

Title: Patient outcomes of genetic counseling: assessing the impact of different approaches to family history collection

Running title: Outcomes of family history collection method

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ABSTRACT

No studies have evaluated whether different modalities for collection of family history data influence patient outcomes of genetic counseling. We retrospectively compared outcomes of genetic counseling between patients whose family history (Fhx) was collected: a) via telephone prior to their appointment (FhxPrior), or b) during the appointment (FhxDuring). We used a psychiatric genetic counseling clinic database, where information about demographics and Fhx timing is recorded and patients complete the Genetic Counseling Outcomes Scale (GCOS, measuring empowerment) and Illness Management Self-Efficacy Scale (IMSES) immediately prior to (T1) and one-month after their appointment (T2). We used ANCOVA to evaluate the effect of Fhx method on patient outcomes at T2. Complete data were available for 240 patients and were used for analysis (FhxPrior, n=206; FhxDuring, n=34). GCOS and IMSES scores increased from T1-T2 ($p<0.0005$, and $p=0.004$, respectively). Though there was no difference between groups for GCOS ($p=0.412$), T2 IMSES scores were significantly higher for FhxPrior than FhxDuring after controlling for T1 scores ($p=0.011$). Our data suggest that obtaining Fhx via telephone prior to genetic counseling may lead to greater increases in patient self-efficacy as compared to obtaining Fhx during the genetic counseling appointment.

Keywords: PROMS; GCOS; genetic counseling outcomes scale; self-efficacy; empowerment; naturalistic study

INTRODUCTION

There is increasing recognition within clinical genetics of the importance of evaluating outcomes of the services delivered. However, despite a growing body of literature, there remains an incomplete understanding of how different aspects of the clinical genetics encounter – such as family history documentation - impact outcomes.

Documentation of family history is fundamental to the practice of genetic counseling^{1,2}. Family history information provides a basis for establishing differential diagnoses, assessing genetic risk, and informs genetic testing, medical care and patient support^{2,3}. In addition to its informational utility, the process of obtaining family history can also be used to explore family relationships and support, risk perception, and experience with the condition^{2,4,5}. The family history is considered a crucial tool in building a shared understanding of the etiology of the indicated condition, and the trust/rapport that is foundational for the positive patient outcomes of genetic counseling^{1,2,4,6}.

Studies of different approaches to family history collection (e.g. questionnaires⁷⁻¹⁰ , pre-appointment phone calls⁶, computer-based family history collection tools¹¹⁻¹⁴, and virtual genetic counselors¹⁵) have assessed: accuracy of information collected^{7,10-15}, accuracy with which individuals at increased risk of a condition can be identified^{7,10-13}, and feasibility of implementing such a tool in a clinical setting^{7,8,16}. These studies have focused on the medical utility of the family history; and although some have investigated patient satisfaction and/or ease of use^{11,15,16}, none (that we were able to identify) have yet investigated the effects of different approaches to family history collection on patient outcomes of genetic counseling. Though the existing literature provides little basis for hypotheses regarding how family history collection methods might

impact patient outcomes, it is theoretically possible that pre-appointment phone calls to collect and document family history may have some advantages. Specifically, first, a pre-appointment phone call could help clarify expectations, and research shows that patient outcomes are best when patients' expectations are met¹⁷. Second, it could initiate the building of trust such that rapport is already closer to being thoroughly established at the beginning of the session itself – again, research shows that patient outcomes are best when a strong rapport (or therapeutic alliance) has been established^{18,19}. Third, and more practically, because of issues around sustaining of attention, patients may be more able to fully attend to the content of the session itself if family history has been documented in advance. Relatedly, last, the genetic counselor may be more able to deliver their best possible level of care with regard to the counseling element of the session if they have not spent energy on eliciting and documenting family history immediately prior.

The purpose of this study was to explore whether different approaches to obtaining family history had different effects on patient outcomes of genetic counseling. Specifically, we sought to test the hypothesis that greater increases in 1) self-reported empowerment and 2) self-efficacy would be seen among those whose family history information was collected via telephone prior to the genetic counseling appointment as compared to those whose family history information was gathered at the beginning of the genetic counseling appointment.

