AHRQ Grant Final Progress Report

Title of Project:
HOPE-Genomics: Empowering Cancer Patients through Innovations in Information Technology-Based Precision Medicine
12/29/2019

Principal Investigator:
Stacy W. Gray, MD, AM
Team Members:
Ilana Solomon, ScM, MA, LCGC
Sarah McGraw, PhD, MA
Jenny Shen, MA
Lisa Lopez, BS
Melissa Sur, BA
Ernesto Sosa, MPH, MSW
Sam Wing, PhD
Organization: City of Hope National Medical Center
Inclusive Dates of Project: 09/30/2016 - 09/29/2019
Federal Project Officer: Steve Bernstein
Acknowledgement of Agency Support: This research was supported by the Agency of Healthcare Research and Quality (AHRQ 1R21HS024984-01)
Grant Award Number: R21 HS24984-02

1. Structured Abstract:

Purpose: Many thousands of cancer patients receive tumor genomic testing yearly, but patients often fail to comprehend basic information about cancer genetics or the genomic characteristics of their disease. The goal of this project was to design a cancer genome sequencing report to improve patient understanding of cancer genetics and their test results to advance the quality of personalized medicine in oncology.

Scope: We evaluated the feasibility and acceptability of delivering sequencing results and genomic education via HOPE-Genomics to cancer patients. We then designed and developed a patient-facing, dynamic, and web-based cancer genome sequencing report -- HOPE-Genomics.

Methods: We conducted a needs assessment survey and qualitative interviews with static mock ups of the HOPE-Genomics report with patients and providers to gather stakeholder feedback on the utility of the application. Interview responses were used to inform subsequent application development, which was done in tandem with a professional application development team.

Results: Stakeholders reported the desire for a patient-friendly report, high acceptability of content, and interest in tool-enabled access to genetic counseling. Clinicians believed the tool could help patients formulate questions and facilitate patients' communication of results to family members. We integrated responses into a manuscript on tool development, which is under review for publication. Stakeholder design preferences were joined with patient data from the electronic medical record into the HOPE-Genomics platform to create a functioning prototype that will be piloted with participants in the coming year.

Keywords: Cancer genomics, patient education, tool development, eHealth

2. Purpose

The introduction of large-scale genomic testing in medicine promises to transform patient care. Cancer is at the leading edge of this revolution and hundreds of thousands of cancer patients receive tumor genomic testing yearly. Early evidence reveals that despite rapid adoption of genomic testing in cancer, many patients fail to comprehend basic information about cancer genetics or the defining genomic characteristics of their disease. The goal of this project was to design a dynamic web-based cancer genome sequencing report in order to improve patient understanding of cancer genetics and their own test results. Through better informing patients, the long-term goal of is to improve the quality and delivery of personalized medicine to oncology patients.

3. Scope

HOPE Pilot Survey

We conducted a needs assessment survey to better understand how a patient-oriented genomics results application would help fill knowledge gaps that current cancer patients face. Responses to this survey uncovered limitations in patient knowledge about both their own disease status, as well as cancer and genetics more broadly.

Qualitative research

To develop a highly patient-centered tool, we conducted patient/family and clinician focus groups to assess tool usability, an initial step in the tool development process. Qualitative methods offer an effective way to approach this task, allowing for the elicitation of open-ended responses and enabling the observation of user interaction with the tool. Our ultimate goal for this line of research is to determine whether patients who use HOPE-Genomics have better knowledge of their disease, more effectively communicate with providers, and are more compliant with genomically-guided therapy.

For both the surveys and focus groups, patients, family-members, and clinicians were eligible to participate in these focus groups. Adult patients with solid tumors at City of Hope (COH) were eligible to participate if they had somatic or germline genomic testing, were English speaking, had an Eastern Cooperative Oncology Group (ECOG) status of ≤ 2, and could provide consent. Because genomic testing often impacts family members, patients were offered the opportunity to invite one adult family member to participate. Clinicians who ordered somatic/germline genomic testing were recruited by convenience sampling. All study activities were approved by the COH Institutional Review Board.

