Strategies for Improving Access to Hereditary Cancer Testing: Recommendations from Stakeholders

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INTRODUCTION

Several studies clearly demonstrate increased cancer risks associated with pathogenic variants in certain genes. *BRCA1* and *BRCA2* are perhaps the best known, but many other genes have been associated with increased cancer risks, including but not limited to *TP53*, *PTEN*, *CDH1*, *PALB2*, *MLH1*, *MSH2*, *MSH6*, *ATM*, *STK11*, *CHEK2*, *BRIP1*, *RAD51C*, and *RAD51D*. National Comprehensive Cancer Network guidelines include management recommendations for patients carrying pathogenic variants in these genes. Both tumor/site-specific and “pan-cancer” panels are available to identify patients at increased risk. Both types of panels have the advantage of addressing syndrome heterogeneity and overlap and are less costly than testing each gene independently. Multigene panels also generate a higher rate of pathogenic findings than testing single or a few genes at a time; however, they generate a higher rate of variants of uncertain significance (VUS).¹

Despite the potential utility of hereditary cancer panels,² access to this testing is limited by insurance coverage challenges, including inconsistent or nonexistent coverage policies, preauthorization burdens, and pretest counseling requirements. In November 2017, expert stakeholders from laboratories, patient advocacy organizations, professional societies, and health-care provider organizations were convened by Genetic Alliance (Washington, DC) to identify mechanisms to address these barriers. Participants and their affiliations are listed in the Acknowledgements. Dialogue, shared experiences, and varied perspectives among participants informed a roundtable discussion of several tactics to address insurance-related challenges, resulting in a number of consensus recommendations. Given the real or perceived conflicts of interest of each participant with respect to multigene panel testing, the roundtable was designed to serve as a beginning to a broader conversation. A key recommendation was the formation of a coalition of diverse stakeholders

that can work together toward a shared goal of improved patient access to hereditary cancer testing.

HEALTH INSURANCE COVERAGE OF HEREDITARY CANCER PANELS

Currently, most insurers cover testing for *BRCA1* and *BRCA2* and Lynch syndrome in patients with suggestive personal or family history. However, few insurers cover panels that include additional high- and moderate-risk genes, resulting in inconsistent and uncertain reimbursement and reducing patient access to testing.² Insurers consider most panels to be experimental due to questions about genotype–phenotype associations, actionability, and clinical utility.²

Three tactics may promote development of the evidence payers desire while maintaining access to testing for appropriate patients. First, laboratories should work together with payers, health-care providers, and professional societies to identify a core set of genes that payers would agree to cover as a panel. This exercise was recently undertaken in the United Kingdom: stakeholders convened a workshop that resulted in consensus regarding genes to be included on UK genetics services panels.³ Second, laboratories need clear guidance from insurers on the evidence they require to institute coverage. A multistakeholder effort should be undertaken to explicitly define how much and what type of evidence would be acceptable to payers. For example, whether retrospective data is sufficient or prospective studies are necessary, and whether use of results to inform medical management recommendations are acceptable or whether long-term morbidity and mortality data are necessary. Third, insurers should institute “hybrid” payment models that enable evidence development. One hybrid model could entail a policy by which insurers cover analysis of well-studied genes on a panel, while allowing laboratories to include on the panel, and collect evidence on, less well-studied genes. Another could entail a policy by which insurers cover panels

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by laboratories that agree to submit variant data to publicly accessible databases, thereby strengthening evidence and decreasing VUS rates on less well-studied genes.

PREAUTHORIZATION AND LABORATORY BENEFIT MANAGEMENT

The rapidly expanding genetic test market has been challenging for payers who lack expertise in clinical genetics. In response, insurers have instituted preauthorization requirements to ensure genetic test orders are medically necessary. Insurers have contracted with laboratory benefit management companies (LBMs) to enforce preauthorization requirements and confirm test orders are in line with medical policy.

