



**Health  
Information  
and Quality  
Authority**

An tÚdarás Um Fhaisnéis  
agus Cáilíocht Sláinte

# **Review of international ethics frameworks used in policy-making in the context of screening**

**30 November 2021**

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## About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent statutory authority established to promote safety and quality in the provision of health and social care services for the benefit of the health and welfare of the public.

HIQA's mandate to date extends across a wide range of public, private and voluntary sector services. Reporting to the Minister for Health and engaging with the Minister for Children, Equality, Disability, Integration and Youth, HIQA has responsibility for the following:

- **Setting standards for health and social care services** — Developing person-centred standards and guidance, based on evidence and international best practice, for health and social care services in Ireland.
- **Regulating social care services** — The Chief Inspector within HIQA is responsible for registering and inspecting residential services for older people and people with a disability, and children's special care units.
- **Regulating health services** — Regulating medical exposure to ionising radiation.
- **Monitoring services** — Monitoring the safety and quality of health services and children's social services, and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health technology assessment** — Evaluating the clinical and cost-effectiveness of health programmes, policies, medicines, medical equipment, diagnostic and surgical techniques, health promotion and protection activities, and providing advice to enable the best use of resources and the best outcomes for people who use our health service.
- **Health information** — Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information on the delivery and performance of Ireland's health and social care services.
- **National Care Experience Programme** — Carrying out national service-user experience surveys across a range of health services, in conjunction with the Department of Health and the HSE.

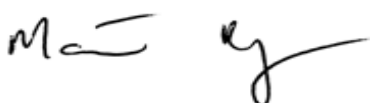
## Foreword

The National Screening Advisory Committee (NSAC) was established in 2019 by the Minister for Health as an independent advisory committee to play a strategic role in the development and consideration of population-based screening programmes in Ireland. The role of the NSAC is to provide advice to the Minister for Health and the Department of Health on new screening proposals and proposed changes to existing screening programmes. At the request of the Department of Health, the Health Technology Assessment (HTA) directorate within the Health Information and Quality Authority (HIQA) undertakes evidence synthesis and provides evidence-based advice to NSAC on behalf of the Minister for Health.

In line with the recommendations of the *Scoping Inquiry into the CervicalCheck Screening Programme* by Dr Gabriel Scally ('the Scally Report'), which emphasised the role of ethics in the consideration of programmes, and as part of the establishment of its working practices, NSAC has outlined that an ethics framework will provide an important structure to support evaluations and deliberations in relation to population-based screening programmes. It is the intention of NSAC that the framework will detail both substantive values for the assessment of screening policy and procedural values to guide the deliberations.

At the request of NSAC, the purpose of this report is to describe a review undertaken by the Evaluation Team at HIQA to outline ethics frameworks used internationally for policy-making in the context of screening, with the goal of informing subsequent stages of development of the NSAC ethics framework.

HIQA would like to thank the Evaluation Team, the members of the Expert Advisory Group and all who contributed to the preparation of this report.



Dr Máirín Ryan

Deputy Chief Executive and Director of Health Technology Assessment

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HIQA further notes that the findings set out in the advice represent the interpretation by HIQA of the available evidence and do not necessarily reflect the opinion of all members of the Expert Advisory Group.

### The membership of the EAG was as follows:

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### Conflicts of interest

None declared.

## List of abbreviations used in this report

<b>BCCDC</b>	British Columbia Centre for Disease Control (Canada)
<b>CCNE</b>	Comité Consultatif National d'Éthique (National Consultative Ethics Committee) (France)
<b>CESP</b>	Comite d'Éthique de Santé Publique (Public Health Ethics Committee) (France)
<b>DG SANTE</b>	Directorate General for Health and Food Safety (European Commission)
<b>EAG</b>	expert advisory group
<b>ECIBC</b>	European Commission Initiative on Breast Cancer
<b>ECICC</b>	European Commission Initiative on Colorectal Cancer
<b>EUnetHTA</b>	European Network for Health Technology Assessment
<b>GB-A</b>	Gemeinsamer Bundesausschuss (Federal Joint Committee) (Germany)
<b>GDG</b>	guidelines development group
<b>GRADE</b>	grading of recommendations assessments development and evaluation
<b>HAS</b>	Haute Autorité de Santé (France)
<b>HIQA</b>	Health Information and Quality Authority
<b>HSE</b>	Health Service Executive
<b>HTA</b>	health technology assessment
<b>INESSS</b>	Institut National d'Excellence en Santé et Services Sociaux (National Institute of Excellence in Health and Social Services) (Quebec - Canada)
<b>INSPQ</b>	Institut National de Santé Publique du Québec (National Institute of Public Health of Quebec) (Quebec – Canada)
<b>IQWIG</b>	Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care)
<b>ITC</b>	Inter-territorial Council (Spain)
<b>JRC</b>	Joint Research Centre (European Commission)
<b>MSSS</b>	Ministère de la Santé et des Services sociaux (Quebec)
<b>NSAC</b>	National Screening Advisory Committee
<b>RedETS</b>	Spanish Network of Agencies for Assessing National Health System Technologies and Performance
<b>RIVM</b>	Rijksinstituut voor Volksgezondheid en Milieu (National Institute for Public Health and the Environment) (The Netherlands)
<b>RIVM-CvB</b>	The Centre for Population Screening (The Netherlands)
<b>SATORI</b>	Stakeholders Acting Together On the ethical impact assessment of Research and Innovation (European Commission)
<b>UK NSC</b>	United Kingdom National Screening Committee
<b>US CDC</b>	US Centers for Disease Control and Prevention
<b>WHO</b>	World Health Organization



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## **Summary, Key Findings, and Advice to the National Screening Advisory Committee**

Recommendations within the *Scoping Inquiry into the CervicalCheck Screening Programme* by Dr Gabriel Scally ('the Scally Report') emphasised the role of ethics in consideration of population-based screening programmes.<sup>(1)</sup> In line with these recommendations, and as part of the establishment of its working practices, the National Screening Advisory Committee (NSAC) has outlined that an ethics framework will provide an important structure to support evaluations and deliberations in relation to population-based screening programmes. It is the intention of NSAC that the framework will detail both substantive values for the assessment of screening policy and procedural values to guide the deliberations. To support the development of the ethics framework, following a formal request from NSAC, the Health Information and Quality Authority (HIQA) agreed to undertake a review of ethics frameworks used for policy-making internationally in the context of screening.

The following methods were used to address the research question and objectives for this review:

- Elements of interest to this review included (i) general criteria used in decision-making, (ii) underpinning theory or approach to the assessment of ethical issues, (iii) stated considerations (such as principles or values), (iv) procedural considerations (such as procedural values), (v) components and structure of ethics framework, and (vi) processes used in the deliberation of ethical issues and justification of policy-making in relation to ethics.
- For the purposes of the present review, a framework was defined as a resource that details the ethical principles (and or values) considered in policy-making (for example, descriptions, considerations, questions or checklists to identify and examine potential ethical issues in relation to screening). This definition includes explicit ethics frameworks for policy-making in relation to screening. Frameworks for policy-making in screening that contain an ethical dimension were also eligible for inclusion, with the review limited to consideration of the ethical dimension.
- In order to identify relevant content for this review, a targeted search was conducted of countries, regions and international agencies, which had been noted in previous reviews to have in place clearly documented decision-making processes in relation to screening. For each country or region, a search was undertaken of the websites of national ministries of health, bodies

with responsibility for screening, national public health agencies, and national ethics bodies for information relevant to the review question. For the international agencies, the primary websites of the agency were searched.

- To supplement the grey literature search (that is, of primary websites), a survey of international practice was circulated to relevant screening organisations within the countries or regions identified. This was conducted in order to validate the findings of the grey literature search and to capture any unpublished processes that may exist.

The findings of this review are reported according to the source of the information (that is, bodies with responsibility for screening policy-making, public health agencies, ethics bodies, and international agencies). The key findings of the review that inform and underpin HIQA's advice are as follows:

- With respect to **bodies with responsibility for screening policy-making**:
  - The majority of the information obtained was identified from governmental organisations (such as designated screening committees) with responsibility for decision-making or that provide recommendations for screening programmes. Other sources included assessment agencies that provide information to decision-makers.
  - The criteria used in decision-making for screening programmes were largely found to be informed by, or derived from, the original criteria for screening programmes outlined by Wilson and Jungner. The criteria were often presented as global criteria for the assessment of all screening programmes. However, a number of countries presented specific criteria for newborn screening, genetic screening and carrier status, and cancer screening. The listed criteria were typically tailored and operationalised at the country level, with differences seen in the level of detail and number of criteria presented. A number of the countries were noted to have explicit criteria of relevance to ethics; these included the balance of benefit and harm, the degree to which the programme is ethically acceptable, equity, informed consent, confidentiality, privacy, and consideration of ethical issues or aspects generally.
  - Details regarding the theoretical basis or approach underpinning the assessment of screening programmes with respect to ethics were very limited in this review. A number of countries broadly defined the approach as being in keeping with specified values.

- The considerations stated to inform screening policy-making included descriptions of criteria relating to ethics, principles, values, ethical dimensions, ethical aspects, justice considerations, and norms. The considerations outlined differed across the included sources in terms of class (for example, values, principles, dimensions), detail, and number. However, some consistency existed in the general topics discussed, including reference to: accessibility (including the consideration of potentially vulnerable subgroups), equity, the balance of benefits and harms, health and well-being, avoidance of harm, resource use, autonomy and informed choice, acceptability, and justice.
- Considerations relevant to procedural elements of decision-making in screening were found to differ across the included sources; variation was found in the descriptors of such elements and in the number of considerations outlined. However, some considerations, such as transparency and openness, accountability, rigour, independence, respect, quality, and excellence, were common to multiple sources.
- For considerations relevant to ethics and to procedural elements (for example, values or principles), the rationale for these considerations, and the process of their selection, were typically not reported.
- The degree of detail relating to ethics varied considerably across the sources included. Methodological approaches included providing isolated lists of criteria or considerations, or providing conceptual descriptions, guiding considerations or questions to guide assessments. The majority of sources incorporated ethical dimensions within an overarching assessment framework (for example, general criteria for decision-making with respect to screening), with a limited number of countries presenting explicit ethics-based frameworks for assessments in the context of screening.
- The majority of sources described the assessment of considerations relevant to ethics as being embedded within the general decision-making processes for screening programmes. A limited number of countries outlined explicit processes concerning ethical analyses, with others outlining criteria to determine if an ethical analysis is necessary and strategies to resolve differences of opinion relating to ethics following the analysis.
- Stakeholder involvement within decision-making frequently included reference to patient representatives and expertise in suitable areas. A

number of countries highlighted the involvement of individuals with expertise in ethics and ethics committees in the decision-making process.

- Where values or ethical principles were explicitly outlined, several countries emphasised the importance of considering these equally (that is, one does not hold a higher weight than another) and highlighted that there may be circumstances in which such values or principles may be in conflict or tension with one another. However, processes for resolving or deliberating such circumstances were generally not reported.
- In terms of the role of ethics as documented by **public health agencies**:
  - General public health ethics frameworks (that is, not specific to screening) were identified from six public health agencies, with three originating from Canada. These frameworks are intended to guide ethical action, facilitate decision-making, and assist in the resolution of ethical issues in the context of public health. As these frameworks are intended to guide general public health decision-making, they may not sufficiently capture the nuances associated with screening.
  - The underpinnings of the frameworks identified were often referenced as being in keeping with agreed higher public health values (for example, respect for persons and the community).
  - The stated considerations differed across the frameworks in terms of number, class (for example, values, principles, dimensions), and description; however, there were some consistencies noted in the topic matter described. These included respect for persons and communities, beneficence, non-maleficence, the balance of benefit and harm, autonomy, solidarity, reciprocity, trust, and well-being.
  - A number of the frameworks highlighted the need to consider the relative weight of the considerations (for example, values, principles or dimensions) listed, noting that their weighting could be context-specific. They also highlighted that there may be circumstances in which there is conflict or tension between them.
  - The considerations relevant to procedural elements of decision-making also differed across sources in terms of number and detail. However, some considerations were common to multiple frameworks; these included accountability, responsiveness, transparency, rigour, and competence.

- Where decision-making processes were outlined, these were typically described in steps or stages, with a cyclical or reflective approach encouraged. Stakeholder involvement in decision-making relating to ethics was frequently cited as important, with a number of frameworks explicitly noting the significance of the consideration of stakeholder values in decision-making.
- The majority of documents identified from **national ethics bodies** related to the ethical considerations associated with specific screening topics. These forms of documents were frequently described as position or opinion statements and were largely concerned with genetic screening, including pre-implantation and prenatal screening.
  - The Nuffield Council on Bioethics in the United Kingdom has published a large document concerning ethical issues in public health (that is, not specific to screening).
  - The Danish Council on Ethics has published a document outlining potential ethical problems faced by general screening programmes and recommendations for how to consider them. It has also published ethical checklists to assist decision-makers in making ethically sound decisions in the context of public health interventions, including screening programmes.
- The **international agencies** included within this review largely presented high-level documents with references to ethics in screening. The exception is the EUnetHTA HTA Core Model<sup>®</sup>, which describes the assessment of screening technologies as part of a broader methodological framework and includes a detailed ethical analysis domain. This ethical analysis domain of the model:
  - aims to provide a thorough understanding of norms and values that need to be taken into account during a health technology assessment (HTA) and in decision-making processes while further acknowledging that these processes are in themselves value-laden.
  - includes six topics (benefit-harm balance; autonomy; respect for persons; justice and equity; legislation; and ethical consequences of the HTA) and 20 issues for consideration. The issues outlined under each topic (framed as relevant questions) are intended to increase awareness and identification of ethical issues, and potential conflicts relevant to a particular screening technology.

