Q&A column, 1/16

Editor: Frederick L. Kiechle, MD, PhD

Submit your pathology-related question for reply by appropriate medical consultants. CAP TODAY will make every effort to answer all relevant questions. However, those questions that are not of general interest may not receive a reply. For your question to be considered, you must include your name and address; this information will be omitted if your question is published in CAP TODAY.

Submit a Question

Q. The current recommendation of the Centers for Disease Control and Prevention to screen baby boomers for hepatitis C virus may cause stress on laboratory resources. Is this the most prudent way to capture those individuals who will progress to liver cancer? Current data/literature suggest that 80 percent of those who may screen positive will not progress to cancer but will eliminate the virus on their own.

A. The rationale for HCV screening of the baby boomer cohort is outlined in the U.S. Preventive Services Task Force recommendation statement. This document examines evidence for the inadequacy of risk-based screening alone and proposes, with ranking of evidence, a cohort and risk-based model. Among the drivers for this guideline and earlier CDC screening recommendations is the large number of still unidentified chronic HCV individuals in the sizable at-risk cohort born between 1945 and 1965 and the availability of dramatically more effective (albeit expensive) treatment options.

The most recent HCV guidelines of the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America (August 2015) also discuss screening, point out the benefits of patients achieving a sustained viral response, and strongly advocate treatment of most identified individuals. This guideline states: "Successful hepatitis C treatment results in sustained virologic response (SVR), which is tantamount to virologic cure, and as such, is expected to benefit nearly all chronically infected persons.... Therefore, the panel continues to recommend treatment for all patients with chronic HCV infection, except those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy." The burden of screening and especially treatment with recently approved direct-acting antiviral agents has been weighed in these and other analyses. The true benefit and cost of this new approach will clearly be the subject of many studies going forward.

- Moyer VA, et al. Screening for hepatitis C virus infection in adults: U.S. Preventive Services Task Force recommendation statement. Ann Intern Med. 2013;159(5):349–357.

David R. Hillyard, MD, ARUP Laboratories, Salt Lake City, Member, CAP Microbiology Resource Committee

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Q. Installing an electronic health record system or a laboratory information system takes a lot of time.

If a pathologist in a private pathology group that has a professional contract with a health system works a lot of hours on an EHR or LIS installation and is not compensated for his or her time, could that be considered to be an inducement under the anti-kickback law? If so, how would one determine when participation becomes an inducement? And what about other contracted private physician groups like hospitalists, radiologists, or intensivists?

A. There is nothing from the federal government that draws a clear line as to when a hospital is asking too much in terms of uncompensated time from members of the medical staff. Unfortunately, the government has provided rather mixed and incomplete guidance on the demands that hospitals might make of hospital-based physicians and when those demands begin to implicate the Medicare and Medicaid anti-kickback law.

The rules are different for employed physicians. For independent members of the medical staff, it is relevant to compare the requests/demands to those made of other independent members of the medical staff. At many hospitals, significant numbers of medical staff members "volunteer" their time to serve on time-consuming medical staff committees or assist with hospital initiatives. Admittedly, their staff privileges are not usually at risk if they don't participate, and they don't typically have a contractual agreement with the hospital. Nevertheless, it still is a relevant consideration.

Another important issue is whether the Part A compensation paid to the pathology group covers this type of work. I have negotiated Part A compensation for clients where we specifically included time on LIS issues as part of the compensable Part A duties. It would be important to review the current hospital contract to see if the description of the Part A duties would cover this work or not. If not, then it is reasonable to ask for some additional Part A compensation for this time.

Jane Pine Wood, Member, McDonald Hopkins LLC, Dennis, Mass.

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Q. Should I validate new reagent lot numbers for chemistry and hematology reagents? What should the acceptable criteria be? How much should the difference be?

A. The CAP checklist requirement COM.30450 addresses the checks of new reagent lots and shipments. New reagent lots must be checked against old reagent lots or with suitable reference materials before or concurrent with being placed in service. The CAP recommends the use of patient specimens, when possible, but will accept the use of other types of materials. Each laboratory is responsible for defining its own acceptability criteria to evaluate if the change in reagent lot will affect patient results. Laboratories may use tolerance limits (e.g. + or − %) based on precision studies performed by the laboratory or following manufacturers' recommendations. The acceptability criteria need to be defined in laboratory policy.

- College of American Pathologists. COM. 30450 New reagent lot confirmation of acceptability. In: All Common Checklist. July 28, 2015.

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Dr. Kiechle is medical director of clinical pathology, Memorial Healthcare, Hollywood, Fla. Use the reader service card to submit your inquiries, or address them to Sherrie Rice, CAP TODAY, 325 Waukegan Road, Northfield, IL 60093; srice@cap.org. Those questions that are of general interest will be answered.