PATIENTS AND METHODS

Overview

We conducted a retrospective, chart review study using data from the psychiatric genetic counseling clinic, based in Vancouver, BC, which provides services to people with a personal or

family history of a psychiatric disorder²⁰. Patients complete validated questionnaires as clinical assessment tools immediately prior to their genetic counseling session (T1), and at a standard one-month follow-up (T2). Specifically, all patients complete the Genetic Counseling Outcomes Scale (GCOS, described below) as a measure of empowerment²¹, and those with personal lived experience of mental illness also complete the Illness Management Self-Efficacy Scale (IMSES, described below) as a measure of confidence/self-efficacy in managing one's mental illness²². Previous research conducted in this clinic has demonstrated higher levels of empowerment and self-efficacy among patients following the genetic counseling appointment²⁰.

For the theoretical reasons outlined above, clinic counselors often attempt to obtain family history information prior to the appointment via telephone (FhxPrior), but for a proportion of patients, due to patient preference or scheduling challenges, family histories are obtained during the appointment (FhxDuring). Due to these clinical procedures, patients in the FhxPrior group have their family history obtained before completion of the T1 questionnaires; patients in the FhxDuring group have their family history obtained after T1 questionnaires. For all patients, family history is collected by the same genetic counselor that conducts the appointment.

All patient data (including demographics, family and personal history of mental illness, main concern at the time of the appointment, number of individuals attending the appointment, and questionnaire scores) is stored in a de-identified database for ongoing clinic management. Length of appointment and family history phone call (when applicable) was recorded in chart notes for a subset.

Instruments

GCOS: a 24 item, 7-point Likert-scale based questionnaire that measures empowerment²¹, with scores ranging from 24-168 and higher scores indicating higher levels of empowerment. The GCOS includes items such as: “I feel guilty because I (might have) passed this condition on to my children” and “I am able to cope with having this condition in my family”.

IMSES: a 9 item, Likert-scale type instrument measuring confidence in managing psychiatric illness²², with mean item scores ranging from 0-10, and higher scores indicating higher levels of self-efficacy. The IMSES includes questions such as: “How confident are you that you can do the different tasks and activities needed to manage your mental illness on your own between visits to your health care provider?”

Inclusion criteria

We reviewed the clinic database and selected all patient data that met the following criteria: 1) completed clinical care (including T2 follow up) between 1 February 2012 and 31 January 2017, 2) family history was obtained from the patient him/herself, and 3) the psychiatric GC appointment was conducted in-person (rather than by telephone or videoconference). Only those with at least one of the two questionnaires (GCOS and IMSES) complete at both T1 and T2 were included in one of the two study groups (FhxPrior or FhxDuring).

Institutional Review Board approval was received from the BC Children and Women’s Research Ethics Board (H15-01579).

Analyses

Descriptive statistics were applied to demographic data, and demographic factors were compared between study groups using Mann-Whitney U tests (age) and chi-square tests of

independence (sex, ethnicity, number of individuals at the appointment, personal or family history of mental illness). GCOS scores were calculated according to instrument-specific instructions. Overall IMSES scores were calculated (after excluding those with more than one missing item) by taking the mean of answered items.

To test differences in patient outcomes between FhxPrior and FhxDuring groups, we conducted one-way between-groups analyses of covariance (ANCOVAs) on T2 GCOS and IMSES scores using baseline T1 scores as the covariate (only data from charts containing both T1 and T2 data were included). Assumptions for continuity, independence of observations, homogeneity of variance, and normality of residuals were met. Tests for (family history method)*(T1 score) interaction terms were performed to confirm homogeneity of regression slopes. To provide context in which to interpret our hypothesis, we also conducted several other tests. First, we performed paired sample *t*-tests to evaluate change in GCOS and IMSES scores from T1 to T2 for both FhxPrior and FhxDuring groups, and for both of the two groups combined.

Second, we compared the two study groups (FhxPrior and FhxDuring) in terms of T1 scores and time spent with the genetic counselor (including length of genetic counseling session, and total contact time (genetic counseling session + family history phone call, if applicable)). We also assessed whether the patients included in our analysis of the hypothesis were representative of patients more broadly by comparing T1 scale scores against those who did not complete T2 data.

