

Cancer Screening Tests March 2018

IAFF continues to receive questions about new cancer screening tests. Many different tests are being marketed ranging from blood, breath and urine tests to imaging tests. We have prepared this information sheet in response.

What are some of these tests?

Blood tests: This is the biggest category and includes ONCOblot®, GeneNews (ColonSentry, BreastSentry, EarlyCDT-Lung), Guardant, and IvyGene just to name a few that we have been asked about

Breath tests: "cancer-sniffing" dogs (also used on urine samples)

Imaging tests: total body CTs or ultrasounds, DermSpectra for skin photographs

How do these tests work?

Blood tests: manufacturers state that they test for different chemicals in the blood that are shed or produced by cancer cells but not by normal cells. The chemicals and cancers that are tested for vary by test.

Breath tests: Chemical detection machines using gas chromatography and mass spectroscopy or trained dogs detect chemicals in the breath of people with cancer that are reportedly different than in the breath of people without cancer.

Imaging tests: tests are designed to detect masses inside the body or on the skin.

Why isn't IAFF recommending these tests in fire fighters without symptoms or cancer?

IAFF understands that fire fighters are concerned about reducing the cancer risks that have been observed in recent studies.^{1,2} However, IAFF does not support the use of any of these tests in fire fighters without any symptoms or signs of cancer unless the use is part of an approved research study. Here are the reasons why:

Cancer screening is challenging

There are established criteria for any screening test:

- How the disease progresses must be known
- Acceptable, non-invasive screening test
- · Early stage of disease to screen for
- Accepted treatment is available when early stage disease diagnosed. Treatment must result in reduced disease severity and death
- Benefits of screening must outweigh the risks. Importantly, the less chance of disease in the population screened, the higher the risk for "false-positive" results where the screening test is positive but the disease is actually not present. "False-positives" result in unnecessary additional testing which has risks

As an example of this challenge in screening, researchers have spent decades studying ways to screen for lung cancer. It used to be thought that chest X-rays would detect lung cancer masses early enough to treat them before the cancer spread. However, although masses could be detected on chest X-rays before symptoms developed, the risk of dying remained the same because no treatment changed the outcome. People just learned they had the disease earlier. The same proved true for sputum cytology (where people cough up material from deep in their lungs). Currently, low dose CT is recommended for certain groups of smokers based on the latest research.

The experience with Prostate Specific Antigen (PSA) is another example. Prostate cancer is very common but, in many men, the cancer does not grow or cause symptoms and they die of completely different causes. Research has now determined that the PSA test does not do a good enough job of separating out those who will have aggressive prostate cancer that could result in death from those who have a small nodule that will never affect them. Treatment for prostate cancer has serious risks including urinary incontinence, impotence, sometimes bowel problems from radiation and even a small risk of death from surgery. Therefore, until a better approach to PSA use is identified, most organizations have stopped routinely recommending it for all men over a specific age. Instead, a discussion of the risk and benefits is recommended so the patient can decide if he wants the test.

- Few of these tests have been studied in large populations followed over time to see if the risk of dying from cancer is decreased. Few have been compared to standard screening tests over time to see if they are better.
- Even the company websites for many of these tests do not recommend them for cancer screening

An example can be found at the ONCOblot® test website (http://oncoblotlabs.com/physician-fags/#section1; now part of lvyGene):

"Cancer screening is not an approved utility of the ONCOblot® test. Therefore, it is not recommended for use in asymptomatic patients (patients with no cancer symptoms, patients with no other positive or suspicious diagnostic results, etc.)"

Instead, the company website (http://oncoblotlabs.com/physician-faqs/#section2) recommends the test for:

- "Confirm cancer presence and tissue of origin
- Identify cancers of unknown primary
- Follow-up to other diagnostics and screening tests. Such as: abnormal mammograms, suspicious PET scans, high PSA, etc.
- Monitor for recurrence
- Post cancer treatment (2+ months post treatment completion)"

NOTE: All of these uses are in patients who have already been diagnosed with cancer.

• The test is not recommended by the American Cancer Society or the US Preventive Services

Task Force

What is the response of regulatory agencies?

The Food and Drug Administration (FDA) sent a letter to Pathway Genomics (https://www.fda.gov/downloads/%20MedicalDevices/ResourcesforYou/Industry/UCM464092.pdf) on September 21, 2015 about their test CancerInterceptTM Detect. FDA noted that this blood test was marketed as a screening tool for the early detection of up to 10 different cancer types in high risk populations. FDA wrote: "We have also examined published literature and have not found any published evidence that this test or any similar test has been clinically validated as a screening tool for early detection of cancer in high risk individuals." FDA commented that the scientific article referenced at the company's website in support of this test had been conducted in patients already diagnosed with cancer, not as a screening test in healthy individuals. In a February 19, 2018 review of cancer tests at the company's website (https://www.pathway.com/products), the test was not listed.

