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PROFESSIONAL ISSUE

Development of a Streamlined Work Flow for Handling Patients' Genetic Testing Insurance Authorizations

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Abstract Obtaining genetic testing insurance authorizations for patients is a complex, time-involved process often requiring genetic counselor (GC) and physician involvement. In an effort to mitigate this complexity and meet the increasing number of genetic testing insurance authorization requests, GCs formed a novel partnership with an industrial engineer (IE) and a patient services associate (PSA) to develop a streamlined work flow. Eight genetics clinics and five specialty clinics at the University of Michigan were surveyed to obtain benchmarking data. Tasks needed for genetic testing insurance authorization were outlined and time-saving work flow changes were introduced including 1) creation of an Excel password-protected shared database between GCs and PSAs, used for initiating insurance authorization requests, tracking and follow-up 2) instituting the PSAs sending GCs a pre-clinic email noting each patients' genetic testing insurance coverage 3) inclusion of test medical necessity documentation in the clinic visit summary note instead of writing a separate insurance letter and 4) PSAs development of a manual with insurance providers and genetic testing laboratories information. These work flow changes made it more efficient to request and track genetic testing insurance authorizations for patients, enhanced GCs and PSAs communication, and reduced tasks done by clinicians.

Keywords Genetic testing · Genetic counselors · Insurance authorization · Insurance issues · Lean evaluation · Patient services associates · Industrial engineer

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Introduction

Advances in genetics and the advent of next generation sequencing technologies has resulted in the introduction of many new genetic tests, test options, and an increase in the number of genetic testing laboratories (Genetic Testing Registry 2017, GeneTests 2017). More patients are being offered genetic testing to inform their medical care, but use is limited due to problems with obtaining insurance coverage of these tests (Capasso 2014; Prince 2015; Secretary's Advisory Committee on Genetics, Health and Society 2006; Spoonamore and Johnson 2016). Obtaining insurance coverage is a multi-step, time-involved process, which often requires genetic counselor (GC) and physician involvement (Fig. 1), and presents several challenges.

Insurance coverage of a genetic test, like other medical tests, generally depends on demonstrated clinical validity and evidence of clinical utility, along with there being documentation of medical necessity (Burke 2014; Capasso 2014; Prince 2015; Secretary's Advisory Committee on Genetics, Health and Society 2006; Spoonamore and Johnson 2016). Generally, insurers have a specific list of criteria that have to be met for genetic testing to be considered medically necessary and some may even require

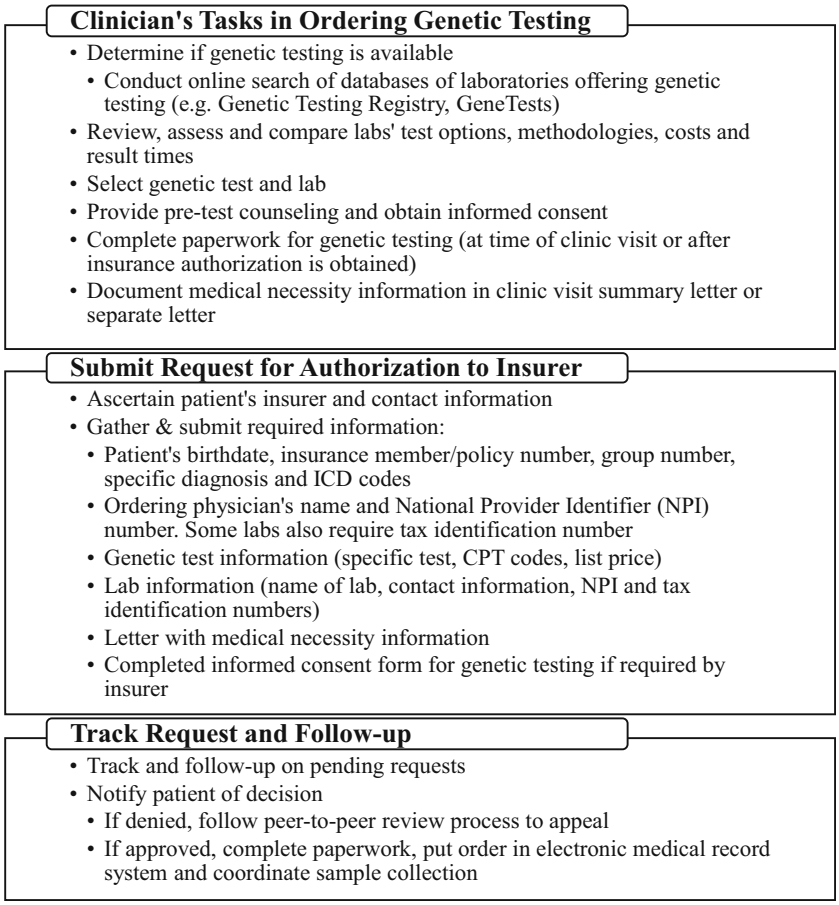

Fig. 1 Steps in ordering genetic testing and obtaining insurance authorization

genetic counseling services to make this determination (Capasso 2014; Latchaw et al. 2010). The newness of many genetic tests and the fact that many genetic conditions affect small subsets of the population means that clinical utility and cost-effectiveness data is often limited or lacking. In addition, few identified genes and their associated syndromes have established practice guidelines for testing decisions and medical management (Uhlmann and Sharp 2012).

