



# Access to personalized medicine: factors influencing the use and value of gene expression profiling in breast cancer treatment

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## ABSTRACT

Genomic information is increasingly being used to personalize health care. One example is gene expression profiling (GEP) tests, which estimate recurrence risk to inform chemotherapy decisions in breast cancer. Recently, GEP tests were publicly funded in Ontario. We explored the perceived utility of GEP tests, focusing on the factors influencing their use and value in treatment decision-making by patients and oncologists.

## Methods

We conducted interviews with oncologists ( $n = 14$ ) and interviews and a focus group with early-stage breast cancer patients ( $n = 28$ ) who underwent GEP testing. Both groups were recruited through oncology clinics in Ontario. Data were analyzed using the content analysis and constant comparison techniques.

## Results

Narratives from patients and oncologists provided insights into various factors facilitating and restricting access to GEP. First, oncologists are positioned as gatekeepers of GEP, providing access in medically appropriate cases. However, varying perceptions of appropriateness led to perceived inequities in access and negative impacts on the doctor–patient relationship. Second, media attention facilitated patient awareness of GEP, but also complicated gatekeeping. Third, the dedicated administration attached to GEP was burdensome and led to long waits for results and also to increased patient anxiety and delayed treatment. Collectively, because of barriers to access, those factors inadvertently heightened the perceived value of GEP for patients relative to other prognostic indicators.

## Conclusions

Our study delineates the factors facilitating and restricting access to GEP, and highlights the roles of

media and organization of services in the perceived value and utilization of GEP. The results identify a need for administrative changes and practice guidelines to support streamlined and standardized use of GEP tests.

## KEY WORDS

Gene expression profiling, breast cancer, patient perceptions, access, decision-making, genomics, risk recurrence, personalized medicine, health care providers, perspectives

## 1. INTRODUCTION

Genomic information is increasingly being incorporated into health care to further personalize medicine by predicting disease susceptibility and treatment response, and to reduce exposure to unnecessary interventions, adverse events, and health care inefficiencies<sup>1</sup>. One example is gene expression profiling (GEP) of breast tumours. Gene expression profiling tests examine expression levels of prognostically-relevant genes to establish the likelihood of benefit from chemotherapy and the recurrence risk within 10 years for node-negative, estrogen receptor–positive patients<sup>2–7</sup>. The recurrence scores produced by GEP tests classify patients into groups with poor or good prognosis: Patients with low scores have a low likelihood of recurrence and will likely derive little-to-no benefit from chemotherapy; those with high scores will have a higher likelihood of recurrence and will likely derive high benefit from adjuvant chemotherapy. The likelihood of benefit from chemotherapy for patients receiving intermediate scores remains uncertain. Gene expression profiling tests have been recommended for clinical practice as a complement to conventional clinical stratification markers to identify patients who might not benefit from adjuvant treatment, potentially reducing unnecessary exposure to toxicity and lowering the cost to the health care system<sup>8–12</sup>.

Gene expression profiling tests represent an important case study for Canada because they are one of the first personalized medicine technologies translated into clinical practice. The tests have been evaluated by several national health technology assessment agencies<sup>13–15</sup>, and Ontario conducted its own health technology assessment. The Ontario Health Technology Advisory Committee recommended the use of Oncotype DX (Genomic Health, Redwood City, CA, U.S.A.) for women with newly-diagnosed early-stage breast cancer that is receptor-positive, HER2 (human epidermal growth factor receptor 2)–negative, and node-negative<sup>14</sup>. Coincidentally, around the same time, considerable media attention was devoted to Canadian women with breast cancer requesting publicly-funded access to GEP<sup>16</sup>. The Ontario Ministry of Health and Long-Term Care decided to reimburse Oncotype DX testing<sup>17</sup> as part of their out-of-country program, becoming the first province in Canada to do so.

The use of GEP tests in Canada is relatively new, and little is known about adoption of this technology and its use in clinical practice. We explored the perceived utility of GEP tests, focusing on the factors influencing their use and value in treatment decision-making.

## 2. METHODS

### 2.1 Study Design

This study is part of a larger, mixed-methods study examining the value of the GEP test for breast cancer patients and medical oncologists. It used qualitative methods and a discrete-choice experiment that aimed to estimate the utility of the GEP test relative to other factors, as described elsewhere<sup>18</sup>. The research ethics boards at St. Joseph's Hospital, Sunnybrook Health Sciences Centre, and Princess Margaret Hospital approved the study. Here, we report on factors influencing the use and value of GEP tests in treatment decision-making.

