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The Application of Lean Methodology in Hereditary Cancer Syndrome Screening: Can a Clinical Chatbot Lead to Improvement?

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Abstract

Background: Approximately 5.6% of the general population carries a germline pathogenic variant in a cancer gene. Current screening methods fail to identify many of these patients. Providers report limitations in time and expertise as barriers to identification of high-risk patients. Gia® (Genetic Information Assistant) is a cloud-based genetic information and assessment chatbot from Invitae designed to assist screening patients for high-risk pathogenic variants and educate regarding genetic testing.

Objective: To utilize Lean methodology to map the current process of screening for high-risk individuals and compare to an ideal future state process that utilizes Gia to model how Gia may increase rates of screening for hereditary cancer syndromes in less time.

Study Design: Current process observations took place in two general gynecology clinics, one that cares for a diverse and underinsured population, and another that serves a population with a higher proportion of privately insured patients. A value stream map was developed based on observations of the current state. Ideal state maps were then developed to incorporate Gia and illustrate how it may be used to improve areas identified as inefficient in the current state.

Results: Screening for hereditary cancer pathogenic variants occurred in 8 of 10 observed encounters in Clinic A and 9 of 9 in Clinic B (80% *vs*. 100%). In Clinic A, 40% (4/10) of patients were high-risk for a pathogenic variant and of these, 75% (3/4) had an appropriate provider action taken. In Clinic B, 33% (3/9) of patients were noted to be high-risk, and all received appropriate intervention from the provider (3/4 in Clinic A *vs*. 3/3 in Clinic B). The average provider time investment to screen in Clinic A was 8.3% of the encounter (average 99 seconds) compared to 9.5% of the encounter (average 114 seconds) in Clinic B. High-risk patient screening in Clinic A occupied 13.9% of the encounter (average 167 seconds) and low-risk patient screening occupied 2.6% of the encounter (average 31 seconds). Similarly, in Clinic B, high-risk screening occupied 14.4% of the encounter (average 173 seconds) compared to 7% of the encounter (average 84 seconds) for low-risk patients.

Conclusion: Screening for pathogenic variants in genes linked to hereditary cancer is not standardized or universal, and may exacerbate disparities in care. Identification of barriers in screening processes and use of technology such as Gia to overcome these barriers may result in more universal and equitable genetic screening.

Keywords: Familial cancer; Genetic screening; Health technology; Pathogenic variants; Quality improvement

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Introduction

It is estimated that 5% to 10% of all cancers diagnosed are secondary to a germline Pathogenic Variant (PV) in a cancer susceptibility gene, and that 5.6% of the general population carries one of these PVs [1,2]. The advances in gene sequencing technology and decreased costs have increased actionable PVs linked to cancer, making the identification of those with hereditary cancer syndromes such as Lynch syndrome and Hereditary Breast and Ovarian Cancer Syndrome (HBOC)

easier than ever. Identification of PVs, ideally before a diagnosis of cancer, subsequently allows for risk-reducing interventions, such as hysterectomy for the prevention of endometrial cancer in those with Lynch syndrome, as well as mastectomy and risk reducing Salpingo-oophorectomy to prevent breast and ovarian cancer in those with HBOC [3-6]. As such, the American College of Obstetricians and Gynecologists recommends routine screening for hereditary cancer risk [7]. Despite guidelines recommending the practice and advances in genetic testing, many individuals with a hereditary cancer syndrome remain undiagnosed, preventing them from accessing high-risk surveillance and risk-reducing care [8,9].

The process for identification of high-risk individuals, or those with a PV in germline cancer susceptibility gene, prior to a cancer diagnosis typically begins in a primary care provider's office, where screening of personal and family history occurs. The provider then assigns a risk, and if the patient is thought to be high-risk, genetic testing is offered or the patient is referred to a genetic counselor or other hereditary cancer specialist. Unfortunately, this pathway is highly variable and fails to identify many high-risk patients. One study found that while 83% of providers reported that they routinely assessed hereditary cancer risk, only 33% collected a detailed family history to include third degree relatives, and even fewer used a risk assessment tool [10]. The same study found that 39% of providers who do not place referrals for genetic counseling and testing reported uncertainty in which patients should be referred. Other reported reasons for not ordering testing include lack of time, concerns about cost and genetic discrimination towards the patient, and discomfort with ordering, interpreting, and managing the results of genetic testing [10-13]. To allow for life-saving care for high-risk individuals, novel approaches to the screening process that address these specific issues are needed.

