Does personal genome testing drive service utilization in an adult preventive medicine clinic?

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Abstract Personal genome testing (PGT) that assesses risk for common diseases may influence the use of preventive health services, but outcome data are limited. We aimed to assess health service utilization following PGT. We conducted a retrospective matched cohort study at an adult health clinic. Medical records of clients who pursued PGT at their comprehensive health assessment (CHA) over a 1-year period ($N = 388$) were reviewed and compared to age- and sex-matched clients who underwent CHA but not PGT ($N = 388$). We measured condition-specific health services used post CHA up to two subsequent visits while accounting for confounding factors (e.g., family history,

health status, and age). A relatively equal number of post CHA services were used by clients who pursued PGT and those who did not pursue PGT (52% and 48%, respectively). Overall and across the majority of conditions examined, clients' service utilization was significantly associated with health status, e.g., clients identified as “at risk” on CHA for heart attack used 2.86 times more services than clients not at risk. Pursuing PGT was not significantly associated with increased use of services post CHA overall or for most of the conditions examined. Our data demonstrate that health status rather than pursuing PGT is the strongest driver of service utilization in this population. Overall, pursuit of PGT and PGT results does not appear to significantly drive the utilization of downstream health services.

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Introduction

Personal genome testing (PGT) that assesses an individual's genetic risk for developing common polygenic conditions has become more accessible to the public through direct-to-consumer companies and specialty clinics (Genetics and Public Policy Center 2011; Bellcross et al. 2012). These tests most commonly use genotype information from single nucleotide polymorphism (SNP) arrays and correlation data from genome-wide association studies to generate risk estimates for common complex conditions, including cardiovascular disease, diabetes, and cancers (Manolio 2010; O'Donnell and Nabel 2011). The marketed value of PGT relies on the premise that these tests identify individuals primarily at risk for developing common conditions, in turn

motivating them to use preventive health services to improve health outcomes (Gollust et al. 2002; Bloss et al. 2011a; Vernarelli 2013). However, empirical data that reflect upon this type of clinical utility for PGT are limited (Bellcross et al. 2012; McBride et al. 2010; Scheuner et al. 2008).

To date, only a few studies have explored the impact of PGT on downstream healthcare services (Kaufman et al. 2012; Bloss et al. 2013; Reid et al. 2012). These have used hypothetical, vignette-based models that capture intent to use services or have relied on self-reported data. For example, a survey of 1046 individuals who had previously purchased one of three direct-to-consumer PGT found that nearly 10% reported undergoing additional lab tests related to their PGT results (Kaufman et al. 2012). Additionally, Bloss et al. surveyed 2240 individuals at two time points (3 months and 1 year) following receipt of PGT risk results. They found no significant increase in the rate of screening test usage at either follow-up time points (Bloss et al. 2011b, 2013). There has only been one study to date, conducted by Reid et al., that examined actual services used following PGT. This study prospectively observed 1959 individuals who were offered PGT free of charge and compared the frequency of physician visit attendance and screening test usage among those who chose to undergo PGT to those who did not. They found no significant changes in overall usage of posttest services between the two groups (Reid et al. 2012).

Although outcome data are beginning to emerge, additional evaluative research focused on actual services used following PGT is needed to better characterize the health system impact of these new tests. Additionally, existing data address direct-to-consumer PGT with little to no data on the impact of clinic-based PGT. To this end and in the context of an innovative collaboration with a large and well-established private health clinic in Canada, we examined whether PGT facilitated through a genetic counselor was associated with subsequent health service utilization for a select group of conditions on the test panel. Specifically, we ascertained whether clients who underwent PGT pursued more health services beyond those services included in the clinic's baseline assessment compared to clients who did not undergo PGT. We selected a private clinic setting to allow for comprehensive tracking of all PGT used and the majority of downstream services initiated. This setting also provided a standardized cohort for initial service utilization, thereby avoiding a confounding factor. This population of typically high-income, well-educated, and health-conscious individuals is also a good representation of a typical consumer of PGT in the larger general population (Kolor et al. 2012). We anticipated that this population would be more likely to demonstrate an impact of PGT, if any, via the pursuit of downstream health services. We explored the influence of

other client characteristics on service utilization. This evidence warrants consideration alongside health service resource planning efforts in the era of PGT.

