Appendix 4 (as supplied by the authors). Mapping of Individual Screening Principles to Consolidated Screening Principles

CONSOLIDATED SCREENING PRINCIPLES (Post-Review and Consensus Process)	**INDIVIDUAL SCREENING PRINCIPLES** (from 41 reviewed sets of screening principles) (*individual principle applies to more than 1 consolidated screening principle; original Wilson and Jungner principles in **bold** font)
I. DISEASE/CONDITION PRINCIPLES (86 unique principles)	
1. Epidemiology of the disease/ condition The epidemiology of the disease/ condition should be adequately understood, and the disease/ condition should be an important health problem (e.g., high or increasing incidence/prevalence and/or causes substantial morbidity/mortality). This consolidated decision principle includes 31 unique principles representing 32 distinct sources.	- **The condition sought should be an important health problem**[1-3] - A genetic screening programme must relate to a health problem or to a condition which can lead to such a problem in those being tested or in their descendants[4] - *Define clearly the adverse health outcome the program is intended to reduce. Define clearly the population that the program intends to screen[5] - Disease is serious[6] - Disease: high morbidity, mortality, and cost[7] - Disease: high prevalence and incidence[7] - *Disease: the disease should cause a sufficient burden of suffering to warrant attention and should have a detectable preclinical phase of sufficient length to allow early detection[8] - Disorder associated with significant morbidity or mortality[9] - Does the burden of the disability from the target disease warrant action?[10] - Important health problem[11] - Important health problem (i.e. common and serious)[12,13] - Important public health concern[14] - Is the condition to be detected of public importance?[15] - Known incidence in populations relevant to UK[9] - Prevalence: known[16] - Screening protocols should be directed toward diseases with a relatively high incidence[17] - The condition is an important health problem[18] - The condition should be an important health problem[19-23] - *The condition should be an important health problem as judged by its frequency and/or severity. 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[24] - The condition sought should be a common and/or serious health problem[25] - The condition to be screened for should have a high death or disability rate[17] - The criteria for inclusion of a screening test are: a) the condition is an important health problem that occurs frequently enough to justify screening an entire population[26] - The disease must be neither too rare, nor too common[6] - The disease or condition should be an important problem (morbidity and mortality)[27] - The disease or condition should be common (prevalence and incidence)[27] - The disease should be a serious health problem and the cause of substantial mortality and morbidity[28] - The disease should be a serious health problem, being common in occurrence and the cause of substantial mortality and morbidity[29] - The disease should be an important health problem[30] - The disease should be an important public health problem in terms of its frequency and/or severity. Historically, the development of this principle was in the general context of screening for infectious and chronic diseases and not related specifically to cancer. Today some of the cancer sites

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	considered for screening are not particularly common diseases, but, nevertheless, early detection and subsequent reduction of mortality can result in a significant benefit in life-years saved[31] - The screening program(me) should respond to a recognized need[22,32] - When weighing up the benefits and drawbacks for the participants in the programme, the final balance should be clearly biased towards the benefits. To assist with this evaluation, those proposing a screening programme must provide information about: a) the prevalence of the disease or disorder in the target group[4]
2. Natural history of the disease/ condition The natural history of the disease/condition should be adequately understood, the disease/condition is well-defined, and there should be a detectable preclinical phase. This consolidated decision principle includes 39 unique principles representing 26 distinct sources.	- **The natural history of the condition, including development from latent to declared disease, should be adequately understood**[1,3] - **There should be a recognizable latent or early symptomatic stage**[1-3] - Can a given biomarker or precursor, predict presence or development of preclinical and overt disease?[33] - Clinically and biochemically well-defined disorder[9] - Disease is detectable in asymptomatic state[6] - Disease: known natural history and biology[7] - Disease: preclinical phase with high prevalence[7] - *Disease: the disease should cause a sufficient burden of suffering to warrant attention and should have a detectable preclinical phase of sufficient length to allow early detection[8] - Disorder: well defined[16] - Early diagnosis leading to better prognosis[11] - Easily recognizable latent stage or early symptomatic stage[11] - Have suitably controlled investigations been carried out to show that the natural history of the disease is favourably influenced by screening procedures, with their consequent possibility of early institution of treatment, as compared with allowing patients to present with the illness when symptoms demand attention?[34] - If the carriers of a mutation are identified as a result of screening the natural history of people with this status should be understood, including the psychological implications[21,24] - Is each abnormality that is being sought adequately defined (e.g. hypertension, hyperglycaemia)?[34] - Long latent period (i.e. time between first detectable signs and overt disease)[12,13] - *Natural history: medically important disorder for which there is an effective remedy available[16] - Natural history of disease is known[6] - Natural history understood including development from latent to declared disease – detectable risk factor, disease marker[12,13] - *Period before onset during which intervention improves outcome[9] - Primary prevention not possible[11] - Sufficient knowledge of natural course of the disease[11] - The condition is a suitable candidate for screening[35] - *The condition should be an important health problem as judged by its frequency and/or severity. 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[24] - The condition should have a recognizable latent or early symptomatic stage[22] - The condition should have an (untreated) natural history that is adequately understood[22] - The disease should have a detectable preclinical phase (DPCP)[30] - 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, disease marker, latent period or early symptomatic stage[19-21] - The natural history of the condition and of gene carriers should be adequately understood[25] - The natural history of the condition should be known[30] - The natural history of the condition, including development from latent to declared disease, must be understood. There should be a recognizable latent (asymptomatic) period or early symptomatic stage[23]

