Appendice C: Criteri essenziali per la proponibilità di un programma di screening in popolazione[1]

1. Circa la condizione oggetto del programma:

1.1 The condition should be an important health problem.

1.2 The epidemiology and natural history of the condition, including development from latent to declared disease, should be adequately understood and there should be a detectable risk factor, or disease marker and a latent period or early symptomatic stage.

1.3 All the cost-effective primary prevention interventions should have been implemented as far as practicable.

2. Circa il test

2.1 There should be a simple, safe, precise and validated screening test.

2.2 The distribution of test values in the target population should be known and a suitable cut-off level defined and agreed.

2.3 The test should be acceptable to the population.

2.4 There should be an agreed policy on the further diagnostic investigation of individuals with a positive test result and on the choices available to those individuals.

3. Circa il trattamento terapeutico

3.1 There should be an effective treatment or intervention for patients identified through early detection, with evidence of early treatment leading to better outcomes than late treatment.

3.2 There should be agreed evidence based policies covering which individuals should be offered treatment and the appropriate treatment to be offered.

3.3 Clinical management of the condition and patient outcomes should be optimised by all health care providers prior to participation in a screening programme

4. Circa il Programma di screening

4.1 There must 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" (e.g. Down's syndrome, cystic fibrosis

[1] Cfr. *National Screening Committee*, Second report of the UK National Screening Committee, Department of the Health, 2000. accessed 18/01/2005 at http://www.dh.gov.uk/assetRoot/04/01/45/60/04014560.pdf

carrier screening), 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.

4.2 There should be evidence that the complete screening programme (test, diagnostic procedures, treatment/ intervention) is clinically, socially and ethically acceptable to health professionals and the public.

4.3 The benefit from the screening programme should outweigh the physical and psychological harm (caused by the test, diagnostic procedures and treatment).

4.4 The opportunity cost of the screening programme (including testing, diagnosis, treatment, administration, training and quality assurance) should be economically balanced in relation to expenditure on medical care as a whole (i.e. value for money).

4.5 There must be a plan for managing and monitoring the screening programme and an agreed set of quality assurance standards.

4.6 Adequate staffing and facilities for testing, diagnosis, treatment and programme management should be made available prior to the commencement of the screening programme.

4.7 All other options for managing the condition should have been considered (e.g. improving treatment, providing other services), to ensure that no more cost effective intervention could be introduced or current interventions increased within the resources available.

4.8 Evidence-based information, explaining the consequences of testing, investigation and treatment, should be made available to potential participants to assist them in making an informed choice.

4.9 Public pressure for widening the eligibility criteria for reducing the screening interval, and for increasing the sensitivity of the testing process, should be anticipated. Decisions about these parameters should be scientifically justifiable to the public.