Materials and methods

Study setting

Health care system and clinic structure

Canada's health care system is comprised of 13 separate provincial/territorial health care insurance plans that provide coverage for medically necessary services delivered by physicians and not-for-profit hospitals (Deber et al. 2010). Medcan is a private health clinic in Toronto, Canada, which offers private-pay options for health services oriented around disease prevention and health promotion (Medcan 2014). These services are outside the scope of Ontario's publically funded insurance plan. Medcan clients can pay for these services out-of-pocket or through private insurance plans.

The main service offered at Medcan is a comprehensive health assessment (CHA), which is a 4–5 hour medical examination involving a physical exam and several diagnostic and screening tests. It provides a baseline measure of the client's health status and is typically completed every 1–2 year(s). In addition to the CHA, the clinic offers a variety of in-house services including Genetics, through which PGT is offered as an optional product for purchase. PGT is facilitated by a genetic counselor and includes a review of the client's family history, as well as pretest and posttest counseling. Medcan clients have the option of purchasing additional clinic memberships that provide access to medical care year-round from Medcan physicians and/or access to additional in-house services/facilities to enhance their existing publicly funded service (e.g., private suite for government funded routine colonoscopy screen).

Personal genome testing platform

During our study period, the PGT platform offered at Medcan was the Navigenics Health Compass (Navigenics 2012). This platform used published SNP association data to generate lifetime risk estimates for common conditions. Of the 28 conditions included on this platform, we selected nine to examine: abdominal aneurysm, atrial fibrillation, colon cancer, type 2 diabetes, glaucoma, heart attack, macular degeneration, melanoma, and prostate cancer. These conditions were selected based on disease incidence and age of onset, as well as availability of follow-up services relevant to potential health concerns. After careful consideration, abdominal aneurysm and macular degeneration

were excluded because of limited available follow-up investigations at the clinic and limited access to assessment data, respectively.

Sample

We conducted a retrospective matched cohort study. The study sample included all clients who pursued PGT during the first year of offer at Medcan: from August 1, 2009 to July 31, 2010. Exclusion criteria included the following: PGT offered to employees or as promotional offers, clients who did not undergo a CHA before purchasing PGT, and clients who opted not to receive PGT results. Using Medcan's internal database, a sample of Medcan clients who did not pursue PGT during the same study window was randomly selected for comparison, matching for age by age group and sex in a 1:1 ratio.

Data collection procedures

Data from clients' medical charts and electronically tracked records at Medcan were extracted for review. We extracted data from patient records at two time points: (1) client characteristic data were captured at the CHA appointment (CHA1) and (2) subsequent services used (denoted post CHA services) were captured after receipt of PGT results for clients who pursued PGT or following CHA1 for clients who did not purchase PGT. Figure 1 illustrates the schematics of the study timeframe, including the two data collection time points [Fig.1].

Measures

Client data collected at CHA1 included age, sex, ethnicity, lifestyle factors (i.e., smoking status, exercise level, and alcohol intake), and clinic membership status. Additionally, data specific to each condition were collected, including related family history and client health status at time of CHA1. Related family history was recorded as positive, negative, or unknown. A positive history refers to having a relative (up to second degree) with the same condition as reported on the

genetic counselor's family history intake. Clients' health status was assigned to be "at risk" or "not at risk" based on the results of the CHA. If the client presented with symptoms of the condition or had an abnormal screening test related to the condition at the time of CHA1, they were classified as at risk.

Data collected post CHA included PGT risk results and related health services used. PGT results were classified as "increased risk" or "average risk." Clients with a risk of 20% or greater than the general population risk were classified according to Navigenics' reporting algorithm as having increased risk for each of the conditions examined. As our main outcome measure, we captured related health services used following receipt of PGT results or following CHA1 up to the time of CHA 3, typically representing a 2–4 year follow-up period. A list of services counted towards related services was compiled for each condition examined [Online Resource 1]. For instance, an advanced cholesterol test and omega score blood test were counted as related services for heart attack. Off-site services that were not recorded in the client's electronic or paper charts were not captured.