Arising from this review, HIQA's advice to NSAC is as follows:

- The national ethics bodies and international agencies considered within this review largely presented high-level overviews and position statements in relation to screening and screening-specific topics. An exception to this was the EUnetHTA HTA Core Model<sup>®</sup>, which presents a detailed methodological framework for ethical analysis within health technology assessments of screening programmes.
- In relation to **bodies with responsibility for screening policy-making**, the normative foundation of the approaches used were typically not described.
  - The following considerations relevant to ethics (for example, values, principles, dimensions) were noted across multiple bodies: accessibility (including the consideration of potentially vulnerable subgroups), equity, the balance of benefits and harms, health and well-being, avoidance of harm, resource use, autonomy and informed choice, acceptability, and justice.
  - Considerations relevant to procedural elements varied across bodies, but frequently included: transparency and openness, accountability, rigour, independence, respect, quality, and excellence.
  - Methodological approaches included providing isolated lists of criteria or considerations; or providing conceptual descriptions, guiding considerations, or questions to guide assessments. Stakeholder involvement was frequently highlighted. The majority of sources incorporated ethical dimensions within an overarching assessment framework, with a limited number of bodies presenting explicit ethics frameworks.
- Detailed ethics frameworks were identified from six **public health agencies**. These frameworks are intended to guide ethical action, facilitate decision-making, and assist in the resolution of ethical issues in the context of public health generally (that is, they are not specific to screening).
  - Some consistencies were noted with regard to stated considerations relevant to ethics. These included: respect for persons and communities, beneficence, non-maleficence, the balance of benefit and harm, autonomy, solidarity, reciprocity, trust, and well-being.

- The procedural elements varied across frameworks and commonly included accountability, responsiveness, transparency, rigour, and competence.
- The methodological approaches were typically described in steps or stages with a cyclical or reflective manner encouraged. Stakeholder involvement in decision-making relating to ethics was frequently cited as important.
- Sources included within this review typically did not describe either the rationale for the inclusion of considerations relating to ethics and procedural elements, or their intended purpose and meaning. Sources frequently described the need to consider the relevance and relative weight of identified values or principles when applied to particular contexts. While the possibility of conflicts or tensions emerging was highlighted, along with the need to resolve such issues, details of processes to assist in their resolution were typically not described.
- Variability was seen in the frameworks and considerations identified from the individual screening bodies and public health agencies. This is likely due to countries having their own unique perspective and value systems that influence how policy-makers explore ethics within decision-making. The transferability of such frameworks to the Irish context is unclear. In developing an ethics framework for use in Ireland, careful consideration should be given to the values and perspectives of the Irish system.
- As public health decisions, in the context of screening activities, are taken at the population or community level, the values and principles that guide such activities differ from those that guide traditional clinical decision-making. Therefore, it is important to consider the balance between the collective and the individual, and to remain cognisant of where the benefits and harms of a specific intervention are likely to accrue.



## **Background to the NSAC and HIQA work programme**

In 2018, the *Scoping Inquiry into the CervicalCheck Screening Programme* by Dr Gabriel Scally ('the Scally Report'),<sup>(1)</sup> recommended the establishment of a National Screening Committee to advise the Department of Health and the Minister on all new proposals for screening and on revisions to current programmes. Following this report, the National Screening Advisory Committee (NSAC) was established in 2019 by the Minister for Health as an independent advisory committee to play a significant strategic role in the development and consideration of population-based screening programmes in Ireland. At the request of the Department of Health, the Health Technology Assessment (HTA) directorate within the Health Information and Quality Authority (HIQA) undertakes evidence synthesis and provides evidence-based advice to NSAC on behalf of the Minister for Health.

Following a request from NSAC, the present document details a review of international ethics frameworks for policy-making in the context of screening.

## **1. Introduction**

### **1.1. Background to the review**

Decision-making about screening is associated with significant challenges, complexities, and a growing need to justify decisions taken. In 1968, a report on screening by Wilson and Jungner, which was commissioned by the World Health Organization (WHO) outlined ten principles that should be considered in decision-making relating to screening (see Box 1.1).<sup>(2)</sup> The authors explained that the term 'principles' was used for ease of description,<sup>(2)</sup> with the ten principles commonly termed 'criteria' in the subsequent literature.<sup>(3)</sup> Commonly referred to as the Wilson and Jungner criteria, they have formed the cornerstone of screening decisions internationally. However, advances in disease understanding, technology and a growing appreciation of the diverse complexities associated with screening have since triggered modifications to, and variations of, the original criteria.<sup>(3, 4)</sup>

Increasingly, there is a requirement for population-level policy decisions to take consideration of the values of the population and contextual circumstances, in addition to such decisions being based on high-quality evidence. <sup>(3)</sup> While the original aim of the Wilson and Jungner criteria was to stimulate discussion and exchange of viewpoints in relation to screening, as opposed to providing a rigid checklist,<sup>(2)</sup> there has been a growing appreciation that even when the ten criteria are satisfied, there may still be logistical, social or ethical reasons that contest screening.<sup>(3)</sup> A 2018 systematic review of principles for population-based screening

decisions, and a subsequent Delphi consensus process, presented a consolidated list of international criteria in use.<sup>(4)</sup> The authors concluded that, while the original Wilson and Jungner criteria have stood the test of time and remain core elements of screening policy internationally, there has been a growth in the emphasis placed on programme or system considerations, including those which relate to the acceptability and ethics associated with screening programmes, and the balancing of benefits and harms.

Similar to the findings from the international literature presented above, and in line with those presented by Wilson and Jungner, NSAC have adopted a modified list of criteria for appraising the viability, effectiveness and appropriateness of a screening programme. These criteria are presented in a categorised format (that is, condition, screening method, intervention, screening programme, and implementation).<sup>(5)</sup> In line with the recommendations of the Scally Report,<sup>(1)</sup> which emphasised the role of ethics in the consideration of screening programmes, and as part of the establishment of its working practices, NSAC has outlined that an ethics framework will provide an important structure to support evaluations and deliberations in relation to population-based screening programmes.<sup>(6)</sup> It is proposed that the ethics framework will complement the defined criteria with a specific focus on ethical considerations. The ethics framework will detail both substantive values for the assessment of screening policy and procedural values to guide the deliberations of NSAC.<sup>(6)</sup>

**Box 1.1** Wilson and Jungner screening criteria<sup>(2)</sup>

- The condition should be an important health problem.
- There should be an accepted treatment for patients with recognized disease.
- Facilities for diagnosis and treatment should be available.
- There should be a recognizable latent or early symptomatic phase.
- There should be a suitable test or examination.
- The test should be acceptable to the population.
- The natural history of the condition, including development from latent to declared disease, should be adequately understood.
- There should be an agreed policy on whom to treat as patients.

- The cost of case-finding (including a diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole.
- Case-finding should be a continuous process and not a “once and for all” project.

### *Ethics, public health ethics, ethical principles, values and procedural values*

Broadly speaking, ethics is the evaluation of the reasons we give for judging actions, individual or collective, to be right or wrong; this evaluation can be purely theoretical or applied to particular fields, such as medicine.<sup>(7, 8)</sup> There are three major branches of ethics:<sup>(9)</sup>

- meta-ethics: broad, high-level philosophical questions about the meaning and scope of ethical concepts
- normative ethics: seeks to provide a definition of ethical action by relying on specific ethical theories (for example, utilitarianism in striving to maximise beneficial consequences, or deontology in considering actions as right or wrong irrespective of the consequences)
- applied ethics: the application of ethics to real-life scenarios (for example, bioethics or environmental ethics).

While medical ethics is a well-established field, public health ethics (which includes population-based screening) is a relatively new and evolving area.<sup>(10, 11)</sup> The US Centers for Disease Control and Prevention (CDC) note that public health ethics, as a field of study and practice, seeks to understand, clarify, and apply values and principles which may be used to guide public health decision-making in terms of ethical issues encountered, and to justify the decisions made.<sup>(12)</sup> As public health decisions are typically taken at the population or community level, the values and principles which guide public health may differ from those which guide traditional clinical decision-making (typically at the individual or patient-level)<sup>(10, 12)</sup>. In public health generally, and in the context of specific public health interventions, there is a complex interplay between individual interests, the community, and the government (or decision-maker). Ethical conflicts may arise as a result of this interrelationship, for example, conflicts between individual autonomy and the health of the population more generally.<sup>(11)</sup> In an analysis of ethics assessment in different fields as part of the European Commission-funded project ‘Stakeholders Acting Together On the ethical impact assessment of Research and Innovation’ (SATORI), it was noted that

public health ethics does not appear to possess an agreed set of values or principles; this was attributed to the relatively recent development of public health as a discipline, and to broad conceptions of the field and varying views on the overall goals of the discipline.<sup>(13)</sup> However, the authors note that certain values, such as social justice and human rights, appear to be widely accepted as inherent to public health.<sup>(13)</sup>

Values may be defined as abstract, general ideals which are held to be important, or which one supports or strives for.<sup>(14)</sup> Principles may be defined as general rules which guide or underpin an action.<sup>(10, 15)</sup> Ethical principles may play a role in decision-making to provide a substantive basis for decisions that aim to promote the best overall outcome in a given set of circumstances.<sup>(15, 16)</sup> When considering complex decisions, or decisions that involve or affect numerous stakeholders, multiple principles may apply and the relevance or weight of each principle will depend on the specific context.<sup>(10)</sup> Justifying an action by reference to ethical principles involves an ability to weigh up the benefits and harms in light of relevant considerations, while acknowledging that the values of stakeholders and organisations will influence the decision made.<sup>(10)</sup> Examples of ethical principles include, but are not limited to, beneficence, minimisation of harm, autonomy, solidarity, justice, and equity. Importantly, the ethical principles that are outlined as relevant to decisions may conflict with one another in certain contexts or scenarios, emphasising the need for robust ethical decision-making processes.<sup>(16)</sup> Even where there is broad agreement about the relevant considerations or ethical principles in question, individuals may still disagree on the course of action given different value-commitments that may exist, or where the available evidence may be uncertain or interpreted in different ways.<sup>(17)</sup>

Within decision-making, there may a number of ways of resolving a given ethically-challenging situation. However, it is crucial that the final decision is reached using a process which is acceptable to all relevant stakeholders and is publicly defensible.<sup>(17)</sup> Procedural values such as openness, fairness, transparency, reasonableness, and accountability assist in ensuring that decisions are defensible and the manner in which they are made is justifiable. <sup>(16-18)</sup>

### *Ethics guidance*

When faced with ethically challenging situations and the need to ensure that actions are ethically justifiable, public health policy-makers require methods for applying and integrating ethics into decisions.<sup>(7)</sup> Ethics guidance, typically as an internal direction, furnishes recommendations that help groups or individuals to make ethically-competent, justifiable decisions. Ethics guidance can take many forms, and may use different tools, depending on the requirements of a particular task. Broadly, ethics

guidance may be understood in terms of four approaches: increasing ethical awareness, providing ethical action guidance, facilitating ethical deliberation, and explaining ethical justification.<sup>(7)</sup>

Depending on the approach, ethics guidance typically denotes a statement or outline of ethical guidelines, principles, rules, or recommendations to which practices should adhere.<sup>(14)</sup> Ethics guidance differs from ethics assessment in that it does not involve moral judgment; rather it sets general standards of rightness or wrongness according to which specific activities or outcomes may be guided or evaluated.<sup>(14)</sup>

### *Theories and frameworks*

When considering ethics guidance, the facilitative role of theories and frameworks is frequently discussed.<sup>(7, 19)</sup> Within the context of public health ethics, the complex relationship between theories and frameworks is noted as well as the challenges in merging theory and practice in decision-making.<sup>(19)</sup>

Ethical theories are conceptual systems which seek to deliberate and justify the rightness or wrongness of a proposed, or taken, action and why the action may be considered right or wrong.<sup>(11)</sup> Broadly, ethical theories may be categorised as traditional (for example, utilitarianism, deontology, virtue ethics) or contemporary (for example, principlism, feminist ethics).<sup>(20)</sup> It is noted that in the field of public health, the choice of a theory should be strongly linked to the practicalities of the discipline.<sup>(19)</sup>

Frameworks can provide methodical approaches or procedures that tailor general ethical theories, principles, and values to the specific ethical challenges that arise in a particular context.<sup>(10)</sup> However, the definition of a framework is broad and may span from simply describing the principles or values taken into account in decision-making to playing more facilitative roles in reaching a decision.<sup>(19)</sup> Further, a framework may be set at the level of discipline (for example, public health) or may be specific to a particular task (for example, screening programmes).<sup>(19)</sup> While often drawing on theory, a framework should ideally offer an applied context to deliberation with a focus on the identification and resolution of ethical issues; in this way, they are closer to the practical aspect of decision-making.<sup>(19)</sup> It is important to note that frameworks, and other such tools, are designed to aid deliberation and decision-making by framing the elements considered relevant. However, frameworks are typically heuristic in nature (that is, they represent generalised guidance and may not apply in all situations) and serve simply to guide the deliberation as opposed to make the decision.<sup>(10, 19)</sup>

## **1.2 Illustrative framework from the Irish context**

As an illustrative example, a framework within the Irish public health setting was developed in 2020 by the Department of Health to guide decision-making within the COVID-19 pandemic. The *Ethical framework for decision-making in a pandemic*,<sup>(16)</sup> and a companion document *Procedural values for decision-making in a pandemic*,<sup>(17)</sup> describes a high-level ethical framework developed to guide policymakers, healthcare planners and providers in acute and community settings in their decision-making within the context of the ethically challenging situations that arise in the context of a pandemic. The framework has been cited and adapted for use in a range of settings within the pandemic including vaccine allocation,<sup>(21)</sup> and long-term care facilities.<sup>(22)</sup> The pandemic has required decisions to be made with unprecedented levels of uncertainty and urgency, and the framework notes that there may be numerous ethically sound solutions to presented scenarios, with disagreements based on empirical and or normative grounds. Generally, decision-making in the context of the pandemic has required a shift from patient-centred practise to one which centres on public health considerations and the interests of the population as a whole.

The developers of this framework note the need for reflection on shared values in order to provide a shared basis for decision-making. The framework is presented as a means to explore the ethical aspects of a particular scenario and to deliberate on these aspects before a decision is made. Given the emergency situation considered, there are clear contextual differences between frameworks for the context of a pandemic and those for screening. Nonetheless, the framework, as outlined below, provides a clear articulation of relevant ethical principles, procedural values and tools to assist in decision-making, which may be of structural relevance to the present ethics framework under development by the NSAC.

### *Ethical principles*

The documents note that the use of ethical principles to guide and inform decision-making can assist in conferring legitimacy and acceptability on the course of action chosen, while enhancing trust and solidarity.<sup>(16, 17)</sup> The framework identifies seven key ethical principles that may apply to decisions made within the pandemic which are described in detail through consideration of each principle in general terms, as they relate to a pandemic context, and how they may interact with other principles. Briefly, the ethical principles outlined are:

- minimising harm
- proportionality
- solidarity

- fairness
- duty to provide care
- reciprocity
- privacy.

