

# Screening Tests: A Boon or Bane

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## ABSTRACT

One of the priority duties, of medical personnel, is to ensure early diagnosis and treatment, through “screening for diseases.” A screening test ideally of reasonable price are secondary preventive measures and what we expect is to correctly identify those who may have the disease from those who do not have the disease there by reducing morbidity and mortality in the population, but every screening test has the potential to harm. Screening tests can also be considered a curse in disguise because the tests are influenced by various factors and can do more harm to individuals than good; few issues of concern include overdiagnosis, false positivity, and false negativity. Cancer screening programs among individuals who are uninsured with financial hardship will cause more maleficence than beneficence. Ethical dilemmas commonly encountered in screening are informed consent versus choice for rejection, standard of care versus no care and confidentiality versus right to information. Many inappropriate screening tests used today as they are proved beneficial. Common loopholes that lead to the conclusion that screening improve health; one is a relic and the other a reflection of biology. Lead-time and length biases distort the apparent value of screening programs. To reduce this disparity between boon and bane, screening tests should be weighed up equally by randomized controlled trials where participants are observed throughout the entire screening chain and nonetheless, screening of asymptomatic populations could do more harm than good.

**Keywords:** Disease, Overdiagnosis, Screening tests, Sensitivity, Specificity

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## INTRODUCTION

One of the priority duties, of medical personnel, is to ensure an early diagnosis and treatment, through “screening for diseases.” In 1951, the United States Commission of Chronic Illness defined screening as “the presumptive identification of unrecognized defect or disease by the application of tests, examinations or procedures which can be applied rapidly, to sort out apparently well persons who probably have a disease, from those who probably do not.”<sup>1</sup>

Iceberg phenomenon in human disease shows us the burden of disease in a community, the clinical cases form only a small fraction in the entire load, majority of the cases of disease lie below the clinical horizon in the community; which can be represented as an iceberg, part which lies above the surface of water is actually a very small part of the total iceberg which lies submerged beneath the water surface.<sup>2</sup>

Assessment of the burden of diseases and their associated risk factors in the community (keeping in mind that the

real load of the disease lies hidden in the community and is not clinically apparent) is the key in preventing failures and developing successful public health programs.<sup>2</sup>

A considerable amount of undetected disease, some of which is serious and some controllable, might be found easily by the new available tests. Ordinary clinical skills and new diagnostic technologies available may be used to detect cases of actual and potential disease in general practice, bringing into picture importance of screening tests.<sup>3</sup>

Diagnostic tests are done to find out what is causing certain symptoms were as screening tests are different and conducted among healthy individuals. A screening test is not intended to be diagnostic. Persons with positive test findings must be referred to the physicians to undergo appropriate diagnostics tests and treatment.<sup>1</sup>

There are different types of screening tests as prescriptive screening (to ensure early detection of a disease among individuals), prospective screening (to protect the community from affected individuals), and weed out (for certain occupations).<sup>2</sup>

There are various screening tests available examples of screening tests include the Pap smear for cervical cancer, mammography for breast cancer, digital rectal exam for prostate cancer, cholesterol level for heart disease, and X-ray for lung cancer.<sup>4</sup>

Rose and Barker in 1978 stated three questions to determine if screening is beneficial; these questions hold good even today they are: (1) Does earlier treatment improve the prognosis? (2) How valid and repeatable is the screening test? (3) What is the yield of the screening service?<sup>5</sup>

What we expect of a screening test is to correctly identify those who may have the disease from those who do not have the disease there by reducing morbidity or mortality in the population. However, every screening test can be harmful too for example, X-ray examinations expose the body to radiation, and endoscopy of the bowel can lead to bleeding.<sup>6</sup>

Routine screening can save lives. It can also cause serious harm. It can be compared to a “double-edged sword.” Thus, the screening tests being a boon or bane are influenced by various factors such as sensitivity specificity of the tests, acceptability, cost of the tests, overdiagnosis, and biases in screening.