Genetic tests can range in price from hundreds to several thousand dollars. Ascertaining the cost of genetic testing and determining what the patient will be billed is challenging. The list price of a genetic test may not be readily available at a laboratory's website for proprietary reasons and can vary significantly depending on the specific test, methodology, testing laboratory and whether the institution, insurer, or patient is billed (Spoonamore and Johnson 2016; Uhlmann 2009). Negotiated contracts between institutions and labs and institutions and insurance companies impact institutional billing and contracts between labs and insurance companies impact direct insurance billing (Spoonamore and Johnson 2016). What the patient is billed and ultimately will pay also depends on institutional "mark-ups," "balance-billing" policies, whether a sample is being sent to an in-network or out-of-network laboratory and the patient's deductibles and coinsurance (Capasso 2014; Spoonamore and Johnson 2016). Additionally, there are fees for obtaining and shipping the specimen.

Some institutions will not permit direct billing for genetic testing by an outside lab, which can be problematic for patients if the lab either does not handle insurance billing or only will handle for in-state patients. If the institution or insurer cannot be billed by the lab, the patient has to have the resources to self-pay and then will need to submit genetic testing expenses to their insurer for potential reimbursement. For patients who need to set up payment plans, this may not be an option offered for genetic testing done by outside laboratories because the institution would have to cover the cost if the patient does not pay. There are some labs that offer patient payment plans for uninsured or underinsured patients who meet their financial assistance program criteria.

Insurance coverage of genetic testing is highly variable and depends on the patient's insurer, the specific plan and test indication (e.g. diagnostic or predictive) (Capasso 2014;

Latchaw et al. 2010; Prince 2015; Secretary's Advisory Committee on Genetics, Health and Society 2006; Spoonamore and Johnson 2016; Uhlmann 2009; Wang et al. 2011). Coverage of predictive genetic testing is particularly variable because individuals are asymptomatic and therefore testing is not being done to inform management of an active medical problem (Prince 2015).

In an effort to circumvent these coverage issues, some genetic testing laboratories have expanded their customer services offerings to include handling the insurance prior authorizations/pre-verifications or providing support (e.g. letter templates). Some laboratories will notify patients if their out-of-pocket payment will exceed a certain amount and /or have established a set fee or discounted price if the patient self-pays fully up front for genetic testing.

It is because of all of the above factors that obtaining insurance authorization for genetic testing is cumbersome and often requires genetic counselors' input and time (Uhlmann 2009). Genetic counselor (GC) and/or physician (MD) expertise is needed to determine if genetic testing is clinically indicated and available, to select the appropriate genetic test and laboratory, to provide pre-test counseling and obtain informed consent, and to clinically interpret and communicate results.

Along with these clinical roles, GCs/MDs are addressing patients' insurance coverage questions and requesting and tracking insurance authorizations, which are all tasks that can be performed by non-clinicians. The scope of GCs/MDs involvement in these insurance tasks is evident from internal experiences and from presentations and discussions nationally with colleagues. Of note, the term "genesurance counseling" was introduced in 2014 and is defined as "that portion of a genetic counseling session, whether intentional or non-intentional, that is devoted to the topic of costs and insurance/3rd party coverage (particularly for genetic testing)" (personal communication Quinn Stein, MS, CGC and Jason Flanagan, MS, CGC 11/2/16; Brown et al. 2016a, b).

Given the increase in insurance authorization requests for genetic testing in the University of Michigan (UM) adult genetics clinics (Cancer Genetics, Medical Genetics, and Breast and Ovarian Cancer Risk Evaluation Clinic), the Department of Internal Medicine leadership requested a lean evaluation. The department's Performance Improvement Team was asked to examine work flows and determine support staff needs.

The lean approach involves industrial engineer assessment of work flows to remove inefficiencies from systems and processes, as well as employees' daily work, in order to take advantage of the resources that are value-added. Industrial engineers are rooted in the sciences of engineering, the analysis of systems and the management of people, and are often tasked with developing improved processes (http://www.iienet2.org/). At the UM, a lean evaluation encompasses an industrial engineer's assessment of work flows while mentoring and coaching individuals in process improvement.

GCs from the Medical Genetics and Cancer Genetics Clinics formed a novel partnership with an industrial engineer (IE) and patient services associate (PSA) with the goal of developing a streamlined work flow for obtaining genetic testing insurance authorizations, including delegation of tasks from GCs to PSAs. Based on UM job descriptions (http://careers.umich.edu), PSAs generally have a high school diploma or equivalent; an associate's degree in health care and/or business field is a desired qualification. Depending on the PSAs role, patient billing may be a responsibility, which includes obtaining insurance authorizations for clinic visits.