While these ethical principles are important in informing decision-making, the developers note that their relative weight is context-specific and may vary with local circumstances. Furthermore, a degree of interaction exists between the principles, highlighting that these cannot be interpreted or implemented in isolation. Similarly, conflicts can emerge between the principles depending on the context, with decisions taken to preserve one principle potentially compromising another.

### *Procedural values*

While more than one justifiable solution may be available for a particular task or question, it is essential that whatever decision is taken is acceptable to all relevant stakeholders and is publicly defensible; this emphasises the need for clear, robust and consistent decision-making processes. Such decision-making processes should ensure procedural fairness and legitimise the action taken. In this context, procedural values facilitate decision-making processes through the establishment of values that should apply to the manner in which decisions are taken. The procedural values outlined within the framework are described in detail with examples of their application. Briefly, these are:

- reasonableness
- openness and transparency
- inclusiveness
- responsiveness
- accountability.

As shown in Table 1.1, a tool is provided to facilitate the application of each procedural value to the decision-making process. For each procedural value, a number of accompanying questions are provided to ensure the value is appropriately fulfilled.



**Table 1.1** Tool to facilitate the application of procedural values to decision-making process, as outlined within the Department of Health’s *Procedural values for decision-making in a pandemic* <sup>(17)</sup>

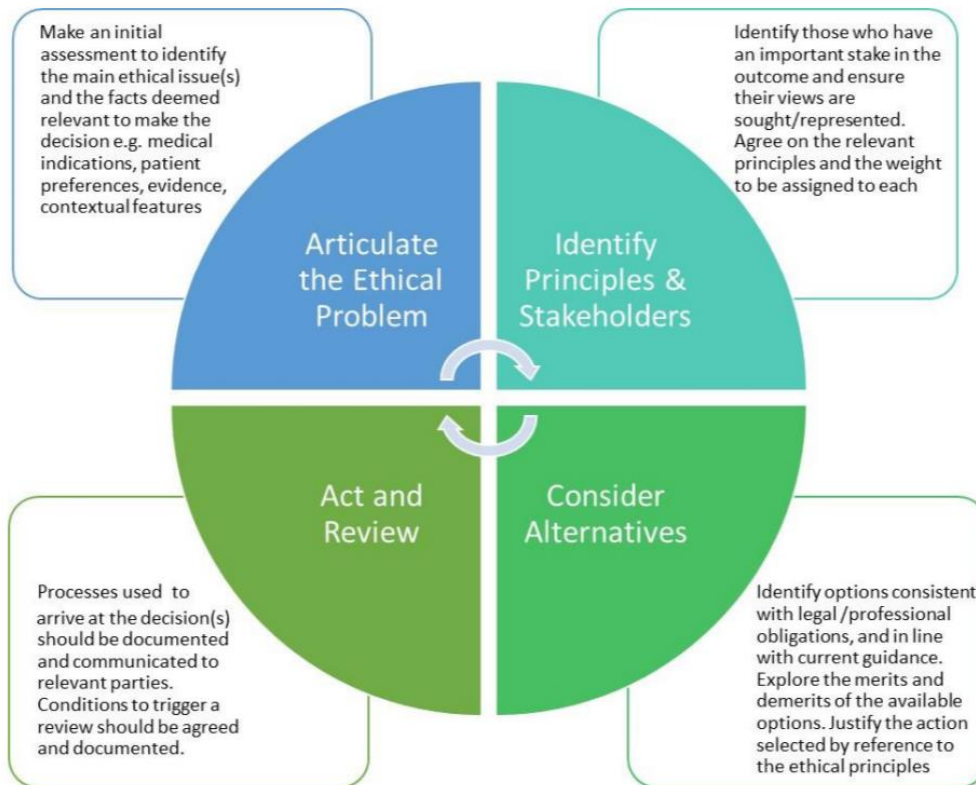
Procedural value	Questions to consider
Reasonableness	<ul style="list-style-type: none"> <li>▪ Is the decision consistent with relevant ethical principles?</li> <li>▪ What are the key reasons for the decision made?</li> <li>▪ Does the course of action decided upon have a reasonable chance of working?</li> <li>▪ Is the decision based on the evidence and information available at the time?</li> <li>▪ Have the alternatives been adequately explored?</li> <li>▪ Are the relevant resources available to enact the decision?</li> </ul>
Openness and transparency	<ul style="list-style-type: none"> <li>▪ How will the decision be communicated, and with whom?</li> <li>▪ Have any value-conflicts been identified?</li> <li>▪ Has the thinking and the rationale that informed the decision been clearly explained?</li> <li>▪ Are there barriers to communicating with key stakeholders?</li> <li>▪ Are any uncertainties around the decision acknowledged and communicated?</li> </ul>
Inclusiveness	<ul style="list-style-type: none"> <li>▪ Who will be affected?</li> <li>▪ Have all the relevant stakeholders been engaged with?</li> <li>▪ Have the appropriate communication methods and formats to reach and include the target audience been used?</li> <li>▪ Will this decision have disproportionate impacts on any particular person/group?</li> <li>▪ Will this decision create, magnify, or remove barriers to service?</li> </ul>
Responsiveness	<ul style="list-style-type: none"> <li>▪ Is the decision being made in a timely manner?</li> <li>▪ Is there any justification for postponing the decision?</li> <li>▪ When and how will the decision be reviewed?</li> <li>▪ What is the mechanism for raising concerns?</li> </ul>
Accountability	<ul style="list-style-type: none"> <li>▪ Who was involved in making the decision?</li> <li>▪ Who is responsible for the decision?</li> <li>▪ Have official guidance, statutory duties and professional codes of conduct been adhered to?</li> <li>▪ Has the decision been appropriately recorded?</li> <li>▪ In situations where there are conflicting opinions, who will act as the final arbiter?</li> </ul>



### Components of decision-making process

The key components of, and activities within, the decision-making process were outlined in a cyclical flow diagram presented within the framework (see Figure 1.1).

**Figure 1.1** Decision-making process to identify and address ethical issues as outlined in Department of Health's *Procedural values for decision-making in a pandemic* <sup>(17)</sup>



### **1.3 Purpose of review and research question**

The process of development of the NSAC ethics framework will include a number of stages. In the first instance, HIQA has been requested to undertake a review of ethics frameworks for policy-making internationally in the context of screening.<sup>(6)</sup>

Accordingly, the aim of this review is to provide an overview of international ethics frameworks for policy-making in the context of screening. The following research question was formulated to inform the overall review:

What ethical principles, substantive values and procedural values are stated to be taken into account internationally to inform policy-making relating to population-based screening, and what processes are used to consider these aspects during the assessment of population-based screening programmes (new or existing)?

The overall objectives of the review are to outline the:

- ethical principles, substantive values and procedural values which underpin and justify policy decisions in relation to population-based screening internationally
- processes used to address ethical issues arising during the assessment of new prospective, or existing, population-based screening programmes.

## 2 Methods

The full methodology for this review has been published in a separate protocol document (available here). Briefly, the process steps completed for the review are outlined below. For the purposes of the present review, a framework is defined as a resource which details the ethical principles (and or values) considered in policy-making (for example, descriptions, considerations, questions or checklists to identify and examine potential ethical issues in relation to screening). This definition is taken in a broad sense to include both explicit ethics frameworks for policy-making in relation to screening, and frameworks for policy-making in screening which include an ethical dimension (of which the ethical dimension will be the focus for this review).

### *Identification and searching of relevant sources*

A targeted search was conducted of countries, regions and international agencies which had been noted in previous reviews,<sup>(23, 24)</sup> as having documented decision-making processes in relation to screening. *A priori*, given defined HTA processes within the HTA Directorate of HIQA, the European Network for Health Technology Assessment (EUnetHTA) Core Model<sup>®</sup> for screening technologies was included as a supplementary international agency to document the ethical considerations taken into account as standard within HTA.<sup>(25)</sup>

### *Screening of sources*

For each country or region, websites of national ministries of health, of bodies with responsibility for screening, of national public health agencies, and of national ethics bodies, were searched for information related to the review question components. For the international agencies, the primary websites of the agency were searched. Where uncertainty or ambiguity existed in the information being extracted (for example, whether a term was considered to represent a value or a principle) this was described as per the original source or noted to be unclear in the description thereof (that is, inference was not drawn).

While the primary focus of this review comprises the ethical principles, substantive values and procedural values considered within the assessment of a screening programme or policy, where a source noted consideration of ethical aspects in line with the ethos or mission values of a particular body or organisation, these were also extracted.

As suggested in the background document prepared by NSAC to inform the development of the NSAC ethics framework, the main focus of the sources searched

was public health ethics, with a lesser emphasis on clinical ethics.<sup>(6)</sup> Research ethics committees were considered out of scope in this review given differences between research ethics (for example, the primary concern for scientific integrity in the study of human subjects) and public health ethics.<sup>(10)</sup>

### *Survey of international sources*

To supplement the grey literature search (that is, of primary websites), a survey of international practice was circulated to relevant screening organisations within the countries or regions identified in order to validate the findings of the grey literature search and to capture any unpublished processes that may exist. Where a conflict was identified between the grey literature search and the returned survey, the answers provided in the survey took precedence.

### *Scope of report with respect to overall findings*

While this report aims to outline ethics frameworks used internationally to inform policy-making about population-based screening programmes, it is not within the remit of the present report for HIQA to assess the relative merits of individual processes or country-specific approaches. The review findings are therefore reported in a narrative format. Findings are reported according to the source of information: national or regional bodies with responsibility for screening policy-making, public health agencies, ethics bodies, and international agencies (sections three to six).

### **3 Bodies with responsibility for screening policy-making**

For each country or region, websites of national ministries of health, and of bodies with responsibility for screening, were searched for relevant information. The following information was sought with respect to the assessment of screening programmes:

- general criteria used in decision-making
- underpinning theory or approach
- stated considerations relevant to ethics (such as principles or values)
- considerations relevant to procedural elements
- components and structure of ethics framework
- processes used in the deliberation of ethical issues and justification of policy-making about ethics.

A survey of international practice was circulated to relevant screening organisations within the countries or regions identified in order to validate the findings of the grey literature search and to capture any unpublished processes that may exist. The information obtained is outlined by country, or region, in Appendices 1.1 to 1.4. The majority of information was obtained from governmental organisations, such as designated screening committees, which hold responsibility for decision-making or who provide recommendations for screening programmes. However, a number of sources were noted to be assessment-based agencies which provide information to decision-makers (see Appendix 1.2 'Responsibility for screening').<sup>(26-28)</sup> Sections 3.1 to 3.6 summarises the information sought across countries or regions, while section 3.7 provides a brief summary of the information at the level of the individual country or region.

#### **3.1 Summary of general criteria used in decision-making**

The general criteria used in decision-making for screening programmes are outlined for each country, or region, in Appendix 1.1. For the majority of countries, these criteria are largely considered to be informed by, or derived from, the original criteria for screening programmes outlined by Wilson and Jungner (see section 1).<sup>(2)</sup> These criteria have been tailored and operationalised at the country-specific level, with differences seen in the level of detail and the number of criteria presented. The

criteria were frequently grouped into categories relating to: condition, test, intervention, programme, implementation, and quality. A number of the countries were noted to have explicit criteria of relevance to ethics including the balance of benefit and harm, being ethically acceptable, consideration of ethical issues or aspects, equity, informed consent, confidentiality and privacy.

While the criteria were often presented as global criteria for the assessment of any screening programme, a number of countries and regions presented specific criteria for newborn screening,<sup>(28-33)</sup> genetic screening and carrier status,<sup>(31, 34, 35)</sup> and cancer screening.<sup>(34, 36)</sup>

### **3.2 Summary of underpinning theory or approach**

Appendix 1.2 outlines details of the theoretical basis or approach underpinning the ethical assessment of the screening programmes. As may be observed in the table, details were found to be very limited. A number of countries broadly defined the approach as being in keeping with specified values.<sup>(26, 37-39)</sup>

### **3.3 Summary of considerations relevant to ethics**

With respect to the values and or ethical principles considered in the assessment of screening programmes, there were substantial differences in terminology and level of detail across the included countries. Items considered relevant to values and or ethical principles have been grouped for the purposes of this review under 'considerations relevant to ethics'. As shown in Appendix 1.2, the considerations relevant to ethics included descriptions of criteria relating to ethics, principles, values, ethical dimensions, ethical aspects, justice considerations, and norms. While the considerations outlined differed across the included sources, the following were noted across multiple sources:

- accessibility (including potentially vulnerable subgroups)
- equity
- balance of benefits and harms
- health and well-being
- avoidance of harm (including overdiagnosis, overtreatment, and stigmatisation)
- resource use

- autonomy and informed choice
- acceptability to target population
- justice.

The rationale, and process of selection, of relevant ethics considerations (for example, values or principles) were typically not reported.

### **3.4 Summary of considerations relevant to procedural elements**

Appendix 1.2 lists considerations relevant to procedural elements of decision-making in screening. As was the case with 'considerations relevant to ethics', the procedural elements were typically heterogeneous across the included sources with varying descriptors and numbers of considerations outlined. However, the following considerations were noted across multiple sources:

- transparency and openness
- accountability
- rigour
- independence
- respect
- quality and excellence.

### **3.5 Summary of components and structure of ethics frameworks**

As noted in the methodology for this review, a framework was defined as any resource which details the ethical principles (and or values) considered in policy-making relating to screening programmes. As shown in Appendix 1.3, the degree of detail relating to ethics varied considerably across the sources included. Approaches adopted included providing:

- isolated lists of criteria or considerations
- conceptual descriptions

- guiding considerations
- questions to guide assessments.

The majority of sources presented ethical dimensions embedded within an overarching assessment framework (for example, general criteria in decision-making for screening). France, Sweden and the United Kingdom presented explicit ethics frameworks for assessments in the context of screening.<sup>(26, 38-40)</sup>

### **3.6 Summary of processes used in deliberation of ethical issues and justification in policy-making**

The processes used in the deliberation of ethical issues and justification in policy-making are outlined in Appendix 1.4. Stakeholder involvement within decision-making frequently included reference to patient representatives and expertise in suitable areas. A number of countries highlighted the involvement of individuals with expertise in ethics and ethics committees in the decision-making process. In general, the sources outlined ethics as being embedded within the general decision-making processes for screening programmes. Sweden, France, and the United Kingdom (currently in development) were noted to describe processes explicitly related to the analysis of ethical issues.<sup>(26, 39-41)</sup> A number of countries further highlighted mechanisms which guide decisions regarding the necessity of an ethical analysis within the assessment of a screening programme.<sup>(26, 42)</sup>

Where values or ethical principles were explicitly outlined, a number of countries emphasised the importance of considering these equally (that is, one does not hold a higher weight than another) and highlighted that there may be circumstances in which values or principles may be in conflict or tension with one another. However, processes for resolving or deliberating such circumstances were generally not reported.