### 2.2 Sample Recruitment

We recruited a convenience sample of early-stage breast cancer patients who were offered GEP after the initiation of public funding in March 2010. Eligible participants included women with early-stage (stage I–II) breast cancer who had completed surgical treatment and used GEP testing.

Eligible patients scheduled for routine follow-up visits were identified from clinical records by participating oncologists and designated site coordinators who offered information about the study after the patients had attended their follow-up clinic appointment. Interested patients contacted the researcher to discuss the study, arrange participation, and provide consent. The researcher contacted eligible patients

who indicated interest, but who did not call the researcher within a few weeks. We also recruited medical oncologists through participating oncology clinics, advertisements on the Web sites of professional societies, and referrals from the research team. Medical oncologists practicing in community hospitals were recruited through e-mail invitations and referrals from the research team.

### 2.3 Data Collection

We conducted individual telephone interviews with the medical oncologists, and two focus groups and individual interviews with the patients to accommodate their schedules and to encourage maximum participation. We developed semi-structured interview guides for the focus groups and interviews based on literature review and clinical consultation. The guides solicited details of awareness, use, and reservations about GEP in treatment decision-making (pertinent excerpts appear in Appendix A). Demographic data were collected using a questionnaire administered before the interviews and focus group.

### 2.4 Data Analysis

Focus group and interview data were digitally audio-recorded for verbatim transcription. All transcripts were checked by the researcher against the sound files for accuracy and were corrected where necessary. All corrected transcripts were merged into a single data set, entered into the HyperRESEARCH software application (ResearchWare, Randolph, MA, U.S.A.), and coded for both anticipated and emergent themes pertaining to factors influencing the participants' awareness, use, and reservations about the test. Data were analyzed using content analysis and constant comparison. Briefly, codes pertaining to awareness, use, and reservations about the test were identified within the transcripts and were described to capture the underpinning factors influencing the use of GEP in decision-making. Emerging factors were contrasted with existing data to search for disconfirming evidence<sup>19</sup> and were then summarized as factors influencing the use of GEP in treatment decision-making. Analyses were validated through peer debriefing, in which developing themes were identified and discussed with the study team.

## 3. RESULTS

### 3.1 Participant Demographics

Fourteen oncologists and 28 patients participated in the study. Telephone interviews were conducted with the 14 oncologists, a focus group was conducted with 4 patients, and interviews were conducted with 24 patients from 2010 to 2011. Most of the patients (Table 1) were highly educated (79%), were married

TABLE I Characteristics of the patients

Characteristic	Value	
	(n)	(%)
Patients	28	100
Age		
<50 Years	6	21
50–59 Years	11	39
60+ Years	11	39
Marital status		
Married	17	61
Never married/separated/divorced/widowed	11	39
Children		
One or more	18	64
Highest level of education (n=27)		
Elementary/some high school/ high school diploma/other	5	18
Completed university or college	22	79
Employment status (n=26)		
Employed	14	50
Unemployed/retired/other	12	43
Chemotherapy treatment		
One or more	9	32
None	19	68

(61%), had children (67%), and did not undergo chemotherapy (68%). Most of the oncologists (Table II) were young (64% ≤ 39 years of age; range: 32–67 years) and had practiced in academic hospitals (71%) for an average of 10 years.

### 3.2 Factors Influencing the Use and Value of GEP

Narratives from the patients and oncologists provided insights into various factors governing access to GEP that proved challenging for the patients and oncologists alike. First, oncologists are positioned as gatekeepers of GEP, providing access in medically appropriate cases. However, varying perceptions of appropriateness led to perceived inequities in access and negative effects on the doctor–patient relationship. In that context, the role of oncologists as gatekeepers emerged as a prominent barrier to GEP access. Second, media coverage emerged as a facilitator, increasing patient awareness of GEP, but also complicating the gatekeeping efforts of oncologists. Third, the dedicated administration attached to GEP was burdensome and led to long waits for results, increased patient anxiety, and delayed treatment. Collectively, those factors inadvertently heightened the value of the test (relative to other prognostic indicators) for patients in their treatment decision-making because of barriers to access.

