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PROSTATE CANCER: ANOTHER TUSKEGEE EXPERIMENT?

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The Tuskegee syphilis experiment was an infamous clinical study conducted between 1932 and 1972 in Tuskegee, Alabama by the U.S. Public Health Service to study the natural progression of untreated syphilis in 399 black men without their knowledge or consent. Researchers knowingly failed to treat patients appropriately after the 1940s validation of penicillin as an effective cure for the disease they were studying. Reaction to the Tuskegee experiment served as the catalyst for medical ethical standards where today, studies require informed consent, communication of diagnosis, and accurate reporting of test results.

Are we headed towards a de facto Tuskegee-like experiment with prostate cancer - the leading cause of cancer for men in the United States with more than 230,000 new cases each year?

On October 7, 2011 the U. S. Preventive Services Task Force (USPSTF) shocked the medical community along with prostate cancer survivors and advocates by issuing this draft recommendation: *"The USPSTF recommends against prostate-specific antigen (PSA) - based screening for prostate cancer. This is a grade D recommendation. This recommendation applies to men in the U.S. population who do not have symptoms that are highly suspicious for prostate cancer, regardless of age, race, or family history."*

The PSA test is the only test currently available for early detection of prostate cancer before the disease could potentially spread, become incurable and fatal. However, it is important to understand that not all detected prostate cancer will spread and become life threatening. There is no test currently available to distinguish with certainty between lethal and non-lethal prostate cancer, and this is a major fundamental issue facing those medical professionals responsible for detecting, treating and researching the disease, along with the men diagnosed with it.

According to data collected and regularly released by the U. S. Government, African American men (AAM) are diagnosed with prostate cancer at a rate 60% higher than white men, and die at a rate 140% higher. Studies funded by the U. S. Government show that AAM on average are diagnosed with prostate cancer at an earlier age, and with prostate cancer at a later stage of progression than other men. Other studies show that the disease is more aggressive among AAM. All of these medical factors are attributed to contributing to the higher death rate for AAM who are **identified as a high risk group** for the disease. Another contributing factor studied and often cited is reduced access to treatment due to lack of insurance coverage.

Early detection guidelines for prostate cancer issued by the American Urological Association, National Comprehensive Cancer Network and American Cancer Society all make provisions for men at high risk for the disease. The USPSTF draft recommendation is against using the PSA test for early detection for any group regardless of risk.

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There has been an ongoing debate about the effectiveness of the PSA test in reducing prostate cancer mortality for years. However, **since the PSA test has been widely used beginning in the early 1990's, the prostate cancer death rate has declined by approximately 40% for all men.** Because this was not a "Randomized Control Trial" (RCT) the USPSTF characterized the PSA test as an "experiment." A large RCT, the PLCO (Prostate, Lung, Colorectal and Ovarian) study for evaluating PSA screening is currently being conducted in the United States. Preliminary data was released from this study in 2009 that did not prove that there was a survival benefit for PSA screening. However, this study is incomplete and has been criticized for issues of crossover (contamination) by the men participating in the study. In addition, the study did not include a statistically significant number of AAM, and there are questions on the number of other high risk men (men with a family history) included in the study. In spite of these issues **the USPSTF cites the PLCO study prominently in its evidence for its recommendation against using the PSA test.**

On September 22, 2011 Dr. Gerald L. Andriole, the Principal Investigator for the PLCO study, spoke at the "7th Annual African American Prostate Cancer Disparity Summit" hosted by the Prostate Health Education Network – PHEN in Washington, DC. Dr. Andriole, a prostate cancer medical expert, presented his views on PSA screening which are completely opposite to the USPSTF recommendation. His views: **"We should INTENSIVELY screen men at increased risk, and INFREQUENTLY screen men at low risk. Who is at high risk? African Americans and all men with relatively high PSA levels in their 40's."** Dr. Andriole not only believes that the PSA test should be used "intensively" for African Americans but at an earlier age for other men to determine if they are at increased risk. You are invited to watch Dr. Andriole on YouTube presenting his views on PSA screening at www.rapcancer.org

On October 12, 2011, just five days after the USPSTF released its recommendation, PHEN assembled a panel of medical experts to review and assess the potential impact of the recommendation on Black men. As the moderator of this panel discussion which was webcast live, I was anxious to understand their perspectives and make them available to the public. These are some of their comments: "When I first started treating prostate cancer, the majority of men presented with metastatic or advanced prostate cancer, now the majority of men present with early prostate cancer." ... "We need to better refine who we screen, and more importantly who we treat but to throw away PSA screening right now I think is a big mistake, it does save lives." - **(Dr. Phillip Kantoff, Dana-Farber Cancer Institute);** "We need to reduce any barriers there are to early detection in men at high risk and I worry that those men who are most in need of early detection would be most likely to avoid having a PSA...I think where we need to go as a country is say, well we are at 40% mortality reduction but we could go even better if we learned how to use the test more intelligently." - **(Dr. James Mohler, Roswell Park Cancer Institute);** "I'm not sure that any of this data really is relevant to the African American community." - **(Dr. Isaac Powell, Karmonos Cancer Institute);** "I can't tell you that there's a magic bullet that's coming next year that's going to cure advanced prostate cancer so that screening is moot, nor can I tell you that there's another screening test that is likely to replace PSA, as imperfect as it is, in the near future." – **(Dr. Levi Garraway, Dana-Farber Cancer Institute).** The webcast can be viewed at www.rapcancer.org

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How did the USPSTF come to its draft recommendation? The USPSTF used the PLCO study and others it selected to conclude that there are more harms inflicted on men taking the PSA test than survival benefits derived from it. The 40% overall mortality rate reduction since PSA tests began was not factored into their data analysis because it was not derived as part of a controlled trial.