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	- The natural history of the disease presents a window of opportunity for early detection. For cancer this generally refers to a detectable preclinical phase (DPCP), and it represents the interface between characteristics of the disease and the screening technology. It is during this period that screening is considered optimal to detect the disease early and prior to the development of symptoms. For screening to be effective, the recommended screening interval must be shorter than the estimate of the DPCP[31] - The natural history of the disease should be adequately understood[14] - The natural history of the disease, including latent to declared disease, should be adequately understood[2] - There is adequate knowledge of the natural history of the condition, with a recognized latent period or early symptomatic stage[18] - There should be a latent stage of the disease[14] - There should be a recognizable early symptomatic stage, latent stage or increased level of genetic risk[25] - Well-recognized pre-clinical stage[12,13] - What is the nature of the (pre-)disease when detected?[33] - When weighing up the benefits and drawbacks for the participants in the programme, the final balance should be clearly biased towards the benefits. To assist with this evaluation, those proposing a screening programme must provide information about: b) The natural course of the disorder, and the variation in degrees of severity[4]
3. Target population for screening The target population for screening should be clearly defined (e.g., with an appropriate target age-range), identifiable, and able to be reached. This consolidated decision principle includes 19 unique principles representing 15 distinct sources.	- *Define clearly the adverse health outcome the program is intended to reduce. Define clearly the population that the program intends to screen[5] - Definition of criteria used to identify target population[36] - Ensure high coverage and uptake rate[37] - Identification of target population[36] - Identify the target population[37] - If the test is for a particular mutation or set of genetic variants the method for their selection and the means through which these will be kept under review in the programme should be clearly set out[24] - If the test is for mutations the criteria used to select the subset of mutations to be covered by screening, if all possible mutations are not being tested for, should be clearly set out[21] - Recruitment[36] - Screening programs should have high rates of participation from the eligible population[31] - The individual women are identifiable[38] - The individuals in the population who stand to benefit from the screening are identifiable[39] - The target group of the screening programme must be clearly defined[4] - The target population has been identified[38] - The target population should be accessible, with a reasonable expectation of response to a screening invitation[28,29] - The target population should be clearly defined and have a reasonable disease prevalence[28,29] - There should be a defined target population[22,25,32] - There should be an appropriate screening strategy for the target population (i.e., an age to begin screening and a screening interval)[31] - What is considered to be the appropriate population to screen for the abnormality, and what is the basis for this selection?[34] - When weighing up the benefits and drawbacks for the participants in the programme, the final balance should be clearly biased towards the benefits. To assist with this evaluation, those proposing a screening programme must provide information about: c) Those target groups which are eligible for testing and the considerations which led to selection of the proposed target group and the proposed time of life for testing[4]
II. TEST/INTERVENTION PRINCIPLES (116 unique principles)	
4. Screening test performance characteristics	- **There should be a suitable test or examination**[1-3] - **The test should be acceptable to the population**[1,3,14,19-21] - A suitable screening test should be available, that is, one that is accurate, acceptable to the population, fairly easy to administer, safe, and relatively

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Screening test performance should be appropriate for the purpose, with all key components specific to the test (rather than the screening program) being accurate (e.g., in terms of sensitivity, specificity, positive predictive value) and reliable/ reproducible. The test should be acceptable to the target population and it should be possible to perform/administer it safely, affordably and efficiently. This consolidated decision principle includes 53 unique principles representing 34 unique sources.	inexpensive[31]. - A test method should be available which is suited to the objective of the screening[4] - Acceptability: as screening is in most instances voluntary and a high rate of co-operation is necessary in an efficient screening programme, it is important that tests should be acceptable to the subjects[40] - Accuracy: the test should give a true measurement of the attribute under investigation[40] - Among a clinically relevant population, does the test distinguish between those with and without the preclinical disease?[33] - Are the cost, accuracy, and acceptability of the screening test adequate for your purpose?[10] - Availability of a simple, innocuous, effective diagnostic test[11] - Ethical, safe, simple, robust screening test[9] - Have epidemiological studies been carried out to establish the incidence or prevalence of the condition in a group similar to the one selected for screening, to serve as a basis for determining the validity (in terms of sensitivity and specificity) of the screening procedure in detecting abnormalities?[34] - If the test is to be used on a wide number of people it should be inexpensive and not require a physician's attention[17] - Infants born anywhere in the United States should have access to screening tests and procedures that meet accepted national standards and guidelines. New screening tests should meet national criteria for newborn screening, with data on the validity of new tests and the clinical utility of screening new diseases collected through pilot programs[26] - Is the test able to distinguish between samples with and without the preclinical disease in laboratory condition?[33] - Is there an efficacious, safe, acceptable, and ethical method for detecting the condition at a sufficiently early stage?[15] - Precision (sometimes called repeatability): the test should give consistent results in repeated trials[40] - Reliable[12,13] - Safe and acceptable[12,13] - Screening test: able to detect disease in preclinical phase[7] - Screening test: acceptable to individuals[7] - Screening test: effective (that is, sensitive and specific)[7] - Screening test: safe[7] - Screening test: simple and inexpensive[7] - Sensitivity: this may be defined as the ability of the test to give a positive finding when the individual screened has the disease or abnormality under investigation[40] - Simple and cheap[12,13] - Simplicity: in many screening programmes more than one test is used to detect one disease, and in a multiphasic programme the individual will be subjected to a number of tests within a short space of time. It is therefore essential that the tests used should be easy to administer and should be capable of use by para-medical and other personnel[40] - Specificity: this may be defined as the ability of the test to give a negative finding when the individual does not have the disease or abnormality under investigation[40] - Test acceptable to target population, high compliance[11] - Test: simple and safe[16] - Test: the screening test should be sufficiently sensitive to detect those cancers that could benefit from earlier treatment. Note that the test does not need to be maximally sensitive but rather "sensitive enough" to detect those cancers that it is important to detect. Cancers that are important to detect are those which are treatable when detected by screening but not when detected clinically[8] - Test: there are usually many more false-positive test results than true-positive results. The screening test should be specific enough to minimize the number of false positive test results so as to minimize their negative consequences[8] - The criteria for inclusion of a screening test are: c) the test is simple, safe, precise, validated, and acceptable[26] - The screening test must be acceptable in its performance characteristics (e.g., sensitivity, specificity), and acceptable to those being screened[29] - The screening test should be accurate (sensitivity, specificity, and predictive value)[27]