We describe the results of the lean evaluation, including benchmarking data of how different UM clinics were handling the insurance authorization tasks as well as challenges identified. We share our streamlined work flow, describe how tasks were delegated, and present the novel shared database we developed to initiate and track insurance authorization requests.

Methods

This work was an evaluation and assessment initiated for quality assurance and improvement and therefore exempt from IRB review. Benchmarking data was collected in 13 UM clinics. Eight were genetics clinics including the Breast and Ovarian Cancer Risk Evaluation Clinic, Cancer Genetics, Cardiovascular Genetics, Medical Genetics, Neurogenetics, Ophthalmology Genetics, Pediatric Genetics, and Prenatal Genetics. Five additional specialty clinics were identified by our Specimen Processing Sendout Lab as clinics ordering a large number of genetic tests and included Cardiology (Adult, Pediatrics); and Neurology (Adult, Ataxia, and Neuromuscular).

The major focus of the data collection was current state mapping of the components and work flow for genetic testing insurance authorization and ascertaining who was responsible for each step in this process. This information was obtained from an online survey, developed by the IE, PSA and GCs (WRU and VMR) that was emailed to the GC or MD lead for each clinic, and from the follow-up interviews. Time needed for insurance authorization tasks was not assessed in this lean evaluation because there were not well-established work flows where the work could easily be tracked and timed.

After survey completion, follow-up interviews were jointly conducted by the IE and PSA with the GC or MD leads from the eight clinics that agreed to participate. The interviews explored the survey questions in greater depth. In addition, the IE observed the Medical Genetics and Cancer Genetics Clinics' lead GCs (WRU and VMR) and PSAs work flows for genetic testing authorization. After obtaining this benchmarking data, the IE and PSA met with the Medical Genetics and Cancer Genetics Clinics' lead GCs

Table 1 Benchmarking data on how clinics handle tasks for genetic testing insurance authorization

Task	Number of clinics/Who is responsible/How handled
Obtain authorization prior to clinic visit	3 clinics, only for some patients
Determine if genetic testing can be ordered	GC or MD **(7)** responsible • Review insurance information in EMR and/or ask patient about coverage (5) • Ask MA/staff (1) • Call insurance company (1) PSA **(3)** responsible
Documentation of medical necessity	Write two separate letters (7 clinics) Write one clinic visit letter with medical necessity information (3 clinics)
Have patient complete informed consent form	10 clinics • 6 at initial visit
Submit insurance authorization requests	GC **(7)** responsible • Fully (n = 4) or partially (n = 3) • "Partially" shared with clinic staff/lab MD **(2)** responsible • MD (1) has assistance from MA. • MD (1) previously had MA PSA **(3)** responsible Patient provided paperwork **(1)**
Track pending requests and notify patients of insurer's decision	GC fully or partially responsible in all clinics
Handle insurance denials	GC or MD in all clinics • GC fully or partially responsible (8)

GC genetic counselor, *MD* physician, *MA* medical assistant, *PSA* patient services associate, *EMR* electronic medical records

to brainstorm ways to increase efficiency, decrease redundancy and reassign tasks from GCs to PSAs, and future state mapping of an "ideal" work flow.

Results

Benchmarking Data

Data is presented in aggregate (Table 1) to preserve the anonymity of the participating clinics. Some clinics did not answer all of the survey questions. It was clear from the benchmarking data that there were several tasks associated with genetic testing insurance authorization and variability in how the clinics accomplished this work. Most clinics handled genetic testing authorization requests on a case-by-case basis and did not have well-established work flows. Several of the tasks needed to initiate, track, and follow-up on authorization requests were handled by GCs/MDs and this was regarded by interviewees as an inefficient use of their time.

Issues with Ordering Genetic Testing

The number of genetic tests ordered in all of the clinics has increased and therefore more time is being spent handling genetic testing for patients. Interviewees noted that selecting a genetic test was a time-involved process. More research and consideration of different testing options is needed due to the increasing number of genetic tests available and labs offering testing. Utilizing different labs also means following different processes, which vary in time needed.

