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New Trends, Applications, and IVD Industry Analysis

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Top of the News: Adoption Quickening for Genomic Cancer Testing in Community Settings

Clinicians are increasingly using genomic cancer testing in community health care settings, although there are lingering questions about the utility of results. These are the findings of several presentations made at American Society of Clinical Oncology's annual meeting (May 31 to June 4, Chicago)

Trend Toward Increased Utilization

Medical Oncologists in the Sarah Cannon Research Institute network (Nashville, Tenn.) ordered commercially available next generation sequencing-based molecular profiling for patients as the standard of care. Data use agreements between the institute,

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Top of the News: CDC Announces Shortage of TB Skin Test Antigen, New TB Testing Guidelines

The U.S. Centers for Disease Control and Prevention (CDC) announced a three-to 10-month national shortage of Aplisol (Par Pharmaceuticals; Chestnut Ridge, N.Y.), one of two purified-protein derivative (PPD) tuberculin antigens licensed by the Food and Drug Administration for use in tuberculin skin tests.

Interruption of supply for Aplisol 5 mL (50 multidose vials) began in June 2019, while interruption of the supply of Aplisol 1 mL (10 multidose vials) is anticipated in November 2019.

As a result of the shortage, CDC recommends three general approaches to prevent a decrease in tuberculosis testing capability. First, clinicians can substitute interferon-gamma release assay (IGRA) blood tests for tuberculin skin tests, with the caveat that clinicians should be aware that the criteria for test interpretation differ between the tests. Second, Tubersol can be used instead of

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Adoption Quickening for Genomic Cancer Testing in Community Settings, *from page 1*

affiliated medical oncology practices, and commercial test providers enabled analysis of patient data from 2012 to 2018.

The researchers report that NGS-based tumor testing utilization increased in the community-setting between 2012 and 2018. Community-based NGS testing rates within the Sarah Cannon network were 5.75 per month in 2012 versus 440 per month in 2018. The number of oncologists ordering molecular profiles increased from 11 to 269 over the same time period. Physician test utilization grew from an average of six tests per physician in 2012 to 22 tests per physician in 2018.

Plasma-based NGS testing grew from 4.9 percent of total testing in 2014, when it was initiated, to 40.1 percent in 2018. NGS tests were performed on 34 different tumor types and biopsies taken from both primary (~40 percent) and metastatic (~60 percent) sites. Tissue-based tests averaged 14 mutations percent sample, while plasma-based tests averaged four mutations per sample. From 2012 to 2018, there was a 74 percent decrease in median time between biopsy collection and NGS test results (131 and 34 days, respectively), indicating a shift toward the use of fresh, non-archival tissue, the authors say.

Test Result Utility Affected by Geography

Analysis included 360 patients with advanced solid tumors who had progressed on standard treatment regimens and had an available test results from Foundation Medicine's multiplex genomic test. Patients had solid tumors and were treated at two community hospital-based oncology practices in central rural Nebraska between 2014 and 2018. Treating community oncologists directed treatment choices based on MGT results.

The researchers report that the average turn-around time from order to reporting was 20.19 days. Reimbursements were through commercial insurance (27 percent), Medicare (66 percent), Medicaid (3 percent), self-pay (2 percent), and financial assistance by company (2 percent). Most common cancer types were non-small cell lung (27 percent), pancreas (9 percent), colon (8 percent), unknown primary (4 percent), sarcoma (4 percent), breast (4 percent), gastro-esophageal (2 percent), and kidney (1 percent).

The vast majority of samples (79 percent) of samples had at least one actionable alteration. Nearly one in five of these patients (19 percent) alterations were matched to one or more on- or off-label targeted therapies approved by the U.S. Food and Drug Administration (FDA) and/or professional guidelines. Just over one-third of patients (26 of 69) with actionable alterations were able to have a new therapy and 12 percent of patients were qualified to participate in locally available clinical trials (MATCH, LUNG-MAP and TAPUR).

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"In addition to established barriers of cost, long turnaround time, adequate tissue, the low yield of new FDA- and/or guideline-approved treatments decreases the utility of multiplex genomic testing," write the authors led by **Mehmet Sitki Copur**, from Mary Lanning Healthcare in Hastings, Nebraska. "Increased variety and availability of precision medicine clinical trials with improved patient access in the rural setting may improve this shortcoming."