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	- The screening test should have acceptable performance characteristics (e.g., sensitivity, specificity) and be acceptable to those being screened[28] - The screening test to be used should be acceptable and safe[30] - The screening tool must be easily applied and be acceptable to patients[17] - The test, from sample collection to delivery of results, should be acceptable to the target population[24] - *The test (inclusive of screening and diagnosis) and the screening program should be acceptable to the population[23] - The test should be safe, convenient, and not prohibitively expensive[6] - The test should be sensitive so that the disease is reliably detected when present[6] - The test should be specific so that false positive results are minimized[6] - The test used in screening should be acceptable to the population[22] - *The test used in screening should be suitable (simple, sensitive, specific, reproducible, validated, safe, and with a known distribution and cutoff points)[22] - There is a simple, safe, acceptable, precise, and validated screening test[18] - There is a suitable test[35] - There should be a simple, safe, precise and validated screening test[19-21,24] - There should be a suitable screening test[25] - There should be a suitable screening test or examination[23] - There should be a test or examination for the condition[14] - Valid (sensitive and specific)[12,13] - What screening methods are available and how do they compare with one another in acceptability, efficiency, and cost? Which seems to be the method of choice?[34] - When weighing up the benefits and drawbacks for the participants in the programme, the final balance should be clearly biased towards the benefits. To assist with this evaluation, those proposing a screening programme must provide information about: d) The specificity, sensitivity and predictive value of the test method to be used and the burden which such testing imposes on participants[4]
5. Interpretation of screening test results Screening test results should be clearly interpretable and determinate (e.g., with known distribution of test values and well-defined and agreed cut-off points) to allow identification of the screening participants who should (and should not) be offered diagnostic testing and other post-screening care. This consolidated decision principle includes 17 unique principles representing 19 distinct sources.	- **There should be an agreed policy on whom to treat as patients**[1,3,22] - Clear agreement on criteria for referring for further examination or treatment[11] - Evidence-based policies covering which individuals should be offered treatment and the appropriate treatment to be offered[12,13] - Evidence-based recommendations should be available regarding who should be offered further diagnostic investigation and/or treatment and the choices available to them[23] - Harms of overtreatment: often earlier detection includes detection of people with intermediate lesions that would never progress to invasive cancer. Screening may lead many people with these lesions to be subjected to treatment that they do not need and which causes harm. To minimize harms, people with lesions that will not progress to clinically important disease should rarely be subjected to potentially harmful and unnecessary treatment[8] - Identification of target population[36] - Screening in the absence of an accepted treatment may be appropriate when it will provide information of benefit to the child or the family[3] - Test performance: distributions of test values in affected and unaffected individuals known, extent of overlap sufficiently small, and a suitable cut-off level defined[16] - The distribution of test values in the target population should be known and a suitable cut-off level defined and agreed[19-21,24] - *The test used in screening should be suitable (simple, sensitive, specific, reproducible, validated, safe, and with a known distribution and cutoff points)[22] - *There are evidence-based policies covering who to treat and how to treat[18] - There is an agreed policy on whom to treat as patients[2] - *There should be agreed evidence based policies covering which individuals should be offered interventions and the appropriate intervention to be offered[24]