Gia® (Genetic Information Assistant), a cloud-based genetic education and assessment chatbot from Invitae , is one new approach designed to assist with the identification of high-risk patients [14]. Through direct patient interaction *via* a computer, tablet, or mobile device, Gia can utilize an individual's personal and family history to assess hereditary cancer risk and educate regarding genetic testing options and results. It also informs providers when genetic testing is indicated based on patient inputs and professional guidelines, and facilitates ordering correct testing, which may offer a solution to barriers regarding provider confidence in their ability to identify and test patients. A link to access Gia can be sent prior to a patient's clinical appointment with a provider, potentially assisting with time limitations for screening, risk stratification, and pre-test counseling in a clinical encounter. Gia is estimated to take 3 min to 5 min of a patient's time for genetic risk assessment.

Considering hereditary cancer risk screening as an opportunity for quality improvement and Gia as a potential solution, we became interested in the application of Lean thinking to the problem. Lean methodology is an operational philosophy with roots in the automobile industry that has been applied to many sectors, including quality improvement in healthcare [15]. Its approach centers on identifying steps in a process that do not add value for a customer, or patient in the healthcare industry, and eliminating these wasteful steps to make a process more efficient.

Given the underdiagnosis of hereditary cancer syndromes and the importance of identifying affected individuals, we sought to use Lean methodology to find areas for improvement in the hereditary cancer risk screening process, and to assess whether Gia may be a solution. We thus created a value stream map of the current process and calculated provider time required to screen for high-risk individuals in two general gynecology clinics to determine areas for improvement. We then mapped an ideal future state process that utilizes Gia to model how it may increase rates of screening and testing for hereditary cancer syndromes in a reduced amount of time.

Materials and Methods

Study setting

Observations of the current state of genetic screening for hereditary cancer took place in two general gynecology clinics affiliated with the University of Virginia (UVA).

Clinic A is located within the main medical center in downtown Charlottesville where residents see patients and are supervised by an attending physician. The patient population of Clinic A is racially and ethnically diverse, and use of an in-person or remote interpreter is frequently required. Approximately half of patients are insured *via* Medicaid or are uninsured (48.6%, Table 1).

Clinic B is located in a medical office building on the outskirts of the city, about 4 miles from the main medical campus. Patients are seen by attending physicians. The patient population of Clinic B is primarily Caucasian, and 24.3% are insured *via* Medicaid or are uninsured (Table 1).

Value stream mapping

Lean methodology insists that the first step in any improvement cycle is to define value for the patient, which in this case is the identification of cancer predisposition PVs and offering of risk-reducing care [16]. The next step is to develop a value stream map, which plots all actions required to produce the defined value, and highlights steps in the process that do not directly add value for the patient [16,17]. We developed value stream maps of the current clinic process of screening for PVs related to cancer, outlining points of time expenditure and process variability. Value stream maps were generated with the assistance of clinic leaders and the study team, and were improved following in-clinic observations by the study team.

Observations in Clinic A were performed over the course of 2 days in April 2023, and all observations in Clinic B were performed on a single day in May 2023. Clinic days were chosen based on researcher and provider availability. The encounters of 3 resident providers were observed in Clinic A and the encounters of 1 attending provider were observed in Clinic B. This is because in a single day in Clinic A, multiple providers work through one large schedule, and in Clinic B, there is a single provider working through a dedicated schedule. All annual physical exam appointments and new patient gynecology encounters were observed, as these are the appointments when a full patient history review and genetic screening are classically performed. There were no formal systems in place or tools utilized for genetic screening in either clinic. Observation of an encounter started when a medical assistant reported to the provider that the patient was ready to be seen and relayed patient concerns, and the observation ended when the patient left the room.

Measures of interest during observations included time spent on genetic screening within an encounter, percent of patients screened of those seen, percent of patients determined to be high-risk for a hereditary cancer PV of those screened, and percent of high-risk patients who received "appropriate intervention" in the form of

confirmation of prior testing results or either an order for genetic testing or referral to a hereditary cancer specialist (defined as either a genetic counselor or provider specializing in hereditary cancer). Patients were classified as high-risk for a PV in a cancer gene if they met criteria for testing based on National Comprehensive Cancer Network (NCCN) guidelines [18,19]. Time spent on genetic screening included time required to review personal and family history, to discuss risk and recommendation for testing or referral, and to order said testing or referral, if indicated. Time for patient questions related to the subject of genetic screening was also included.

The pre-test genetic screening value stream map was finalized with insight from observations of the current state. Points in the process that required significant provider time or were below a set goal of 90% screening or intervention were then identified as areas for improvement. Ideal future state maps were then developed to incorporate Gia and how it may be used to remove those points requiring improvement in the current state maps [16]. All value stream maps were created with Microsoft Excel and Visio.