In all clinics, the specimen for genetic testing is collected on the day of the clinic visit when the patient has prior authorization for genetic testing. In eight clinics, a specimen is collected the same day if 1) the lab can hold the specimen until authorization is obtained or 2) if the patient opts to proceed without the prior authorization either because their insurer will only make a determination after a claim is submitted or because s/he does not want to wait to have the test done. When a patient opts to proceed with testing without prior authorization, the patient is informed that s/he may end up being responsible for the full cost of the test if coverage is

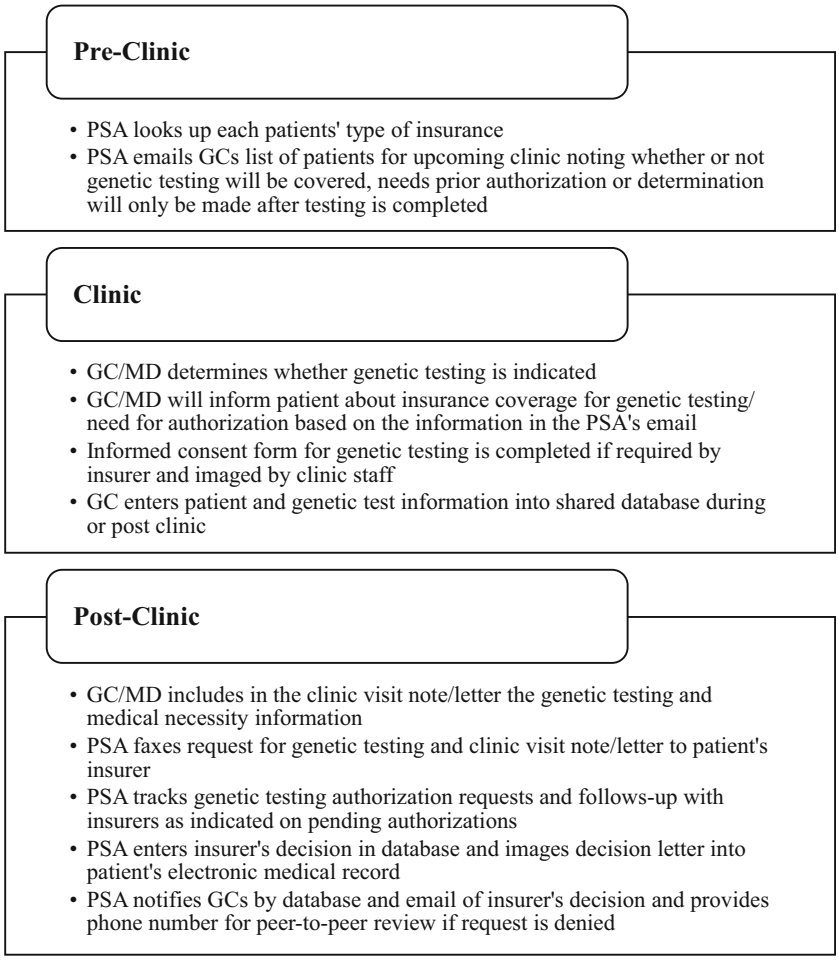

Fig. 2 Work flow for requesting insurance authorization for genetic testing initiated after lean evaluation

denied. If a specimen is not obtained the day of the clinic visit, after insurance authorization is obtained, patients will either return for genetic testing or arrangements will be made for sample collection locally.

Handling Insurance Authorization Requests and Impact

Interviewees shared that insurance companies seem to have limited knowledge about the importance of genetic testing and that many requests for coverage are denied. Multiple interviewees indicated that handling insurance authorization requests and appeals was not a productive use of GC/MD time and often a lower priority than other competing clinical tasks. Interviewees noted that this is problematic because delays in obtaining insurance approval and proceeding with genetic testing subsequently delays receiving results and is particularly an issue when timely information is needed to make a decision about patient management.

All interviewees expressed frustration and shared that the capacity to grow their clinical volume is negatively impacted by the logistical work involved with genetic testing insurance authorizations. Interviewees also shared that their knowledge of insurance requirements/ coverage of genetic testing was limited and expressed the need for additional support to assist with authorizations.

Work Flow Changes Made and Resources Developed

The major changes made by the Medical Genetics and Cancer Genetics Clinics were the establishment of a consistent work flow for genetic testing insurance authorizations, which previously had been handled on a case-by-case basis, and the redelegation of several tasks from the GCs to the PSAs. Figure 2 shows our streamlined work flow and the tasks now done by PSAs.

Determining whether Genetic Testing is a Covered Benefit

One example of a work flow change and responsibility shift from the clinician to the PSA is determining whether genetic testing is a covered benefit. Having this information available

Table 2 Genetic counselors and patient services associates shared database

Data fields entered by genetic counselors	Comments
Patient name	Fixed column[a]
Appointment date	Fixed column[a]
CPI	This is the patient's medical record number
Physician	Drop-down list of physicians' names
Diagnosis	ICD code(s) are obtained from the patient's clinic visit note
Genetic test name	Select from drop-down list of common tests ordered or type in test name obtained from lab website
	Include lab test number/code if provided
CPT code(s)	Obtain from lab website or call lab
Cost	Obtain from lab website or call lab
Lab	Select from drop-down list of common labs used or type in name of lab
Proceed?	Drop-down options:
	"Yes, Blood sample was drawn at clinic visit" "Yes, Insurance authorization needed"
	"No." "No" is selected if a patient subsequently declines genetic testing after learning testing will either be partially or not covered by their insurance.
	The PSA knows to proceed with obtaining insurance authorization for all patients in the database, except where outside lab does pre-verification (noted by GC in "Comments" field).
GC assigned[b]	Drop-down list of genetic counselors' names
GC action[b]	Drop-down options:
	LM (left message), testing arranged, testing pending, testing completed, testing declined, other
GC notes[b]	Field used as needed. May be used to indicate if message was left for patient, date testing was arranged/paperwork sent, date results were disclosed and follow-up.
Data fields entered by patient services associates	**Comments**
Decision	Approval or denial
Authorization number	If test is approved, authorization number is provided.
Authorization date	Authorization date and effective dates of approval are noted
Comments	Used to record date request made to insurer and other information (e.g. lab is handling pre-verification)