CONSOLIDATED SCREENING PRINCIPLES (Post-Review and Consensus Process)	INDIVIDUAL SCREENING PRINCIPLES (from 41 reviewed sets of screening principles) (*individual principle applies to more than 1 consolidated screening principle; original Wilson and Jungner principles in **bold** font)
	- *There should be agreed evidence-based policies covering which individuals should be offered treatment and the appropriate treatment to be offered[19-21] - There should be an agreed policy on who to treat[14] - There should be an agreed policy on whom to categorize as "screen positive", "screen negative" and "screen indeterminate", and a defined process for each group following disclosure of screening results[25] - What is to be done about findings which are neither clearly normal nor obviously abnormal (the "borderline" problem)?[34]
6. Post-screening test options There should be an agreed upon course of action for screening participants with positive screening test results that involves diagnostic testing, treatment/ intervention and follow-up care; that will modify the natural history and clinical pathway for the disease/condition; is available/ accessible/acceptable to those affected; and results in improved outcomes (e.g., increased functioning/quality of life, decreased cause-specific mortality). The burden of testing on all participants should be understood/acceptable and the impact of false-positive and false-negative tests should be minimal. This consolidated decision principle includes 50 unique principles representing 33 distinct sources.	- **There should be an accepted treatment for patients with recognized disease**[1-3,22] - Adverse outcome(s) are rare with a false-positive test[14] - Agreed policy on the further diagnostic investigation of individuals with a positive test result and on the choices available to those individuals[12,13] - An effective treatment for the target cancer should be available[28] - An effective treatment should be available that favorably alters the natural history of the disease. Usually for cancer this means a reduction in cause-specific mortality[31] - *Are diagnostic facilities available for the follow-up of abnormalities revealed by the screening procedure, and is there an acceptable form of treatment for each condition revealed?[34] - Confirmatory testing is available as needed[6] - Cost-effective[12] - Disease: effective treatment of early stage disease[7] - Does early diagnosis really lead to improved clinical outcomes (in terms of survival, function, and quality of life)?[10] - Effective, acceptable and safe treatment available[12] - Effective treatment available[9] - *Ethical: procedures following a positive result are generally agreed and acceptable both to the screening authorities and to the patients[16] - Follow-up, diagnosis and treatment[36] - Follow-up is available for all screening positives[6] - For a screening protocol to be of value, it is essential that early treatment should reduce death or disability[17] - If carriers are identified, genetic counseling is provided[14] - Is there evidence of increased benefit with earlier detection (as opposed to waiting until symptoms appear)?[15] - Natural history of disease is modifiable with treatment[6] - *Natural history: medically important disorder for which there is an effective remedy available[16] - *Period before onset during which intervention improves outcome[9] - Practical courses of action must be open to the participants[4] - Screening in the newborn period is critical for prompt diagnosis and treatment[14] - Screening leads to earlier treatment[2] - Sustainable[12] - The criteria for inclusion of a screening test are: b) the treatment for the condition is effective when initiated early, accepted among health care professionals, and available to all screened newborns[26] - The disease or condition should have a readily available and acceptable treatment[27] - The disease should be treatable, and there should be a recognized treatment for lesions identified following screening[30] - The treatment should be more effective if initiated during the presymptomatic (or earlier) stage than during the symptomatic (or later) stage; that is, if treating early (presymptomatic) has no advantage over treating late (symptomatic) then the cost and the risk of screening cannot be justified[31] - *There are evidence-based policies covering who to treat and how to treat[18] - There is an agreed policy on the further diagnostic intervention[18] - There is an effective and accessible treatment or intervention for the condition identified through early detection[35] - There is an effective treatment or intervention[18]

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	- There should be a treatment for the condition[14] - *There should be agreed evidence based policies covering which individuals should be offered interventions and the appropriate intervention to be offered[24] - *There should be agreed evidence-based policies covering which individuals should be offered treatment and the appropriate treatment to be offered[19-21] - There should be an accepted intervention (ex. prevention, treatment, family planning) that forms part of a coherent management strategy[25] - There should be an advantage to treating the disease earlier than at the stage it would present spontaneously[2] - 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[19-21,24] - 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. Evidence relating to wider benefits of screening, for example those relating to family members, should be taken into account where available. However, where there is no prospect of benefit for the individual screened then the screening programme shouldn't be further considered[24] - 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[19-21] - There should exist an agreed upon and effective treatment for the disease discovered in the population by screening[29] - Treatment available that is effective, acceptable, safe, cost-effective, sustainable[13] - Treatment costs may be covered by third parties (either private or public)[14] - Treatment is available[6] - Treatment or intervention that improves survival or quality of life (compared with not screening) should be available for patients with recognized disease[23] - Treatment: there must be a treatment for the disease that is more effective when applied to screening-detected cancers than clinically detected cancers. By "more effective," we mean that people will live longer or better as a result of this earlier treatment[8] - What is the test's intended role in the clinical pathway?[33] - When weighing up the benefits and drawbacks for the participants in the programme, the final balance should be clearly biased towards the benefits. To assist with this evaluation, those proposing a screening programme must provide information about: e) The available courses of action if a health problem or carrier status are revealed[4] - When weighing up the benefits and drawbacks for the participants in the programme, the final balance should be clearly biased towards the benefits. To assist with this evaluation, those proposing a screening programme must provide information about: h) The likelihood of erroneous results, the possible consequences of this for participants and the measures taken to limit any harm which such an error might cause[4]
III. PROGRAM/SYSTEM PRINCIPLES (171 unique principles)	
7. Screening program infrastructure There should be adequate existing infrastructure (e.g., financial resources, health human resources, information technology, facilities, equipment, test technology), and/or a clear plan to develop adequate infrastructure, that is appropriate to the setting to	- **Facilities for diagnosis and treatment should be available**[1,3,14,22] - Adequate facilities are available for having the tests and interpreting them[39] - Adequate facilities exist for diagnosis and appropriate treatment[39] - Adequate facilities must exist for diagnosis and for appropriate treatment of confirmed neoplastic lesions[38] - Adequate staffing and facilities for recruitment, testing, diagnosis and follow-up, treatment and program management should be available[23] - Adequate staffing and facilities for testing, diagnosis, treatment, and programme management should be available prior to the commencement of the screening programme[12,13,19-21,24] - *Are diagnostic facilities available for the follow-up of abnormalities revealed by the screening procedure, and is there an acceptable form of treatment for each condition revealed?[34] - *Availability and acceptability: the screening test, workup, and resultant treatment should be available to all and acceptable both to clinicians and to the people being screened[8]