Statistical analysis

Frequency data are presented to describe client characteristics by study cohort. Fisher's exact tests were used to determine if client characteristics differed by group (PGT vs. no PGT). We examined post services used overall and per condition. We investigated the independent effects of age, sex, membership status, study cohort (i.e., clients who underwent PGT vs. clients who did not), family history, and CHA health status on post services used. For the overall analysis, we developed and assigned tallied risk scores (ranging from 0 to 7) for each individual for the condition-specific data, including related family history, CHA health status, and Navigenics risk result. For related family history, conditions that had a positive history were tallied to represent the "cumulative related family history." For CHA health status, conditions with at risk entries were tallied to represent the "cumulative CHA health status." For Navigenics risk result, conditions with increased risk entries were tallied to represent the "cumulative

Fig. 1 Schematics of data collection timeframe

Navigenics risk result.” Unadjusted relative rate (RR) values were independently generated for each variable using binomial log link regression analysis with a 95% confidence interval (CI). Multi-hypothesis-testing correction

using the Benjamini and Hochberg method was applied with a 0.05 false discovery rate cutoff (Benjamini and Hochberg 1995). Stratified analysis of significant factors was performed to examine the influence of confounding factors.

Table 1 Sample characteristics overall and by cohort study

Sample characteristics	Total N (%)	PGT N (%)	No PGT N (%)
Age			
Under 40 years old	155 (20)	77 (19.8)	78 (20.1)
41–50 years old	252 (32.5)	131 (33.8)	121 (31.2)
Over 50 years old	369 (47.6)	180 (46.4)	189 (48.7)
Sex			
Female	274 (35.3)	137 (35.3)	137 (35.3)
Male	502 (64.7)	251 (64.7)	251 (64.7)
Ethnicity			
European	313 (40.3)	313 (80.7)	N/A
Other	51 (6.6)	51 (13.1)	N/A
Unknown ^a	412 (53.1)	24 (6.2)	N/A
Smoking status			
No	450 (57.9)	224 (57.7)	226 (58.2)
Previous smoker	242 (31.2)	111 (28.6)	131 (33.8)
Yes	75 (9.7)	51 (13.1)	24 (6.2)
Unknown	9 (1.2)	2 (0.5)	7 (1.8)
Exercise level			
None	193 (24.9)	58 (14.9)	135 (34.8)
Low (leisurely exercise or active lifestyle)	127 (16.4)	74 (19.1)	53 (13.7)
Moderate (vigorous exercise 1–5 times per week)	426 (54.9)	232 (59.8)	194 (50)
High (vigorous exercise >5 times per week)	30 (3.8)	24 (6.2)	6 (1.5)
Alcohol intake			
<3 per week	229 (29.5)	108 (27.8)	121 (31.2)
3–5 per week	150 (19.3)	80 (20.6)	70 (18)
6–10 per week	204 (26.3)	100 (25.8)	104 (26.8)
>10 per week	186 (24.0)	99 (25.5)	87 (22.4)
Unknown	7 (0.9)	1 (0.3)	6 (1.5)
Membership status			
Nonmember	343 (44.2)	134 (34.5)	179 (46.1)
Medcan member ^b	433 (55.8)	254 (65.5)	209 (53.9)
Cumulative related family history			
Negative or unknown	190 (24.5)	48 (12.4)	142 (36.6)
Positive	586 (75.5)	340 (87.6)	246 (63.4)
Cumulative CHA health status			
Not at risk	309 (39.8)	148 (38.1)	161 (41.5)
At risk	467 (60.2)	240 (61.9)	227 (58.5)
Cumulative Navi risk result			
Not done or average risk	478 (61.6)	90 (23.2)	388
Increased risk	298 (38.4)	298 (76.8)	N/A

N/A not applicable

^a Ethnicity is not consistently recorded for all clients; those who do not see Medcan’s genetic counselors were categorized as unknown

^b Member of Medcan extended plans

Results

Sample characteristics

During our study window, 448 PGTs were ordered at Medcan. Sixty of these were excluded based on our exclusion criteria. The remaining 388 clients who underwent PGT were matched 1:1 to clients who did not pursue PGT, bringing the final sample size to 776. As shown in Table 1, the majority of the clients were over the age of 40 (80.1%) and of European descent (40.3%). Males represented 64.7% of the sample population. This is consistent with the overall client population at Medcan. Approximately 10% were smokers, 31% were previous smokers, 55% exercised between 1 and 5 times per week, and 30% consumed less than three alcoholic beverages per week. More than half (56%) of the clients sampled had extended Medcan memberships. Individuals in the PGT cohort had higher exercise levels ($p < 0.001$) and were more likely to purchase extended memberships compared to individuals who did not pursue PGT ($p < 0.001$). Interestingly, there were more smokers in the PGT cohort, but fewer previous smokers ($p = 0.003$).

