2014 Duke AHEAD Grant Proposal
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(Limit 5 pages)

Title: Development and Assessment of an Interdisciplinary Collaborative Education Workshop Series on Personalized Medicine

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Focused question: To assess the effectiveness of a multi-modal workshop series to promote knowledge and delivery of personalized genomic medicine through interdisciplinary education and practice, respectively.

Background: (including brief review of prior research). Personalized genomic medicine is a growing field with applications in multiple medical specialties. Many providers have expressed interest in integrating personalized medicine into their practice (Levy & Young, 2008), but do not feel prepared to begin using the clinical applications (Najafzadeh et al, 2012; Nipert et al, 2011; Selkirk et al, 2013; Scheuner et al, 2008). In particular, nurses and physicians of various specialties report having limited knowledge of genetics (Klitzman et al, 2013; Mainous et al, 2013; Skirton et al, 2012), which may impede their ability to offer personalized medicine services and appropriately interpret and apply the clinical information to care. Further, based on our research as well as the research of others, few providers have experience using components of personalized medicine such as pharmacogenomics (Stanek et al, 2012; Haga et al., 2012).

Evidence is emerging supporting the use of inter-disciplinary approaches in the practice of personalized medicine (Erskine et al, 2013; IOM, 2013). As defined by Erskine et al (2013), an interdisciplinary team is made up of professionals from different specialties who work together for the benefit of the patient throughout the care of the patient. Interdisciplinary practice has become common among many medical specialties including oncology (Rabinowitz, 2000), geriatrics (Dyer et al, 2003), primary care (Field et al, 1995), and genetics (Grosse et al, 2009), and can result in shorter and less expensive hospital stays (Curley et al, 1998), improved use of diagnostic testing (Menon et al, 2009), and overall survival (Curtis et al, 2005). Interdisciplinary practice will be important to the successful implementation of personalized medicine in order to address patient concerns, promote patient understanding and engagement, and coordinate care of multiple providers (Battista et al, 2012). For example, an interdisciplinary group caring for patients affected by cardiovascular disease includes pediatric and adult cardiologists, nurses, psychologists, geneticists, genetic counselors, and specialists in ethics (Erskine et al, 2013). Each provider plays a unique and important role, and only through this type of interdisciplinary care is the patient able to have appropriate testing (from geneticists), medical management (from cardiologists), and emotional support (from nurses, social workers, and psychologists). Likewise, one personalized medicine test for the pharmacogenetic marker CYP2D6 impacts more than 25 different drugs used in multiple disciplines including psychology, cardiology, oncology and pain management (pharmgkb.org). Further, few patients are familiar with personalized medicine (KRC Research, 2014) and will likely seek or need support from multiple members of a healthcare team to guide them through the process.

Thus, educational strategies to promote interdisciplinary care are needed and can involve participation of multiple members of a clinical team, often utilizing interactive learning approaches (Reeves et al., 2013). As a result, in addition to the information that participants are learning from the instructor, they are learning from each other. It has been suggested that multimedia methods and multi-instructional techniques are more effective in improving knowledge and practice performance compared to single method educational options (Bordage et al, 2009; Davis et al, 2009; Marinopoulos et al, 2007). The use of hypothetical case studies (Davis et al, 1999) and standardized patient

actors (Crofts et al, 2008) provide opportunities to apply the knowledge in a classroom setting and develop real-world skills.

Although some curricula have been developed about genomics and personalized medicine, many of these programs have been developed as part of a clinical trial or are limited to a single discipline, healthcare system or program. For example, as part of the MedSeq trial, which is studying the integration of whole genome sequencing into primary care, an educational curriculum was developed for participating providers (Vassy et al, 2014). That curriculum includes two in-person group sessions as well as online modules and uses case examples to review basic genetic concepts, genomics of common diseases, and pharmacogenetics (Vassy et al, 2014). In recent years, several open access online courses have been developed. For example, a 7-week online course was developed by researchers at the University of California, San Francisco on Genomic and Precision Medicine (https://www.coursera.org/course/genomicmedicine). However, online courses do not provide any (or limited) opportunity for engagement with the instructors or other learners.

To our knowledge, there are no opportunities for interdisciplinary education in personalized medicine. Therefore, the proposed program to pilot an interdisciplinary education program in personalized medicine is the first of its kind.

Specific aims: We aim to develop, implement, and assess an inter-disciplinary workshop series for educators (instructors and training program directors), providers (physicians and nurses), and trainees/fellows and students to promote knowledge and awareness of personalized medicine applications, understanding and practice of inter-disciplinary, team-based care for personalized medicine, patient-provider communication (pre/post-genomic testing), and interpretation and application of genomic information in a clinical setting.

Methods: Overview: We propose to develop, implement and evaluate an inter-disciplinary workshop series to increase providers' knowledge of personalized medicine and the differing but integrated roles of multiple providers in delivering this type of care. The overall goals of the educational program are 1) to familiarize learners with a range of personalized medicine applications and how to apply these in a clinical setting (e.g., identifying patients for whom genetic/genomic testing may be appropriate, promoting informed decision-making, how to discuss genomic testing with patients, how to communicate test results, etc.), and 2) how to work within an interdisciplinary team to provide personalized medicine care.