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allow for timely access to all components of the screening program (e.g., recruitment, testing, information access, diagnosis, referral, treatment, follow-up, patient education/support, staff training, program management/ evaluation). This consolidated decision principle includes 36 unique principles representing 32 distinct sources.	- Can you manage the additional clinical time required to confirm the diagnosis and provide long-term care for those who screen positive?[10] - *Consider implementing the program in light of criteria for implementation (question 2 at the beginning of the Materials and Methods section of the text), including nonevidence considerations (resources available, other priorities, population preferences, etc.)[5] - Data infrastructure and health information systems[36] - Ensure adequate facilities for screening and the interpretation of the screen material[37] - Ensure adequate facilities for the diagnosis and appropriate treatment of screen detected disease, and for the follow-up of treated individuals[37] - Ensure adequate training for all key personnel[37] - Estimate resources required for successful implementation of the program. Fill in this estimate in the outcomes table[5] - Facilities are adequate[12,13] - Facilities for treatment should be available[2] - Facilities: available or easily installed[16] - *How will the adoption and implementation of screening (and the related diagnostic and intervention services) affect equity in health and the allocation of health resources? Are resources available to carry out the entire sequence of relevant screening, diagnostic, and timely intervention procedures in a population-based fashion, i.e., first targeting those groups in greatest need who may not be current users of health services?[15] - Public health infrastructure is in place to support all phases of the testing, diagnosis, and interventions[14] - Resources/mechanisms are available to encourage high coverage and attendance (e.g. health education, a personal letter of invitation and reminders where possible)[39] - Screening programs for a particular geographic area should take into account specific resources available for screening, diagnosis, and treatment so that countries can focus on optimal recommendations based on available resources[31] - Screening programs should ensure prompt follow-up of positive tests with a diagnostic examination and prompt treatment of cases[31] - *State public health agencies should assume responsibility for assessment, assurance, and policy development in the context of newborn screening, giving particular attention to the adequacy of system structures, oversight, and funding[26] - Sufficient facilities for diagnosis and treatment[11] - Sufficient personnel and facilities should be available both for screening and for subsequent diagnosis and therapy[28,29] - Test facilities for screening and analysis[36] - The health care system will be capable of supporting all necessary elements of the screening pathway, including diagnosis, follow-up and programme evaluation[35] - The infrastructure for screening, including education, testing, clinical services and program management, should be in place before the start of the program[25] - *The need for screening, the goals and objectives, the roles and responsibilities, and the financing required should be defined from the outset[25] - The organization of the screening program allows for an important part of the population to be screened[2] - The program(me) should promote equity and access to screening for the entire target population[22,32] - There are adequate field facilities for taking the smears and adequate laboratory facilities to examine them[38] - There should be sufficient facilities for follow-up testing, to carry out the selected courses of action and to inform and support the participants[4] - Treatment is available for all symptomatic cases, as well as all confirmed screening positives[6] - *When weighing up the benefits and drawbacks for the participants in the programme, the final balance should be clearly biased towards the benefits. To assist with this evaluation, those proposing a screening programme must provide information about: j) the costs which are linked to the screening and to the attainment of the requisite infrastructure[4]

CONSOLIDATED SCREENING PRINCIPLES (Post-Review and Consensus Process)	INDIVIDUAL SCREENING PRINCIPLES (from 41 reviewed sets of screening principles) (*individual principle applies to more than 1 consolidated screening principle; original Wilson and Jungner principles in **bold** font)
8. Screening program coordination/integration All components of the screening program (e.g., recruitment, testing, information access, diagnosis, referral, treatment, follow-up, patient education/support, staff training, program management/ evaluation) should be coordinated and, where possible, integrated with the broader health care system (including a formal system to inform, counsel, refer and manage screening participants) to optimize care continuity and ensure no screening participant is neglected. This consolidated decision principle includes 20 unique principles representing 14 distinct sources.	- **Case-finding should be a continuing process and not a "once and for all" project**[1,3] - Case finding should be a continuous process, not a "once and for all" project[14] - A referral system exists for management of any abnormalities found and for providing information about normal screening test[39] - Ensure a reliable, fail-safe procedure to ensure that action is taken on all positive results[37] - Establish an agreed referral system[37] - Increased coordination and uniformity, among state newborn screening systems and other child health programs, will greatly benefit families, health care professionals, and public health agencies[26] - Infants should have a "medical home" (identified by parents before or after birth) that is linked to a newborn screening system and includes access to appropriate care and treatment, if a condition is diagnosed[26] - Measures are available to guarantee high coverage and attendance such as a personal letter of invitation[38] - Newborn screening is an essential public health prevention activity that requires integration of parent education, sample collection, laboratory analysis, primary and specialty medical care, and related services for families with affected children[26] - Newborn screening is more than testing – it should always be part of a system that includes screening tests, follow-up, diagnosis, treatment, and evaluation as necessary. The primary objective of each state's newborn screening system should be to ensure that every newborn receives appropriate and timely services[26] - Screening is continuous process[11] - Screening should be a continuing process and not a "once and for all" project[25] - The "diagnostic odyssey" for the patient/family may be reduced or eliminated[14] - The program(me) should integrate education, testing, clinical services, and program(me) management[22,32] - The screening program should be a continuing process and not a 'once and for all' project[22] - The test may be multiplexed or overlaid onto an existing structure or system[14] - There is a carefully designed and agreed referral system, an agreed link between the woman, the laboratory and the clinical facility for diagnosis of an abnormal screening test, for management of any abnormalities found and for providing information about normal screening tests[38] - There should be an agreed policy for early recall of individuals with suspicious findings and on the frequency of routine recall for those with negative findings[28,29] - There should be an integrated screening program that incorporates the education, testing, clinical services and program management levels[25] - When weighing up the benefits and drawbacks for the participants in the programme, the final balance should be clearly biased towards the benefits. To assist with this evaluation, those proposing a screening programme must provide information about: f) The time allowed by the procedure for consideration and possible implementation of the choice made[4]
9. Screening program acceptability/ethics All components of the screening program (e.g., recruitment, testing, information access, diagnosis, referral, treatment, follow-up, patient education/support, staff training, program management/ evaluation) should be clinically, socially, and ethically acceptable to screening participants, health professionals and society, and there should be effective methods	- *Availability and acceptability: the screening test, workup, and resultant treatment should be available to all and acceptable both to clinicians and to the people being screened[8] - Action in the face of uncertainty may be justified in exceptional circumstances[3] - Adequate pretesting information or counseling is available to parents/guardians[14] - Before newborn screening, parents (on behalf of their children) have a right to be informed about screening, and have the right to refuse screening. They also have a right to confidentiality and privacy protections for information contained in all newborn screening results[26] - *Consider implementing the program in light of criteria for implementation (question 2 at the beginning of the Materials and Methods section of the text), including nonevidence considerations (resources available, other priorities, population preferences, etc.)[5] - Consumers should be included in screening policy-making and family members should be implicated in the screening process[25] - Decisions about screening should include community values, rights and duties alongside any cost-effective assessment[3] - *Ethical: procedures following a positive result are generally agreed and acceptable both to the screening authorities and to the patients[16] - Evidence that the complete screening programme (test, diagnostic procedures, treatment/intervention) is clinically, socially and ethically acceptable to health professionals and the public[12,13] - Evidence-based information, explaining the consequences of testing, investigation, and treatment, should be made available to potential participants