Last, we used hierarchical multiple regression to assess the effect of total contact time on patient GCOS and IMSES scores at T2, after controlling for T1 scores. This analysis was performed with the subset of patient charts for which total contact time was recorded. Sample sizes were

insufficient to allow simultaneous testing of total contact time and study group (FhxPrior or FhxDuring) effects on T2 scores; thus the regression was conducted on the group as a whole.

Data distributions were assessed for normality using Shapiro-Wilk tests. Independent *t*-tests were applied to data that was normally distributed (baseline GCOS T1 scores, total time spent with GC); and Mann-Whitney U tests used for data that was not normally distributed (baseline IMSES T1 scores; length of appointment). We used a significance threshold of 0.025 for hypothesis testing, and for all other analyses (conducted simply to allow for more comprehensive interpretation of the hypothesis), we used a significance threshold of $p < 0.05$. All analyses were performed using IBM SPSS Statistics version 23 (IBM Corp., Armonk, N.Y., USA).

Given that this was a retrospective study using a convenience sample, we conducted post hoc power calculations²³.

RESULTS

The clinic database contained 363 patient charts that met all inclusion criteria. Of these, 240 included at least one of the two questionnaires completed at both T1 and T2; and were therefore included in testing of our hypothesis (FhxPrior $n=206$, FhxDuring $n=34$). The remaining 123 patient charts were not included in testing our hypothesis due to absent T2 data, and were simply used to assess whether the patients included in analysis of our hypothesis were representative of clinic patients more broadly.

Demographic data are shown in Table 1.

<<Insert Table 1 about here>>

Contextual data

Scale scores by group and timepoint are shown in Figures 1 and 2. GCOS scores increased from T1 to T2 for FhxPrior ($p<0.0005$), for FhxDuring ($p<0.0005$) and for the sample overall ($p<0.0005$) (Table 2). IMSES scores increased from T1 to T2 for FhxPrior ($p<0.0005$) and the sample overall ($p=0.004$) but there was no significant change in IMSES scores for FhxDuring ($p=0.198$).

<<Insert Table 2 here>>

FhxPrior and FhxDuring groups had similar demographic characteristics to each other, and to clinic patients more generally (see Table 1). Baseline GCOS and IMSES scores did not differ between FhxPrior and FhxDuring study groups (GCOS $p=0.950$; IMSES $p=0.882$); or between patients that had T2 data (who were included in testing the hypothesis) and patients that did not have T2 data ($p=0.782$ and $p=0.843$, respectively).

Mean *appointment length* was similar between groups (FhxPrior 86.0 minutes; FhxDuring 91.4 minutes; $p=0.349$, see Table 1). However, the *total contact time* between the patient and counselor (length of appointment + length of family history phone call, if applicable) was significantly greater for the FhxPrior group (124.1 minutes) than for the FhxDuring group (91.4 minutes; $p<0.0005$). Despite this, no significant relationship was observed between total contact time and T2 GCOS or IMSES scores. After controlling for T1 GCOS scores (which explained 39.4% of T2 GCOS score variance; $p<0.0005$), total contact time did not significantly improve the

regression model and accounted for 0.7% of T2 GCOS score variance (R square change=0.007, F change (1,70)=0.874, p =0.353; n =73). Similarly, after controlling for T1 IMSES scores (which explained 49.5% of T2 IMSES score variance; p <0.0005), total contact time accounted for 1.1% of T2 IMSES score variance (R square change=0.011, F change (1,45)=0.956, p =0.333; n =48).

Given our sample sizes, we had 80% power to detect a difference in GCOS and IMSES scores between groups with a minimum effect size of d =0.20 and d =0.26, respectively. Post-hoc power calculations revealed adequate power for detecting changes in scores from T1 to T2 (GCOS P =1.00; IMSES P =0.84).

Patient outcomes for FhxPrior and FhxDuring groups

There was no difference in GCOS T2 scores between FhxPrior and FhxDuring groups after controlling for T1 score ($F(1,227)$ =0.68, p =0.412, d =0.12). Testing for (family history method)*(T1 GCOS score) interaction was not significant (p =0.936).