IRB review

This study was performed as a quality improvement initiative, and therefore Institutional Review Board (IRB) approval was not required, and the IRB confirmed this upon being alerted of intent to publish.

Results

A value stream map of the observed current state of screening for hereditary cancer PVs is shown in Figure 1, with opportunities for value loss noted in red. In total, 10 patient encounters were observed in Clinic A and 9 were observed in Clinic B. The method utilized to screen patients for hereditary cancer risk in every encounter in which screening was performed involved the provider asking if a patient had any personal or family history of cancer, and if so, which cancers and at what age was it diagnosed. In total 8 patients were screened for hereditary cancer risk in Clinic A and 9 were screened in Clinic B (80% *vs.* 100%). In Clinic A, 40% (4/10) of patients were noted by the observer to be high-risk and of these, 75% (3/4) had an appropriate provider action taken, meaning they were counseled regarding hereditary cancer and offered a referral to a hereditary cancer specialist or results of prior genetic testing were confirmed. The fourth high-risk patient received no intervention for her high-risk status. In Clinic B, 33% (3/9) of patients were noted to be high-risk, and all received appropriate intervention from the provider.

Each annual or initial patient appointment was scheduled for 20 min. The average provider time invested in the screening process in Clinic A was 99 sec per encounter compared to 114 sec in Clinic B (Table 2). This equated to 8.3% of the encounter in Clinic A and 9.5% of the encounter in Clinic B. When stratifying time invested by patient risk level in Clinic A, high-risk patient screening occupied 13.9% of the encounter (average 167 seconds) and low-risk patient screening occupied 2.6% of the encounter (average 31 seconds). Similarly, in Clinic B, high-risk screening occupied 14.4% of the encounter (average 173 seconds) compared to 7% of the encounter (average 84 seconds) for low-risk patients.

After mapping the current state process, we were able to build an idealized future state value stream map that incorporates Gia as a potential solution to the identified issues of 1) missed opportunities for screening ("Provider inquiries about personal/family history" step in Figure 1), 2) missed opportunities for intervention ("Provider assigns risk" and "Provider educates, offers referral to CG or HR clinic" steps in Figure 1), and 3) limited provider time (all 3 red steps in Figure 1). The future state value stream map can be seen in Figure 2. In this future process, every patient scheduled for a new or annual appointment receives a link prior to their appointment that invites them to interact with Gia, helping to standardize who gets screened and how they are screened, and reducing time to review history in the office. After the patients complete the brief screening with Gia, a report is sent to the provider that states whether that patient should have genetic testing ordered, which criteria from professional guidelines are fulfilled that support the recommendation, and which test should be ordered.

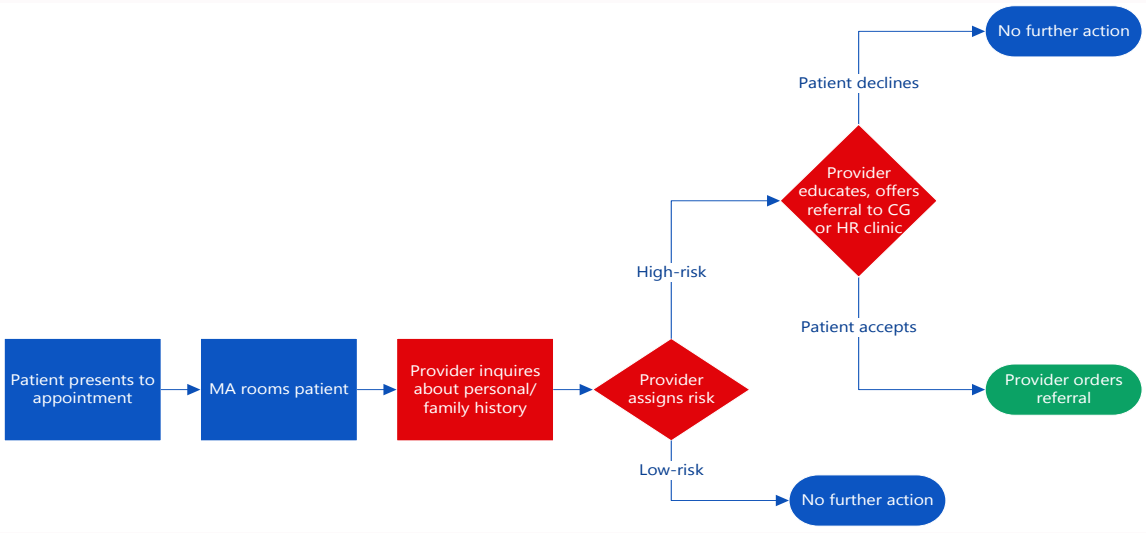

Figure 1: Current state value stream map of screening for hereditary cancer risk. This map illustrates the current, as is process of screening for genetic predisposition to cancer in two general gynecology clinics, starting from patient presentation to placing referral for genetic testing, if indicated.
Blue: necessary points; Green: value added; Red: opportunity for value loss; Rectangle: process point; Oval: endpoint; Diamond: decision point; MA: Medical Assistant; CG: Cancer Genetics; HR: High-Risk