## SCREENING TESTS AS BOON

### Reduces the Burden of Disease

Screening tests are secondary preventive measures. The factual of screening tests is to reduce the burden of disease. Cancer has become major cause of death occurring in the country due to communicable and life-style ailments, followed by tuberculosis.<sup>7</sup> With more than 1300 persons capitulating to cancer every day; it is expected to rise to 700,000 by 2015. “The number of cancer cases in India is increasing every year,” as stated by Julka, Head of the Oncology Department at the All India Institute of Medical Sciences.<sup>8</sup> As the numbers of cases are increasing, this is a crucial point; when we can counts the screening tests as a blessing, which can identify the disease even before the development of signs and symptoms.

### Significance of Early Diagnosis

It is very essential for diagnosing the disease early as it reduces the burden of cancer. This is possible with reliable screening tests, early diagnosis by screening the disease helps in reducing its mortality and morbidity. By screening and early diagnosis, we are greatly increases the chance of favorable outcome and successful treatment. Early diagnosis is remarkably relevant for various cancers of the breast, cervix, mouth, larynx,

colon and rectum, and skin, etc.<sup>9</sup> The screening of disease in the early stage will reduce the further deterioration of health and its complication in turn decreases the economic burden, loss of wages due to absenteeism and save the patients from out of pocket expenditure due to the disease management.<sup>10</sup>

### The Fundamental Principals in Screening for a Disease

The success of screening programs depends on a number of fundamental principles where the first principle is the target disease should be a common form of cancer with high associated morbidity or mortality, second principle is that effective treatment should be available reducing morbidity and mortality, the third principle is that the test procedures should be acceptable, safe, and relatively inexpensive.<sup>9</sup>

We would like to quote an example of cervical cancer where several tests can be used to screen the disease, but the Pap smear (cytology) is the only test which can be used in large populations. It had been shown that as Pap smear is the only test where Wilson criteria of screening test have been followed and is having high sensitivity and specificity. Hence, this test has universal acceptability as it had been shown that it reduces the cervical cancer incidence and mortality. Various other tests, such as VIA, VILI, human papillomavirus, show promising results but there is yet no comparable evidence on their effectiveness.<sup>9</sup>

### Ideal Screening Test

A screening test to be ideal should be reasonably priced, noninvasive procedure that is highly sensitive and specific, to maximize a patient’s well-being and minimize suffering. The usefulness of the screening test is evaluated by its sensitivity and specificity. Sensitivity is the true positive rate; that is, the probability that a patient with a positive test result has the disease. For example, a mammogram that detects an early-stage breast cancer can lead to a more definitive and curative procedure. The specificity of the disease is the probability that if the person does not have the disease, the test will be negative. That is, the specificity is the percentage of healthy people who are correctly identified as not having the condition. Further, the ideal screening test must be for a disease that has a preclinical phase, a pre-symptomatic stage for which the disease is detectable.

If there were an ideal screening program, it would correctly identify those who have the disease (true positive) from those who do not (true negative), and absolutely no positive test results among those who do not have the disease (false positive), but practically it’s not the same, it depends on the sensitivity and the specificity of the tests.<sup>6</sup>

## Periodic Health Examination and General Health Check Up

In late 20<sup>th</sup> and early 21<sup>st</sup> Century, advancing technology in modern medicine have prioritized preventive care, which has led to rapid increase in eagerness for screening in apparently healthy populations. General health check (also termed periodic health evaluation or routine medical examination) is the usual mechanism used to screen asymptomatic people for the disease. Though there is no specific definition for periodic health examination and general health checkup, all general health checkups have a common objective that is to reduce morbidity and mortality of the disease or modifiable risk factors at an earlier stage which outweighs the benefits of waiting until symptoms develop.<sup>11</sup>

As every coin has two sides, though general health checks are popular, recent discussion has concentrated on the unintended consequences of these health examinations, including overdiagnosis. Numerous medical organizations have agreed that routine annual checkups for healthy adults should be abandoned in favor of a more selective approach to preventing and detecting health problems.<sup>12</sup>