Strong dissatisfaction with LBMs and preauthorization requirements are pervasive among many health-care providers and health advocacy groups because they create barriers to appropriate patient care.^{4–6} These include online LBM portals that are nonintuitive and time-consuming, denials even when medical necessity criteria are met, and restrictions on which health-care providers (ordering provider versus laboratory provider) may request preauthorization.⁷ Ordering providers are spending extraordinary amounts of time on preauthorization requirements and report that they are associated with delays in care and abandoned treatment.⁴

Strategies to reduce barriers associated with preauthorization requirements include education for health-care providers, documentation of experiences, and advocacy to reform preauthorization. Insurers with preauthorization requirements and laboratories performing tests subject to such requirements should work together to create educational resources that inform ordering providers about requirements and assist them in efficiently interacting with LBMs. Concurrently, ordering providers interacting with LBM portals should establish a standard to document the amount of time spent navigating portals and instances of inappropriate denials. Insurers and LBMs could use this information to improve the preauthorization process.

Several organizations have engaged in advocacy activities aimed at reducing the burden of preauthorization and ensuring that patients have access to genetic testing. The American College of Obstetricians and Gynecologists (ACOG) published a position statement in early 2018 calling these types of preauthorization requirements “an unfunded mandate that leads to inefficiency in the healthcare system.”⁵ Additionally, the American Medical Association (AMA) has developed a set of principles to which preauthorization requirements should adhere to ensure they are clinically valid and implemented in a way that is transparent, timely, efficient, flexible, and standardized.⁸ More than 100 medical specialty societies, state and local medical societies, and other health-care organizations have signed onto the principles. This level of endorsement implies that improvement in preauthorization procedures is a priority for health-care providers; improving these procedures should therefore be a focus of the collaborative work among stakeholders moving forward.

PRETEST COUNSELING REQUIREMENT

Pretest genetic counseling is intended to determine the need for genetic testing, educate the patient about potential test results, and provide psychosocial support. Several insurers have instituted pretest counseling requirements with a genetics specialist as part of preauthorization. Shortages in the genetics workforce raise questions about how to efficiently provide pretest counseling to all patients for whom it is mandated. Additionally, early studies suggest pretest counseling requirements are barriers to clinically appropriate testing, as they are associated with increased test cancellation among patients who meet medical criteria, with no corresponding improvement in the detection of at-risk patients.⁹

Armed with information about workforce limitations and studies finding that alternative mechanisms to in-person counseling, such as online services, appear to be no less effective in preparing patients for genetic testing, insurers should revisit their pretest counseling requirements. An additional solution to meet the objectives of pretest counseling is to entrust nongenetics health-care providers with genetic counseling and pretest education. The ACOG, AMA and American Society of Clinical Oncologists support removing restrictions on the type of provider permitted to provide pretest genetic counseling.^{5,6,10} An important component of this model will be the development of a minimum set of genetic counseling competencies and associated educational resources for use by nongenetics health-care providers.

CONCLUSIONS AND FUTURE DIRECTIONS

Technological advances in medicine have long outpaced the ability of coverage policies to stay up-to-date. As medical policies lag behind and insurers institute requirements like preauthorization and pretest counseling, patients are not able to access testing that could have a substantial impact on their health outcomes. Discussion among roundtable participants identified a number of strategies by which stakeholders can work together to address barriers to access. However, as the voice of payers was absent at this roundtable, it will be critical to engage with them in ongoing discussion. Payer input may result in revisions to the strategies recommended here, as well as additional strategies that have not yet been explored.

Multistakeholder implementation was recommended through the formation of a coalition of stakeholders, including payers, aligned toward the goal of improving access to hereditary cancer testing. An example of a coalition focused on coverage is CAPS (Coalition for Access to Prenatal Screening; <http://capsprenatal.com/>), comprised of six laboratories working to improve access to noninvasive prenatal screening for all pregnant women. Thoughtful collaboration among stakeholders, whose shared ambition is to ensure that patients receive appropriate hereditary cancer testing, has the potential to result in creative and effective solutions.

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DISCLOSURE

K.R. and K.J.T. are employees of Counsyl, Inc., which markets a hereditary cancer testing panel. Counsyl provided partial funding for the meeting described in the paper. The other authors declare no conflicts of interest.

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