Decision-making processes, including the consideration of ethics, were typically described as being consensus-based. Where disagreements occurred, various strategies were outlined to resolve these. Such strategies included majority verdicts, votes, peer review, external consultation, and the provision of opposing perspectives to decision-makers.



## **3.7 Summary of information for individual countries or regions**

### **Australia**

In Australia, policy- and decision-making responsibility for population-based screening programmes varies, depending on the governance of the individual programmes.<sup>(43)</sup> For example, states and territories are responsible for their respective newborn screening programmes, while, in contrast, for the country's breast cancer screening programme, decision-making is shared between the Commonwealth Government and the state and territory governments. Assessments of screening programmes are undertaken by the policy- and decision-makers for each of the screening programmes; there is no overarching body responsible for population screening governance or ethics.<sup>(43)</sup>

Separate policy frameworks guide decision-making about general population-based screening programmes, newborn bloodspot screening, and genomic testing, with specific screening criteria listed for each (see Appendix 1.1).<sup>(29-31)</sup> Ethics are embedded within the policy frameworks and criteria with the following noted as consistent across the documents:

- The principles of access and equity underpin Australia's population-based screening programmes.
- Decisions are made under the ethical obligation to maximise benefits and minimise harm (including psychological, physical, social, cultural, ethical and legal harms).
- A key principle is that when community resources are used to fund screening there should be community consensus that the benefits of screening justify the expense of screening.
- Informed choice, confidentiality and respect for autonomy are noted as key considerations.
- Screening programmes must be acceptable to the target population and society (including culturally and linguistically diverse groups, Aboriginal and Torres Strait Islander peoples, and within vulnerable populations such as those with a disability).

In terms of procedural values, the policy documents emphasise the importance of transparency and accountability in decision-making for population-based screening programmes.<sup>(29)</sup> While considerations relevant to ethics are embedded within the

policy frameworks and respective criteria, the framework for newborn bloodspot screening provides additional questions to guide decision-making under each relevant criterion (see Box 3.1).<sup>(30)</sup>

While no explicit processes were identified about ethics, Australia presents defined decision-making processes, which includes the analysis of ethical issues, where appropriate.<sup>(29, 43)</sup> Given the criterion that a programme should be ethically acceptable to all relevant parties, the supporting documentation notes the inclusion of stakeholders within the decision-making process with regard to ethical issues. These include organisations for individuals and families affected by the relevant condition, Aboriginal and Torres Strait Islander representative groups, health care provider organisations, research organisations, and bioethicist expertise.

**Box 3.1** Guiding questions for ethics considerations as applied to assessment of newborn bloodspot screening in Australia<sup>(30)</sup>

*The condition*

Criteria: There should be a benefit to conducting screening in the newborn period.

- Does detection provide families with actionable information that helps them in making informed choices about reproduction in the future?
- What emotional or social benefits does early protection provide?
- What harms may arise from screening?

*The screening test*

Criteria: The test protocol should, on balance, be socially and ethically acceptable to health professionals and the public.

- Can the test protocol detect other conditions of clinical or unknown significance and or carriers and, if so, what are the implications?
- What are the potential benefits and harms associated with the preferred test protocol(s)?

*The intervention*

Criteria: Health care services for diagnosis and management should be available so that these services can be offered if there is an abnormal screening result.

- Is there equitable access to these health care services for families, including those from rural and remote areas?

Criteria: There should be an accepted intervention for those diagnosed with the condition.

- Is the intervention readily available and accessible?
- What are the potential harms associated with the intervention, and to what extent can these harms be mitigated or managed?
- Is there equitable access to the intervention for families, including those from rural and remote areas?

*Additional considerations*

Criteria: The benefit of screening a condition must be weighed against its impact on the programme as a whole.

- Is the addition of this condition likely to require ethical considerations that may warrant a separate consent process?
- Would it be likely that screening for the condition would impact negatively upon other elements of the programme?

## **Belgium**

In Belgium, policy- and decision-making were noted to be devolved to three separate regions (they are, Brussels, Flanders, and Wallonia). No information relevant to this review was identified for Brussels.

### *Flanders*

In the Flanders region, a population screening working group is noted to provide advice to the Flemish government.<sup>(44)</sup> The latter has outlined a list of defined criteria for decision-making about population-based screening programmes.<sup>(44)</sup>

Considerations relevant to ethics are embedded within these criteria, including aspects consistent with accessibility and equity, balance between benefit and harm, and informed choice.

Ethical principles are further outlined in the code of ethics for all health promotion and disease prevention activities. These principles comprise: reducing inequalities, empowerment, access, community-oriented approach, autonomy, independence, non-discrimination, and avoidance of stigmatisation.<sup>(45)</sup> Principles of action are noted to be transparency, accountability and responsibility.

No further information of relevance to this review was identified for the Flanders region.

### *Wallonia*

In Wallonia, the Minister for Health, supported by their administration, has responsibility for policy-making about population-based screening programmes.<sup>(46)</sup> While no formal criteria for the assessment of population-based screening were identified, screening programmes were noted to be based on European recommendations and or best practices from other European countries. Concerning ethics, particular attention is paid to social inequalities in health with the following considerations further outlined:<sup>(46)</sup>

- Screening programmes should be accessible to the greatest number of people (number of centres, provided free of charge).
- Screening programmes should be at a level which is considered the least harmful.
- Where an individual has already been treated for or is in remission from a condition, they should be excluded from screening invitation lists in order to reduce psychological impact. Systems are put in place to ensure that positive results from screening programmes are communicated to the patient.

Concerning decision-making processes, ethical points are noted to be discussed by a steering committee comprising broad stakeholder representation, including patients, as part of the overall consideration of a programme.<sup>(46)</sup>

## **Canada**

In Canada, policy-making is devolved to the individual provinces. As outlined in the methodology, a targeted search was performed for Alberta, Ontario, and Quebec.

### *Alberta*

Within Alberta, policy-making for population-based screening programmes is the responsibility of Alberta Health Services.<sup>(32)</sup> Limited information was identified within this review about ethics; however, it is noted that previous assessments of newborn bloodspot screening programmes within Alberta have utilised the screening criteria and policy framework developed by Australia (as described previously).<sup>(47)</sup>

### *Ontario*

The government of Ontario has responsibility for screening, and has oversight of groups that manage screening activities, such as, Newborn Screening Ontario and Ontario Breast Screening Programme.<sup>(48, 49)</sup> Within this review, information relevant to the review question was only identified from the Newborn Screening Ontario group.<sup>(33)</sup>

Criteria for the assessment of conditions in newborn bloodspot screening are outlined with a number noted to concern ethical considerations; these include acceptability to relevant stakeholders, equity, weighing of benefit and harms, and resource use.<sup>(33)</sup> Decision-making is supported by a number of guiding questions; the ethical dimension questions are as follows:

- Is there any reason to be concerned about test acceptability in the population?
- Is there a reason to be concerned about the acceptability of diagnostic investigations among families of screen-positive infants?
- Are there concerns about inequities in access to care in different patient groups?
- Is there reason to be concerned about the acceptability of the intervention named, either to families of screened infants or to health professionals?
- Is there evidence to support the acceptability of screening for this condition in newborns among families of screened children, the public or health professionals?
- What harms are anticipated in the event of overdiagnosis?
- What harms are anticipated in the event of incidental identification of non-affected heterozygous mutation carriers for the condition?

The assessment of ethical considerations is embedded within the general decision-making processes with a task force completing assessments based on all necessary criteria.<sup>(33, 48)</sup> The task force present their collecting findings, including those which relate to ethics, to an advisory council consisting of appropriate stakeholders. Based on the collective information presented, a recommendation is made preferably by consensus. If consensus is not achieved, a majority-based decision, through a majority vote, is made.

### *Quebec*

In Quebec, the Ministry of Health and Social Services (MSSS) has responsibility for the coordination and management of screening services, with expert bodies providing evidence and advice to the ministry. These include the Institut National De Santé Publique du Québec (National Institute of Public Health of Quebec) and the Institut National d'Excellence en Santé et en Services Sociaux (INESSS), which carries out health technology assessments.<sup>(50)</sup> The MSSS also appoints an advisory committee to advise on the evolution and follow-up of a programme.<sup>(51)</sup> For example, the "comité consultative sur le programme Québécois de dépistage neonatal sanguine et urinaire", which is comprised of clinicians, laboratory specialists and public health experts, has an advisory role in the Québec Neonatal Blood and Urine Screening Program; this advisory role extends to consideration of implementation.

For population-based screening decision-making, specific criteria are outlined for cancer screening programmes and for the neonatal blood and urine screening programme.<sup>(28, 36)</sup> Evaluations of public health interventions are made on the judgement of what value they provide to the Quebec context with regard to clinical, population and economic considerations.<sup>(37)</sup> This judgement of value is based around five principles, namely:

- The technology improves the health and well-being of users.
- It contributes to a better state of health and well-being for the population, with a concern for equity.
- It optimises the use of resources for their responsible and sustainable management.
- It fits into the organisational context of care and services in a way that helps strengthen the system's health and social services.
- It fits into the context of Quebec society in a way that promotes the society's development towards the common good.

In completing health technology assessments and within the subsequent decision-making, including those that relate to screening, MSSS and INESSS note that assessments are conducted with consideration of the following values: excellence, independence, openness, scientific rigour, transparency, probity, and fairness towards those who use health and social services.<sup>(37, 51)</sup>

Stakeholder involvement (including public and patient representation) is noted throughout the decision-making process.<sup>(51)</sup> Guided discussions, weighting and consensus methods are implemented when considering population-based screening programmes.<sup>(51)</sup>

## **Denmark**

The Danish National Health Board has responsibility for screening programmes in Denmark, with advice on new or existing programmes provided by the Advisory Committee for National Screening Programmes.<sup>(52)</sup> Decision-making for the assessment of screening programmes is guided by a defined set of criteria, including those which relate to ethics.<sup>(52)</sup> These criteria are further elaborated through an ethical considerations dimension. This dimension is cited as being modelled on central duty and utility ethics. The core ethical considerations outlined are:

- benefits should outweigh harms

- self-determination and informed free choice
- avoidance of stigmatisation
- fair distribution of healthcare services.

As highlighted in Appendix 1.2, each ethical consideration is further expanded to provide contextual relevance and examples of these considerations in practice. The National Health Board notes that there is unlikely to be one single answer as to whether or not a screening programme is ethically acceptable, and therefore it is important that ethical perspectives are included throughout an assessment. In the assessment of a screening programme, there should be analysis of each ethical consideration, and whether there any conflicts between considerations.

## **Finland**

In Finland, the Ministry for Social Affairs and Health is responsible for decision-making about screening programmes. In doing this, the Ministry is supported by an established screening working group who assess screening programmes and make recommendations.<sup>(53)</sup> The recommendations for screening programmes are based on defined screening criteria (as shown in Appendix 1.1), with specific criteria relating to ethics, and guiding principles. These include:<sup>(53)</sup>

- Acceptability of the screening programme and associated treatments to the population.
- Evaluation of the ethical and psychological consequences for the examinees, stigmatisation, and the consequences of false positive and false negative test results.
- Participation in the screening programme must be voluntary.
- Inhabitants of municipalities should have access to sufficient information on the objectives and effectiveness of the screening programme.

In terms of decision-making, general processes, including the consideration of ethics, are cited as having been adopted from the United Kingdom National Screening Committee.<sup>(53)</sup> The committee define the health goals, existing evidence for each criterion, and what information could be learned by a pilot study.

## **France**

The Haute Autorité de Santé (HAS) is responsible for the appraisal of screening programmes in France, while local authorities hold responsibility for the

implementation of recommended programmes.<sup>(26)</sup> Screening programmes are assessed against a defined list of criteria as shown in Appendix 1.1;<sup>(54)</sup> however, HAS further outlines an explicit methodological framework for the assessment of ethical aspects associated with an intervention and its implementation, including ethical issues relating to screening programmes.<sup>(26)</sup>

The development of the framework for assessment of ethical aspects involved a review of international literature, including the use of the EUnetHTA HTA Core Model (see section 6.1) as a reference model, general reference to principlism, and reflection on previous assessments where ethical aspects were particularly prominent.<sup>(26)</sup> Stakeholders and experts were further consulted to ensure the framework was relevant and appropriate to the French context. The final framework was peer-reviewed for clarity, quality of guidance, and practicality in meeting objectives.

The ethical principles listed within the framework are: beneficence and non-maleficence, respect for autonomy, and justice.<sup>(26)</sup> For each ethical principle, guiding concepts are outlined for consideration, with associated examples and contextual references provided in the source document (Box 3.2). Additional principles including respect for dignity, integrity and vulnerability, are highlighted as further possible principles for consideration depending on the technology being assessed. HAS also cites process values of independence and impartiality, scientific rigour, and multidisciplinary approaches.<sup>(26)</sup>

HAS states that an ethical analysis would ideally always be carried out, but that, due to limitations, this is not always possible. Therefore, the guide outlines questions to determine whether a topic is likely to involve significant ethical issues; if identified, these issues are then subjected to an ethical analysis. With regards to the processes associated with an ethical analysis, HAS outlines a three-stage process:<sup>(26)</sup>

- Stage 1: Identifying ethical arguments:
  - Ethical arguments are identified according to the parameters of the framework. This is achieved through a literature search and maybe further supported through theoretical identification of ethical arguments as well as consultation with working and or peer review groups.
- Stage 2: Presenting the ethical arguments:
  - Ethical arguments are next classified to determine whether or not they warrant further investigation or examination. The arguments are explored against a defined set of relevant principles, with the reference



being the principles set out by Beauchamp and Childress (as listed in Box 3.2).

- Stage 3: Examining the ethical arguments:
  - The final steps involve the examination of ethical arguments alongside conclusions of other dimensions of the assessment, analysis of conflicts between arguments and classification of reasonable disagreements.

