

**Criteria for Appraising the Viability,  
Effectiveness and Appropriateness of a  
Screening Programme**

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## **Introduction**

This document outlines the criteria for appraising the viability, effectiveness and appropriateness of a screening programme. These criteria have been developed in line with the Wilson and Jungner criteria for appraising the validity of a screening programme.

## **What is Population-Based Screening?**

Screening is defined as the presumptive identification of unrecognized disease in population that has no symptoms of the condition or conditions by means of investigations, examinations or other procedures that can be applied rapidly and easily to the target population. A screening programme must include all the core components in the screening process from inviting the target population to accessing effective treatment for individuals diagnosed with disease<sup>1</sup>. Within any population, consideration should be given to the needs of vulnerable or potentially vulnerable groups that require specific screening. This targeted screening may be as a result of many variables; therefore, specific investment will be required to ensure the best possible outcomes in relation to equity of health and wellbeing.

### **A. The Condition**

1. The condition should be an important health problem. The epidemiology, incidence, prevalence and natural history of the condition should be understood, including development from latent to declared disease and/or there should be robust evidence about the association between the risk or disease marker and serious or treatable disease.
2. All the cost-effective primary prevention interventions should have been implemented as far as practicable.
3. If the carriers of a mutation are identified as a result of screening, the natural history of people with this status should be understood. The psychological implications should be considered, and the necessary psychological supports should be in place.

### **B. The Screening Method**

4. The screening method should be, as far as is practicable:
  - a) simple
  - b) safe
  - c) precise
  - d) reliable
  - e) validated

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<sup>1</sup> Source: WHO website <https://www.who.int/cancer/prevention/diagnosis-screening/screening/en/>

5. The distribution of screening values in the target population should be assessed and suitable cut-off levels/measurements defined and agreed by the applicant.
6. The screening process should be acceptable to the target population.
7. There should be an agreed policy on the further diagnostic investigation of individuals with a positive screening result and on the choices available to those individuals.
8. If screening is for a particular mutation(s) or set of genetic variants the method for their selection should be kept under review.

### **C. The Intervention**

9. There should be an effective intervention for patients identified through screening, with evidence that intervention at a pre-symptomatic phase leads to better outcomes for the screened individual compared with usual care.
10. There should be agreed evidence-based policies covering which individuals should be offered interventions and the appropriate intervention to be offered.

### **D. The Screening Programme**

11. Ideally there should be evidence from high quality randomised controlled trials that the screening programme is effective in reducing mortality or morbidity. Where screening is aimed solely at providing information to allow the person being screened to make an informed choice, there must be evidence from high quality trials that the test accurately measures risk. The information that is provided about the test and its outcome must be of value and readily understood by the individual being screened.
12. There should be evidence that the complete screening programme (test, diagnostic procedures, treatment/ intervention) is acceptable and can be implemented.
13. The benefit gained by populations and individuals from the screening programme should outweigh the harms. The public should be informed of these harms and of their associated undesirable physical and psychological consequences.
14. The opportunity cost of the screening programme (including testing, diagnosis and treatment, administration, training and quality assurance) should be economically balanced in relation to expenditure on medical care as a whole (value for money). Assessment against these criteria should have regard to evidence from cost benefit and/or cost effectiveness analyses and have regard to the effective use of available resource.

## **E. Implementation Criteria**

15. Clinical management of the condition and patient outcomes should be in place before a screening programme is initiated.
16. Adequate staffing and facilities for testing, diagnosis, treatment and programme management should be available prior to the commencement of the screening programme.
17. All other options for managing the condition should have been considered (such as improving treatment or providing other services), to ensure that no more cost-effective intervention could be introduced, or current interventions increased within the resources available.
18. There should be a plan for managing and monitoring the screening programme against an agreed set of quality assurance standards. This should include monitoring performance against different sub-groupings in the population.
19. The potential benefits and harms of screening, investigation, preventative intervention or treatment, should be made available and explained to the eligible participants to assist them in making an informed choice. There should be a clear system of communication incorporated into each screening programme to ensure patients are kept aware of any developments in their case.
20. Decisions about commencing, expanding or ceasing a programme should be based on scientifically validated evidence.

Applicants will be kept informed of developments throughout the application process by the NSAC Secretariat.