### Economic Impact

A screening test is said to be ideal when it is affordable and cost effective, i.e., tests have to be reasonably priced, otherwise health insurers may not provide enough coverage, and the patient may be unable or unwilling to pay for the tests themselves. For example, the annual screening of cervical cancer by Pap smear and the random blood sugar which are the most cost effective and widely accepted screening tests by the public. Another example is the clinical breast examination which is yet another cost-effective approach in screening breast cancer in the developing countries. Promising preliminary results show that the age-standardized incidence rate for advanced-stage breast cancer is lower in the screened group compared to the unscreened group.<sup>13</sup>

### Screening Tests for All

Screening tests need to be popularized widely that it gets implemented even at grass root levels, i.e., at the sub center level. Screening tests must be implemented at grass root level as it must be approachable by all the individuals living in a community. It shouldn't be the case that only people who can approach tertiary care center, or corporate hospitals get benefited by the widely marketed screening test in the community. Prevention is one of the responsibilities of the primary care physicians, i.e., to detect the disease at an early stage before the symptoms appear.

## Essential Steps in Cancer Screening

As stated by Labahni *et al.* the nine essentials steps required to implement cancer screening in any setup are always a prior evaluation of community perspectives if screening in the community is required; development of appropriate education messages for motivation and re-motivation for screening and follow-up; to adopt ways of communicating messages and meeting stakeholders and elders of the community, group talks, announcements, and personal communication at the doorstep; use the extent possible help from health care infrastructure-ASHAs, ANMs and Medical officer; provide training on motivation of study group; provide training on screening techniques, referral, and adherence to quality control; advocate three visit approach to health care center-screening visit, screen positive confirmation and treatment visit at referral hospital; adopt strict concurrent monitoring mechanism and concurrent evaluation of screening implementation. Utilization of ASHAs is important for motivation, achievement of good coverage and strict monitoring for good response and clinical management of screen positives.<sup>14</sup>

## SCREENING TESTS AS BANE

Screening tests are helpful but at times involves exposure to danger (undergoing mammogram causes exposure to radiations). Hence, it is a concerning issue that we know the disadvantages of the test. It is also more important for us to understand that identifying the disease by screening alone is not sufficient to ameliorate health or expand the survival rate after diagnosis; there is a necessity for appropriate diagnostic tests and treatment.

### Overdiagnosis

Screening does not do much good with rapidly spreading cancer or in case of secondaries. In few cases, cancers found on a screening may never cause symptoms or become life-threatening, identifying them is called overdiagnosis. In such cases, screening does not increase the survival rate but instead treatment would cause more adverse affects. In such situations, it is even hard to predict which cancers identified in screening cause problems and which ones will not.<sup>15</sup>

Overdiagnosis is one of the burning issues and is being called the modern epidemic. The disadvantages of overdiagnosis include the harmful effects of unnecessary labeling, the harms of unneeded tests and therapies, and the opportunity cost of wasted resources that could be better used to treat or prevent genuine illness. The increasing evidence on overdiagnosis states that the problem may exist to varying extents across many conditions one example for this is 25% or more of screening detected lung cancers may be overdiagnosis.<sup>16</sup>

## Burden of False Positive and False Negatives

False positive test results on screening may cause psychosocial harm including an increase in stress and anxiety and further leading to undergo unnecessary diagnostic tests. Brodersen *et al.* stated that 3 years after a false positive finding, women experience psychosocial consequences that range between those experienced by women with a normal mammogram and those with a diagnosis of breast cancer.<sup>17</sup> Women who had a false-positive screening mammogram reported feeling anxiety months later, even though cancer was not diagnosed and women who feel anxiety after false positive test results are more likely to schedule regular breast screening exams in the future.<sup>17</sup>