The overall risk scores for related family history showed that approximately 75% of individuals had a positive family history for at least one of the conditions examined. Approximately 60% of individuals had signs or symptoms for at least one condition examined through their CHA evaluation. The overall Navigenics risk results score indicated that approximately 40% had an increased risk identified from PGT testing for at least one condition examined [Table 1].

Post services used

A total of 1180 services were used post CHA with nearly equal distribution among clients who underwent PGT and clients who did not (52% and 48%, respectively). When analyzed by condition, the number of services used varied. Services related to heart attack accounted for the greatest proportion of services used (28.1%) [Fig. 2].

Factors associated with post services used

By individual condition

When looking at each condition independently, only CHA health status was significantly associated with post service utilization for all seven conditions, except glaucoma [Online Resource 2]. Being identified as at risk for a condition was strongly associated with increased use of related services compared to being not at risk. For instance, a client who presented with a heart-related symptom or had an abnormal heart health screen (i.e., Framingham Score, total cholesterol) at CHA1

Fig. 2 Post services used by study cohort and condition

was 2.86 (95% CI = 2.32, 3.52) times more likely to pursue subsequent heart-related services than a client who had a normal heart health screen at CHA1.

Analyses of relative rates for the other factors examined (age, sex, membership status, family history, study cohort) showed different drivers of service utilization for each condition examined [Online Resource 2]. Clients over the age of 40 years used more services related to heart attack and colon cancer compared to clients under age 40 [$RR_{\text{heart attack}} = 2.92$, 95% CI (1.87, 4.54), $RR_{\text{colon cancer}} = 3.24$, 95% CI (1.92, 5.47)]. Clients who had Medcan memberships used more post services related to melanoma and glaucoma than nonmembers [$RR_{\text{melanoma}} = 1.74$, 95% CI (1.33, 2.27), $RR_{\text{glaucoma}} = 2.44$, 95% CI (1.72, 3.46)]. Family history and sex were not significantly associated with post services used for any condition studied.

Comparing clients who underwent PGT to clients who did not, pursuing PGT was significantly associated with subsequent service utilization for only glaucoma. Clients who underwent PGT used 1.72 (95% CI = 1.27, 2.34) times more services related to glaucoma than clients who did not pursue PGT. Comparing the overall relative rate for PGT ($RR = 1.72$) to relative rates for PGT after stratifying by Medcan membership ($RR = 1.53$) and nonmembership ($RR = 1.53$), we noted that there was a greater proportion of Medcan members among those who underwent PGT compared to those who did not.

Across all conditions examined—cumulative analysis

When investigating the independent effects of each factor on overall services used, no significant association with cohort study (PGT and no PGT) was identified ($p = 0.085$) [Table 2]. Similarly, cumulative related family history, cumulative Navigenics risk result, and sex were not significantly associated with overall services used ($p = 0.89$,

Table 2 Relative rate (RR) of cumulative post services used

	Post services used		RR (95% CI)	<i>p</i> value	Adjusted <i>p</i> value
	None <i>N</i> (%)	Any <i>N</i> (%)			
Age					
Under 40 years old	82 (52.9)	73 (47.1)	Reference	Reference	Reference
41–50 years old	96 (38.1)	156 (61.9)	1.31 (0.99–1.74)	0.054	0.324
Over 50 years old	101 (27.4)	268 (72.6)	1.54 (1.19–2.00)*	0.001	0.006
Sex					
Female	112 (40.9)	162 (59.1)	Reference	Reference	Reference
Male	167 (33.3)	335 (66.7)	1.13 (0.94–1.36)	0.206	1.000
Membership status					
Nonmember	160 (46.6)	183 (53.4)	Reference	Reference	Reference
Medcan member	119 (27.5)	314 (72.5)	1.36 (1.13–1.63)*	9.6×10^{-4}	5.76×10^{-3}
Cohort study					
No PGT	151 (38.9)	237 (61.1)	Reference	Reference	Reference
PGT	128 (33.0)	260 (67.0)	1.10 (0.92–1.31)	0.310	1.000
Cumulative CHA health status					
Not at risk	116 (24.8)	351 (75.2)	Reference	Reference	Reference
At risk	163 (52.8)	146 (47.2)	1.59 (1.31–1.93)*	3.0×10^{-6}	1.8×10^{-5}
Cumulative related family history					
Negative	67 (35.3)	123 (64.7)	Reference	Reference	Reference
Positive	212 (36.2)	374 (63.8)	0.99 (0.80–1.21)	0.891	1.000
Cumulative Navi risk result					
Not done or average risk	180 (37.7)	298 (62.3)	Reference	Reference	Reference
Increased risk	99 (33.2)	199 (66.8)	1.07 (0.90–1.28)	0.453	1.000