Clinicians Report Confidence Using Tumor Genomic Testing

Researchers led by **Suanna S. Bruinooge** form the American Society of Clinical Oncology (Alexandria, Virginia) surveyed physicians seeing patients as part of the Targeted Agent and Profiling Utilization Registry (TAPUR) Study, a multibasket study of marketed agents targeting tumor genomics. Analysis included 112 physician respondents at 54 TAPUR sites, including community oncology practices. Questions assessed use of tumor genomic testing, barriers to ordering testing, and genomic confidence. Surveys included 3 scenarios for test ordering 1) pretreated advanced cancer patients without options, 2) newly diagnosed, untreated, metastatic patients and 3) early-stage, potentially curable patients with standard options.

Respondents reported that a median of 25 percent of their pts had tumor genomic testing in past 12 months for trials or routine care (range 0 to 85 percent). Barriers to testing primarily included access to tumor specimen (86 percent), insurance coverage (67 percent), concerns that results will not be actionable (55 percent), and test issues (wait time, unsure which test or lab to use, and test accuracy; 54 percent).

TGT was ordered most often for scenarios 1 (96 percent) and 2 (70 percent), but one-third of physicians said they would order testing in scenario 3. For clinicians reporting ordering testing for scenarios 1 and 2, most explained to patients that results could inform treatment, prognosis, and access trials (97 percent), but may be uninformative (84 percent). Clinicians said that for scenarios, they discussed patients' expectations of test results prior to testing. More than one-third of respondents reported frequently telling patients in advance that results could inform heritable cancer susceptibility (37 percent), despite growing evidence of germline findings in somatic testing.

Confidence in using tumor genomic testing was high with more than 95 percent saying they are somewhat or very confident in their ability to recommend treatment based on test results and their ability to explain test results to patients. However, confidence drops to 66 percent in providers practicing for than 15 years.

Takeaway: While it is encouraging that genomic oncology test ordering and confidence in interpretation of test results is growing among community-practicing oncologists, there is concern that geography may hamper the utility of results by limiting access to clinical trials.

Business of Testing: Expanded Access to Genetic Testing for Cardiomyopathy Is Cost Effective

Expansion of genetic testing in asymptomatic relatives of patients with dilated cardiomyopathy (DCM) to guide clinical surveillance is cost-effective, according to a study published in *Genetics in Medicine*. The authors call for greater access to called cascade testing, rather than just periodic clinical surveillance.

"As the DCM pathogenic variant detection rate rises and new evidence for personalized treatment of at-risk individuals becomes available, the cost-effectiveness of cascade testing will further increase," write the authors led by **Max Catchpool**, from the University of Melbourne in Australia. "This has important implications for the evaluation of DCM and suggests that those with a family history of the condition should have improved access to specialized cardiac genetic services."

Asymptomatic DCM is estimated to affect more than one in 250 individuals. Yet, international professional associations do not routinely recommend genetic testing for all patients diagnosed with DCM and their relatives. The eight-year old recommendations call for testing only among patients with significant cardiac conduction disease and/or a family history of premature unexpected sudden death, but do call for periodic clinical surveillance (every 1 to 5 years) for relatives (e.g., physical examination, electrocardiography, and echocardiography).

The researchers built a model that incorporated findings from 87 patients with idiopathic DCM or other nonhypertrophic cardiomyopathies who underwent exome sequencing between April 2016 and September 2017. Eligible participants were either diagnosed younger than 40 years or had a family history of DCM (more than 2 relatives) and/or early sudden unexplained death before 35 years. A multidisciplinary team of clinical geneticists, cardiologists, genetic counselors, medical scientists, and bioinformaticians reviewed variant classifications.

The model assumed

- 40 percent of relatives to accept cascade testing
- Identification of a pathogenic variant means lifetime periodical clinical surveillance, whereas identification of no variants exempted relatives from clinical surveillance
- Familial DCM occurs in 35 percent of idiopathic DCM cases and in a cohort of first-degree relatives about 7 percent would have an identifiable variant
- 13.7 percent diagnostic rate
- Cost of performing exome sequencing (analysis of up to 100 genes) in a proband was $1,200 with initial and follow-up genetic counseling costs of $184 and $147, respectively
- Clinical surveillance occurred every 2 years

The researchers found that the incremental cost per additional quality-adjusted life year (QALY) for cascade genetic testing prior to periodical clinical surveillance of first-degree relatives was AUD $6,100. At the standard threshold of $50,000 per QALY, the probability that genetic testing-guided clinical surveillance is cost-effective versus clinical surveillance alone was 90 percent. The results were similar even with the addition of second-degree relatives and when the costs were raised to $2,400.