Throughout the process, stakeholders are consulted, including external working groups of experts and patient representatives.<sup>(26)</sup> Ethicists may be recruited to assist in the process when a major ethical issue is identified. HAS acknowledges that during the ethical analysis process, disagreements may occur; however, rather than offering a process for resolution it suggests that these disagreements should be outlined, so that they can be taken into account by the final decision-makers. HAS also suggests that explicitly highlighting these disagreements helps to identify social values that may be of relevance to an intervention.

**Box 3.2** Guiding concepts under ethical principles in assessment of ethical issues by the French Haute Autorité de Santé<sup>(26)</sup>

- Beneficence and Non-maleficence:
  - benefits
  - risks
  - side effects
  - safety
  - quality of life
  - clinical efficacy
  - self-esteem.
- Autonomy:
  - consent
  - freedom of choice
  - confidentiality (data protection)
  - dependence
  - vulnerability.
- Justice:
  - efficiency
  - equity
  - discrimination
  - geographical disparity
  - social inequality
  - accessibility
  - compensation.

## Germany

The Federal Joint Committee (G-BA) has responsibility for policy-making about screening in Germany.<sup>(55)</sup> Screening programmes are introduced with reference to, and application of, the legal basis (German Social Code, Book Five) for consideration of interventions by the G-BA.<sup>(55)</sup> The G-BA is a public legal entity comprising the four leading umbrella organisations of the self-governing German healthcare system: the National Associations of Statutory Health Insurance Physicians, the National Associations of Statutory Health Insurance Dentists, the German Hospital Federation, and the Central Federal Association of Health Insurance Funds. In addition to these four pillar organisations, patient representatives also participate in all sessions.<sup>(56)</sup> The Institute for Quality and Efficiency in Health Care (IQWiG) conducts assessments of screening to support the G-BA.<sup>(55)</sup>

Criteria for the assessment of screening programmes are outlined and categorised as considerations for benefit, medical necessity, and economic viability.<sup>(55)</sup> In terms of procedural elements, the G-BA emphasises the importance of standardised and transparent processes, while IQWiG note independence and patient-orientated, standardised and transparent processes.<sup>(27, 57)</sup> The following ethical considerations are embedded within assessments:<sup>(27, 55, 57, 58)</sup>

- Patients should be examined and treated according to the best standard of care.
- There should be balance between benefit, quality and economy.
- Benefits should be weighed up against harms.

The evidence-based evaluation ensures objectivity, transparency and verifiability in determining the current standard of care.<sup>(59)</sup> Ethical aspects of medical services, including screening programmes, are stated to be taken into account via: the universal health coverage in Germany, the legal basis of the work of the G-BA, the participation of patient representatives, and the evidence-based evaluation of benefits and harms of medical services.<sup>(55)</sup>

The plenum is the decision-making body of the G-BA. It comprises 13 members with voting rights and meets once or twice a month in a public session. The plenum appoints subcommittees, who meet in closed sessions, to prepare decisions and resolutions. Patient representatives are further involved in the process. They draft the results of their discussions as recommended resolutions for the plenum. Where disagreements or differences of opinions are presented, a summary can be included in the recommendation submitted.<sup>(55)</sup>

## Italy

The Ministry of Health in Italy outlines a defined list of requirements which a screening programme must meet.<sup>(60)</sup> A number of these requirements are noted to have an ethical dimension, including: a balance between positive and negative effects, the need for benefit to outweigh harm, guarantee of maximum equity (offering the possibility of a health gain to all citizens, regardless of their socio-cultural level and economic resources), consideration of important ethical aspects, and the requirement for the target population to be actively involved and informed about the benefits and possible risks of the screening programme.

No further information relevant to this review was identified for Italy.

## The Netherlands

In the Netherlands, the Ministry of Health, Welfare and Sport has responsibility for final decision-making about screening programmes, with support from the Health Council of the Netherlands and specific subcommittees such as the Committee on Population Screening.<sup>(34, 61)</sup> The Centre for Population Screening (RIVM-CvB) coordinates national screening programmes.

A defined list of criteria, which include ethical dimensions, are outlined. Screening programmes must satisfy this criteria (see Appendix 1.1), with further specifications for programmes which involve genetic screening, cancer screening, or the use of ionising radiation.<sup>(34, 62)</sup> All screening programmes must satisfy the following criteria in relation to ethics:<sup>(61)</sup>

- scientific validity
- benefits must outweigh harms
- respect for autonomy
- appropriate use of resources
- compliance with legal rules for medical action
- importance for public health.

When considering a screening programme for implementation, it must align with the public values of the Netherlands: quality, accessibility, affordability, and involvement of society.<sup>(61)</sup> As shown in Appendix 1.3, each public value is further expanded to

provide considerations that should be taken into account in the assessment of screening programmes.

In terms of decision-making, the collective evidence is assessed, including those criteria which relate to ethics.<sup>(34, 61)</sup> Subcommittees comprise varying stakeholders, depending on the programme being considered; however, they always include council members, clinical experts, ethicists and law experts. Patient and public representatives are sometimes involved to give their targeted input if deemed to be required, but do not contribute directly to decision-making. If disagreements on the overall advice occur, differing views are included in the final text, including the possibility of minority advice.

## **New Zealand**

The National Screening Advisory Committee in New Zealand is responsible for making assessments and recommendations to the National Screening Unit about new and existing screening programmes, while accountability for decisions lies with the Ministry for Health.<sup>(63, 64)</sup> A defined list of assessment criteria for screening programmes is outlined in Appendix 1.1, which includes explicit consideration of social and ethical issues.<sup>(64-66)</sup>

In terms of considerations relevant to ethics, concepts such as informed consent, and the appropriate balance of harms and benefits, have always been considered in the context of screening programmes.<sup>(64, 65)</sup> In more recent years there has been increased demonstration of the importance of fairness and equity, with the Government's duty to meet its obligations under New Zealand's Treaty of Waitangi.<sup>(64)</sup> The following quality principles are further outlined in relation to screening programmes:

- The overall benefits, such as reductions in morbidity and mortality, of screening, must outweigh the harms, including potential physical and psychological harms caused by the test, diagnostic procedures or treatment.
- Screening should be people-centred and acceptable to individuals, whānau (family) and the populations being screened.
- Screening programmes will achieve equitable access and equitable outcomes for all groups.
- Informed consent is a priority throughout the screening pathway.

Concerning procedural elements, the following are listed when considering screening programmes: accountability of policy-makers, rigour, quality assurance, Māori

consultation, and provision of full information and transparency around significant decisions.<sup>(64, 66)</sup> With regards to overall decision-making, the collective evidence is interpreted by the National Screening Advisory Committee. The committee has a multidisciplinary membership including experts in public health, screening programmes, epidemiology, ethics, health services delivery, monitoring, and equity and patient representation.<sup>(64, 66)</sup> Stakeholder views are further sought within the process including health professionals, scientific experts, Māori and Pacific members, and patients. Decision-making is based upon the overall assessment criteria outlined in Appendix 1.1., with ethics noted to be implicitly assessed within a number of criteria, as well as explicitly in terms of considering social and ethical issues.<sup>(64, 66)</sup> Committee members work collectively to provide advice to the National Screening Unit, and decision-making for advice on the overall screening programme is by consensus. When consensus cannot be reached this is resolved using a vote system.<sup>(63)</sup>

## Spain

In Spain, the Inter-territorial Council (ITC) of the National Health System has responsibility for screening programmes. A special committee was set up in 2017, with this committee making recommendations to the public health committee of the council for decision-making.<sup>(42, 67)</sup> The Spanish Network of Agencies for Assessing National Health System Technologies and Performance (RedETS) completes assessment reports which are then considered by the technical committee in order to inform decision-making. There are three different types of decisions that can be considered: implementation of a new screening programme, changes to an existing programme, or withdrawal of a programme. Such decisions are approved or rejected by the Institutional Committees, and once the committees are in agreement regarding a screening programme, it is presented to the ITC for approval. Approved screening programmes can then be included in the *National Health System common portfolio* following a Ministerial Order to update the Royal Decree 1030/2006.<sup>(42)</sup>

A framework document is outlined, which includes criteria for the assessment of screening programmes (see Appendix 1.3), with specific ethical considerations embedded.<sup>(67)</sup> The committee further considers the ethical principles of beneficence, non-maleficence, justice and autonomy in the assessment of screening programmes, with ethical risks outlined under each principle, as shown in Box 3.3.<sup>(67)</sup> Principles of action for all public health initiatives are further protected under associated legislation, with the following ethical and procedural principles presented (of note, these have been translated directly from Spanish, and these translations may not fully reflect the intended meaning):<sup>(42)</sup>

- principle of equity
- principle of health in all policies
- principle of relevance
- precautionary principle
- principle of evaluation
- principle of transparency
- principle of integrality
- principle of security.

In terms of ethical analysis, based on examination of the criteria presented, if an assessment of ethics is deemed to be required, an ethics committee develops an ad hoc report.<sup>(42)</sup> Stakeholders are included within the assessment of screening programmes completed by the HTA agency and within the subsequent decision-making, as required. If there are disagreements or differences of opinion in relation to the ethics associated with a screening programme, the Ministry of Health may request a report from an ethics committee.

**Box 3.3** Potential risks to ethical principles<sup>(67)</sup>

- **Beneficence:**
  - Screening may benefit the population but many individuals may not benefit.
- **Non-maleficence:**
  - Psychological harm in the context of false positives.
  - False reassurance in the context of false negatives; possibility of delays in diagnosis and treatment.
  - Potential harm caused by the diagnostic process and or subsequent interventions.
- **Justice:**
  - Inequalities increased if no measures are in place to promote equity in access.
  - Discrimination or stigmatisation may occur in detected conditions.
  - Programme may take funding away from other preventative measures or more cost-effective disease control.
- **Autonomy:**
  - Individuals may not understand the implications of participating in the programme.

## Sweden

The National Board of Health and Welfare in Sweden has responsibility for policy- and decision-making in relation to screening programmes, with each region responsible for implementation.<sup>(39)</sup> Screening programmes are assessed against a defined list of criteria derived from Wilson and Jungner with modifications to the Swedish Context, as outlined in Appendix 1.1.<sup>(39, 40)</sup> One of the criteria explicitly states that programmes be acceptable from an ethical perspective; hence, Sweden also presents a defined framework for considering ethical aspects relating to screening.

The approach to the analysis of ethical aspects relating to screening is based on national and international values, norms and principles. These are highlighted as (of note, they have been translated directly from Swedish and hence may not fully reflect the intended meaning):<sup>(39, 40)</sup>

- The balance between the benefits and harms that screening may have on individuals.
- Autonomy and integrity of individuals offered screening.
- Justice, including concepts of equality, equal treatment, human dignity, vulnerable groups and redistributive issues:
  - The human value principle states that all people have equal value and prohibits unfair discrimination.
  - The principle of need and solidarity states that care should be provided based on the greatest need and solidarity, and on equal terms. Also, vulnerable groups should receive special consideration.
  - The cost-effectiveness principle states that health care should strive to reasonably balance cost and effect.
- Long-term consequences concerning human value and equality; these include the changes in responsibility between healthcare and the individual, stigma, and changes in indication.

In terms of ethical acceptability, the analysis seeks to answer some questions from different ethical perspectives, as outlined in Box 3.4.<sup>(39, 40)</sup> Within the decision-making processes, experts in medical ethics describe the programme to the decision-makers from an ethical perspective.<sup>(39)</sup> Stakeholder views are included in decision-making, including ethical aspects, with an ethics committee, expert group and the

national screening board contributing to discussions. The collective recommendations regarding a screening programme are sent for open review.

**Box 3.4** Questions addressed by ethical analysis of screening programmes in Sweden<sup>(39, 40)</sup>

- How can any negative effects be handled?
- How do you take into account the individual's autonomy and integrity?
- Privacy issues include protection of privacy-sensitive information handled in the screening programme.
- Can the screening programme affect human value and equality in the long term?
- Are there relevant groups with values and interests which require special attention, even if the screening program is acceptable to the general population? This applies, for example, to vulnerable groups with reduced ability to bring their own action. This includes considering the risk that the screening programme will increase the stigma or discrimination of any group of people.
- Can the screening programme be seen as an expression of a fair distribution of health care resources in relation to other options for action?
- Does the screening programme change the division of responsibilities and roles between health care and the individual? If so, how should it be handled?
- Are there legislation and other guidelines that can provide guidance for ethical positions in relation to the above points in the ethical analysis?

## Switzerland

Decision-making is devolved to the 26 individual cantons of Switzerland, with national recommendations made by expert committees on screening programmes, including the National Advisory Commission on Biomedical Ethics, who evaluate ethical aspects.<sup>(68)</sup> No further information relevant to this review was identified.

## United Kingdom

The National Screening Committee (NSC) in the United Kingdom complete assessments of, and make recommendations on, population-based screening programmes.<sup>(35, 38, 69)</sup> NSC has outlined criteria for the assessment of screening programmes,<sup>(35)</sup> within which four ethical principles are embedded and further elaborated on within an ethical framework (as shown in Box 3.5):<sup>(38)</sup>



- Improve health and wellbeing.
- Treat people with respect.
- Promote equality and inclusion.
- Use public resources fairly and proportionately.

The ethical principles are noted to all be equally important. NSC emphasise that deciding how these ethical principles apply in any given situation is unlikely to be straightforward, and often there will be a need for balancing across them. The ethical principles can be in tension with each other and create dilemmas, particularly in balancing individual and collective interests.

NSC consider evidence and views in the case of each screening programme assessed and makes judgements, ensuring it functions under its defined procedural values of: rigour, independence and accountability (impartiality, integrity, objectivity and collective responsibility), inclusiveness and respect, transparency (openness and honesty, accessibility of information), and responsiveness.<sup>(38, 41)</sup>

To note, a formal process for decisions concerning the need for a detailed ethical analysis for a screening topic and the process for such an analysis is cited as being in development currently.<sup>(41)</sup> The UK NSC reports that this process may involve setting up a temporary task group to carry out an ethical analysis. Such task groups could include members of the UK NSC and its reference groups, as well as people with professional and personal expertise relevant to the screening programme being discussed. The groups would gather evidence and views in order to describe and clarify the ethical issues and present their analysis to the UK NSC for it to make a recommendation.<sup>(41)</sup>

Recommendations of NSC on a screening programme as a whole are preferably by consensus; however, if consensus cannot be reached, a voting system may be used.<sup>(69)</sup>

### **Box 3.5** NSC ethical framework for screening<sup>(38)</sup>

Principle 1. Improve health and wellbeing:

- The general purpose of public health screening programmes should be to improve the health and wellbeing of the population. No screening programme should be adopted unless its potential benefits (to health and wellbeing) outweigh any potential harms. The focus should be on the individuals who will be offered screening. If there is a prospect for screened

individuals to benefit, the benefits and harms for others and society more broadly can also be taken into consideration.