Educational Program: The inter-disciplinary workshop series will include 7 sessions that meet twice a month over the course of 4 months. Each workshop will be scheduled for 2 hours at a location on the Duke Hospital campus convenient to most providers. Based on feedback from the Education Workgroup of the Center for Personalized & Precision Medicine (Dr. Haga is chair) and review of other genomic and personalized medicine courses (Vassy et al, 2014; https://www.coursera.org/course/genomicmedicine) and the literature (Ginsburg & Willard, 2010) including professional competencies in interdisciplinary care (AACN, 2011) and genomics (Greco et al, 2012; Korf et al, 2014), we have identified 7 topics for the workshop series that we believe will provide a comprehensive overview of personalized medicine. The first workshop will include a general overview of basic genetics and genomics and principles of inter-disciplinary practice, including the development of personalized medicine, and general practice implications such as interpreting testing, communication strategies, and knowing when to refer to a genetics specialist. The second workshop will continue to provide background information, but specifically focus on how to take a family history, and understanding and assessing genomic risk. Building on those basic concepts, specific areas of practice where personalized medicine has emerged will be covered in four subsequent workshops: oncology, cardiology, neurology/psychology, and infectious disease. Each of these lectures will focus on applications for genomic screening and risk assessment, diagnosis, and treatment. The final seminar (workshop #7) will highlight key applications discussed in the various workshops, and identify provider resources to facilitate teaching and sharing with colleagues, other continuing education opportunities in personalized medicine, and patient resources. Each seminar will be presented by a Duke provider from the appropriate medical specialty.

With the exception of the first and last workshop, each session will include two components that will each last about an hour: 1) knowledge-based training (utilizing didactic teaching methods) and 2) an interactive, skills-

based training involving role-playing and interactive dialogue. The interactive component is intended to provide attendees an opportunity to practice skills relating to risk assessment, pre and post-testing communication and answer potential patient questions in a manner and vocabulary understandable to patients while developing an understanding of the roles of providers on an inter-disciplinary team. The interactive component will involve small-group discussion of case studies and role play related to the lecture topic with a standardized patient actor. The use of standardized patient actors has been reported to be highly effective in providing trainees a simulated experience in a range of disciplines including genetics (Holt et al.,2013). For example, during workshop #2, the patient actor will be used to enable participants to practice taking a family history. The case scenarios will be prepared by a panel of genetic counselors in consultation with the lecturer and other providers in that specialty. The participants will be divided into small groups and assigned a case study to review; they will discuss how they would approach treatment of that patient using personalized genomic medicine and explore each practitioner's role. For each class, one group will be asked to role-play with a patient actor using the information provided during the lecture. Following the role-playing, instructors and participants will discuss, make recommendations for improvement, and consider the other case studies. These simulated experiences will incorporate key components of delivering personalized medicine including: collecting family and personal health history, estimating disease risk based on that information, determining appropriate screening or testing, having a pre-testing discussion with patients regarding screening/testing, interpreting testing, and having a post-test discussion with patients reviewing testing results. We will provide an overview of the hypothetical patient and their case scenario to the patient actors in advance; we will meet or talk by phone with each actor to ensure the actors' understanding of the cases, emotions to be conveyed, and potential questions/responses to the providers.

Attendees: Invitations for participation will first be extended to residency/training directors throughout Duke, as well as instructors in the School of Nursing and School of Medicine, and departmental leaders. Enrollment will be limited to 25 attendees to enable active participation and interaction between attendees, and therefore, registration will be required. If additional slots are available, enrollment will be opened to all practicing nurses and physicians, and nursing and medical students/trainees. Participants will be asked to commit to attend all sessions [twice a month for 4 months] since topics will build upon one another. We will aim to enroll a balanced number of physicians and nurses; other types providers will not be excluded if they express interest as there has also been support for providers such as physician assistants (Rackover et al, 2007) and pharmacists (Owusu-Obeng et al, 2014) to utilize genetics and genomics in their clinical care.

Surveys: Attendees will be asked to complete a total of 9 surveys: 1) one prior to the start of the first workshop (Baseline), 2) at the conclusion of each of the 7 workshops (Post-session), and 3) one 3-months after of the final workshop (Follow-up). Participants who complete all 9 surveys will receive $50 compensation for their time and effort. For those attendees seeking continuing education credit, a separate questionnaire will be required to obtain credit and will be issued by and submitted to the Duke CME office.

Outcome measures: The Baseline and 3-month Follow-up surveys are intended to measure and assess changes in knowledge and attitudes about personalized medicine and inter-disciplinary care while the post-session surveys will assess seminar-specific knowledge learned and satisfaction with the session. We will use a collection of previously published and validated scales in our survey tools. The survey responses will be coded with an identification number to maintain privacy of the participant and also allow comparison to the post-workshop surveys (see Table and Appendix 1).