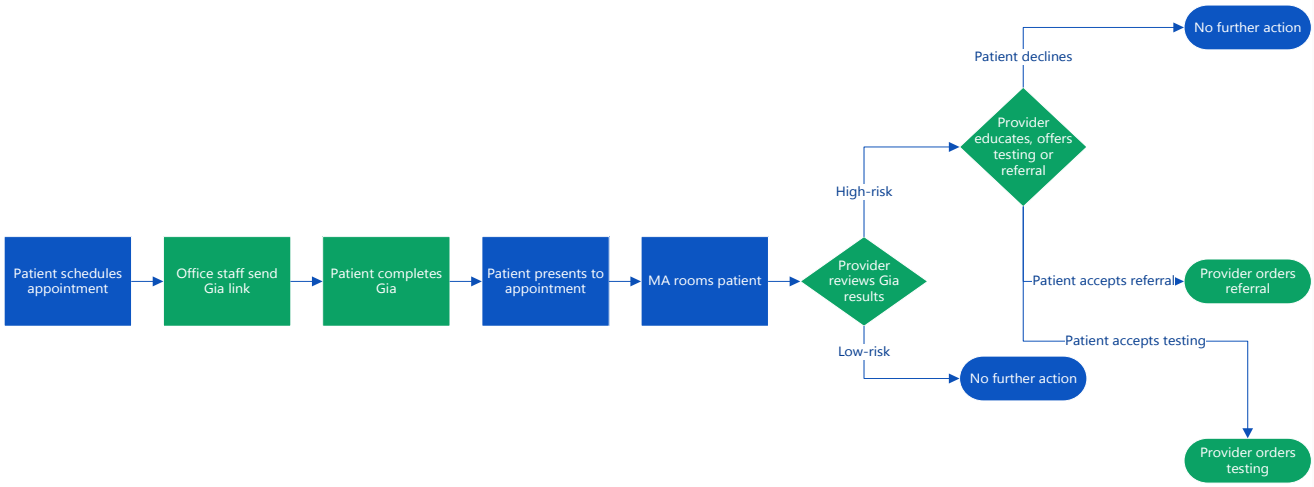

Figure 2: Ideal future state value stream map of screening for hereditary cancer risk. This process map illustrates the ideal future state process of screening for genetic predisposition to cancer that incorporates Gia as a tool to solve issues of limited time and missed opportunities for screening and intervention as seen in the current state.
Blue: necessary points; Green: value added or improved; Rectangle: process point; Oval: endpoint; Diamond: decision point; Gia: Genetics Information Assistant; MA: Medical Assistant; CG: Cancer Genetics; HR: High-Risk

Table 1: Insurance coverage of patients in the observed clinics.

Coverage Type	Percent of Patients in Clinic A	Percent of Patients in Clinic B
Private	42.70%	71.40%
Medicare	6.00%	3.60%
Medicaid	27.20%	20.40%
Uninsured	21.40%	3.90%
Other	2.70%	0.70%

Table 2: Provider Time investment in hereditary cancer risk screening.

Patient Risk Assessment	Time per Encounter in Clinic A	Time Per Encounter in Clinic B
	Average time in seconds (range)	Average time in seconds (range)
All	99 (11-252)	114 (24-378)
Low-risk	31 (11-60)	84 (40-117)
High-risk	167 (108-252)	173 (24-378)

Comment

Principal findings

In this quality improvement project, observations of the current state of screening for PVs linked to hereditary cancer revealed several areas for process improvement, including the percent of patients screened and percent of high-risk patients receiving appropriate intervention. Ideally, 100% of patients would be screened for hereditary cancer risk, and while this goal was met in Clinic B, Clinic A screened 80% of patients. Similarly, of high-risk patients in Clinic B, all received an appropriate provider intervention, whereas only 75% received appropriate action in Clinic A.

Another area for improvement identified in the current process is time spent on screening during a patient encounter. With many annual exam and new patient appointments only scheduled for 20 min in these clinics, spending nearly 2 min, and closer to 3 min for high-risk patients, is 10% to 15% of that allotted time.