While the authors do urge expansion of DCM genetic testing beyond current recommendations, they caution that evidence is lacking that shows improved clinical outcomes as a result of pathogenic variant identification.

"Our findings indicate that genetic testing in patients with DCM is very likely to be cost-effective and thus should be offered to more patients with DCM than is currently recommended," write the authors. "Similarities in the cost of genetic testing and the management guidelines for the treatment of DCM, as well as extensive sensitivity analyses conducted as part of the economic evaluation, are likely to support the generalizability of our findings to other contexts, such as the United States and Europe."

Takeaway: Clinical surveillance that is guided by genetic testing is cost effective among asymptomatic relatives of DCM patients.

Business of Testing: Upfront Next-Generation Sequencing for Lung Cancer Patients Saves Time, Money

Use of upfront next-generation sequencing (NGS) testing at diagnosis of patients with metastatic non-small-cell lung cancer (mNSCLC) is associated with substantial cost savings, according to a study published in the *JCO Precision Oncology*. The authors say the findings hold true for patients covered by Medicare or commercial payers.

There are several currently approved therapies targeting EGFR, ALK, ROS1, and BRAF

V600E alterations, while targeted therapies for MET, HER2, NTRK1, and RET alterations are currently in clinical trials. Despite genetic testing becoming the standard of care for patients with lung cancer, the authors say that only a small percentage of patients with NSCLC currently receive NGS. Barriers include a lack of awareness of its benefits, limited coverage, and low reimbursement rates. So, the authors undertook an assessment of the economic impact of various genetic testing strategies to inform future policymaking.

"As more clinically relevant genetic targets in NSCLC emerge that require routine testing at diagnosis, it is vital to identify the molecular testing

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Upfront Next-Generation Sequencing for Lung Cancer Patients Saves Time, Money, *from page 5*

strategy that is timeliest, spares the most tissue, and is most cost efficient, as this must be done in every new patient," write the authors led by **Nathan A. Pennell**, M.D., Ph.D., from the Cleveland Clinic in Ohio.

The researchers developed a model that evaluated four testing scenarios and assessed time to results, the proportion of patients identified with genetic alterations, and total testing costs. The four genetic testing scenarios included:

- Upfront NGS for EGFR, ALK, ROS1, BRAF, MET, HER2, RET, and NTRK1 (all alterations tested simultaneously) plus KRAS
- Sequential testing (sequence of single-gene tests)
- Exclusionary testing (KRAS plus sequential testing)
- Hotspot panels (EGFR, ALK, ROS1, and BRAF tested simultaneously plus single-gene tests or NGS for MET, HER2, RET, and NTRK1)

All four testing strategies included programmed death ligand 1 (PD-L1) and routine immunohistochemistry testing. The model assumed that in the case of insufficient tissue sample, a rebiopsy would be attempted, which may or may not be successful. Additional assumptions included that immunohistochemistry or fluorescence in situ hybridization tests would be used for ALK, ROS1, MET, RET, and NTRK1 testing, while real-time polymerase chain reaction would be used to perform KRAS, EGFR, HER2, and BRAF testing.

Costs were based on the 2017 Clinical Lab Fee Schedule for the Medicare-insured population (costs ranging from $180.20 for BRAF to $433 for HER2), while commercial costs were calculated using two U.S. administrative claims databases (ranging from $406 for BRAF to $1,127 for HER2). Multigene panels were reimbursed at $1,345 for Medicare and $3,299 for commercial payers, while NGS was calculated based on $627.50 and $2,860, respectively. Finally, PD-L1 was reimbursed at $433 and $1,127, respectively.

For both Medicare and commercial payers, the model assumed a hypothetical health plan covering 1,000,000 members (either 65 years and older or 18 to 65 years of age). This yielded and estimated 2,066 Medicare-insured patients and 156 commercially insured patients having mNSCLC and eligible for testing. Time-to-test results were 2.0 weeks for both NGS and the hotspot panel versus 2.7 and 2.8 weeks, respectively, for exclusionary and sequential testing. NGS was associated with cost savings for both Medicare and commercial payers. NGS yielded savings of $1,393,678 versus exclusionary testing, $1,530,869 versus sequential testing, and $2,140,795 versus hotspot panels for Medicare $3,809, $127,402, and $250,842, respectively, for commercial payers.

