Assessment of Laboratory-Based Quality Control Processes to Ensure Appropriate Utilization of Genetic Testing for Hereditary Cancer Risk

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INTRODUCTION

Increased awareness of the benefits associated with establishing inherited cancer risk for patients has led to an expansion of clinical genetic testing beyond specialty genetics clinics. This increased access to testing has raised concerns that non-specialty providers may lack sufficient expertise to order testing appropriately, leading to patients receiving tests for the wrong condition, or tests that are more elaborate than necessary, resulting in increased costs. To address these concerns, our laboratory has developed Standard Operating Procedures (SOPs) to identify potentially incorrect test orders and work with both genetics and non-genetics providers to modify testing, as well as provide education to increase knowledge and/or raise awareness of specialty genetics resources. Here we assess the outcomes from these quality control processes.

METHODS

For FY 2012 we retrospectively reviewed clinical information provided on test request forms submitted with samples, notes entered in our case processing/client contact database, and a prospective activity tracking system set up for this study. We determined 1) the percentage of BRACAnalysis and COLARIS test orders that met established clinical indications for testing based on the submitted clinical histories. Only 0.5% of cases received lacked apparent clinical risk factors for the test ordered. Quality control SOPs were highly effective in reducing these and other test order errors. Test order review and pre-order consultations with providers resulted in 3000 orders being avoided, cancelled or revised, resulting in substantial testing cost savings and improved outcomes for patients. The most common errors were duplicate test orders and orders for comprehensive analysis when a single-site test was indicated. Case review also identified 2000 cases where laboratory and field-based clinical staff discussed referral to a cancer genetics specialist with providers and patients.

RESULTS

During FY 2012, 93% of BRACAnalysis and COLARIS test orders met established clinical indications for testing based on the submitted clinical histories. Only 0.5% of cases received lacked apparent clinical risk factors for the test ordered. Quality control SOPs were highly effective in reducing these and other test order errors. Test order review and pre-order consultations with providers resulted in 3000 orders being avoided, cancelled or revised, resulting in substantial testing cost savings and improved outcomes for patients. The most common errors were duplicate test orders and orders for comprehensive analysis when a single-site test was indicated. Case review also identified 2000 cases where laboratory and field-based clinical staff discussed referral to a cancer genetics specialist with providers and patients.

CONCLUSIONS

Laboratory-based protocols provide an effective mechanism for the identification and resolution of the relatively small fraction of genetic test orders containing errors. Clinical laboratories should allocate resources for this purpose in order to reduce costs, improve patient care, and facilitate expanded testing access for patients at risk of hereditary cancer syndromes.