Application Development

Using stakeholder feedback on design and usability, we have collaborated with a developer to build a functional, dynamic, web-based prototype of the HOPE-Genomics app. Application development has involved an external expert developer, as well as an internal City of Hope informatics team. This internal team has assisted in ensuring data security as well as addressing scalability issues as the application approaches clinical deployment.

4. Methods

HOPE Pilot Survey

87 patients participated in the needs assessment baseline survey. The survey assessed patient demographics, patient's knowledge of their disease characteristics, their genomic test results and their willingness to participate in prototype evaluations of the HOPE-Genomics application. Patient self-reported history of genomic testing was compared to their electronic medical record (EMR) to assess testing recall. Patients were also asked a short battery of questions to assess their knowledge about cancer and genetics.

Qualitative Research

Eight patients and five family members participated in four patient focus groups, while nineteen providers participated in three focus groups. During these meetings, participants discussed genomic testing generally and were shown static mock ups of the HOPE-Genomics application. Focus groups were 90 minutes in length and participants were 1) asked about their experiences with genomic testing, 2) observed using the tool, 3) asked to test the prototype animation, 4) guided through the tool, and 5) discussed tool use, clarity and content. Following the focus group, participants completed a survey about HOPE-Genomics' usability.

Using Atlas.ti,v8™ we employed qualitative content analysis to examine participants' perceptions of the tool content, format, and interactive elements.[1,2] Codes were both deductive or defined a priori (based on focus group questions and tool elements) and inductive (based on new topics

found through the focus groups).[3] Inductive code development continued until we named all new topics (one form of data saturation).[4,5]

Application Development

Initially, a static mockup of the HOPE-Genomics application was designed to display to focus group participants with the goal of using their responses to guide further application development. This prototype consisted of twelve webpages and included interactive features, visual cues to aid in comprehension (e.g, result types consistently color-coded), and hyperlinks to access external information. Unknown results (i.e., variants of uncertain significance [VUS]) were reported separately from results with clinical utility. We used a figure to "bin" genomic results into three types: actionable cancer, additional, and unknown (i.e., "actionability dial"). Prognostic information was "locked," ensuring that disclosure of prognostic information only occurred after patient opt-in. To model the types of results that would be returned to patients, the focus group tool included clinical and sequencing data from a hypothetical lung-cancer patient.

The developer has built the web-based, dynamic version of the HOPE-Genomics application on the SMART on FHIR platform, which can be directly integrated with electronic health record systems for improved scalability and integration into clinical workflows. COH informatics personnel are developing processes to automate laboratory data uploads to improve the speed and accuracy with which data enters the HOPE-Genomics application.

5. Results

HOPE Pilot Survey

Only 69% who had germline testing accurately self-reported a past germline test. Similarly, 69% recalled having a somatic test while 95% actually received this testing. These results indicate that, while genomic testing is relatively common, many patients do not remember it as part of their past care. When examining knowledge about cancer generally, patients accurately answered an average of 5 of 9 questions correctly. When asked about genetics, patients accurately answered an average of 10 of 19 questions correctly. While these patients are personally affected by cancer and its relation to genomics, there still exists a large knowledge gap that improved patient education could bridge. Finally, 80% of patients reported a desire to learn if their cancer had a gene change and interest in viewing a patient-friendly version of their gene sequencing results. The results of this survey identified a role for the HOPE-Genomics application as a tool to aid in the return of genomics results to cancer patients.

Qualitative Research

Patient and family member participants in focus groups reported desire to view a "patient friendly" report, a desire to receive multiple types of genomic information (e.g., prognostic and uncertain), high acceptability of report content, and interest in tool-enabled access to genetic counseling. In line with prior work on patient-directed genomic decision aids, our participants thought the tool would facilitate patient engagement by helping patients formulate questions for providers.[6] Participants expressed a range of preferences as to when the tool would be deployed during the return of results process. Although there was not a clear consensus on whether the tool would be best utilized prior to, during, or after a provider appointment, patients generally responded that they would want to use the tool (preferably at home) and that it could help them better understand their cancer.