TABLE II Characteristics of the medical oncologists

Characteristic	Value	
	(n)	(%)
Medical oncologists	14	100
Age		
≤39 Years	9	64
≥40 Years	5	36
Work setting		
Community clinic/community health centre/community hospital	4	29
Academic health sciences centre	10	71
Patient care setting (n=15 <sup>a</sup> )		
Solo practice	1	7
Group practice	6	40
Interprofessional practice	8	53
Patient population served (n=19 <sup>a</sup> )		
Inner city/urban/suburban	16	84
Small town/rural/geographically isolated/remote	3	16
Work experience (years)		
In clinical practice		
Mean	10	
Range	1–33	
Working with breast cancer patients		
Mean	10	
Range	1–33	

<sup>a</sup> More than one response could be selected.

The factors representing key facilitators and barriers to access are summarized in the subsections that follow as themes, using illustrative quotes from patients and oncologists.

#### 3.2.1 Gatekeeping Was a Barrier to GEP Access

One key factor that influenced the use and value of GEP was the role of oncologists as facilitators or gatekeepers, which ultimately conditioned access to the test. Oncologists are often tasked with providing (or not providing) access in medically appropriate cases where there is uncertainty about the potential value of chemotherapy.

Well, I think I use it in very selective patients....  
Ones where I really am uncertain about the value  
of chemo, or I think I'd like to give chemo and the  
patient is uncertain. That's mostly when I use it.  
— Oncologist 8

However, the oncologists' perceptions about medical appropriateness varied. Some described using the test in a wider group of patients, acknowledging that this approach likely diverged from the practices of some of their colleagues.

I do offer it to every patient.... That's in the lymph-node-negative setting and otherwise fit and healthy enough to go ahead with chemotherapy and willing to go ahead with chemotherapy.  
— Oncologist 12

The variations led some patients to perceive inequities in access to GEP, which negatively affected the doctor–patient relationship. One way in which the negative impact emerged was the manner in which patients learned about GEP. Some were told about GEP by their oncologists early in the consultation—but this was not always the case. Many participants described learning about the test from their oncologist late in their consultation or feeling that their oncologist had not been forthcoming about the test.

In several cases, patients felt that the later delivery of information about GEP occurred because their oncologist had decided on chemotherapy *a priori*. Initially told that the test would not affect their treatment, several patients insisted on having it anyway and received low-risk GEP results that allowed them to forgo chemotherapy.

He had already set me up for chemo ... and I said that I was interested in the Oncotyping, and he said, "Well, it won't make a difference," and ... I was very insistent upon it.... And so they agreed to do it, but he wanted me to proceed with my first chemo treatment anyway because it wasn't going to be back on time.... I refused.  
— Patient 17

Other patients felt that information about the test was not offered to them because of its high cost. One patient voiced a commonly-shared feeling when she challenged the logic of withholding access to the test, giving rise to emotional, last-minute reprieves.

My sense was "We don't really talk about it because, looking at your case, we don't think that it would be worth it" because it's a \$4000 test.... As it turns out [I] got the Onco results then, and [the oncologist] said, "I can't believe it, but your score indicates that you don't need to do chemo." ... I was surprised when I reflect back ... that they didn't talk to me about it as an option. They never mentioned it to me as a possibility of a test.... Why wait? ... Why think you have to go into chemo, and then all of a sudden, it's like the day before, and it's "Whew, you know what? You're okay. You don't have to."  
— Patient 20

Such delays or omissions in mentioning the test often left patients confused or feeling that something of great value was being withheld. Indeed, access to the test was often framed as an issue of entitlement: "I

think that people who have cancer should have every tool they can get, to know what the best treatment for them is" (patient 21). Importantly, these experiences created an atmosphere of scarcity, giving the test a heightened sense of importance for the patients.

Beyond interaction with their oncologists, patients also learned about the test through friends and family, newspaper articles, and the Internet. Media attention to GEP<sup>16,17</sup> was especially influential, not only in shaping patient perceptions, but also in complicating the gatekeeping role, as described next.

### 3.2.2 *The Media Was a Catalyst to GEP Access*

The second factor associated with the use and value of GEP was the media, which served as a catalyst to GEP access. Some patients described learning about GEP through media coverage that focused on the lack of public funding in Canada, framing the issue as one of inequitable access to a highly effective, game-changing technology<sup>16,17</sup>. A number of patients described initiating conversations with their oncologists on the basis of such information.