- Potential benefits include prevention of death and disease, improvements in physical and mental health, and improved quality of life. Potential harms include unnecessary and harmful tests or treatment, uncertainty of screening results, false reassurance, and increased anxiety. Efforts should be made to reduce any risks of harms.

Principle 2. Treat people with respect:

- People's rights, wishes and feelings as individuals should be respected. This involves enabling people to make informed choices about screening that align with their personal values and acknowledging the role that relationships with family members and others can play. People's choices about screening must be respected and supported.
- Where screening is offered to people who are not able to make choices for themselves, those who make choices on their behalf should be appraised of the balance of benefits and harms to the screened individual. Policy decisions about screening programmes should take account of the views of those affected and the reasons for policy decisions should be clearly communicated.

Principle 3. Promote equality and inclusion:

- Screening programmes should not act to increase health inequalities and should aim to reduce them. Access to and delivery of screening should be as equitable and inclusive as possible. Any potential wider consequences of screening for society in the initiation and implementation of screening, both in the short and long term, should be considered.

Principle 4. Use public resources fairly and proportionately:

- The entire cost of a screening programme should entail the fair and proportionate use of available public resources. Decisions about screening should have regard to evidence from cost-effectiveness analyses.

## **United States**

The United States Preventative Services Task Force makes independent national-level recommendations on health policy, including screening programmes.<sup>(70)</sup>

General criteria in the assessment of interventions were identified as outlined in Appendix 1.1 with a number considered to possess an ethical dimension including: balance of benefit and harm (at the individual and population levels), patient preferences, and physiological and social harms.<sup>(70)</sup> No further relevant information was identified for the United States.

## **4 Review of public health agencies**

The primary websites of public health agencies corresponding to the countries and regions included in this review were searched for relevant ethics frameworks. No ethics frameworks specific to screening were identified; however, some non-specific ethics frameworks to assist decision-making concerning general public health initiatives were identified from Canada,<sup>(71-73)</sup> Denmark,<sup>(74)</sup> the United Kingdom,<sup>(75)</sup> and the United States.<sup>(76)</sup> The core components and structure of each of these frameworks are summarised in Appendix 2.1 and 2.2, and are outlined by country of origin below.

### **4.2 Canada**

Three ethics frameworks for decision-making in public health were identified from Canada, including the national Public Health Agency of Canada, and regionally from British Columbia and Quebec.<sup>(71-73)</sup>

#### *Public Health Agency of Canada*

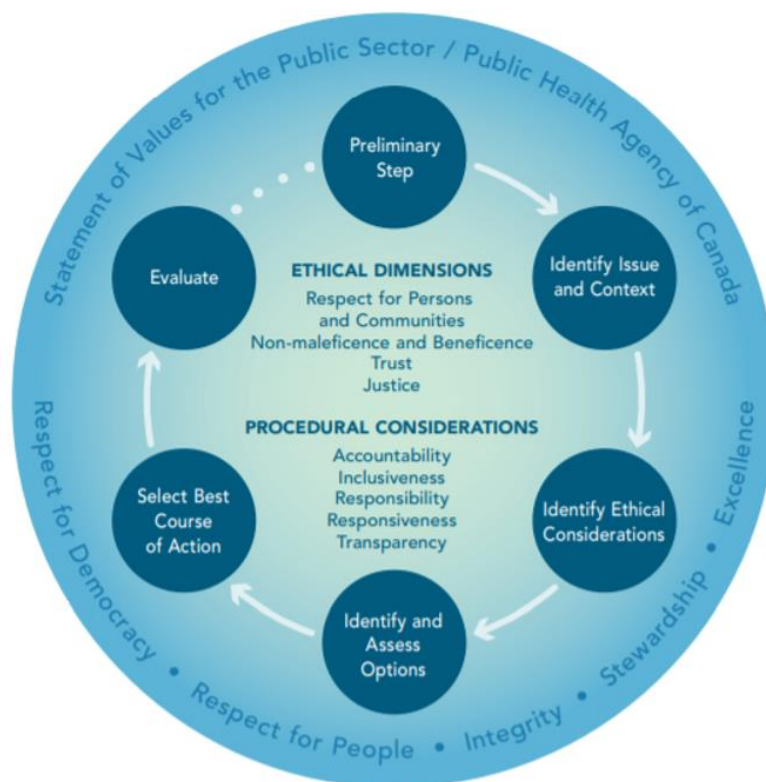
The Public Health Agency of Canada published a national level framework in 2017 to facilitate ethical deliberation and decision-making in public health.<sup>(73)</sup> The framework aims to guide public health practitioners, policy-makers and decision-makers to:

- Articulate ethics questions raised by decisions related to public health practice and policy.
- Identify ethics tensions and competing values and principles.
- Articulate trade-offs between the relevant values and principles.
- Adopt a systematic approach for working through ethical issues and challenges in public health.

The developers note that decision-making in public health often involves making difficult choices among competing or conflicting ethical considerations, including values and principles. In this context, decision-making requires being attentive to the interests at play (including individuals, institutions, populations and communities) and explicitly stating the values and principles at stake, reflecting on them and considering how they are interrelated. The core ethical dimensions and procedural considerations outlined within the framework complement the shared values of the public sector and Public Health Agency of Canada (that is, respect for democracy, respect for people, integrity, stewardship, excellence).

The primary document presents detailed overviews of the included core ethical dimensions (respect for persons and communities, non-maleficence and beneficence, justice and trust) and procedural considerations (accountability, inclusiveness, responsibility, responsiveness and transparency). As shown in Figure 4.1, the framework is presented as six steps with detailed guiding questions for each step provided and summarised in Appendix 2.2. The guiding questions are typically open-ended, and the developers note that these questions are intended to guide deliberation rather than being prescriptive or exhaustive. It is noted that specific questions may be more relevant than others, depending on the issue at hand. Additionally, while presented as a cyclical process, information from one step may further inform a previous step, and therefore, the framework should be considered to have a reflective approach.

**Figure 4.1** Public Health Agency of Canada decision-making framework<sup>(73)</sup>



### *British Columbia Centre for Disease Control*

The above framework from the Public Health Agency of Canada refers to a framework published by the British Columbia Centre for Disease Control (BCCDC) in 2011 and reviewed in 2015.<sup>(71)</sup> The BCCDC report presents an ethics framework and decision-making guide intended to give consistency and clarity in guiding ethical action and resolving ethical issues in the context of public health. The framework first outlines values and beliefs considered key assumptions inherent to a public health perspective relating to the nature of health, community and environment, and bases for action (see Appendix 2.1). The framework then provides detailed descriptions of 15 principles of the ethical practice of public health, including a number that were noted to possess procedural elements (see Appendix 2.2). These principles are described as giving expression to the shared values and beliefs outlined. The 15 principles are not considered to be exhaustive. However, they serve as a statement of the normative behaviours and the virtues the BCCDC and its staff aspire to, and follow in the creation and practice of policies and programmes relating to public health.

The developers note that, invariably, ethical dilemmas may become apparent when the values and principles are in tension or when they may support two or more divergent goals. It is encouraged that these dilemmas are worked through with relevant stakeholders. However, where a course of action is not clear, the framework provides a nine-step decision-making process intended to assist decision-makers in a fair process to build trust among stakeholders and lead to collaborative and consensual outcomes. Each step is presented with associated guiding questions and considerations as outlined in Appendix 2.2. The nine steps are presented in Box 4.1 below.

The framework further highlights that decision-making should ideally be unanimous. If a unanimous decision is not possible, then decision-makers should engage in a deliberative process and decide whether a unanimous decision is required to proceed or if a majority vote is acceptable.

#### **Box 4.1** BCCDC steps in ethical decision-making<sup>(71)</sup>

1. Identify the ethical question.
2. Identify the stakeholders.
3. Clarify the facts, gather information.
4. Analyse the problem in light of the values and principles in the Code. Try to identify the origins of tensions from the conflicting values and principles.
5. Identify the relevant legal and normative guidance.

6. Identify possible courses of action.
7. Make a decision.
8. Implement a decision.
9. Evaluate the decision.

### *National Institute of Public Health of Quebec*

The National Institute of Public Health of Quebec (Institut National de Santé Publique du Québec) published a framework of values to support ethical analysis of public health actions in 2017.<sup>(72)</sup> The framework provides clear working definitions of core concepts such as principles, values, and norms, with the authors citing a preference to speak to values rather than principles in the context of the framework so as to highlight that no value is considered to be dominant or to outweigh any other. The goal of the framework is to provide a common basic vocabulary and articulation of values considered important in public health discourse to support clear communication, with a view to informing decision-making on the basis of transparent and coherent justifications. The developers note communication-based conflicts may emerge from:

- False consensus: different individuals agree on a statement without checking to see whether they all give it the same meaning or scope.
- False disagreement: different individuals disagree on a statement because it fails to adequately express a meaning which, worded differently, would have been agreed upon by all concerned.

The framework outlines 21 values of relevance to public health, with the selected values based on public health ethics literature, professional documents, and stakeholder engagement. The values are divided into three categories (public health, societal, professional) described in-depth within the framework with key considerations and challenges to each value presented. The values and categorisation are presented in Table 4.1, with the developers noting that these categorisations are simply groupings of similar motivations and should not be considered absolute in terms of categories or hierarchical in terms of individual values.

**Table 4.1** Values and categorisation included in National Institute of Public Health of Quebec framework<sup>(72)</sup>

Public health	Societal	Professional
Health	Autonomy and empowerment	Competence
Well-being	Liberty	Scientific rigour
Common good	Equality	Impartiality and integrity
Beneficence and non-maleficence	Equity	Responsibility and accountability
Utility and effectiveness	Justice	Transparency
	Reciprocity	Prudence
	Solidarity	Openness
	Respect for the environment	Confidentiality and privacy

The framework further details an ethical review process adopted by the public health ethics committee (CESP) to approach a situation to identify the ethical concerns that it might raise. The process is described as a reflective approach that questions the norms and values at hand instead of a scenario of 'readymade' decisions resulting from a mechanistic application of rules or principles. The developers note that the reflective approach encourages judgment to be exercised with full awareness of the elements that shape individual thinking and the consequences of decisions for the relevant stakeholders. The main elements of the ethical review process and key considerations as they relate to values are described in Appendix 2.2 and Box 4.2 below.

**Box 4.2** Process and considerations in ethical review for Quebec public health ethics committee<sup>(72)</sup>

***Process***

- Taking ownership of the project under review, in other words understanding its different components and how they relate to one another (purposes, goals and expected outcomes, means under consideration, targeted groups, and context).
- Clarifying the values involved and any tensions existing between them or between these values and various applicable norms (for example, ethical, scientific, or legal) and naming the ethical issues.



- Analysing the meaning and scope of these values and norms for the groups concerned and establishing which of the values should be given priority in the context at hand.
- Guiding choices of action in accordance with the value(s) selected, clarifying the justifications for these choices, and assessing the consequences, while striving to minimise negative consequences.
- Decision-making that incorporates an ethical perspective results in a reasoned decision, in terms of values as well as other more conventional considerations (for example, scientific or legal).

### ***Considerations***

- The values' meanings must be transparent and shared by all parties involved, which may entail adapting their definitions, depending on the situation examined.
- The values should serve as guides and not as prescriptions.
- No value is absolute (that is, no value outranks any other) and the weight assigned to each value may differ depending on the situation under examination.
- Ethical review of values with a view to deciding or carrying out an action requires flexibility and judgment, as is the case for professional judgment.
- The values are to be used to stimulate discussion and debate on the orientations or measures to adopt, including those associated with risk management.
- Examining values entails a search for balance between different interests and concerns, as well as the indispensable weighing of diverse priorities.

## **4.3 Denmark**

In 2009, the National Board of Health (Sundhedsstyrelsen) in Denmark published an ethics framework to consider ethical issues in health promotion and prevention.<sup>(74)</sup>

The guidance seeks to clarify central ethical issues and value conflicts that they contain that may be faced by public health decision-makers at national, regional and municipal regions in Denmark. The authors' note that within decision-making for health promotion and prevention, there will inevitably be controversial choices and conflicts between values and basic perceptions. The ethical issues and values outlined were developed through literature searches on health promotion and

prevention, the authors' professional expertise in moral, political and legal philosophy, and through interviews with relevant expert stakeholders to ensure the issues and values addressed were perceived as relevant and comprehensive.

The document outlines core harms that may be presented when considering interventions related to health promotion and prevention; they are: worry creation, morbidity, stigma and medicalisation. Should these harms be presented by a situation, they should be subject to an ethical analysis, which the authors describe as identifying the underlying ethical values at stake.

The ethical issues (intermittently termed ethical values) discussed within the framework are: balance of benefits and harms, inequality, autonomy and paternalism, responsibility and accountability, solidarity, evidence, documentation and risk, action and omission. For each ethical issue outlined, detailed descriptions of their relevant considerations and possible applications are provided, alongside a discussion of how these issues may be weighted within a given context. Further information is presented in Appendix 2.2.

#### **4.4 United Kingdom**

In 2017, Public Health England released a background paper on public health ethics in practice.<sup>(75)</sup> While not explicitly a framework in itself, the paper serves as a precursor to the development of public health ethics frameworks. The authors highlight that policymakers cannot adequately answer questions about action in public health without reference to values and ethical arguments; similarly, that particular public health interventions cannot be legitimised without fully understanding their ethical implications.

The document emphasises that ethics in public health should not be treated as an ad hoc approach and should be seen as an integral component of decision-making in both policy and practice. Within public health decision-making, it should not be presumed that respective stakeholders will share moral values equally and that groups may reasonably disagree on relevant values and their respective weighting within a decision. Previous experience and knowledge can influence decisions, and different moral conclusions may be reached for the same question by various stakeholders. These issues are essential when considering how ethical frameworks are developed and used.