[a] Makes it easier to know that you are following the right patient across the 17 data fields without having to keep checking the first column with the patient's name. The date column is fixed to easily determine when the patient was seen and whether enough time has passed to follow-up on the authorization request. Patient rows alternate between white and gray for easier readability

[b] These data fields appear in the database after the data fields entered by the patient services associates

during the clinic visit helps to better guide the discussion about genetic testing and next steps with obtaining insurance authorization. Every week, the PSA looks up each patient's type of insurance to ascertain whether or not genetic testing will be covered, needs prior authorization or if determination of coverage will only be made after a claim is submitted. The PSA sends a pre-clinic email to the GCs listing the names of patients under each of the coverage options noted above. This email is printed by the GC and put with the clinic schedule in the staffroom so that this insurance information is accessible to all clinicians, which has reduced interruptions during clinic visits to ascertain this needed information.

Inclusion of Medical Necessity Information in the Clinic Visit Summary Note

Another time-saving work flow change is the documentation of medical necessity. The clinic visit summary note contains the relevant patient family and medical history information and diagnostic impression. Writing a separate letter of medical

LETTER OF MEDICAL NECESSITY

Re: [**Name of Patient**] DX:

DOB: ICD10:

INSURANCE:

Contract: Group:

TO WHOM IT MAY CONCERN:

This is a letter requesting prior authorization for Genetic Testing. The information is as follows: [**name of test**] using CPT codes [**specific codes**] at a cost of **$**. We will be sending the specimen to the following laboratory:

Name of lab
Address
Tax ID: **NPI:** **Phone:** **Fax:**

Enclosed you will also find our clinical notes from [**name of patient**] last visit. If more information is needed, please contact us at [**phone number**].

Please fax any Approvals or Denials to [**fax number**].

Fig. 3 Coversheet faxed to insurer by patient services associates with clinic visit letter to request insurance authorization for genetic testing

necessity for genetic testing was duplicative effort. Therefore, the documentation of medical necessity is now incorporated into the clinic visit summary, for example:

> "The patient's history is consistent with Ehlers-Danlos syndrome Type IV (vascular type). This condition results in increased morbidity and mortality. Genetic testing is recommended and results will impact medical decision-making: COL3A1 gene sequencing with reflex to deletion/duplication analysis, [name of lab], [CPT codes], [list price]."

Creation of Password Protected Shared Database between GCs and PSAs

The most impactful work flow modification was the development of a shared database, allowing GCs and PSAs to efficiently communicate about genetic testing insurance authorization requests and status updates (Table 2). This shared Excel database is stored on a restricted access, password protected server. The database established a single, dynamic resource for GCs and PSAs to enter, track, update, and review all genetic testing insurance authorization requests. Patients having genetic testing performed by laboratories that handle the insurance prior authorizations are also included. This means that all genetic tests ordered by the clinicians can be efficiently monitored in a single location, facilitating follow-up and clinician cross-coverage. The database is checked weekly and as indicated by both the PSAs and GCs. Database use has notably reduced the number of emails and phone calls between GCs, MDs and PSAs to determine the current status of genetic testing authorization requests.

After each clinic or even between patients, GCs enter patient information into the shared database. Drop downs, when possible, were generated for specific fields which save data entry time (Table 2). Using Excel's search functions and entering the test name, it is possible to also save time by "cutting and pasting" genetic test information from previous requests in the database; however, it is important to confirm that the information is up-to-date. Searching the "Proceed" column for "Yes" or the "GC Action" column for "Testing Pending" readily generates the patients who have testing in progress and the date submitted can be used to determine if follow-up is needed.

PSAs Contact Insurers to Initiate and Follow-Up on Test Authorization Requests

The PSA checks the shared database within three work days after clinic is held, which allows the GCs time to enter genetic testing insurance authorization requests and for clinic visit summary letters to be completed and posted in the electronic medical records. The PSA calls each patient's insurer to initiate the authorization request (some provide a case reference number) and faxes the necessary documentation and forms (described below).

The PSA faxes to the insurer the clinic visit summary letter (which also serves as the letter of medical necessity) and a one-page cover sheet (Fig. 3). The PSA is able to obtain the necessary patient information (e.g. birthdate, insurance policy number) for the cover sheet from the

electronic medical records and the diagnosis and genetic test information from the shared database or clinic visit letter. The manual, described below, is used to ensure the correct insurance specific forms and processes are completed.

