What GAO Found

Health care providers use biopsies—the removal and examination of cells or tissue—to diagnose diseases like cancer. Biopsy specimen source errors include the misidentification or contamination of one patient's biopsy with another.

Centers for Medicare & Medicaid Services (CMS) officials and stakeholders with direct knowledge about specimen source errors told GAO that such errors are infrequent. Representatives from one accreditation organization said they only cited two such errors in the last 2 years. GAO identified six studies that estimated the prevalence of specimen source errors, though these studies cannot be generalized. The highest estimated rate of specimen source errors was 2.3 percent. Studies GAO reviewed attributed specimen source errors to a variety of causes that may occur at different points in the biopsy process. For example, a lab technician may mix up specimens when manually cataloging them upon their arrival to the lab. Integrating technology—like a printed barcode system that allows for specimens to be easily identified and tracked throughout the process—and effective specimen collection and handling procedures may decrease the risk of specimen source errors, according to the literature and stakeholders.

CMS regulations require labs to establish procedures related to preventing specimen source errors. CMS ensures lab compliance with these regulations through biennial inspections conducted either by surveyors acting on behalf of CMS or by lab accreditation organizations. Surveyors also review a sample of labs inspected by each accreditation organization to ensure inspection quality or in response to a complaint. CMS data show that in 2018, 3.8 percent (364 out of 9,655) of labs inspected by surveyors were cited as deficient in at least one of the regulations relevant to specimen source errors. These types of deficiencies were not among the agency’s list of the top 10 lab-related deficiencies reported in October 2018.

Lab Inspection Findings in Calendar Year 2018

View GAO-21-59. For more information, contact Jessica Farb at (202) 512-7114 or farbj@gao.gov.