The document highlights the four principles of bioethics described by Beauchamp and Childress (autonomy, justice, beneficence, and non-maleficence). However, it also notes core differences in public health ethics relative to medical and clinical ethics and emphasises that their overall utility may be limited. In particular, when

considering public health policy and practice, there is a need to understand and account for a number of distinctions in ethics, including:

- What it means to take a population approach, including population-level ethical analysis.
- The principle that responsibility for health is shared across society and is not a question for individuals considered in isolation.
- The need to consider ethical methods of social coordination which incorporate measures that target whole populations whose constituents are not, as yet, unwell.

The document further discusses the need for decision-making tools relating to ethics to be well-grounded in theory. Further, it emphasises that the users of such tools should be able to engage in public health ethics without direct engagement with theory. Ethical frameworks can aid deliberation in a number of ways, depending on how they are developed. Manners in which they may aid deliberation include: increasing awareness, providing direct guidance, deepening deliberation, or showing whether an activity is justified by explaining an ethical basis. When considering ethical guidance, the authors highlight that this guidance should be context, task and level specific.

## **4.5 United States**

The Centres for Disease Control and Prevention (CDC) in the United States published a 2019 training manual to support state, tribal, local, and territorial health departments in addressing ethical issues that arise in public health.<sup>(76)</sup> The guide was developed in accordance with *Principles of the Ethical Practice of Public Health* from the American Public Health Association,<sup>(77)</sup> and outlined 12 principles as shown in Appendix 21.

The document presents concept definitions, case studies for the application of the principles and a simplistic three-step ethical analysis framework with guiding considerations and questions under each step as shown in Appendix 2.2:

1. Analyse the ethical issues in the situation.
2. Evaluate the ethical dimensions of the alternate courses of public health action.
3. Provide justification for a particular public health action.

## **4.5 Summary of public health agencies**

Within this review, six general public health ethics frameworks were identified from public health agencies which were intended to guide ethical action, facilitate decision-making, and assist in the resolution of ethical issues in the context of public health. While not specific, these frameworks may offer transferable content and or structure when considering the development of an ethics framework for screening.

The stated considerations relevant to ethics varied across the frameworks in terms of number, class (for example, values, principles, dimensions), and description; however, there were some consistencies noted in the topic matter described (including respect for persons and communities, beneficence, non-maleficence, the balance of benefit and harm, autonomy, solidarity, reciprocity, trust, and well-being). A number of the frameworks further highlighted two common considerations concerning these factors. Firstly, the need to consider the relative weight of factors listed according to the context (that is, their respective weights may change in different contexts). Secondly, that there will be circumstances in which there is conflict or tension between given factors which requires appropriate assessment and consideration. Similarly, the considerations relevant to procedural elements of decision-making were generally heterogeneous in terms of amount and detail; however, a number were noted across multiple frameworks (including accountability, responsiveness, transparency, rigour, and competence).

Where decision-making processes were outlined, these were typically described in steps or stages with a cyclical or reflective approach encouraged. Stakeholder involvement in decision-making relating to ethics was frequently cited as important, with a number of frameworks explicitly noting the significance of the consideration of stakeholder values in decision-making.

## **5 Review of national ethics bodies**

The primary websites of ethics bodies corresponding to the countries and regions included in this review were searched for relevant information. The majority of returned documents related to the ethical considerations associated with specific screening topics. These forms of documents were frequently described as position or opinion statements and were identified from ethics bodies in Australia,<sup>(78)</sup> Finland,<sup>(79)</sup> France,<sup>(80-86)</sup> Germany,<sup>(87, 88)</sup> Italy, Sweden,<sup>(89)</sup> and the United Kingdom.<sup>(90)</sup> The documents identified primarily concerned genetic screening, including pre-implantation and prenatal screening, with additional singular documents identified for cystic fibrosis, child deafness, and tuberculosis screening. While not the primary purpose of this review, for information, the ethical considerations outlined for these specific screening topics are summarised in Appendix 3.1. Two documents were identified from Denmark,<sup>(91, 92)</sup> and one from the United Kingdom,<sup>(93)</sup> with direct relevance to the present review and which are outlined below.

### **5.1 Denmark**

The Danish Council of Ethics (Det Ethiske Råd) published a statement on ethical problems faced by screening programmes and associated recommendations in 1999,<sup>(91)</sup> and has produced ethical checklists to assist decision-makers in making ethically sound decisions in the context of public health interventions, including screening programmes.<sup>(92)</sup>

As outlined in Appendix 3.1, the council recognises four major themes of screening in which ethical issues may arise; they are:

- social and psychological effects of participating in a screening programme
- false investigation results
- prioritisation and management of screening programmes
- information that should be included in an invitation to participate in a screening programme.

For each theme outlined, the council presents the advantages and disadvantages of screening programmes, the ethical issues that may arise, application to case screening scenarios, and recommendations for addressing the ethical issues under each theme.

The council has subsequently produced ethical checklists to assist decision-makers in reaching ethically sound decisions in the context of public health interventions (including screening programmes).<sup>(92)</sup> The checklists are provided for use at the regional and municipality level; however, their content remains similar. The checklist outlines questions that should be asked, which should help stimulate ethical debate relevant to the intervention under consideration. The structure and content of the checklist for the municipality level are outlined further in Appendix 3.1 with the five core components outlined below (of note, the checklist has been translated directly from Danish and hence may not fully reflect the intended meaning):

- professional basis (collective interpretation of the evidence)
- alternative options
- estimated positive effects
- estimated negative effects
- reflected position (autonomy and consent).

## **5.2 United Kingdom**

The Nuffield Council on Bioethics published a report on ethical issues in public health in 2007.<sup>(93)</sup> Similar to the public health agency findings in section 4.3, the report is directed towards general public health interventions and initiatives. The report includes an ethical framework, described as 'the stewardship model', which takes a revised liberal approach and an intervention ladder.

As outlined in Appendix 3.1, the ethical framework outlines ethical principles that should be considered by public health policy-makers; through a series of outlined goals and constraints. The framework incorporates the 'harm principle', which is considered a central part of the approach; however, the authors note that there are many contexts in public health in which this principle is limited. Hence, the framework incorporates a broader perspective. When considering ethical principles in policy-making, the developers highlight that debate is required about ethical principles themselves and how principles should be applied in context and how to resolve possible conflicts between principles. It is further highlighted as inappropriate to define a hierarchy of ethical principles or to state which principle(s) should take precedence. The report emphasises that a fixed set of ethical norms is unlikely to be an appropriate tool for solving the central ethical problems of public health and some principles are more relevant than others in different circumstances. The goals and constraints outlined are noted to provide obligations that should

ideally not be infringed; however, where an infringement is seen as necessary, sound justification is required.

The report further outlines an intervention ladder, which is a tool to assist policy-makers in public health in comparing different policy options according to their degree of intrusiveness. The ladder aims to assist in thinking about the acceptability and justification of different policy initiatives in light of relative intrusiveness (extending from a do-nothing approach up to the elimination of choice). The tool is closely linked to the concept of proportionality with the higher rungs on the ladder at which the policy-maker intervenes, the stronger the justification required to implement the intervention.

## **6 Review of international agencies**

The primary websites of the international agencies outlined were searched for relevant information to the present review; these included agencies of the European Union (the European Council and the European Commission), and the World Health Organization (WHO). A priori, given defined HTA processes within the HTA Directorate of HIQA, the EUnetHTA HTA Core Model<sup>®</sup> for screening technologies was included as a supplementary international agency to document the ethical considerations taken into account as standard within HTA.<sup>(25)</sup>

### **6.1 European Network for Health Technology Assessment**

The European Network for Health Technology Assessment (EUnetHTA), through an international collaboration of relevant HTA stakeholders, produced and iteratively refined the HTA Core Model<sup>®</sup>, culminating in version 3.0 in 2016.<sup>(25)</sup> The model represents a methodological framework for the completion and dissemination of HTAs. The model was developed through an application-based approach of four broad health technology areas, with a specific application identified for screening technologies (the others being medical and surgical, pharmaceuticals, and diagnostics). For each application, the model captures nine domains of HTA, with ethical analysis forming one of these domains.

While ethics is acknowledged as playing a significant role in multiple domains, the ethical analysis domain presents a summarised view of the relevant ethical considerations for a health technology. In this way, while the results and information gained from the other domains may guide the ethical analysis, it should remain a distinct analysis. Moral values and norms play a key role in shaping the context in which health technologies are used. The ethical analysis domain aims to provide a thorough understanding of norms and values that need to be taken into account during the HTA and decision-making processes; while further acknowledging that these processes are value-laden.

Overall, the ethical analysis aims to explore the relevant, often competing, moral values in the HTA and consider their relative weights and merits. It should be noted that some of the findings of the ethical analysis will align closely with the legal and social assessments domains, albeit typically through a different evaluation perspective. The model notes that ethical considerations are particularly relevant when considering screening technologies due to a number of factors, including:

- These technologies are typically directed towards asymptomatic individuals (that is, individuals who do not have symptoms).



- The benefit to risk ratio is generally different from targeted diagnostics.
- The accuracy of screening tests may be reduced in low prevalence populations.
- The balance of risks and benefits of interventions may be different for those detected early through screening compared to those identified through later diagnostic strategies.
- Screening raises moral questions of overdiagnosis and overtreatment.

### *Model structure*

For each domain, the model comprises three overarching components:

- **Ontology** (that is, the make-up or composition of the model): each of the nine domains is subdivided into topics, with each topic divided into one or more issues. The issues outline the specific questions that should apply to the topic and domain being assessed. While certain HTAs may carry specific requirements, the issues should be considered for relevance to the specific technology under assessment and in line with any project constraints (for example, time or resources). The model provides judgement as to the general importance of each issue outlined (described as critical, important, or optional). Collectively, the domain, topic and issue represent an assessment element to provide information to inform decision-making. In addition, the model outlines how various issues may interact with other issues from the same or different domains.
- **Methodological guidance**: provides examples of methods that may be used to inform the questions outlined within the issues of each topic.
- **Common reporting structure**: provides a standardised format for the reporting of information within an HTA.

For the present review, the ontology and methodological guidance components related to the ethical analysis domain for the application to screening technologies are summarised below. However, as a prerequisite to using the model as a whole, the broader application of ethics within the field of HTA and the value judgements that are made are first discussed.

### *Ethics of HTA and value judgements*

The model outlines that the assessments should in and of themselves be conducted in a way that key ethical principles are considered and respected. Prior to

undertaking an HTA, a number of ethical issues should be considered in an open and transparent manner, including the:

- motivations (and valued interests) behind the assessment should be identified, including those of the stakeholders and the HTA agency.
- morally relevant reasons for completing or not completing an assessment on the technology.
- interests of the relevant stakeholders to the assessment.
- morally relevant issues related to the selection of methods and information sources.
- scope of the HTA and the choice of methods. To note, the significance of the ethical analysis domain is emphasised within this issue, whereby literature searches for clinical effectiveness seldom capture sufficient information relating to ethical challenges.

With respect to value judgements, the model outlines that whether explicit or implicit, value judgements are made throughout the conduct of HTAs and within subsequent decision-making. Specifically, to the collection, synthesis and appraisal of evidence, the developers cite value judgements will occur in selecting criteria, specification of criteria, appraisal of validity and weighting of results. These value judgements that will be encountered across an assessment as a whole and within each HTA domain individually. The explicit acknowledgement of value judgements serves to enhance the transparency and validity of the assessment undertaken.

#### *Ontology of ethical analysis in screening technologies*

The ethical analysis domain includes six topics and 20 issues for consideration. The topics outlined are (1) benefit-harm balance, (2) autonomy, (3) respect for persons, (4) justice and equity, (5) legislation, and (6) ethical consequences of the HTA. The topics and associated issues, alongside their consideration of importance, are summarised in Table 5.1, with further details on clarifying questions and relevance to other issues provided in the primary source document.

**Table 6.1** Topics and issues within the ethical analysis domain of HTA<sup>(25)</sup>

Topic	Issue
Benefit-harm balance	<ol style="list-style-type: none"> <li>1. What are the symptoms and the burden of disease or health condition for the patient? (critical)</li> <li>2. What are the known and estimated benefits and harms for patients when implementing or not implementing the technology? (critical)</li> <li>3. What are the benefits and harms of the technology for relatives, other patients, organisations, commercial entities, society? (critical)</li> <li>4. Are there any other hidden or unintended consequences of the technology and its applications for patients, relatives, other patients, organisations, commercial entities, society? (critical)</li> <li>5. Are there any ethical obstacles for evidence generation regarding the benefits and harms of the intervention? (critical)</li> </ol>
Autonomy	<ol style="list-style-type: none"> <li>6. Is the technology used for individuals that are especially vulnerable? (critical)</li> <li>7. Does the implementation or use of the technology affect the patient's capability and possibility to exercise autonomy? (critical)</li> <li>8. Is there a need for any specific interventions or supportive actions concerning information in order to respect patient autonomy when the technology is used? (critical)</li> <li>9. Does the implementation or withdrawal of the technology challenge or change professional values, ethics or traditional roles? (critical)</li> </ol>
Respect for persons	<ol style="list-style-type: none"> <li>10. Does the implementation or use of the technology affect human dignity? (critical)</li> <li>11. Does the implementation or use of the technology affect the patient's moral, religious or cultural integrity? (critical)</li> <li>12. Does the technology invade the sphere of privacy of the patient or user? (critical)</li> </ol>
Justice and equity	<ol style="list-style-type: none"> <li>13. How does implementation or withdrawal of the technology affect the distribution of health care resources? (critical)</li> <li>14. How are technologies with similar ethical issues treated in the health care system? (important)</li> <li>15. Are there factors that could prevent a group or person from gaining access to the technology? (critical)</li> </ol>
Legislation	<ol style="list-style-type: none"> <li>16. Does the implementation or use of the technology affect the realisation of basic human rights? (critical)</li> <li>17. Can the use of the technology pose ethical challenges that have not been considered in the existing legislations and regulations? (important)</li> </ol>
Ethical consequences of the HTA	<ol style="list-style-type: none"> <li>18. What are the ethical consequences of the choice of endpoints, cut-off values and comparators/ controls in the assessment? (critical)</li> <li>19. Are there any ethical problems related to the data or the assumptions in the economic evaluation? (important)</li> <li>20. What are the ethical consequences of conducting the technology assessment at this point of time? (important)</li> </ol>

### *Methodological guidance and approaches to ethical analysis in screening technologies*

The issues outlined under each topic within the ethical analysis domain are intended to increase awareness and identify ethical issues and potential conflicts relevant to a particular technology. An ethical analysis subsequently serves to explore these issues in more detail. The purpose, complexity, and weight given to the ethical analysis domain will depend on the technology and the role of the group completing the HTA. A greater number of value conflicts identified or challenges to norms by a technology will require a more complex analysis. Additionally, the role of the body or individuals completing the HTA relative to the decision-makers bears considerable importance. For example, suppose an HTA is completed independently of decision-makers. In that case, the ethical analysis may suffice as a description of values, norms, attitudes and conflicts that should be taken into account within decision-making for the use of a technology; this may be considered in contrast to the approach of proposing potential courses of action or solutions to ethically challenging situations.