The difference in T2 IMSES scores between groups after controlling for T1 score was significant ($F(1,138)$ =6.64, p =0.011). Estimated marginal means were higher for the FhxPrior group (7.849) than the FhxDuring group (7.225; mean difference 0.624 points), with a moderate effect size (d =0.44). Testing for (family history method)*(T1 IMSES score) interaction was not significant (p =0.369).

<<Insert Figures 1 and 2 about here>>

DISCUSSION

This study is the first to report on the impact of method of family history collection on patient outcomes of genetic counseling. We found that although method of family history collection had no impact on the patient reported measure of empowerment (after adjusting for T1 GCOS scores, there was no difference in T2 GCOS scores between our study groups; $d=0.12$), it did seem to impact self-efficacy. Specifically, after adjusting for T1 IMSES scores, the method of obtaining family history had a significant effect on T2 IMSES scores ($d=0.44$), with scores increasing for the FhxPrior group, and decreasing for the FhxDuring group (see Limitations for considerations related to group size and power).

The contextual data in which to interpret the results of testing the hypothesis showed large increases in empowerment following genetic counseling for both groups individually, and combined. This finding was expected based on previous research conducted in our clinic²⁰. Larger effect sizes were observed in the present study (overall $d=1.21$, as compared to prior study $d=1$), likely due to greater sample size.

Similarly, the increases in self-efficacy with a small to moderate effect size for the combined groups ($d=0.25$) is broadly consistent with our previous findings²⁰. However, very different effects were found for FhxPrior and FhxDuring groups, with the former group demonstrating a larger positive change than the group overall ($d=0.34$), and a non-significant negative trend for the latter group.

Our finding that the method of obtaining family history impacted patient reported self-efficacy but not empowerment warrants exploration, given that these are related constructs^{24,25}. A possible explanation for this finding is that the effects of family history gathering on patient

empowerment could be masked. Specifically, the study revealed large increases in empowerment following psychiatric genetic counseling across groups. The magnitude of this increase may be large enough that smaller effects on empowerment (such as those resulting from the method of obtaining family history) could not be detected. Indeed, when analyzing our study groups separately, the effect of genetic counseling was quantitatively larger for those whose family history was obtained in advance; however the difference was not statistically significant, likely because the effect sizes – although different - were very large for both groups ($d > 1$). In contrast, change in self-efficacy scores was of small to moderate overall effect size ($d = 0.25$), which may allow influence of factors such as the method of family history collection to be more clearly revealed.

Though appointment length was the same between groups, significantly more total clinical time was spent on patients in the FhxPrior group compared to patients in the FhxDuring group - in real terms, approximately 30 minutes. This highlights interesting and complex questions for the practice of evidence-based genetic counseling regarding how to manage the tension inherent to situations where practices that allow greatest efficiency are in conflict with those that produce optimal patient outcomes.

Genetic counselors in the studied clinic devote substantial attention to obtaining family history, regardless of whether this is done prior to or during the appointment. The process is used as an opportunity for psychosocial exploration with the patient (indeed, this and the session itself could be described as “psychotherapeutically oriented” rather than educationally oriented – a stance adopted due to evidence that the former are associated with better patient outcomes²⁶). The family history gathering process is used as an opportunity to explore patients’ existing

explanations, experiences and family interactions – all of which are integrated into the genetic counseling discussion. However, despite the often-cited value of the family history as a psychosocial tool^{2,4} and the theoretical advantages to obtaining family history prior to a GC appointment (to clarify patient expectations and initiate the development of rapport, and to enable patients and their genetic counselor to more fully attend to the *counseling* portion of the session), we found no evidence that the process of obtaining family history alone has a positive impact on patient empowerment or self-efficacy. Specifically, for the FhxPrior group, family histories were obtained *before* completing T1 questionnaires and for the FhxDuring group, they were obtained afterwards (because for all patients, questionnaires were completed at the beginning of the face-to-face interaction) - therefore there was potential for baseline scores to differ between groups. However, we found no significant interaction terms between family history method and T1 scores, indicating that the process of obtaining family history alone does not significantly impact patient outcomes. Further, there was no statistical difference in T1 scores between groups, suggesting that it is likely that the full value of the family history as a counseling tool cannot be realized until it is incorporated into the body of the genetic counseling session – for example, by using the pedigree to anticipate psychosocial needs⁴ and to personalize risk discussions⁶ - but additional studies are needed to explore this further.