NGS identified all 446 of 2,066 Medicare-insured patients having alterations targetable by U.S. Food and Drug Administration- (FDA-)

approved therapies, as well as all 34 of 156 commercially insured patients. This identified 2.3 percent to 5.9 percent more patients than other testing strategies. Further, NGS identified all 156Medicare-insured patients and all 12 commercially insured patients estimated to have alterations without FDA-approved therapies, identifying 32.2 percent to 43.7 percent more patients than other testing strategies.

The researchers say that increasing the proportion of NGS-tested patients translated into substantial cost savings for both CMS and commercial payers. By increasing the proportion of NGS-tested patients from 25 percent to 50 percent, Medicare would save $492,251 and a commercial payer $52,421.

"Our model illustrates that moving from sequential single-gene tests or even panels of tests to broader NGS testing for patients with advanced NSCLC is already the best strategy in these three areas and will only become more relevant as the list of tests grows," the authors conclude. "Stakeholders should consider moving to NGS as the preferred method for biomarker testing."

The study was funded by Novartis Pharmaceuticals.

Takeaway: Using NGS to target treatment in patients with newly diagnose mNSCLC yields both cost savings and speeds time to treatment initiation, compared to other testing strategies.

Testing Trends: Genetic Testing Guidelines for Hereditary Cancer Miss Many At Risk

The National Comprehensive Cancer Network genetic testing criteria for hereditary cancer miss almost one in five at-risk for breast and ovarian cancer, and more than one in three at-risk for Lynch Syndrome, according to a study published in the July issue of the *Journal of Molecular Diagnostics*.

"These data suggest that personal history alone is a poor indicator of pathogenic variant carrier status," write the authors led by **Cynthia Neben**, from Color Genomics in Burlingame, Calif. "More individuals are at genetic risk for hereditary cancer than are identified by current testing guidelines and/or use of single-gene or single-site testing."

Color Genomics reports the results from 23,179 individuals (83.1 percent women; 52.1 percent Caucasian) who were referred, independent of current testing guidelines, for the Color Hereditary Cancer Test, a 30-gene next-generation sequencing panel testing that examines hereditary

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Genetic Testing Guidelines for Hereditary Cancer Miss Many At Risk, *from page 7*

cancer risk for breast, ovarian, uterine/endometrial, colorectal, melanoma, pancreatic, prostate, and stomach cancer) between May 2016 and September 2017. Every variant was reviewed by at least two variant scientists and all pathogenic and likely pathogenic variants were confirmed — single-nucleotide variants and insertions and deletions were confirmed with Sanger sequencing, while structural variants were confirmed by variant-specific polymerase chain reaction, array comparative genomic hybridization, or multiplex ligation-dependent probe amplification.

Overall, testing identified 2,811 pathogenic variants in 2,698 individuals for a pathogenic frequency of 11.6 percent or 9.1 percent when excluding common low-penetrance alleles. Irrespective of the presence of pathogenic variants, the frequency of individuals having a variant of uncertain significance in was 19.0 percent.

The researchers report that 3,845 individuals had a personal history of breast cancer (16.6 percent), 341 had ovarian cancer (1.5 percent), 438 had colorectal cancer (1.9 percent), and 1476 had another hereditary cancer associated with genes on the panel (6.4 percent). A personal history of stomach, colorectal, or ovarian cancer correlated with the highest pathogenic frequencies at 23.4 percent, 23.1 percent, 17.3 percent respectively, or 19.1 percent, 17.1 percent, or 17.3 percent when excluding common, low-penetrance alleles. Among the 42.4 percent of the cohort not reporting a personal history of cancer, the pathogenic frequency was 10.2 percent (7.1 percent, excluding common, low-penetrance alleles.

A majority of the 2,811 pathogenic variants identified (61.5 percent) were in CHEK2, BRCA2, MUTYH, and BRCA1, followed by 9.5 percent in APC and 6.2 percent in ATM. After excluding common low-penetrance alleles, of the 2,698 positive results, 846 were from BRCA1 and BRCA2, 189 from a Lynch syndrome gene (MLH1, MSH2, MSH6, and PMS2), 147 low-penetrance allele (a monoallelic MUTYH pathogenic variant or APC p.I1307K), and 1,016 other genes.