CONSOLIDATED SCREENING PRINCIPLES (Post-Review and Consensus Process)	**INDIVIDUAL SCREENING PRINCIPLES** (from 41 reviewed sets of screening principles) (*individual principle applies to more than 1 consolidated screening principle; original Wilson and Jungner principles in **bold** font)
for providing screening participants with informed choice, promoting their autonomy and protecting their rights. This consolidated decision principle includes 43 unique principles representing 27 distinct sources.	to assist them in making an informed choice[19,21] - Evidence-based information, explaining the purpose and potential consequences of screening, investigation and preventative intervention or treatment, should be made available to potential participants to assist them in making an informed choice[24] - If scientific research is carried out within the framework of screening, the participants should be properly informed about this in advance[4] - If screening is for a mutation, the programme should be acceptable to people identified as carriers and to other family members[21] - Parents and consumers must be involved in all parts of the policy-making process[26] - Participation in a genetic screening programme should be completely voluntary and should be conditional on consent based on good information[4] - 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[19,21,24] - Screening is not a diagnostic test. The follow-up investigation to diagnose malignancy, as well as the subsequent treatment, must be acceptable to patients[17] - Screening programs should be sensitive to patient and provider concerns[31]. - Testing may be declined by parents/guardians[14] - The complete newborn screening system (testing, follow-up, diagnostic procedures, treatment, and evaluation) should be clinically, socially, and ethically acceptable to the public and health professionals[26] - The limitations of screening and risks of a false-negative test are explained to parents/guardians[14] - The procedures used for the storage of medical information and cellular material must incorporate adequate measures to protect both the personal privacy of the participants and their rights regarding their personal data and cellular material[4] - The program(me) should ensure informed choice, confidentiality and respect for autonomy[22,32] - The purpose of the programme must be to enable the participants to determine the presence or the risk of a disorder or carrier status, and to take a decision on the basis of that information[26] - The screening procedure (programme) should be acceptable to the patient and society[27] - The screening test and the entire screening program should be acceptable to the target population and to society[25] - The target group should be supplied with good quality, comprehensible information[4] - *The test (inclusive of screening and diagnosis) and the screening program should be acceptable to the population[23] - There is a consideration of social and ethical issues[35] - There is evidence that the complete screening programme (ie test, diagnostic procedures, treatment/intervention) is clinically, socially, and ethically acceptable[18] - There should be a reasonable expectation that individuals having positive screening tests will undergo diagnostic workup and that individuals diagnosed with disease and their physicians will comply with appropriate therapeutic practices[28,29] - There should be a reasonable expectation that recommendations for the appropriate management of the lesions discovered from a screening programme will be complied with both by the individual with the lesion and by the physician responsible for his (or her) health care[30] - There should be a separate consent process for research that differs from the consent for clinical purposes[25] - There should be an education program in place from the outset of the program and individual risk counselling should be available throughout the screening process[25] - *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” (such as Down’s syndrome or cystic fibrosis 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[24] - 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[19-21,24] - There should be promotion of human rights, including upholding the principles of equity, autonomy and confidentiality[25] - Those offered screening must be able to make informed choices[12,13] - Treatment risks and the impact of a false-positive test are explained to parents/guardians[14]

