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Cancer

PS2-11:
Validation of KRAS Mutation Testing Across Five Certified Laboratories

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KRAS mutation testing helps oncologists decide whether patients diagnosed with metastatic colorectal cancer (CRC) should be treated with epidermal growth factor receptor (EGFR) inhibitors. These drugs block the EGFR signaling pathway in tumor cells, and thus can slow tumor progression. Mutated KRAS is found in 30-45% of all CRC tumors, with mutations occurring at codons 12 and 13 being the most common. Patients with a mutated KRAS found in tumor tissue show limited clinical response to EGFR inhibitor therapy. Several factors can influence the results of KRAS mutation testing in tumor specimens. Variation can result from tumor heterogeneity, sample handling, DNA preparation, and differences in assay design and methodology. The purpose of this study was to evaluate comparability of KRAS test results among five labs currently used to determine KRAS mutation status of colorectal cancer specimens in a large multi-center study.

Three commercial labs (Genzyme, Clarient, Quest Diagnostics), one clinical lab (Henry Ford Health System), and one research lab (Oregon Health Sciences University) were contracted to analyze KRAS mutational status; all are Clinical Laboratory Improvement Amendments (CLIA) certified. Twenty formalin-fixed paraffin-embedded (FFPE) human CRC samples that had been previously tested for KRAS mutations were selected based on mutation status (7 wild type samples, 7 with codon 12 mutations, and 6 with codon 13 mutations) from two clinical settings (Kaiser Permanente Colorado and Northwest). To ensure sufficient sample quantity, only surgical specimens from colon resections were used. Before being sent to each lab, the FFPE samples were reviewed by a pathologist to determine that the sample was of sufficient quality and quantity for testing. We asked each lab to use their standard clinical testing procedures. Clarient uses a polymerase chain reaction (PCR) method for mutation detection, Genzyme uses single nucleotide primer extension assay with fragment analysis by capillary electrophoresis, and the other three labs all use sequencing. Preliminary data (n=11 samples tested to date) suggests good agreement across laboratories despite differences in mutation detection methodologies.
Keywords: Colorectal cancer, Genetic testing
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PS2-04:
Effectiveness and Satisfaction with Webinar Training for Multi-site Medical Chart Abstraction: The BOWII Experience

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Background: Abstractor training is a key element in creating valid and reliable data collection procedures. The choice between in-person vs. remote or simultaneous vs. sequential abstractor training has significant consequences for time and resource utilization. We conducted a web-based (webinar) abstractor training session to standardize training across six individual Cancer Research Network (CRN) sites for a study of breast cancer treatment effects in older women (BOWII). **Aims:** To describe the web-based training session, its participants and participant-reported effectiveness and satisfaction with the training. **Methods:** A webinar was held for all six data collection sites with the primary purpose of simultaneously training staff and ensuring consistent abstraction across sites. The web-based training session involved sequential review of over 600 data elements outlined in the coding manual in conjunction with the display of data entry fields in the study's electronic data collection system. Post-training evaluation was conducted via Survey Monkey© to assess the effectiveness of the webinar modality for data collection training and participant satisfaction with the training. Inter-rater reliability measures for abstractors within each site were conducted three months after the commencement of data collection. **Results:** Ten of the 16 people who participated in the webinar training completed the online survey. Almost all (90%) of the 10 trainees had previous medical record abstraction experience and nearly two-thirds reported over 10 years of chart review experience. Half of the respondents had previously participated in a webinar, among which three had participated in a webinar for training purposes. While most (90%) respondents preferred in-person training, all rated the knowledge and information delivered through the webinar as useful and reported that the webinar adequately prepared them for data collection. Consistent with participant-reported training effectiveness, results of data collection inter-rater agreement within sites ranged from 89 to 98 percent, with a weighted average of 95% agreement across sites. **Conclusions:** Conducting training via web-based technology was an acceptable and effective approach to standardizing a complex chart review across the six participating health plans for this group of experienced chart abstractors. Researchers should consider this cost-effective approach to ensuring high quality data collection in multi-site studies.
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