

## Skid row cancer study has implications for treatment today, researcher says

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An ethically dubious medical research study from the 1950s and 60s, known as the "Bowery series," foreshadowed and shared commonalities with prostate cancer screening and treatment measures as they are carried out today, argues University of Pennsylvania physician and historian Robert Aronowitz in two new publications.

In papers published in the *American Journal of Public Health* and the *Bulletin of the History of Medicine*, Aronowitz, professor and chair of Penn's Department of History and Sociology of Science, characterizes the events then and screenings for prostate-specific antigen, or PSA, in more recent years as "part of one continuous story of how medical and lay people came to believe in the efficacy of population screening followed by aggressive treatment without solid supporting scientific evidence."

"This is a call to reflection about how we deal with medical knowledge production and medical technological innovation," Aronowitz said.

In 2012, the U.S. Preventive Services Task Force recommended that healthy men not be screened for prostate cancer with PSA tests. Millions of men, before and after this recommendation, have had screening PSA tests. If an individual's PSA level is above a certain value, he may be counseled by a doctor to have repeated tests or a tissue biopsy to look for cancer cells. The biopsy is an invasive procedure, and can lead to additional procedures that escalate in their potential for detrimental effects. The recent Task Force decision states that the test has "very



small potential benefit and significant potential harms."

Interested in how the PSA test and other <u>prostate cancer screening</u> measures rose in prominence, Aronowitz was researching the history of screening when he came upon a "largely forgotten" story.

In 1951, a young New York urologist began a study to determine whether biopsying the prostate glands of men without signs or symptoms, and then aggressively treating those individuals who had tissue diagnoses of cancer, could reduce deaths from prostate cancer.

Aronowitz details the history of the urologist's trial, which lasted more than a decade and to which more than 1,200 homeless, alcoholic men from New York's Bowery neighborhood were recruited. Participants traveled to Francis Delafield Hospital, where they received a physical exam, X-rays, and various invasive tests, including a prostate biopsy that involved the removal of a sizable amount of tissue. Men whose samples were found to contain cancerous cells then underwent aggressive treatment, typically including the removal of the prostate gland and testes and administration of a synthetic estrogen.

Though records are unclear, some men may have given a form of "informed consent" and some may have been aware that they were participating in research, Aronowitz found. But their vulnerable status, as homeless and alcoholic, calls into the question whether they were entering into the research with true free will and understanding, Aronowitz said. Given the state of clinical knowledge, he noted, these largely asymptomatic men clearly were also being exposed to undue risk.

Even though the prostate biopsy procedure today requires the removal of far less tissue and is less dangerous, Aronowitz draws a connection between the vulnerable Bowery population and the millions of men who each year are biopsied for cancer after recording a high level on a PSA



screening test.

"Patients today are often not fully informed about risks and benefits of PSA screening," Aronowitz said. "More importantly, and like the Bowery men, many men today, and certainly men in the era before results from good clinical trials were available, have not been informed in the sense of knowing whether the test, and all that it may trigger, is worth it or not."

In the *Bulletin of the History of Medicine* paper, Aronowitz writes that society's attitudes toward prostate cancer changed as a result of subsequent medical innovation that modified many aspects of the Bowery series but had similar goals. Where prostate cancer was once only diagnosed in very late stages when it was nearly always fatal, new screening tests enabled many diagnoses at much earlier stages, before patients displayed symptoms.

According to Aronowitz, however, the evidence we now have from randomized controlled trials either does not show that screening saves lives or shows a very small benefit that many men will feel does not outweigh the many known harms from cancer treatments, especially incontinence and impotence. Whether efficacious or not, the mass diffusion of screening and related practices occurred in an "evidence-free" way and transformed prostate cancer as a disease, Aronowitz argued.

"It's not just costly or a little bit inconvenient to let innovation happen and deal with the ethical and clinical consequences later," he said. "We ended up with not just 1,200 but millions of men who were screened, and maybe a fifth of them go on to get more radical treatment.

"I think when you look back at the Bowery series, those involved were acting in good faith," he added. "So were many people who promoted



PSA testing when they thought or continue to think it is only logical to use a test that detects cancer early enough for radical treatments to remove it from the body. But when a medical procedure will be offered at a population level with the potential to transform society and everything we think we know about the targeted disease, we ought to proceed with a very high level of caution, reflection, knowledge production and evaluation."

## Provided by University of Pennsylvania

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