CONSOLIDATED SCREENING PRINCIPLES (Post-Review and Consensus Process)	**INDIVIDUAL SCREENING PRINCIPLES** (from 41 reviewed sets of screening principles) (*individual principle applies to more than 1 consolidated screening principle; original Wilson and Jungner principles in **bold** font)
	- When weighing up the benefits and drawbacks for the participants in the programme, the final balance should be clearly biased towards the benefits. To assist with this evaluation, those proposing a screening programme must provide information about: g) the potential psychological, social and other repercussions (both positive and negative) of an offer and of participation or non-participation in the screening, for the person to be tested and for members of their family or for groups within the community[4] - When weighing up the benefits and drawbacks for the participants in the programme, the final balance should be clearly biased towards the benefits. To assist with this evaluation, those proposing a screening programme must provide information about: i) What guarantees there are to prevent participants experiencing unjustified impediments (as a result of their participation or non-participation in the screening programme or follow-up testing) to obtaining employment or private insurance cover[4] - Where screening is aimed solely at providing information to allow the person being screened to make an 'informed choice' (for example, Down's syndrome and cystic fibrosis 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[19,21] - Will the patients in whom an early diagnosis is achieved comply with your subsequent recommendations and treatment regimes?[10]
10. Screening program benefits/harms The expected range/magnitude of benefits (e.g., increased functioning/quality of life, decreased cause-specific mortality) and harms (e.g., over-diagnosis, over-treatment) for screening participants and society should be clearly defined and acceptable, and supported by existing high quality scientific evidence (or addressed by ongoing studies) that indicates that the overall benefit of the screening program outweighs its potential harms. This consolidated decision principle includes 30 unique principles representing 21 distinct sources.	- *A clear definition of the objectives of the programme, and the expected health benefits[39] - Benefit or harm to the family should be considered a benefit or harm to the child[3] - Benefits and harms: overall benefits (in terms of people living longer or better) must outweigh overall harms (including harms from the screening test, harms from the workup, the adverse effects of earlier treatment and overtreatment, the psychologic effects of labelling, and the downstream effects of surveillance)[8] - Benefits and risk are well known to health care providers and population[11] - Define the important potential health benefits and harms of the screening program; draw an outcomes table that your evaluation will fill in[5] - *Do health outcomes in the whole society improve by introducing the new screening strategy at an acceptable cost?[33] - Do patients who undergo the screening strategy fare better (in their ultimate outcome) than similar patients who do not?[33] - Evidence from high-quality randomized controlled trials that the screening programme is effective in reducing mortality and morbidity[12] - Evidence from high-quality RCTs that the screening programme is effective in reducing mortality or morbidity[13] - Has the effectiveness of individual components of a periodic health examination or multiphasic screening program been demonstrated prior to their combination?[10] - How broad are the confidence intervals around the estimated size of the beneficial effect, and what are, at each end of the confidence intervals, the: NNT; numbers adversely affected? (This question is particularly important because the size of the effect found in the ideal circumstances of the trial may not be reproducible in a routine screening service.)[41] - How many people have to be screened to find one case or prevent one death (the number needed to treat: NNT)?[41] - How many people would be adversely affected by screening: per thousand screened; per life saved?[41] - Infants should benefit from and be protected by newborn screening systems[26] - Is there evidence from a good-quality RCT, analysed on an intention-to-treat basis, that the proposed screening programme is effective in reducing mortality?[41] - The benefit from the screening programme should outweigh the physical and psychological harm (caused by the test, diagnostic procedures and treatment)[19-21] - The benefit gained by individuals from the screening programme should outweigh any harms for example from overdiagnosis, overtreatment, false positives, false reassurance, uncertain findings and complications[24] - The overall benefit of the screening program should outweigh the potential harms from its application[23] - The overall benefits of screening should outweigh the harm[22,32] - The overall benefits of screening should outweigh the potential harms, including psychological, physical and social harms[25] - The potential benefit from the screening programme should outweigh the potential physical and psychological harm (caused by the test, diagnostic procedures and treatment)[35] - There is evidence from high-quality RCTs that screening reduces mortality or morbidity[18]

CONSOLIDATED SCREENING PRINCIPLES (Post-Review and Consensus Process)	INDIVIDUAL SCREENING PRINCIPLES (from 41 reviewed sets of screening principles) (*individual principle applies to more than 1 consolidated screening principle; original Wilson and Jungner principles in **bold** font)
	- There is evidence that overall benefit from the screening programme outweighs the physical and psychological harm[18] - There is high quality evidence, ideally from randomized controlled trials, that a screening programme is effective in reducing mortality or morbidity[35] - There should/must be evidence from high-quality randomized controlled trials that the screening programme is effective in reducing mortality or morbidity[19-21] *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" (such as Down's syndrome or cystic fibrosis 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[24] - There should be scientific evidence of screening program(me) effectiveness[22,25,32] - Use the outcomes table and modeling (if possible) to weigh the absolute magnitude of benefits and harms. Estimate the net benefits in general terms (the 3 categories below); use, to the extent possible, the values of the population to be screened. The key question is this: compared with other programs for other conditions, is this net benefit 1) zero/negative (i.e., no net benefit), 2) small (i.e., close call between benefits and harms), or 3) moderate/substantial (i.e., important net benefit)? If reasonable people would disagree about the way the benefits and harms were weighed, say so[5] - Using a systematic review of the evidence, estimate the absolute magnitude of the potential benefits (Table 3) of the screening program. One should make this estimate under a range of assumptions about adherence by the health care system and the population to be screened. Fill in the outcomes table with the estimate. If the evidence is insufficient to make this estimate without uncertain extrapolations, say so[5] - Using a systematic review of the evidence, estimate the absolute magnitude of the potential harms (Table 3) of the screening program. Fill in the outcomes table with the estimate. If the evidence is insufficient to make this estimate without uncertain extrapolations, say so[5]
11. Economic evaluation of screening program An economic evaluation (e.g., cost-effectiveness analysis, cost-benefit analysis, cost-utility analysis) of the screening program, using a health system or societal perspective, should be conducted (or a clear plan to conduct an economic evaluation) to assess the full costs and effects of implementing, operating and sustaining the screening program while clearly considering the opportunity costs and impact of allocating resources to other potential non-screening alternatives (e.g., primary prevention, improved treatments, other clinical services) for managing the disease/condition. This consolidated decision	- **The cost of case-finding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole**[1,3,22] - All other options for managing the condition should have been considered (e.g. improving treatment, providing other services)[20] - All other options for managing the condition should have been considered (for example, improving treatment and providing other services), to ensure that no more cost-effective intervention could be introduced or current interventions increased within the resources available[19,21] - 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[24] - All the cost-effective primary prevention interventions should have been implemented as far as practicable[19-21,24] - Clinical management of the condition and patient outcomes should be optimized in all healthcare providers prior to participation in a screening programme[19-21,24] - Cost: the expense of screening should be considered in relation to the benefits resulting from the early detection of disease, i.e., the severity of the disease, the advantages of treatment at an early stage and the probability of cure[40] - Cost-effectiveness of screening[9] - Costs and benefits of program favorable in relation to total cost and benefits of health care[11] - Costs: the net health benefits must come at a reasonable cost[8] - *Do health outcomes in the whole society improve by introducing the new screening strategy at an acceptable cost?[33] - Economic evaluations should add to evidence favouring of screening, but should not be the sole criterion for deciding whether or not to offer screening[25] - Financial: cost-effective[16] - *How will the adoption and implementation of screening (and the related diagnostic and intervention services) affect equity in health and the allocation of health resources? Are resources available to carry out the entire sequence of relevant screening, diagnostic, and timely intervention procedures in a population-based fashion, i.e., first targeting those groups in greatest need who may not be current users of health services? [43] - Is the cost of the screening-and-timely-intervention operation warranted, given all the considerations covered above, in comparison with alternative uses of the resources, including actions outside the realm of health services?[15]