Limitations

This was a naturalistic study based on a convenience sample and was therefore influenced by the nature of the routine practice in the clinic in which the study was conducted, which involves collection of family histories during the appointment only when a phone call could not be scheduled in advance, or when this was the patient's preference. This raises three issues. First, the possibility that those in the FhxDuring group were qualitatively different from other patients

in some way. However, this reasoning is unlikely to fully account for our results, because: 1) study groups were similar according to demographic characteristics recorded, 2) differences in T2 IMSES scores were observed *after correcting for T1 scores*, meaning that family history method had an effect regardless of patients' baseline state; and 3) T1 GCOS and IMSES scores were *not* different between our study groups, indicating that patients whose family history was obtained during their appointment had similar baseline levels of empowerment and self-efficacy as those whose family history was obtained in advance. We cannot rule out the possibility that there were qualitative differences between groups that were not captured in the present study – this would constitute a fruitful area for future investigation.

Second, as discussed above, the nature of the clinical procedures (completion of questionnaires at the beginning of the face-to-face interaction for all patients) resulted in collection of family history before completion of T1 scales for the FhxPrior group, and collection of family history after completion of T1 scales for the FhxDuring group. However, as discussed above, our analytical approach to hypothesis testing accounted for this difference, and further, there was no difference in T1 scores between groups. The last effect of the clinical practice on our study was that there was a discrepancy in sample sizes between groups (FhxPrior n=206; FhxDuring n=34), however, post hoc power calculations revealed good power to detect effects for our study questions, with the exception of the effect of family history timing on patient empowerment, where the effect size was very small.

Given the difference in total contact time between groups, we investigated whether this could explain our results. However, we found no significant effect of total contact time on T2 scores for GCOS or IMSES for patients overall. This suggests that the difference in T2 IMSES scores is not

explained by the greater amount of clinical time spent with the FhxPrior group. However, further studies that can more clearly delineate between the effects of family history method, length of appointment and/or total contact time, and content of the genetic counseling session are warranted.

Our outcome measures were limited in terms of duration (1-month post-genetic counseling; longer term effects were not assessed), and the majority of patients were female, European and had a personal history of mental illness. Caution must be used in generalizing these results to other genetic counseling settings.

Conclusion

This is the first study of which we are aware to examine patient outcomes of different family history collection methods. Our findings suggest that obtaining family histories in advance of a psychiatric genetic counseling appointment requires more time, but leads to greater benefits for patients. Given the challenges many clinics face regarding patient volume, further studies should examine the effects of additional family history collection methods – such as using genetic counseling assistants, questionnaires or web-based tools – on patient outcomes. In addition, these studies may help identify patient groups who are less likely to benefit to the same extent as others, and who may benefit from additional counseling, support or follow-up. Our results also support previous findings of the important positive patient outcomes of psychiatric genetic counseling²⁰. Though there is a great need for additional research in this area²⁷⁻³⁰, our results add to the growing literature of genetic counseling outcomes research, which will inform future evidence-based practice in clinical genetics.

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Figure Legends

Figure 1. GCOS scores prior to GC (T1) and one month post-GC (T2) for FhxPrior and FhxDuring study groups. The Y-axis scale reflects the range of possible GCOS scores. GC=genetic counseling; GCOS=Genetic Counseling Outcomes Scale; FhxPrior=family history obtained prior to the GC appointment; FhxDuring=family history obtained during the GC appointment.

Figure 2. IMSES mean scores prior to GC (T1) and one month post-GC (T2) for FhxPrior and FhxDuring study groups. The Y-axis scale reflects the range of possible IMSES mean scores. GC=genetic counseling; IMSES=Illness Management Self-Efficacy Scale; FhxPrior=family history obtained prior to the GC appointment; FhxDuring=family history obtained during the GC appointment.