## The Financial Burden of Screening

Although screening tests are simple and cost effective over other diagnostic tests, many such screening tests as full body scan are being used. Enthusiasm for ruling out existence of disease - combined with the industrial opportunity to make fat profits may mean that soon none of us will be normal.<sup>18</sup>

Irrespective of the sensitivity and specificity of the tests, many such tests are popularized and available in the market which is being universally accepted such as random blood sugar which has a low sensitivity of 39-55%.<sup>19</sup>

With the advancement of technology, various screening tests availability is also increasing. The fear of not knowing is haunting us, and we try to rule out diseases by screening. It simply is not sensible to try to know everything. Ignorance can be bliss.<sup>18</sup>

## Ethical Issues in Screening

Advancing technology in the medical field has generated several bioethical dilemmas which are now a challenge to the physicians of this century. Discussions screening ethics have always been focused on two specific questions: (1) The voluntary, informed consent of subjects, and (2) the appropriate relationship between risk and benefit to subjects.<sup>20</sup>

Cancer screening programs among individuals who are uninsured with financial hardship will cause more harm (maleficence) than good (beneficence). Ethical dilemmas commonly encountered in screening are informed consent versus choice for rejection, standard of care versus no care, and confidentiality versus right to information.<sup>20</sup>

A case study: Trials of screening for cervical cancer conducted by Tata memorial center, Mumbai violated the

principle of justice by not providing standard of care and withholding available interventions for control group.<sup>21</sup>

The recent era emphasizes to the Ethics of standard care in Medical research. Here, the key issue of concern is the use of a placebo or "no treatment" control groups in the study designs of the randomized control trails. The ethics of standard care points out to the declaration of Helsinki - the ethical principle "do no harm." The placebo control controversy led to amendments in the declaration of Helsinki's ethical guidelines on medical research.<sup>21</sup>

## Biases with Screening

Lead-time bias: It is longer perceived survival with screening, even when the course of the disease is not altered. Screening could advance the diagnosis of cancer without necessarily prolonging the overall duration of the woman's life. When early detection has no effect on the course of disease, screening test ends up making the patient more anxious and worried rather than promoting health.<sup>22</sup>

Length bias: Cases with very short preclinical phases have little chance of being detected before they become clinical, but cases with long preclinical phases are very likely to be detected by the screening program. For example, Screening by mammography test leads to cancer detection 2 years earlier than would have ordinarily occurred, yet the screening does not prolong life. This gain in longevity is apparent and not real: Screening allows women to live 2 years longer with the knowledge that they have cancer but does not prolong survival, an example of zero-time shift.<sup>23</sup>

Selection bias/volunteer bias: Individuals more cautious about their health tend to comply with screening programs compared to uneducated and socially deprived individuals, this is more likely seen in cases with opportunistic screening. If a screening study does not include a randomized process for selection, volunteers for the study are likely to be in better health than the general population.<sup>23</sup>

Does a screening program really improve health is the question in the current scenario? Many inappropriate screening tests used today as they are proved beneficial. Common Loopholes that lead to the conclusion that screening improves health; one is a relic and the other a reflection of biology.<sup>23</sup>

## CONCLUSION

Screening tests have become universal they can improve or impair health, depending on its usage. As the screening tests are conducted in a healthy

population, it raises many ethical issues. Screening tests have the potential to correctly identify subjects with an early stage of disease, i.e., before symptoms develop and therefore, reduce morbidity and mortality of the disease. The ideal screening test would be inexpensive, not invasive, and perfectly discriminate between those who may have or may not have the disease. In practice, screening tests exhibit false positives and false negatives - errors with consequences that need to be carefully considered when evaluating the advantages and disadvantages of the test. The predictive value of the test depends on Sensitivity, specificity, and prevalence of the disease in the population. Lead-time and length biases distort the apparent value of screening programs. For this reason, both the benefits and harmful effects should be weighed up equally by randomized controlled trials in which participants are observed throughout the entire screening chain and nonetheless screening of asymptomatic populations is not always appropriate and could do more harm than good.

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