Results in the context of what is known

This study highlights inequity in screening and testing for patients presenting for annual gynecologic care, consistent with the underdiagnosis of hereditary cancer syndromes outlined in available literature [8-10,13]. Our findings also support reports that provider time is a barrier to genetic screening [10-13]. One such study found that 25% of primary care providers felt they did not have time to address patient concerns regarding genetic risk [10]. Provider concern regarding time is validated by our study, given that up to 15% of encounter time was dedicated to genetic screening, a substantial amount considering the myriad of issues needing to be addressed in an annual or initial visit. Standardization of family history collection and risk assessment with a tool such as Gia that can function outside the clinic visit has the potential to increase the identification of high-risk patients while decreasing provider time in the clinic.

While there are many other studies that have applied Lean methodology to quality improvement initiatives in healthcare, its application to enhance genetic screening has been limited. This study is unique in that it describes precisely where and when a chatbot like Gia may be used to correct inefficiencies identified in a genetic screening value stream map.

Clinical implications

Mapping the current state process was essential for identifying weaknesses in screening, such as rates of screening and intervention in Clinic A below 100%. Reasons for different rates of screening and intervention between clinics may stem from provider experience or confidence, as patients in Clinic A were seen by residents who have not been practicing as long as the attending in Clinic B. It may also be because new patient visits are sometimes treated as problem-focused patient visits in which a patient's full history is not explored. Regardless of the reasoning, this pattern is troubling not just for missed opportunities for patient care, but also for the possibility of widening disparities, as the diverse and underinsured population of Clinic A received less appropriate care than the more affluent population of Clinic B in our observations.

In future state, Gia presents time savings for the provider and may improve provider confidence in their ability to perform genetic

screening and testing. Ideally, this would increase the number of general gynecologists placing orders for genetic testing, an important option given evidence that patients are more likely to complete genetic testing if it is ordered at the time of their appointment rather than waiting for a referral [20]. While Gia may ease the burdens of provider time and self-efficacy, implementation of new technology into the standard workflow of a clinic would not be without challenges. Some of the time saved for providers by implementing Gia would shift onto the office staff, who would need to send Gia links prior to appointments. Gia would need to be integrated with a clinic's electronic medical record for maximum time and efficiency benefit for providers and office staff alike, which is possible but requires upfront effort.

Another challenge is barriers patients may face. Similar to how provider time saved would shift onto office staff, it would also shift onto patients. The minutes saved for a provider to screen the patient would now be spent by the patient outside of the appointment time, highlighting that green "value added" steps in the value stream maps most directly add value for providers rather than patients. However, time shifted to patients may open time to discuss other concerns during an encounter, and may add value. Accessibility of Gia is another potential barrier. Currently, Gia is only available in English and Spanish. This would need to be addressed if disparities in screening are to be prevented. Furthermore, access to electronics and internet may be an issue for some patients, though if they were able to reach the office for an appointment, this barrier could be surmounted with tablets provided in clinic.

Research implications

In addition to changes in clinic workflow and infrastructure, adoption of new technology faces the hurdle of provider and patient acceptability. Will patients use Gia? Will providers feel like standardized screening for a genetic predisposition to cancer is important enough to add to their to-do lists for a short annual exam? Available literature suggests that use of chatbots is acceptable to patients for aspects of genetic testing and counseling [2,21]. Our team is currently studying perspectives of both patients and providers on genetic screening and use of technology to assist in the diagnosis of hereditary cancer syndromes. Our hope is to use the information from this quality improvement initiative to guide implementation of Gia within our system.

Strengths and Limitations

Strengths of this quality improvement study include a single observer of all encounters for standard results collection. The inclusion of two clinics with differing provider and patient populations is also a strength, as this increases the generalizability of results to clinics elsewhere.

The Hawthorne Effect, when subjects change their behavior when they know they are being studied, is a potential limitation of this study. It is possible the observed providers screened more patients than they typically would because they knew they were being observed. Another limitation is the lack of direct comparison between the current state process and a state after Gia implementation. The process map including Gia is theoretical at this point, and benefits are hypothesized. Our future direction is to integrate Gia and perform a direct comparison between processes, with hopes of realizing the hypothesized benefits.

Conclusion

Identification of individuals with a genetic predisposition to cancer is essential to offering high-quality, life-saving healthcare. The current process of screening patients for PVs in our institution was found to have opportunities for improvement that are actionable, and we look forward to harnessing the power of technology such as Gia to promote more universal and equitable genetic screening.

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