The major harms that the USPSTF identify as resulting from PSA screening would mostly be derived from treating prostate cancer should a man decide to be treated. Dr. Philip Kantoff made this observation during the PHEN webcast: “I think the Task Force lumped a bunch of different complex issues together in coming forward with this conclusion.....we have to separate screenings from treatments and do a much better job of talking to people...not everybody that has prostate cancer needs to be treated.” Dr. Mohler stated: “I think the recommendation that healthy men should not have a PSA is akin to throwing the baby out with the bath water.”

As a member of the National Comprehensive Cancer Network’s Prostate Cancer Treatment Guidelines Committee where Dr. Mohler is the chair and members include Dr. Kantoff and many other leading prostate cancer medical experts from the major cancer research centers in this nation. I am witness to an ever present emphasis within this committee to incorporate watchful waiting and active surveillance within the guidelines, where applicable, so as to reduce treatment where it may not be necessary. This is a process requiring much study, consideration and caution.

The USPSTF conclusion and solution is that it is best that men not know that they have prostate cancer unless they “have symptoms that are highly suspicious of prostate cancer.” Most prostate cancer medical experts will tell you that once a man begins to experience symptoms for the disease there is a high probability that the cancer has already spread and may be incurable. This is the precise reason that the PSA test has been used for early detection of cancer before symptoms appear. During the pre-PSA test era prostate cancer was indeed detected when men had symptoms. Implementing the USPSTF recommendation would literally turn the clock back twenty years to the pre-PSA test era. To my knowledge there exists no data or study that implies that the prostate cancer death rates would not again reach the levels of that era. In our aging population this could mean upwards of 60,000 as opposed to the current 30,000 prostate cancer deaths annually.

In essence the USPSTF’s message is that if men do not have evidence of a lethal form of cancer as indicated by symptoms then it is best to remain ignorant of the fact that cancer is present because you could be treated and harmed for non-lethal cancer. The problem with this, according to the experiences of the pre-PSA test era, is that most of those men detected with symptoms would be in a fight for their lives battling advanced disease. I am an eleven year prostate cancer survivor where a PSA test detected my cancer and other tests showed that it was an aggressive form. I initially had two types of treatment and was treated again for a recurrence nine years later. I have never experienced a prostate cancer symptom, neither have I experienced any of the side effects (harms) identified by the USPSTF. However, I lost my father, both grandfathers and only brother-in-law to the disease where they were all detected because of symptoms. Prostate cancer is a serious disease and it kills!

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The USPSTF is an independent panel of non-Federal experts in prevention and evidence-based medicine and is composed of primary care providers (such as internists, pediatricians, family physicians, gynecologists/obstetricians, nurses, and health behavior specialists). There are no oncologists or prostate cancer medical experts on the panel. The recommendation against PSA screening was developed strictly from data selected and reviewed by the panel. However the USPSTF's recommendation will drive public health policies and practice for prostate cancer within the United States. Insurance coverage by Medicare/Medicaid and private insurers, while not dictated by the panel's recommendations, usually follows in line. A lack of insurance coverage would certainly preclude many men who may want to continue getting PSA's from doing so, and I suspect this would be a harsh reality for many African American men.

Are we headed towards another Tuskegee – like experiment with prostate cancer if the draft USPSTF recommendation is allowed to be translated into public policies and medical practice? I think the resulting experiment, which would be conducted in plain sight of the national public, would be much worse because the history of the pre- PSA test era teaches us what the human toll will be before the experiment begins - making it both inhumane and unethical to undertake. Since neither the PLCO study nor any other major PSA screening trial reviewed by the USPSTF included a statistically significant number of African American men, wouldn't it be scientifically irresponsible to simply conclude that the results of a PSA screening study for AAM would parallel those for low risk white men? Because of this lack of evidence, the high risk of AAM for prostate cancer and the existing crisis level mortality rate, wouldn't it be extremely unethical to include AAM in any USPSTF recommendation against the use of PSA for early detection? This argument would also be applicable to high risk men of all races. Is not it the responsibility of the U. S. Government to agree on a process to identify all high risk men, and conduct a PLCO type trial to gain scientific evidence before undertaking any change in the existing USPSTF "Grade I" recommendation? Otherwise, where is the scientific evidence that AAM and all high risk men will not experience increased deaths and suffering resulting from the USPSTF draft recommendation? Dr. Andriole outlined one process for identifying high risk men that could be studied for implementation.

Finally, while the U. S. Preventive Services Task Force dismissed the 40% reduction in the mortality rate since PSA testing began, the U. S. Government's National Cancer Institute has not. Dr. Kathy Cronin, Chief, Data Analysis & Interpretation Branch, National Cancer Institute presented at the same PHEN summit in September 2011 as did Dr. Andriole. Dr. Cronin presented the following: "Mortality for prostate cancer has declined nearly 40% between 1994 and 2007, from 38.5 to 23.5 deaths per 100,000...Models suggest between 45% and 70% of the mortality decline observed in the 1990s could be attributed to the stage-shift induced by screening." (Dr. Cronin's presentation is available at www.rapcancer.org). **Dr. Jacques Carter, Beth Israel Deaconess Medical Center** made these comments during the PHEN webcast on October 12th: "My personal feeling is that the Task Force is wrong.....as we look at the data there is certainly data to support the fact that PSA screening has saved lives....the Task Force made a mistake." Dr. Carter's remarks echo those of many other doctors around the country. We cannot allow a mistake of this magnitude to occur within our country. The enormous cost in lives lost and unnecessary suffering would be indefensible.