The PSA is responsible for tracking pending genetic testing insurance authorization requests. The information faxed for each patient is kept in a folder, allowing the PSAs to easily ascertain which insurance requests are pending. The PSA will call the insurer if a determination has not been received within 1–2 weeks of submission (timeframe dependent on insurer).

Communication of Insurer's Decision about Genetic Testing Authorization

Communication of the genetic testing coverage decision by the insurer varies and may be conveyed verbally and/or by letter. Letters received by the PSA are scanned by the PSA into the patients' electronic medical records. Sometimes the insurer will also send a letter directly to the patient and/or provider. The PSA notifies the GCs about the insurer's decision through the database and additionally by email. The emails sent by the PSA about the insurer's decision can be copied and pasted into the patient's electronic medical record along with the GCs documentation.

If authorization for genetic testing is approved and a specimen has not been collected, the GC notifies the patient, completes test request forms, obtains informed consent, and coordinates specimen collection. If the request for test authorization is denied, the PSA will send the GC an email with the phone number for a peer-to-peer review request; for some insurers, a written request for appeal is required.

The GC/MD contacts the insurer for the peer-to-peer review and if insurance authorization is subsequently denied, the GC (sometimes the MD) will notify the patient, discuss next steps (e.g. potentially testing another family member if indicated) and the follow-up for their medical management. Patients are given the option to self-pay for genetic testing, which generally is declined.

PSAs Creation of a Manual with Needed Information about Insurers and Genetic Testing Laboratories

The PSAs for the Medical Genetics and Cancer Genetics Clinics created a manual containing key information needed for genetic testing insurance authorization requests including:

1. Insurance provider information: *phone and fax numbers, 1–3 sentences about whether prior authorization is needed, processes, and required forms.*
2. Genetic testing laboratories information: *address, phone and fax numbers, tax identification and National Provider Identifier (NPI) numbers.*
3. List of the clinics' physicians and genetic counselors' names and their NPI numbers.

The PSAs compiled this information because they recognized the steep learning curve and the extent of information required to submit a genetic testing insurance authorization request. It can be time-consuming to go through insurers' phone trees to ascertain specific numbers to call and/or fax a request or appeal. Time is saved by having the insurers and laboratories' contact information compiled and accessible so this needed information is not searched for each time the PSA submits an authorization request.

Work Flow Issues to Address

As part of the Performance Improvement Team evaluation, we identified additional issues that need to be addressed to improve the workflow for genetic testing:

Informing Patients about Insurance Coverage Issues with Genetic Testing

We developed an information sheet that is provided to patients at check-in by clinic staff notifying them that genetic testing may be discussed during their clinic visit. It notes that insurance authorization for genetic testing takes time, testing may be fully, partially, or not covered and introduces the PSA (name and phone number) as a resource for addressing billing questions. This approach facilitates informing patients that we know insurance coverage is a concern and proactively lets patients know that the PSA, not the GC, is the best resource for insurance questions. However, sometimes provision of this information has created additional patient worry and questions about insurance issues at the onset of the session before it has even been determined if genetic testing is clinically indicated. How, who and when to inform patients about insurance coverage continues to be a work flow task to optimize.

Specimen Collection Issues

A major issue to address is specimen collection. When genetic testing is not done at the clinic visit, additional clinician and/or staff time is needed to contact the patient and coordinate testing logistics. The patient has to take additional time to return to the clinic or a blood-drawing station. If a patient lives far away, arrangements need to be made with the patient's local physician or a hospital so that the patient does not drive hours for just a blood draw. It can be time-consuming to coordinate genetic testing locally since a site/provider needs to be identified, the testing logistics and overnight shipping requirement

need to be explained and arranged/kit sent and completed paperwork needs to be provided to send with the sample.

Oftentimes, given work or school schedules, conflicts with other medical appointments or travel logistics, patients cannot have the sample collected within the specified authorization dates, which results in a second insurance authorization request to extend these dates. It takes additional time for the GCs/MDs and PSAs to handle these extension requests and further delays the time to results.

Some genetic testing laboratories offer a "DNA extract and hold" option, allowing for a blood sample to be collected at the clinic visit and held at the lab until the insurer has rendered a decision. However, not all labs offer this option and therefore, unless the patient is willing to assume potential financial responsibility for the genetic testing, specimen collection is deferred until after insurance authorization is obtained. While the "DNA extract and hold" option is convenient for patients, obtaining and sending a sample to the testing lab and the lab's DNA extraction incurs fees, unnecessary expenses if genetic testing is not performed.

