EDITORIAL

Prostate Cancer Genomics: Understanding the New Landscape

In late 2013 the FDA notified the company marketing the "23andMe Saliva Collection Kit" and their Personal Genome Service that they were doing so without approval and were in violation of the Federal Food, Drug and Cosmetic Act. Before this, several states had banned the sale of the test. The company advertised the Personal Genome Services to provide direct consumer information on 254 diseases and conditions, such as carrier status, health risks and drug response. The company promised this information would serve as a first step in prevention and enable users to take steps toward mitigating serious diseases such as diabetes, heart disease and breast cancer. A genomic analysis for only $99 with no doctor's order, no blood test and just a simple cheek swab. On first glance, a bargain, but the FDA had a different view.

Quality health care involves shared decision making and provides essential information that empowers patients to be active participants. Genomic data is fairly new, somewhat complicated and often incompletely understood. Providing potentially life altering genomic data to patients without the input of a provider or genetic counselor may not be in anyone's best interest.

The genomic explosion over the last 10 years is due to two major events: the completion of the Human Genome Project in 2003 and the development of high-throughput DNA sequencing technologies. The sequencing technologies have made it possible to characterize complex genomic signatures in a rapid and affordable manner. Numerous start-ups and existing biotechnology companies have joined in what has become the "omics" revolution that includes genomics, proteomics, metabolomics, and pharmacogenomics. Genomic testing is becoming the cornerstone of personalized medicine and pharmacogenomics are part of prescribing several newer oncology medications.

With easy access to direct consumer genetic tests it is unclear if the general public can accurately interpret their test results without the assistance of health care professionals. A study in the journal Public Health Genomics notes that while the general public thinks that these mail order genomic test results are easy to understand, they may not interpret them correctly.[1] The authors found that the public believes these self-administered genetic test results are more helpful in making medical care decisions than do professional genetic counselors who interpret genomic testing every day.

Urology has now entered the genomic era with the FDA approval of several new tests for prostate cancer. However, unlike the laundry list of genomic profiles directly marketed to patients, these recently approved prostate tests focus on specific clinical questions. If the prostate biopsy was negative did it miss the cancerous area? Does the prostate cancer have genomic characteristics of a more aggressive behavior than our current clinical parameters might suggest? Decisions for active surveillance or adjuvant radiation therapy following radical prostatectomy will likely be guided by genomic testing in the near future as these tests become more commonplace.

The widespread adoption of prostate cancer genomic testing will take some time and be tempered by several important issues. These include the novelty of the technology, provider familiarity with testing specifics, lack of extensive independent validating publications and the several thousand dollar price tag for the FDA approved tests that might not be covered by insurance.

While genomic information is a powerful medical tool, most providers today have only a basic understanding of how to incorporate genomics into patient care. Before a barrage of genomic information is released to our patients the medical profession needs to evaluate critically what is useful and what is not. In other malignancies such as breast cancer and leukemia, genomics are more established and are assuming a prominent role.

All current prostate cancer genomic tests rely on prostate tissue for the DNA analysis. Until a cheek swab based prostate cancer genomic test becomes available, our patients will have to rely on provider interaction to place any genomic profile in proper perspective.

Leonard G. Gomella, MD
Thomas Jefferson University
Philadelphia, PA

References

1. Leighton JW, Valverde K, Bernhardt BA. The general public's understanding and perception of direct-to-consumer genetic test results. *Public Health Genomics* 2012;15(1):11-21.

OLYMPUS®

Your Vision, Our Future

Discover Where Innovation Can Take You

The World's ONLY

Articulating HD 3D Video System

ENDOEYE FLEX 3D

THUNDERBEAT

The World's ONLY

Fully-Integrated Ultrasonic and Advanced Bipolar Technology

For more information please contact your local Olympus Representative or call 1.800.387.0437