The test is not very risky. Why wouldn't a fire fighter want this information?

The reason is that if the test is positive in someone with no diagnosed cancer, there is no medical information to help decide what to do next. One option for blood, urine or breath tests would be CT or MRI scans. But CT scans expose patients to radiation which we know causes cancer. And what parts of the body should be scanned? Furthermore, the more you look, the more chance of what we call "false-positive" tests, meaning the test is positive for disease but the person does not really have the disease. With any new test, there is the risk that the cancer

is just diagnosed earlier but not in time to reduce the risk of death as discussed above with early screening for lung cancer. If the scan is positive, there may be need for additional testing or procedures, like a biopsy or surgery. In some cases, the additional testing may lead to complications. An inaccurate test result could also lead to extra time away from work, unnecessary anxiety, and other potential harms.

Regarding the use of ultrasound for thyroid cancer screening, the U.S. Preventive Services Task Force has stated that although ultrasound of the neck followed by needle biopsy if positive, can identify thyroid cancers, it is unclear if "screening can decrease mortality rates or improve important patient health outcomes. Screening that results in the identification of indolent thyroid cancers, and treatment of these overdiagnosed cancers, may increase the risk of patient harms" (https://www.uspreventiveservicestaskforce.org/Page/Document/evidence-summary/thyroid-cancer-screening1).

Although not a cancer screen, the risks from ultrasound are stated even more clearly by the U.S. Preventive Services Task Force regarding screening for carotid artery blockage in people with no symptoms: "Ultrasound screening does not by itself cause physical harm. However, this screening often leads to a cascade of follow-up testing and surgeries that can cause serious harms, including stroke, heart attack or death. In addition, screening all adults will lead to many false-positive results because few people have carotid artery stenosis. This is when a test result says a person has a condition that he or she actually does not have. False-positive results lead to unneeded tests and surgeries." (Screening for Carotid Artery Stenosis: Consumer Guide at: https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/carotid-artery-stenosis-screening).

Finally, a recent American Society of Clinical Oncology and College of American Pathologists Joint Review on tests of genetic variation in tumor DNA in blood/serum samples concluded that there was no evidence that such tests were useful for cancer screening, outside of a clinical trial.³

What does IAFF recommend?

Prevent exposure — Fire fighters should continue to use self-contained breathing apparatus during all fire suppression and overhaul activities. Fire fighters should decontaminate their skin after fire suppression activities with wipes at the scene and shower as soon as possible after firefighting and/or overhaul activities. Turnout gear, helmets, and equipment should be cleaned regularly per the manufacturers' recommendations in order to reduce exposure to chemical contaminants.

Wellness Fitness Initiative

<u>Cancer screening:</u> should be based on recommendations of established organizations such as the American Cancer Society and the US Preventive Services Task Force with modifications to address the increased risk of certain cancers in fire fighters.

(https://www.cancer.org/healthy/find-cancer-early/cancer-screening-guidelines/americancancer-society-guidelines-for-the-early-detection-of-cancer.html).

Fire fighters interested in any of these new tests should only pursue them by collaborating with researchers in clinical trials that have received approval by an Institutional Review Board. Participation in clinical trials will permit fire fighters to be appropriately consented to the potential medical risks and benefits of the technique, under appropriate ethical oversight. Such participation would also improve the likelihood that the results of such testing would further inform the scientific literature.

Reduce non-occupational risks: fire fighters should avoid tobacco (smoking and smokeless), maintain a healthy weight, exercise regularly, eat a diet rich in fruits, vegetables, and whole grains, use sun screen, and get a medical physical annually.

References

¹ LeMasters GK, Genaidy AM, Succop P, Deddens J, Sobeih T, Barriera-Viruet H, Dunning K, Lockey J. Cancer risk among firefighters: a review and meta-analysis of 32 studies. J Occup Environ Med. 2006;48:1189-202

² Daniels RD, Kubale TL, Yiin JH, Dahm MM, Hales TR, Baris D, Zahm SH, Beaumont JJ, Waters KM, Pinkerton LE. 2014 Mortality and cancer incidence in a pooled cohort of US firefighters from San Francisco, Chicago and Philadelphia (1950-2009). Occup Envion Med. 71(6): 388-97.

³ Merker JD, Oxnard GR, Compton C, et al. Circulating Tumor DNA Analysis in Patients With Cancer: American Society of Clinical Oncology and College of American Pathologists Joint Review. J Clin Oncol. 2018;36:1631-1641