CONSOLIDATED SCREENING PRINCIPLES (Post-Review and Consensus Process)	**INDIVIDUAL SCREENING PRINCIPLES** (from 41 reviewed sets of screening principles) (*individual principle applies to more than 1 consolidated screening principle; original Wilson and Jungner principles in **bold** font)
principle includes 28 unique principles representing 27 distinct sources.	- Opportunity cost of the screening programme (including testing, diagnosis and treatment) should be economically balanced in relation to expenditure on medical care as a whole[12,13] - Screening programs should be cost-effective[31] - The opportunity cost of the screening programme (including testing, diagnosis and treatment) should be economically balanced in relation to expenditure on medical care as a whole[20] - 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 (ie value for money)[19,21] - 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 this criteria should have regard to evidence from cost benefit and/or cost effectiveness analyses and have regard to the effective use of available resource[24] - The resources allocated to the screening program (including testing, diagnosis and treatment of patients diagnosed) should be economically balanced in relation to other health care priorities[23] - The screening procedure (programme) should have a reasonable cost (health and financial risk and costs)[27] - The screening program is considered cost-effective to others[6] - The total cost of finding a case should be economically balanced in relationship to medical expenditure as a whole[14] - There is a consideration of cost-benefit issues[35] - What are the financial costs of the screening programme, and what health benefits would be obtained by using those resources allocated to screening on: a) other ways of managing the health problem the screening programme has been designed to tackle, for example, improving the treatment of breast cancer; b) other services for that population the screening programme has been designed to benefit; c) any other service for any other population group?[41] - What are the implications in terms of resources (education of the public, availability of staff, operating costs) of introducing on a large scale a screening programme which has been shown to be worthwhile in a pilot study, and what difficulties are envisaged in moving from essentially a research investigation to routine everyday practice?[34] - *When weighing up the benefits and drawbacks for the participants in the programme, the final balance should be clearly biased towards the benefits. To assist with this evaluation, those proposing a screening programme must provide information about: j) the costs which are linked to the screening and to the attainment of the requisite infrastructure[4]
12. Screening program quality and performance management *The screening program should have clear goals/objectives that are explicitly linked to program planning, monitoring, evaluating and reporting activities, with dedicated information systems and funding, to ensure ongoing quality control and achievement of performance targets.* This consolidated decision principle includes 23 unique principles representing 19 distinct sources.	- *A clear definition of the objectives of the programme, and the expected health benefits[39] - A quality control procedure should be implemented to maintain the sensitivity and specificity of the test and high compliance with diagnostic and therapeutic follow-up[28,29] - Adequate resources to register health information to be used for evaluation and monitoring of the programme[39] - Clear management, monitoring and quality assurance[12,13] - Ensure adequate quality control both within and between centres for the screening procedure and its interpretation[37] - Ensure systematic evaluation and monitoring of the whole programme[37] - Evaluation and monitoring of the total programme is organized in terms of incidence and mortality rates among those attending, among those not attending, at the level of the total target population. Quality control of the epidemiological data should be established[38] - Programme data are maintained so that evaluation and monitoring of the programme can be done regularly[39] - Program(me) evaluation should be planned from the outset[22,32] - Programme planning[36] - Provision should be made for continual quality assurance of the effectiveness, efficiency and safety of the test procedure, any follow-up work, as well as information and support given to the participants[4] - QA (quality assurance) and QC (quality control) procedures for whole screening program[11] - Quality control programme[36] - Screening programs as concerted actions meeting organizational and managerial requirements[11]

CONSOLIDATED SCREENING PRINCIPLES (Post-Review and Consensus Process)	**INDIVIDUAL SCREENING PRINCIPLES** (from 41 reviewed sets of screening principles) (*individual principle applies to more than 1 consolidated screening principle; original Wilson and Jungner principles in **bold** font)
	- Screening programs should be monitored and regularly evaluated[31] - *State public health agencies should assume responsibility for assessment, assurance, and policy development in the context of newborn screening, giving particular attention to the adequacy of system structures, oversight, and funding[26] - *The need for screening, the goals and objectives, the roles and responsibilities, and the financing required should be defined from the outset[25] - The objectives of screening should be defined at the outset[22,32] - There is an organized quality control programme for both the screening tests and for their interpretation[39] - There is an organized quality control programme on taking of the smears and on interpreting them[38] - There should/must be a plan for managing and monitoring the screening programme and an agreed set of quality assurance standards[19-21,24] - There should be quality assurance incorporated at all levels of the screening program and ongoing program evaluation should be planned from the outset[25] - There should be quality assurance, with mechanisms to minimize potential risks of screening[22,32]

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