Right before I was going to see her for the first time, there was an article in the newspaper about a woman who had had the test and didn't have chemotherapy. And I took it to the meeting and showed it to her.... And so that brought the subject up right away.... There was a big to-do about OHIP not paying for it at that time ... and so I was more interested in finding out ... what she thought about it. And, lo and behold, she said, "You qualify for it" ... and that she would present a form to OHIP.  
— Focus group patient 1

But although media attention raised awareness of GEP among the patients, it also complicated gatekeeping efforts. Several oncologists acknowledged that they felt increased pressure to offer the test because they did not want patients to feel that oncologists were withholding information.

When there's a lot of buzz around something, I will often even just say, "You know, there are other tests ... which you don't need for this and this reason.... It's better that they hear it from me upfront than think that I was kind of withholding it  
—Oncologist 10

Media-driven awareness of GEP among patients was also felt to complicate discussions and decisions to order the test for their patients.

I did feel that my hand was a little bit forced after the publications in the *Globe and Mail* ... and I do feel, medico-legally, that my hand is a bit forced, because if I was to not mention the test in a room with a patient who would meet



criteria based on their tumour that I'm potentially at risk of having someone come back and say, "Oh, [Doctor], this patient was eligible for this test. Why did you not offer it?" or have the patient come back and say, "I read about this. How come you're not telling me about this?"  
— Oncologist 9

Thus, oncologists felt that media-driven awareness of GEP challenged gatekeeping, especially for ineligible patients (that is, those without HER2-negative, node-negative, receptor-positive disease) who were likely to feel that they were unfairly being denied access to an important test.

### 3.3.3 Administrative Requirements Were a Barrier to GEP Access

Another factor that influenced the use and value of GEP was additional administrative tasks attached to GEP, which were construed as a barrier to accessing the test. The GEP tests are conducted exclusively out of country. Patients and oncologists are required to complete additional documentation to establish eligibility for public coverage (though the out-of-country program). Oncologists are then required to obtain government approval before sending tumour samples out of country for testing. Typically, the process takes 3 weeks to receive GEP results. This additional administrative step constitutes another factor that served to heighten patient perceptions that GEP is hard to access and, therefore, is a particularly valuable test.

A number of participants experienced delays, confusion, and increased anxiety because the paperwork requisitioning the test was mishandled.

He gave me a range of time. It didn't arrive.... They had to cancel the appointment.... Waiting was torment.... I felt very, very powerless, and you don't just call up your oncologist.... And I finally called ... and I just said to them, "I want to know. Now you're saying it's likely to come in, in such-and-such a time. If it hasn't come in before two days before my next appointment with him, I want to know." ... I was no longer trusting the system.  
— Patient 26

Several patients asked why the test was not part of the routine battery of investigations.

It frustrates me that the oncologists have to ask the patient, who has to sign a consent, who then the pathologist has to send off the tumour down to California.... I think it should be part of the process; that it does not have to be the patient consents that you can send the information off to OHIP.... I think there should be some changes within the system

that liberates the doctors... The system of getting your genome testing has to change.  
— Patient 10

Moreover, although there was no suggestion of conscious decisions being made to limit use of the test because of the paperwork required, one oncologist felt that the added burden could affect use of the test in community settings with limited resources.

In a community [hospital] ... the workload is enormous.... It's not just Oncotype, it's all of these types of tests in a community centre where you don't have drug navigators, you don't have a nurse or somebody just doing all of this for you.... Sometimes, honestly, you don't bring it up with the patient because you don't have the time to follow through on the extra work that's needed.... So I think that's a big issue.... I think the threshold changes based on your resources—absolutely.  
—Oncologist 12

Added administration also led to concerns about missing the window for initiating chemotherapy, which increased anxiety about diagnosis and treatment: "I was having kittens waiting for the results. It took so long" (patient 27).

In sum, the dedicated administrative requirements attached to GEP were experienced as cumbersome, time-consuming, and anxiety-provoking. They also inadvertently reinforced the impression that the test was special, because it warranted special treatment.

## 4. DISCUSSION

As Canada increasingly invests in personalized medicine technologies<sup>20</sup>, our study offers timely insights into how health service delivery and the organization of one such technology in Ontario can create challenges for patients and providers and can lead to perceived inequities in access among patients.