The pre-workshop survey will collect demographic information, prior experience and confidence in delivery of personalized medicine (Jenkins et al, 2010; Calzone et al, 2010), knowledge and experience with genomics (Ward et al, 2011), and attitudes about interdisciplinary care (Pollard et al, 2004; 2005). We will assess prior experience and confidence in delivery of personalized medicine applications using a survey adapted from a nursing survey on knowledge and adoption of genomics (Jenkins et al., 2010; Calzone et al., 2010). To assess overall knowledge and experience with genetic/genomic applications, we will use the survey tool "Genomic Nursing Concept Inventory" (Ward et al, 2011); this scale has been validated to assess genomic knowledge in nurses that will serve our needs adequately as it addresses the concepts we intend to cover throughout the workshop series for all provider types. To

assess attitudes toward inter-disciplinary education and practice, we will utilize the validated subscales developed by Pollard et al. (2004, 2005).

Following each seminar, the participant will answer a series of 3-4 knowledge-based questions specific to the learning objectives of the session that, satisfaction with the seminar, and a series of questions to assess the participant's likelihood of sharing information learned in the workshop with learners/students and colleagues. The knowledge-based questions will be developed by the lecturers and study staff based on each session's learning objectives. Satisfaction will be measured using a validated 13-question scale developed by Shewchuk et al (2007) to assess satisfaction and perceptions of the seminar and its relevance/value for practice.

Finally, the survey to be conducted 3-months following the conclusion of the workshop will reassess knowledge and experience with genomics (Ward et al, 2011), attitudes about interdisciplinary care (Pollard et al, 2004; 2005), and transfer of knowledge and skills through self-reported adoption and confidence (Jenkins et al, 2010; Calzone et al, 2010). Satisfaction with the workshop series as a whole (Shewchuk et al, 2007) and information-sharing will also be assessed at that time.

		Demographics	Confidence in clinical delivery	Genomics Knowledge	Interdisciplinary Care Attitudes	Learning Objectives Knowledge	CME Satisfaction	Information-Sharing
Baseline	Prior to start of workshop series	✓	✓	✓	✓			
Post-session	Following each of the 7 sessions					✓	✓	✓
Follow-up	3-months after workshop series		✓	✓	✓		✓	✓

Data management and analysis: A summary of demographics of participants will be generated. Summary scores (per question and overall score) of the knowledge survey and the three inter-professional survey sub-scales will be calculated using the mean and standard deviation of their scores. Changes in binary outcomes will be studied using logistic regression with generalized estimating equations (GEE) to account for the paired (before/after) nature of the data. These models allow studying how the odds of a response change after the intervention. Proportional odds regression will be used for ordered responses (Likert items). Accounting for the ordered nature of the outcome is often more powerful than treating the outcome as an unordered categorical response. Assumptions underlying the proportional odds models will be tested and alternative models (such as multinomial regression) will be considered if suggested by diagnostics. All models will be fit in SAS Version 9.3.

IRB Status: This project has not yet been submitted for review to the Duke IRB. If awarded, we will promptly prepare and submit the protocol for IRB review. Given the low risk of the study and the prior development of components such as the survey measures, we estimate that it will take approximately 1 month for the study to be submitted and approved.

Challenges: One of the potential challenges for this educational proposal will be recruiting a range of providers at different levels of practice or training who are willing to commit to attend the entire workshop series. We will attempt to overcome this challenge by first targeting invitations to potential attendees with the assistance of our collaborators. We will also try to vary the schedule the workshops (early morning, noon, or late afternoon) to maximize attendance.

Sustainability: We plan to record a 'clean' version of each presentation and post the recorded presentation on the CAGPM web-site so the series is available for other interested providers. If successful and reviewed as useful by

participants, this series may continue and expand annually with support from the Center for Applied Genomics and Precision Medicine (CAGPM).

Opportunities for subsequent scholarship: Subsequent scholarship will entail developing educational approaches to broaden the outreach of engagement beyond the three targeted provider groups and to increase accessibility of the training. Particularly for busy practitioners, many who are in private practice, we recognize that their time is extremely limited and therefore, we envision developing online learning strategies such as gaming or other interactive approaches that can be accessed remotely and will seek foundational or federal funding for such work.

Broader Impacts: As genomics and personalized medicine becomes more broadly used, it is important for providers to be educated and able to provide these services effectively. Further, due to patients' likely limited understanding of genomics, providers will need to be able to effectively translate their knowledge to patients in an understandable way. Further, by targeting this course to the teachers and leadership, we hope that they will share the knowledge gained with their students and colleagues, further promoting knowledge and education about genomics and personalized medicine.

Timeline: In summary, we estimate it will take about a month to acquire IRB approval, confirm the lecturers and room reservations for each workshop, design posters/announcements, and identify targeted attendees. Advertising and registration will begin in January 2015 and the course would begin in mid-February 2015. The course will meet twice a month for 4 months (7 total sessions) and conclude by June 2015. Data from the follow-up survey will be collected in early September 2015 and analysis of that data, manuscript preparation, and application for follow-up funding will occur in the final months of the project.