

LETTER TO THE EDITOR

Organized prostate cancer screening and the declaration of Helsinki

Takeshi Takahashi 

Health and Welfare Bureau, Kitakyushu City Office, Kitakyushu, Japan

This article presents a descriptive study of the Swedish regional, population-based, organized prostate cancer screening program [1]. The program aims to: (1) improve cost-effectiveness compared to unorganized testing, (2) enhance equity by offering all men in the target population an opportunity to make an informed choice, and (3) increase knowledge about diagnosis and organization.

Despite these objectives, the Swedish National Board of Health and Welfare renewed its recommendation against prostate cancer screening [1]. This aligns with the stance of the United States Preventive Services Task Force (USPSTF), which is composed of public health physicians and is even stricter [2]. The authors' ideas align with many urologists' guidelines and review articles [3–5], but these guidelines are fundamentally contradictory.

Prostate cancer screening does not benefit the average healthy individual and can cause harm through invasive testing and treatment. It should be considered a clinical trial rather than an established medical practice [2, 6].

Regarding the aim (1), the cost-effectiveness is questionable because the benefits do not justify the costs [7]. Regarding the aim (2), the program violates the Declaration of Helsinki by failing to provide appropriate information and obtain informed consent. It is more ethical for healthy individuals to avoid participation in such trials [6]. Regarding the aim (3), the authors' understanding of biopsy-based diagnosis is flawed, and the program perpetuates these misconceptions. They dismiss the Swedish National Board of Health and Welfare's recommendations [8, 9] without scientific support, making their claims unethical and unscientific [6].

The study provides descriptive data without a control group or examination of overall survival (OS) as a meaningful outcome for patients, lacking scientific interpretation [1]. They proposed a hypothetical treatment plan and tested its feasibility, not its scientific validity. This approach is unsuitable for a scientific study and raises questions about its alignment with the journal's aims and scope.

Screen-detected prostate cancer is diagnosed solely based on histopathology findings from a random needle biopsy without confirming mass formation. The diagnostic criteria originated from a hypothesis in the 1950s based on knowledge of latent cancer at the time [10]. There has been no verification

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of whether these lesions are biologically cancerous through observation of their natural course and comparison of OS with the general healthy population. Dr. Chodak, who reviewed prostate cancer screening before PSA testing became available, emphasized that without definitive evidence, such screening remains experimental [11].

In the 1990s, PSA test thresholds for biopsy were set retrospectively based on histopathology results. However, validating the OS of screen-detected cancer as an endpoint is impossible, making these decisions arbitrary. PSA is organ-specific but not a cancer marker. High values indicate advanced cancer, but the association of physiological range values with cancer is uncertain. Similarly, the Gleason score and diagnostic imaging such as CT, US, and MRI have not been validated for screen-detected cancer. Hence, comparative studies on treatments are not feasible because the natural history OS of screen-detected cancers is unknown.

Three scientifically valid RCTs (ERSPC (European Randomized Study of Screening for Prostate Cancer), PLCO (The Prostate, Lung, Colorectal and Ovarian), CAP (Cluster randomised trial of PSA testing for prostate cancer)) agree that screening does not improve OS, providing Level 1 evidence [2]. Some guidelines cite the ERSPC's cancer-specific mortality reduction [3–5], but these figures are unreliable. Measuring cancer-specific deaths is challenging, especially in older individuals where OS diverges from cancer-specific survival (CSS). Positive RCT results do not necessarily validate screening, as clinical cancer deaths are unrelated to screen-detected cancer. Concerns about 'contamination' in the PLCO trial's non-screening arm need no consideration for negative results.

These RCTs randomized screening, diagnostic, and treatment phases, making it unclear which phase affects outcomes [2].

CONTACT Takeshi Takahashi  jazzy@kuhp.kyoto-u.ac.jp  Health and Welfare Bureau, Kitakyushu City Office, Jyonai 1-1, Kitakyushu, Japan

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Before undertaking extensive studies, it would be wiser to validate diagnostic tests by comparing the natural history OS of screen-detected prostate cancer with the general population. Validation of tests and treatments can follow as needed by comparing with historical data.

If the OS rate for prostate cancer detected through screening is worse than that of a generally healthy individual, and this disparity disappears when focusing solely on elderly individuals, it suggests overdiagnosis. However, this hypothesis is not validated in the context of prostate cancer, making it inappropriate to label these cases as overdiagnosis. Overdiagnosis refers to the identification of a lesion that does not exhibit cancerous behavior as if it were cancer, based on the accuracy of the diagnosis [12]. This occurs because deaths from other causes are more common and happen sooner than cancer-related deaths in older adults. In cases of screen-detected prostate cancer, cancer-related deaths are minimal, regardless of age group and duration of observation. Therefore, the issue lies in the diagnosis itself, not the observation period.

The USPSTF states that ‘the certainty of the evidence that screening reduces cancer mortality is insufficient’, emphasizing that screening should only follow a patient’s informed preference [2]. It is unethical to recommend a medical procedure without benefit to the healthy population. This aligns with the Declaration of Helsinki, which mandates information provision and consent for clinical trials. Dr. Chodak’s insights remain relevant [11].

Urology guidelines recommend shared decision making post-PSA testing, assuming testing is necessary [3–5], which contradicts USPSTF’s and the Declaration of Helsinki’s informed consent requirements.

Urology guidelines clash with EBM principles, medical research ethics, and the Declaration of Helsinki. Despite this, urologists’ influence promotes prostate cancer screening globally, increasing prostate cancer cases. Future prostate cancer screening, whether organized or opportunistic, should be considered a clinical trial requiring informed consent and a

no-treatment control group to avoid unwarranted harm and to provide scientifically interpretable data.

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