Access to GEP, a new and expensive technology, is currently subject to careful administration and oversight. However, that care has created unintended consequences, including complex gatekeeping responsibilities for oncologists and perceived inequities in access by patients. Moreover, media attention facilitates patient awareness of GEP, but complicates gatekeeping efforts, negatively affecting the doctor–patient relationship. Collectively, an atmosphere of scarcity was inadvertently created, which, for patients, heightened the desire for and value of GEP testing results relative to other clinical indicators<sup>18</sup>.

Our study is consistent with others that have highlighted the role of delivery or reimbursement policies<sup>21–26</sup> and of resource allocation decisions made by individual clinicians<sup>21</sup> in creating tensions underlying access to and utilization of genetic

services. It is also consistent with studies that have shown how increased access to genetic services might be prompted by patients who act as their own health care advocates<sup>27,28</sup>.

Delivery of new genomic technologies is a relatively understudied area in health services research and genomics translation<sup>1,29,30</sup>, which previously focused on the hereditary disease context<sup>22–24,31</sup> or on quality assurance issues<sup>32,33</sup>. Our results contribute to this literature by highlighting the roles of the media and health service organization in creating additional challenges in access and delivery of genomic services. Although the role of the media in shaping public opinion about health care and genetics is well documented<sup>34,35</sup>, our study illustrates the influence of media-driven pressure on the doctor–patient relationship and on perceptions of inequities in access, warranting further investigation. In addition, our study highlights the unintended consequences that result when the organization and delivery of care diverge from standard practice governing access to other technologies. Specifically, we found that patient perceptions of GEP<sup>18</sup> and its value in supporting treatment decisions was heightened relative to other prognostic indicators because of barriers to access created by the organization and delivery of the test.

There are several caveats in the interpretation of our findings. Patients were drawn from two tertiary centres and constituted a highly educated group, all of whom had undergone GEP testing. Patients might also be self-selected, in that some had to advocate for access to the test and were therefore more motivated to share their story. Many of the oncologists were young, in the early part of their career, and had been trained at one or more of the academic hospitals participating in this study. Future research that includes eligible patients who did not undergo GEP testing and who come from other jurisdictions would provide additional insights. Although not intended to represent the views of the population or to be fully generalizable to other jurisdictions, this qualitative study provides timely, in-depth insights about the factors influencing the adoption and use of GEP tests in clinical practice.

## 5. CONCLUSIONS

Our study delineates factors facilitating and restricting access to GEP, and highlights the roles of the media and service organization in the perceived value and use of GEP. It is partly through its organization and delivery that GEP emerged as the “deciding factor” in treatment decisions by patients<sup>18</sup>. Those results identify a need for administrative changes and practice guidelines to support streamlined and standardized utilization of the test.

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## 7. CONFLICT OF INTEREST DISCLOSURES

The authors have no financial conflicts to disclose.

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**APPENDIX A: EXCERPTS FROM DISCUSSION GUIDE****For patients<sup>a</sup>:**

People sometimes describe their cancer experience as a journey. What we'd like to hear about today is the part of your journey that involved making decisions about whether or not to have chemotherapy and then, more specifically, about the part that genetic profiling played in that decision-making process.

...

2. When did the idea of having genetic profiling enter the conversation [with your oncologist]?

- Suggested by the oncologist because ...
- I knew about it from media coverage/Internet/own research and asked about it ...
- I knew about it from some other person and asked about it ...

...

8. Do you think there are any downsides to having a test like this?

~

**For medical oncologists:**

I understand that there are clinical algorithms that inform decision making about whether to prescribe chemotherapy for women with breast cancer depending on their individual circumstances. That said, every physician will have their own way of engaging with patients, and their own sense of how useful different decision support tools are. So it's really that side of things that we're hoping to learn about from you today.

...

3. As you're aware, since March 2010, the province of Ontario has been funding gene expression profiling for women with breast cancer. What's your experience of using *GEP* as a decision support tool?

- Was suggesting it on a patient pays basis prior to March 2010
- Was involved in a clinical trial
- Have been using it since it was funded
- Patients ask for it
- No direct experience

...

7. Do you have any misgivings or reservations about the test?

<sup>a</sup> From Bombard *et al.*, 2014<sup>18</sup>.