Single-nucleotide variants accounted for 58.9 percent of all pathogenic variants, while insertions and deletions accounted for 35.4 percent and structural variants 5.7 percent. Just over half of all insertions and deletions were found in BRCA2 and BRCA1 (51.7 percent). In addition, nearly one-third (32.1 percent) of structural variants were also in BRCA1.

Overall, more than one-third of those tested and provided a complete family history (38.7 percent) would not have met guideline-driven testing criteria. In this ineligible population, the pathogenic frequency was 8.2 percent (6.2 percent when excluding, common low-penetrance alleles). However, more than one in five individuals with pathogenic variants in genes with well-established genetic testing recommendations did not meet corresponding National Comprehensive Cancer Network testing criteria (21.7 percent). Specifically, of the 749 individuals who had a pathogenic

variant in BRCA1, BRCA2, TP53, or PTEN, 138 (18.4 percent) would not have met criteria for genetic testing for breast and ovarian cancer, while 144 individuals who had a pathogenic variant in MLH1, MSH2, PMS2, or MSH6, 52 (36.1 percent) would not have met criteria for genetic testing for Lynch syndrome.

"As the cost of sequencing continues to decrease and genetic testing becomes more accessible to a broader population, we will gain a better understanding of the genes associated with elevated risk for hereditary cancer," the authors write. "With this additional knowledge, it will be imperative to reevaluate the genes included on multi-gene panels. The genes on this panel were selected on the basis of studies in high-risk cohorts and, thus, the population-based prevalence and penetrance of many of these genes are unknown."

Takeaway: Use of personal cancer history and National Comprehensive Cancer Network testing criteria both miss individuals that carry pathogenic variants raising hereditary cancer risk.

Familial High-Risk Genetic Assessments

Breast and ovarian: BRCA1, BRCA2, TP53, and PTEN
Colorectal: MLH1, MSH2, MSH6, PMS2, EPCAM, APC (excluding APC p.I1307K), biallelic MUTYH, SMAD4, and BMPR1A

Gastric: CDH1

Testing Trends: Guidelines At a Glance

Screening for HIV

Published June 11 in the *Journal of the American Medical Association*.

The U.S. Preventive Services Task Force (USPSTF) recommends screening for HIV infection in adolescents and adults aged 15 to 65 years. Younger adolescents and older adults who are at increased risk of infection should also be screened. The USPSTF also recommends screening for HIV infection in all pregnant persons, including those who present in labor or at delivery whose HIV status is unknown.

The USPSTF found insufficient evidence to determine appropriate or optimal time intervals or strategies for repeat HIV screening, although acknowledged that repeat screening is "reasonable" for individuals at increased risk of HIV infection.

The task force recommends that when using a rapid HIV test for screening (e.g., women in labor), positive results should be confirmed.

This update confirms the guidance in the 2013 USPSTF recommendations.

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Testing Trends: Guidelines At a Glance, *from page 9*

Early-Pregnancy Screening for Preeclampsia

All pregnant women should be screened for preterm preeclampsia during the first-trimester with risk calculator assessing maternal risk factors and biomarkers, according to the International Federation of Gynecology and Obstetrics' guidelines published May 20 in the International Journal of *Obstetrics & Gynecology*.

The test includes maternal risk factors, measurements of mean arterial pressure, serum placental growth factor, and uterine artery pulsatility index. If maternal serum pregnancy-associated plasma protein A is measured for routine first-trimester screening for fetal aneuploidies, the test result can be included for preeclampsia risk assessment. This screening can be adapted for screening in twin pregnancies.

FIGO considers early screening to be a measure that would most likely increase savings to the health system, but calls for more cost-effective analyses to be conducted to demonstrate the financial benefit of the screening strategy. These recommendations support earlier guidance published by the Fetal Medicine Foundation.

Recommendations for Clinical CYP2C9 Genotyping Allele Selection

A joint recommendation of the Association for Molecular Pathology and College of American Pathologists (CAP), published May 7 in the *Journal of Molecular Diagnostics*, defines a list of alleles that should be included in clinical CYP2C9 pharmacogenomic (PGx) tests.