Application Development

Based on stakeholder feedback, we have collaborated with a team of developers to create a functioning prototype of the HOPE-Genomics application (prototype available at: https://sketch.cloud/s/bM11Z/a/p5Dn0G/play). Results from the aforementioned focus groups revealed that the final version of the application should include refined tool formatting and content, including more dynamic functionality to share information with family members; further detail in definitions and resources for patients, family members, and providers; screens that list all the genes tested for a given patient, and more detailed educational content. Additionally, an animation firm was contracted to integrate a 3.5-minute animated video, available in English, Spanish, and Mandarin Chinese, that reviews several of the topics covered in the web-based report (e.g., the differences between somatic and germline testing, possible implications of testing).

The application was built and then integrated into a secure server at City of Hope and has been validated with real patient data. We have recently established a process for integrating individual-level patient data into the app for clinical deployment behind the COH firewall. Unfortunately, unanticipated technical problems with the app development and City of Hope integration delayed the pilot testing in the clinic. However, the application is now ready for pilot testing and we are actively recruiting patients and providers for the pilot study. The pilot will involve showing patients the HOPE-Genomics tool with their own genomics test results during a regular return of test results visit with a clinician. Within the weeks following this disclosure and tool viewing, patients will be contacted for a debriefing session that will as ask patients about the usability and usefulness of HOPE-Genomics, relevant outcomes, and elicit feedback for process improvement.

Next Steps

As a direct result of the work conducted with the support of this AHRQ grant, Dr. Gray was recently awarded an NHGRI R35 award (1R35HG010721-01) to continue developing and deploying the HOPE-Genomics application over the next five years. To accomplish this, the grant has three specific aims. First, the effectiveness of the HOPE-Genomics intervention in the context of cancer in a randomized controlled trial. The trial will compare usual care to those who receive their genomic test results with the HOPE-Genomics tool, with the goal of assessing whether the guideline-concordant care differs between the two arms. We hypothesize that use of the HOPE-Genomics tool will improve rates of uptake of evidence-based genetically-guided care.

Second, the HOPE-Genomics tool will be used in different patient populations and disease contexts. To accomplish this, HOPE-Genomics will be translated into Mandarin Chinese and Spanish, which represent major components patient population served by City of Hope National Medical Center patient population. This process will be conducted through certified medical translation services and be validated by native-language study staff. Moreover, this intervention will be adapted to the context of diabetes.

Third, the social networks will be integrated into the HOPE-Genomics application to optimize genomic information sharing. We will adapt an existing moderated, secure social network platform for patients, physicians, and family members and combined into the functionality into HOPE-Genomics. It will use complementary methods (e.g., interviews, natural language processing) to assess stakeholder attitudes toward, and the quality of information shared through, the networks. Through this, we

anticipate that participants will engage with the social networks and find them to be highly useful in connecting to others affected by cancer and relevant evidence-based resources.

6. List of Publications

Solomon IB, McGraw S, Shen J, Albayrak A, Alterovitz G, Davies M, Del Vecchio Fitz C, Freedman RA, Lopez LN, Sholl L, Van Allen E, Mortimer J, Fakih M, Pal S, Reckamp KL, Yuan Y, Gray SW. Engaging Patients in Precision Oncology: Development and Usability of a Web-Based Patient-Facing Genomic Sequencing Report. JCO Precision Oncology. Revise & Resubmit.

This work was also presented at the American Society of Clinical Oncology (ASCO) 2018 Annual Meeting, and the Collaborative Group of the Americas on Inherited Colorectal Cancer (CGA-ICC) 2018 Annual Meeting

7. References

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