Establishing a way to collect and store specimens the day of the clinic visit would make genetic testing more efficient for both patients and clinicians. Logistics about storing samples (and discarding if insurance coverage is denied), fees, and determining storage location (clinic/institution or the genetic testing lab) would need to be worked out. Another option to explore is the use of saliva and buccal swab kits which provide a convenient and time efficient home alternative to travel for a blood sample draw. Specimen collection kits could be sent to the patient by the laboratory after insurance authorization is obtained. Utilizing these different options may circumvent some of the logistical issues of specimen collection outlined above and should be explored.

Communicating that Specimen was Obtained

For patients who have genetic testing done on a different day than the clinic visit, it is important for patients to notify the GC/clinic so that tracking and timely communication of results occurs. Notification of the GC/clinic is especially important when the blood draw occurs at an outside facility since, unless there is an integrated electronic medical record system, there is no documentation in the patient's records that a sample has been drawn for genetic testing. Therefore, the GCs/MDs will not know that genetic testing was done and results are available unless notified or a report is received.

Completion of Paperwork for Genetic Testing

Completion of paperwork for genetic testing is an unnecessary use of clinician time if testing will not be approved. However, if paperwork is not completed until after insurance authorization is obtained, the paperwork will need to be electronically sent or mailed to the patient. It is not uncommon for a patient to misplace the paperwork or to forget to bring the paperwork to the blood draw which requires re-completion of the paperwork by the GC/MD if a printed copy is not available or accessible in the electronic medical record.

During a genetics clinic visit, the benefits, risks, and alternatives to genetic testing are discussed, however formal documentation of informed consent by means of patient signature, is not routinely completed unless a patient opts to undergo genetic testing. If it is known that an insurer requires written documentation of informed consent to consider a genetic testing authorization request, this process can be completed during the clinic visit. When an informed consent document is not completed and is then required for insurance authorization, additional time needs to be spent calling the patient to cover points in the specific informed consent form, sending the form to the patient to sign, tracking return and forwarding to the insurer. If the genetic testing lab does not provide an informed consent document, time needs to be spent by the GC/MD to either identify or create a form.

Electronic Medical Records Issues

In our electronic medical record system, it currently is not possible to enter an order for genetic testing and note that the sample should not be drawn until insurance authorization is obtained. Therefore, we do not enter the genetic testing order in the electronic medical record the day the patient is seen. This averts having the blood sample for genetic testing obtained and sent at the time other blood work is done, which would have financial implications for the patient if insurance authorization is subsequently denied.

Another electronic medical record issue to address is currently there is not a way to directly link the patient's imaged genetic testing paperwork with the order. Therefore, in order for the genetic testing paperwork to be sent with the specimen, the patient either needs to have the genetic testing paperwork in hand when the sample is collected (required if drawn locally) and/or the blood draw station needs to know to look for the paperwork in the patient's electronic medical records imaged documents/media section (inaccessible outside the institution).

The work flow would be smoother if the electronic medical records issues could be resolved so that an order for genetic testing could be entered at the clinic visit, a notation made that insurance authorization is pending and a blood sample should not yet be drawn and the test forms could be imaged and attached to the electronic order when completed.

Delegation of More Tasks to PSAs/Clinic Staff

There is a significant amount of information needed to initiate a genetic testing insurance authorization request, as noted in the fields in our database (Table 2) and the coversheet the PSA

sends with the clinic visit note (Fig. 3). To continue to reduce GC's time, it may be possible to delegate more of the shared database field entries to the PSAs. Generally, the list price of a genetic test is not available on the lab's website for proprietary reasons and therefore the lab needs to be called, which can be done by PSAs. Since all of the information needed to make a genetic testing insurance authorization request is in the clinic visit letter, potentially the PSAs could be tasked each week with reviewing letters from all patients seen and entering the information in the database with the GCs only responsible for double-checking the entered information.

In addition, ordering genetic testing often requires completion of multiple forms and potentially the patient's contact information and insurance sections could be completed by the PSA or clinic support staff. For patients who receive insurance approval for genetic testing, the PSA and/or clinic support staff could take on the responsibilities of notifying patients, sending the testing paperwork, and making arrangements for samples to be obtained and sent.

Discussion

This is the first paper to describe the different tasks and work flow issues with obtaining insurance authorization for genetic testing. Through our GC's novel partnership with an IE and PSA, we developed a streamlined work flow that standardized our genetic testing insurance authorization process, eliminated tasks that were redundant or unnecessary and clearly defined roles, responsibilities and points of handoff. We successfully decreased the time GCs spend in this process and identified tasks that could be delegated to PSAs. We have comprehensively described the components of our work flow to assist other clinics. Laying out the steps and tasks involved will also help clinicians, clinic staff, trainees, administrators, insurers, and policy-makers to understand the cumbersome time-involved process of obtaining insurance authorization for genetic testing and work towards both optimizing this process and staffing appropriately.

Our experience demonstrates that genetic testing insurance authorization tasks can be effectively delegated to PSAs and do not need to be done by clinicians. Delegating these tasks to PSAs is feasible given their responsibilities and work they already do to obtain authorizations for clinic visits. In order for the PSAs to successfully take on the tasks associated with genetic testing insurance authorizations, establishment of work flows, much like we have described, and clear communication and handoffs between PSAs and clinicians are needed.

