (3)
Medicaid	14.3% (3)
Medicare	4.8% (1)
Experienced an insurance denial for genetic testing	52.4% (11)
Financial assistance for genetic testing via PAP	33.3% (7)

Table 2. Themes Related to the Burden on Patients Accessing an Assistance Program

THEME	ILLUSTRATIVE QUOTES
Navigating the Complex Application Process	• *"I wrote them letters about how the $4200 was going to be a hardship on me. And that I had appealed on my own and my doctor had appealed to Aetna and that I had hit the end of the road."* • *"I applied for all sorts of financial aid and grants…and I kept getting [responses like], 'we are already funded' or 'we are already this or that' or 'come back in a year'…and it was kind of like, a year is too late. So, it was tough. But I did it for my daughters…"*
Time Required to Apply	• *"…I asked my oncologist about it and he said I could meet with the genetic counselor that works in the office. And [the genetic counselor] had this whole questionnaire that I had to fill out. It was a huge amount of paperwork…"* • *I went through the same [long process] and then the [genetic testing] company called me and said, 'How much do you make? What are your details? What is your history?' It was a lot."*
Psychological Burden	• *"…When [the genetic testing company] called me and said …you need to pay a certain amount of money…I just broke down and started crying."* • *"… I didn't know what to expect, but I had to deal with the cost of [the testing]."* • *"Paying [for the testing] was going to be a financial hardship because of all that my radiation treatments…"*

Table 3. Themes Related to the Burden on Providers Assisting Patients with Access to an Assistance Program

THEME	ILLUSTRATIVE QUOTES
Navigating the Complex Application Process	• *"I wrote them letters about how the $4200 was going to be a hardship on me. And that I had appealed on my own and my doctor had appealed to Aetna and that I had hit the end of the road."* • *"I applied for all sorts of financial aid and grants…and I kept getting [responses like], 'we are already funded' or 'we are already this or that' or 'come back in a year'…and it was kind of like, a year is too late. So, it was tough. But I did it for my daughters…"*
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Table 4. Themes Related to Socioeconomic Status (SES) of Patients Accessing an Assistance Program

THEME	ILLUSTRATIVE QUOTES
Education	• *"So, I understand the whole, you know, the CPT Codes and the billing and stuff like that, and how that all works. I also worked for a [health insurance company] for a while. So, I understand that they have their ways of saying, 'Yes you can have this test. No, you can't.'"*
Self-Efficacy	• *"I had to fall back on my own sales skills and my own negotiation skills, and I talked to them several times."* • *I have always been someone who researched since I have such a strong history of family breast cancer and cancers…and so I decided I was going to take charge."*
Social Network	• *"My neighbor told me that the genetic test [company] has this outline of what the insurance will pay, if you do qualify. And there are also grants you can get, but you just basically ask for the grant to help you, which is very nice."* • *"Within 2 years I did the second test. Which I didn't do with my [oncologist]. I actually did with [a genetic counselor] I met through [my friend] … It was not covered by insurance. If insurance doesn't pay, they have it worked out that you never have to pay more than $100.00."*

CONCLUSIONS

Findings reveal that navigating and applying can burden many patients who can benefit from these assistance programs. As genomic medicine rapidly integrates into clinical practice, genetic testing is increasingly used in routine clinical practice across various conditions, including breast cancer[6]. This raises questions about the effectiveness of PAPs in supporting access to more expensive healthcare services for underinsured individuals, suggesting instead that these programs possibly reproduce existing disparities.

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