*Adjusted $p < 0.05$

$p = 0.45$, and $p = 0.21$, respectively). Conversely, there was a significant association between cumulative CHA health status and overall service utilization. Clients with at risk status on CHA evaluation for at least one condition were 1.59 (95% CI = 1.31, 1.93) times more likely to use post services than clients with not at risk CHA health status collectively. Membership status was also associated with 1.36 (95% CI = 1.13, 1.63) times more likelihood of using post services compared to nonmembers. Age was significantly associated with overall service utilization for only those over age 50. Clients over 50 years old were 1.54 (95% CI = 1.19, 2.00) times more likely to use post services than client under 40 years old.

Discussion

Our findings demonstrate that individuals who purchase PGT use a similar number of overall services as individuals who do not. These results align with existing evidence that PGT does not increase downstream use of healthcare resources (Kaufman et al. 2012; Bloss et al. 2013, 2011b; Reid et al. 2012).

Among this population of typically high-income, well-educated, and health-conscious individuals, we found that the strongest driver of post services used was health status rather than the pursuit of PGT. However, the CHA risk for glaucoma was not associated with increased use of related services. This

may reflect a limitation in our ability to ascertain services pursued outside of Medcan, i.e., clients who have an abnormal CHA screen may pursue follow-up optometry services off-site, since it is not uncommon for individuals to have eye specialist(s) (optometrist/ophthalmologist) outside of their primary care setting.

Pursuit of PGT and PGT risk results does not appear to motivate clients to use more or fewer services overall or for the majority of specific conditions examined. This is consistent with previously reported findings (Bloss et al. 2011a, b, 2013; Reid et al. 2012). Our findings further mitigate concerns that PGT results would prompt an overutilization of resources and unwarranted follow-up services, as well as concerns that individuals may interpret PGT risk results as deterministic, leading them to overlook the value of medical screening and health-promoting behaviors (Kaphingst et al. 2012; Leighton et al. 2012; O'Neill et al. 2010). Pursuit of PGT was associated with increased overall services used only for glaucoma, although this effect can be attributed to the confounding effect of membership status.

Of the other factors examined, only age and membership status influenced downstream services overall. In particular, age was significantly associated with post services used for heart attack and colon cancer. Given that older clients are at increased risk for developing these conditions, it is not surprising that those over the age of 50 pursued related services. Membership status was significantly associated with increased services overall and particularly for glaucoma and

melanoma cancer. Medcan members are more likely to be aware of and purchase services in-house compared to non-members. Sex and family history did not significantly impact the use of related services for any of the conditions examined or collectively. It is possible that the relatively equal distribution of health service consumption among men and women reflects the unique client population of health-conscious consumers at Medcan. The finding related to family history was surprising given that lived experience is thought to impact risk interpretation and decision-making (Uhlmann et al. 2009). We would have expected those with positive family histories to perceive themselves to be at higher risk and therefore pursue related services. It is possible that this population may have felt reassured by the extensive approach to preventive health care advocated by this clinic.

The data from this study reflect the impact of PGT on a population of typically healthy individuals with increased access to health services and may not reflect the impact of PGT on all individuals who purchase PGT through a healthcare provider. Given that individuals in our cohort underwent a baseline medical exam, they might have been sufficiently reassured by the comprehensive nature of the assessment and opted not to pursue additional services. This could result in an underestimate of the impact of PGT on downstream service utilization. However, our findings demonstrated that additional services beyond those offered on the CHA were pursued in the follow-up period at nearly equal frequency among clients who pursued PGT and those who did not. An additional limitation pertains to our inability to access documentation of all downstream services, specifically services pursued outside of Medcan. Services not recorded in Medcan charts could have impacted the significance of the study findings. However, it is often more difficult to obtain health services in the public health sector without presenting clinical symptomatology.

This study is the first to examine the impact of PGT on subsequent health service utilization by examining actual services used in an existing healthcare setting. We also ascertained the influence of client characteristics including age, sex, membership status, personal health status, and family history in parallel. To gain further insight into the influence of PGT on healthcare utilization, future translational research capturing services used and downstream clinical outcomes would be valuable on a broader population level.

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Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the Hospital of Sick Children's Research Ethics Board and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Informed consent Appropriate consent was obtained from clients at Medcan.

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