Tier 1 recommended alleles (CYP2C9 *2, *3, *5, *6, *8, and *11.) are those that 1) have been well characterized and found to significantly affect the function of the protein and/or gene leading to a change in a drug response phenotype, 2) have a minor allele frequency in a population/ethnicity group, and 3) have publicly available reference materials. Alleles and variants that currently meet at least one, but not all three of the tier 1 criteria are included as tier 2 variant alleles (CYP2C9 *12, *13, and *15). The recommendation says that the variants can be applied to all CYP2C9-related medications.

The workgroups identified seven commercially available platforms for CYP2C9 genotyping. All platforms include Tier 1 alleles *2 and *3, however, only two include all recommended tier 1 alleles and the tier 2 alleles. The authors note, though, that most laboratories participating in CAP and the North American Specialized Coagulation Laboratory Association's proficiency testing programs currently test for tier 1 alleles and the U.S. Food and Drug Administration recently approved 23andMe's direct-to-consumer PGx test that includes most of the CYP2C9 tier 1 alleles.

"Our goal is to promote standardization of testing PGx genes and alleles

across clinical laboratories," writes **Victoria M. Pratt**, from CAP's PGx work group.

Updated Guideline for Melanoma Management Calls for BRAF Testing

The National Comprehensive Cancer Network (NCCN) has issued an updated guideline for the management of cutaneous melanoma that recommends testing for BRAF mutations in patients with stage III melanoma who are at high risk for recurrence for whom future BRAF-directed therapy may be an option.

For patients with stage IV disease at either initial presentation or clinical recurrence being considered for targeted therapy, the updated guideline recommends obtaining tissue to ascertain alterations in BRAF, and possibly KIT, from preferably a biopsy of the metastasis or archival material.

More comprehensive genomic profiling (e.g., next-generation sequencing panels) canbe considered if the test results might guide future treatment decisions or eligibility for participation in a clinical trial, particularly if BRAF single-gene testing was negative.

NCCN recommendations for BRAF testing are similar to those from the European Association of Dermato Oncology and the European Society for Medical Oncology.

CDC Announces Shortage of TB Skin Test Antigen, New TB Testing Guidelines, *from page 1*

Aplisol for skin testing. Previous studies have shown the two skin tests produce similar results.

"While overall test concordance is high, switching between PPD skin test products or between tuberculin skin tests and blood tests in serial testing may cause apparent conversions of results from negative to positive or reversions from positive to negative," the CDC cautions. This may be due to inherent inter-product or inter-method discordance, rather than change in M. tuberculosis infection status."

Additionally, the CDC is recommending consultation with state and local public health authorities in order to prioritize allocation of tuberculin skin tests to high-risk groups, while deferring others. Groups at high-risk for tuberculosis include: people who were recently exposed to persons with TB disease; people born in or who frequently travel to countries where TB disease is common; people living in large group settings, such as homeless shelters or correctional facilities; people with weaker immune systems; and children under the age of 5 years in one of the previously mentioned risk groups.

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CDC Announces Shortage of TB Skin Test Antigen, New TB Testing Guidelines, *from page 11*

Annual TB testing of health care personnel is not recommended unless there is a known exposure or ongoing transmission (see box).

Health Care Personnel No Longer Need Annual TB Testing

U.S. health care personnel do not need routine, serial TB testing after a baseline test in the absence of a known exposure or ongoing transmission, according to recommendations from the National Tuberculosis Controllers Association and CDC, published May 17 in Morbidity and Mortality Weekly Report.

Based upon a systematic literature review that showed a low percentage of health care personnel have a positive TB test at baseline and upon serial testing, the joint workgroup revised the CDC's 2005 TB testing recommendations for annual testing.

The revised recommendations call for baseline TB screening, including an individual risk assessment for all U.S. health care personnel. Postexposure, health care personnel should have a timely evaluation and additional testing, if warranted with either an interferon-gamma release assay or a tuberculin skin test. No routine, serial TB testing at any interval after baseline is called for in the absence of a known exposure or ongoing transmission.

Condition: Tuberculosis
Source: Recommendations from the National Tuberculosis Controllers Association and CDC
Date of Issue: May 2019
Link: https://www.cdc.gov/mmwr/volumes/68/wr/mm6819a3.htm?s_cid=mm6819a3_w

Takeaway: Adjustments in tuberculosis testing will be needed during a nationwide shortage of Aplisol, a tuberculin antigen used in tuberculin skin tests. Changes in recommendations calling for only baseline TB testing among U.S. health care personnel may help with prioritization of testing during the shortage.