The creation of a centralized password restricted database, accessible to both GCs and PSAs, was a critical step in making it efficient to initiate insurance authorization requests for genetic testing and track the outcomes. The database has enabled a smooth handoff of responsibility between the PSAs and GCs, decreasing emails and phone calls. For the PSAs, creating a manual with needed information about the insurers, genetic testing laboratories and clinicians was an important time-saving step.

In the National Society of Genetic Counselors (NSGC) (2016) Strategic Plan 2016–2018, one of the strategic initiatives is to "Engage with technology innovators to facilitate the development of practice tools and resources to support efficient delivery of genetic services." We think the development of our database is an example of technology use that increases the efficiency of GCs. Another successful technological approach for handling the insurance benefits process and informing patients of their out-of-pocket expenses was presented at the 2016 NSGC Annual Education Conference. Williams et al. (2016) developed a prospective insurance benefits work queue within the EPIC electronic medical record system between the genetics clinic, the patient admissions group and the clinical laboratory (Williams et al. 2016).

While these work flow changes have helped, the reality remains that an appreciable amount of time is needed to initiate, track, and follow-up on insurance authorization requests for genetic testing. Time spent on these tasks by clinicians does not add value to patient care. The time spent addressing insurance coverage issues also detracts from important discussions clinicians need to have with patients about potential genetic testing results, limitations and implications. Furthermore, with all of the tasks to complete in the insurance authorization process, workarounds and wait times, it is possible for patients to inadvertently "fall through the cracks" and not have timely follow-up on authorization requests, testing done or prompt communication of results.

Genetic testing generally takes several weeks to months to complete so adding the time needed to obtain an insurance authorization and subsequently a sample means the patient could wait additional weeks to learn a result that could impact their care. Testing delays can also impact relatives' care since identification of a familial pathogenic variant is needed to implement cascade testing of at-risk relatives and subsequently initiate evaluation and screening if indicated. Notably, some patients do not proceed with the recommended genetic testing if it cannot be done the day of the clinic visit, which has implications for their care and potentially their relatives.

Generally, in other areas of medicine, testing is done or arranged at the clinic visit and pages of paperwork do not need to be completed to order or seek authorization for a medical test. For many medical tests, support staff in the clinic/doctor's office handle billing and insurance authorizations and a clinician is not routinely actively involved in this process. By default, because of the complexity of genetic testing and the information needed to determine coverage, the clinicians at our institution and elsewhere have ended up being responsible for several tasks in initiating and tracking insurance authorization requests.

Some of the time investment by clinicians in seeking insurance authorizations for their patients is being alleviated by those labs that offer pre-verification/pre-authorization services and contact patients to communicate the outcome of these requests. Few labs were offering pre-verification/pre-authorization services at the time our lean evaluation was conducted. Labs provision of these services is potentially a "game-changer" in reducing the time clinicians spend handling insurance issues but does raise considerations as to whether the ease of obtaining insurance authorization for patients will influence lab and test selection by the clinician. Generally, commercial labs may have more resources to offer pre-verification/pre-authorization services than academic labs.

There is much work to be done on a national level with insurers so that ordering and obtaining authorization for genetic tests has a similar process as other medical tests and patients can have genetic testing done as part of their clinic visit like other bloodwork. As noted in the Secretary's Advisory Committee on Genetics, Health and Society 2006 report (p. 9): "Although advances in genetics and genomics are driving the development of new genetic tests and services, problems with coverage and reimbursement of current genetic tests and services are limiting their accessibility and integration into the health care system." In an effort to address insurance coverage issues, the American College of Medical Genetics and Genomics in 2015 issued a policy statement about the clinical utility of genetic tests in patient care, disagreeing with the narrow view held by some payers, and emphasizing the clinical utility of results for patients, families and society (American College of Medical Genetics and Genomics Board of Directors 2015). The use of genetic testing in patient care will continue to increase and therefore it is critical to address these insurance coverage issues.

Our time needs to be spent in the genetic testing process where clinician expertise and skills are needed – patient risk assessment, researching tests to offer and providing pre- and post-test counseling. In order for clinicians to meet increasing demands for genetic services and genetic testing, tasks that can be done by non-clinicians need to be identified and delegated and work flows simplified. The electronic medical record issues described in our paper need to be addressed and other ways of integrating insurance and testing tasks electronically should be explored. Above all, nationally policies on insurance coverage of genetic testing need to be addressed and the work involved to make requests reduced in order for clinicians to best provide care for patients and facilitate patients having genetic testing in a timely manner.

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Compliance with Ethical Standards

Conflict of Interest Wendy R. Uhlmann, Katie Schwalm and Victoria M. Raymond declare that they have no conflicts of interest.

Ethical Treatment of Subjects All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all participants for being included in the study. No animal studies were carried out by the authors for this article.

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