The potential sources to inform the ethical analysis of a screening technology are broad and will be determined by the scope of the ethical issues and conflicts encountered. However, common sources include systematic reviews, scoping literature reviews, expert opinion, professional guidelines, and patient and stakeholder input. The model outlines that the ethical analysis should be completed by an individual with expertise in ethics but in collaboration with scientific and clinical experts to ensure uniformity in the assessment as a whole. Importantly, the ethical analysis should be viewed as iterative and cyclical in nature; there should be initial consideration of potential ethical issues followed by subsequent reflection and expansion as new issues may come to light from other domain assessments.

The ethical evaluation of a screening programme has multiple perspectives and typically concerns a large number of stakeholders. The role of stakeholders in the ethical analysis is highlighted as an integral part of the process. Stakeholders who are both directly and indirectly impacted by decisions to implement, not implement or withdraw a technology should be consulted within the ethical analysis and their views embedded in the resulting output.

While the sources to inform the ethical analysis outlined above reflect typical research methodologies, the model emphasises that no one methodological approach is likely to be sufficient to complete the ethical analysis from a technology. A variety of approaches have been used by HTA agencies internationally in the conduct of ethical analyses, including:<sup>(94, 95)</sup>

- **Casuietry** *Uses practical cases with an undisputed solution to attempt to resolve moral challenges presented.*
- **Coherence analysis:** *Analysis of the absence of truth in morals through testing of consistency and coherence.*
- **Interactive participatory approach:** *Concept that assessment processes are embedded in different sorts of institutional settings, within which scientists, decision-makers, and advocates communicate to define relevant questions for analysis, mobilise certain kinds of experts and expertise, and interpret findings in particular way.*
- **Wide reflective equilibrium:** *Concept that the validity of a moral judgment depends on the coherence between general moral principles, moral judgment, and background theory.*
- **Principlism:** *The four principle approach proposed by Beauchamp and Childress.*
- **Triangular method:** *Approach which suggests that it is possible to gain knowledge of what is true in morals just as it is possible for empirical science to gain knowledge about the world, and that it is possible to acknowledge undisputed moral principles from which moral judgments can be derived in order to be applied.*
- **Social shaping of technology:** *Concept which moves from the evaluation of social impacts towards a social perspective, in which the development and implementation of technology in society are inherently normative.*

While a clear direction on the most suitable approach could not be presented, the model notes the **axiological approach** to potentially be the most functional. This approach views health technologies as social activities governed by a variety of contextually derived values and norms; it serves to elicit open and transparent ethical reflection by highlighting potential normative issues relevant to assessment and decision-making through a set of defined morally relevant questions. The questions encompass moral issues relating to general society, stakeholders, methodologies, the technology, and HTA and decision-making processes. The axiological approach consists of six steps, namely:

1. Identify and analyse the moral challenges that are typical for the health technology.
2. Identify stakeholders directly or indirectly impacted by the technology.

3. Select a set of morally relevant issues from a list of questions which highlight value issues with regards to the implementation of the health technology and justify the selection.
4. Perform a literature search from the outcomes of the first three steps.
5. Analyse the selected questions on the basis of the literature search, stakeholder engagement, and qualitative input (such as expert opinion).
6. Summarise the analysis and outline the value issues identified.

## **6.2 World Health Organization**

In 2020, the WHO released a high-level guidance document for policy-makers and public health leaders who are involved in planning, designing and implementing screening programmes, titled *Screening programmes: a short guide*.<sup>(96)</sup> The purpose of the guide is to raise awareness of key aspects in decision-making related to the starting, continuing or ceasing of screening programmes for newborn, child and adult populations. The Wilson and Jungner criteria are cited as forming the foundational basis for the assessment of screening programmes, with the ten principles of screening seeking to inform whether a programme is an appropriate course of action to improve public health in terms of benefits, harms, cost and ethics.<sup>(2)</sup>

The document emphasises that when assessing screening programmes, policy-makers must examine the associated benefits and harms and decide in the context of the perspective of the health system, values and ethics of their respective countries whether or not the programme is viable. Associated benefits may include reduced mortality, reduced morbidity, and improved quality of life while harms may include the impact of false positives and false negatives, overdiagnosis, overtreatment, and health resource use.

The ethics associated with screening programmes are noted as playing an important role in decision-making when balancing the associated benefits and harms identified. The document highlights that ethical frameworks may be used to assist policy-makers in their decision-making for whether or not to proceed with a programme. Examples of ethical positions are provided including:

- Utilitarian position: where policy-makers may justify a screening programme based on benefits outweighing harms at a reasonable cost.

- Deontological position: where policy-makers may reason that a screening programme cannot be morally justified based on any harm to an individual, despite potential benefits to others.
- Principlism: policy-makers may elect to guide their decisions with the four principles outlined by Beauchamp and Childress (that is, autonomy, non-maleficence, beneficence, and justice).

A WHO consultation group examining the ethics of individual health assessments for asymptomatic individuals, in the context of radiology, prescribed a pragmatic set of values for consideration to which this document refers. These considerations are intermittently cited as values or principles across the supporting documents but include:<sup>(97, 98)</sup>

- respect for dignity and autonomy
- non-maleficence and beneficence
- justice and equity
- prudence and precaution
- honesty and transparency.

It is further acknowledged that in certain circumstances these considerations may be in direct conflict with one another, and agreed strategies to explore and potentially resolve such conflicts are important. The authors again emphasise that the short guide is not intended to be prescriptive, but rather to raise awareness of important considerations in decision-making for screening programmes, with each country having its own set of values which will influence how policy-makers balance ethics, benefits and harms within decision-making.

The WHO has further presented detailed guidance on the ethical issues associated with public health surveillance.<sup>(99)</sup> While distinct from screening, the guidance presents detailed accounts of the role of public health ethics in developing the guidance, and notes that the guidance is based on the considerations of common good, respect for persons, and good governance.

### **6.3 European Council and European Commission**

The European Council produced *Council Recommendation of 2 December 2003 on cancer screening*.<sup>(100)</sup> The document was created for consideration by the EU member states, and included an invitation the European Commission to report on



progress in taking forward the recommendations outlined. While not an ethics framework, the document outlines 29 criteria for best practices for screening programmes, with two explicitly relating to ethics:

- Criteria 10: Ethical, legal, social, medical, organisational and economic aspects have to be considered before decisions can be made on the implementation of cancer screening programmes.
- Criteria 23: It is an ethical, legal and social prerequisite that cancer screening should only be offered to fully informed people with no symptoms if the screening is proved to decrease disease-specific mortality, if the benefits and risks are well known, and if the cost-effectiveness of the screening is acceptable.

Additionally, the ethical principles of 'benefits should outweigh the harm' and 'equal access' are implicitly referred to in criteria number nine and 22, respectively. As well as the aforementioned criteria, the document provides 24 recommendations on high-quality cancer screening for the EU. These recommendations were made across seven aspects of screening: implementation, registration and management of screening data, monitoring, training, compliance, the introduction of novel screening, and implementation report and follow up. Of these recommendations, three were noted to have an ethical dimension. Two of the three outline the need for informed consent from the target population to both understand the benefits and risks of screening, as well as in the overall compliance of the screening programme itself. The third refers to ensuring equal access and consideration of particular socio-economic groups.

The EU Commission has also published guideline documents for quality assurance in breast, colorectal, and cervical cancers, published in 2006, 2008, and 2010 respectively.<sup>(101-103)</sup> While each of these guidelines are specific to each of the cancer types mentioned, the ethical principles and considerations referred to within the guidelines may have transferability to general population screening programmes. A brief summary of ethical principles within these guidelines is outlined below:<sup>(101-103)</sup>

- Autonomy: the obligation to respect the decision-making capacities of autonomous persons. It emphasises that patients should normally be in a position to choose whether to accept an intervention or not as part of their general right to determine their own lives.
- Non-maleficence: the obligation to avoid causing harm intentionally or directly (the principle is not necessarily violated if a proper balance of benefits exists;



that is, if the harm is not directly intended, but is an unfortunate side effect of attempts to improve a person's health).

- Beneficence: the obligation to provide benefits balancing them against risks.
- Justice: obligation of fairness in the distribution of benefits and risks.

These four principles are intended to provide a framework for health professionals offering screening when developing appropriate ways of communicating with client groups.

## 7 Discussion

This review sought to identify ethics frameworks used internationally to inform policy-making in the context of screening. Information was obtained from a number of relevant sources throughout this review, namely: bodies with responsibility for screening policy-making, public health agencies, national ethics bodies, and international agencies. In terms of bodies with responsibility for screening, the country profiles presented within this review were noted to largely consider ethics as a dimension embedded within overarching frameworks for the assessment of population-based screening (generally considered as adaptations of the original Wilson and Jungner criteria). A limited number of countries, specifically France, Sweden and the UK, presented explicit ethics frameworks for assessments in the context of screening.<sup>(26, 38-40)</sup> The underpinning theory or approaches to the assessment of ethics in screening programmes were typically either not reported, or broadly stated to be aligned with specific values. Across countries within this review, considerations relevant to ethics (such as values or principles) and to the procedural elements of decision-making differed in terms of their description, number and level of detail; however, some consistencies were noted in terms of the general subject matter discussed. The rationale and methods by which these considerations were selected were typically not described. The structure of the frameworks to facilitate the consideration of ethics varied from high-level descriptions to guiding concepts and questions to be considered. In terms of decision-making processes, general decision-making processes, of which ethics were noted to be a component, were most frequently presented, with a limited number of countries outlining specific processes for ethical analyses.

A number of general public health ethics frameworks (that is, not specific to screening) were identified from public health agencies, with detailed overviews of underpinnings, components and processes for the use of these frameworks. While across sources, the components included (for example, values or principles) differed in terms of their number and level of detail, some consistency was noted in the general topic matter included. These frameworks were typically described as cyclical and reflective in nature and intended to guide ethical action and assist in the resolution of ethical issues in the context of public health. Information identified from national ethics bodies was mostly concerned with ethical considerations associated with specific screening topics such as genetic screening. The international agencies included within this review largely presented high-level documents with references to ethics in screening. An exception to this was the EUneHTA HTA Core Model<sup>®</sup> which presents a detailed ethical analysis domain for the assessment of screening technologies.

While the underpinning theory or approach to the assessment of ethics in this review was often not articulated, ethics frameworks are inherently designed to provide a practical application for the identification of and potential resolution of ethical issues.<sup>(19)</sup> In this way, they are concerned with the practicalities of decision-making as opposed to theoretical considerations. However, while it may not be considered essential for the underlying theory or approach to be detailed within the framework itself, it is important that its development is based on a robust foundation.<sup>(19, 104)</sup> While there is clear merit in a framework providing a methodological process for decision-makers to work through ethical issues in an applied manner, the normative foundation of the framework must also be thoroughly considered.<sup>(19)</sup>

A variety of approaches to ethics exist, from the more traditional perspectives such as utilitarianism (that is, striving to maximise beneficial consequences) and deontology (that is, actions are right or wrong irrespective of the consequences) to more applied contexts such as principle-based and case-based approaches.<sup>(105, 106)</sup> Within the public health literature, principle-based approaches are frequently encountered as a means to assist decision-makers in their discourse and deliberation of ethical issues and to support them to reach decisions and courses of action that are justifiable on the basis of agreed ethical principles.<sup>(105)</sup>

A number of countries within this review outlined specific values or principles for consideration in decision-making. While there were some consistencies noted, the values or principles were largely heterogeneous. This is perhaps unsurprising given that each country will have its own perspective and values, which will influence how policy-makers explore ethics within decision-making.<sup>(96)</sup> As such, it is important to consider how transferable such values or principles are to the Irish context, and in developing up an ethics framework for the Irish setting, local values and perspectives require careful consideration. In a similar vein, while detailed ethics frameworks were identified from public health agencies, it must be considered that these frameworks have been developed with consideration of the local cultural context and value system.

Where frameworks appeal to values or principles to inform decision-making, these should be explicit with their intended meaning, purpose and rationale for inclusion presented, along with details of how they may relate to each other.<sup>(19, 104)</sup> The use of such values or principles are generally considered to be a starting point which requires further specification and refinement, depending on the specific context in which they are considered.<sup>(105, 106)</sup> When considering complex decisions, multiple principles may apply, and the relevance or weight of each principle may change.<sup>(10)</sup> Furthermore, there may be tensions or conflicts between certain values or principles that must be adequately considered (that is, decisions taken to preserve one may potentially compromise another).<sup>(10, 19)</sup> Even where there is broad agreement about

the relevant ethical issues or principles in question, individuals may still reasonably disagree on the course of action.<sup>(16)</sup> It is in these contexts that the importance of robust decision-making processes is underscored.<sup>(17)</sup> While the possibility of conflicts or tensions between values and principles, and the need to resolve such events, were frequently highlighted by the sources within this review, details of processes to assist in the resolution were typically not described.

It is worth noting that the four principles synonymous with Beauchamp and Childress (that is, beneficence, non-maleficence, autonomy, and justice),<sup>(3)</sup> were presented within a number of the sources identified by this review. These principles, and their relevance to public health decision-making, have been discussed at length within the literature.<sup>(105, 106)</sup> While their presence in public health ethics is not necessarily impractical, careful consideration is required regarding how they may be applied to the population-level context as opposed to their original intended context of individual-level decision-making.<sup>(105, 106)</sup> Furthermore, these four principles may be considered insufficient in isolation when considering issues in public health, where additional concepts such as trust, solidarity, proportionality, precaution, and prudence are frequently cited.<sup>(104, 105)</sup> In a similar manner, caution is recommended in using an approach that begins with the identification of values or principles relevant to the individual and attempts to aggregate up to a population level in public health.<sup>(104)</sup> As public health decisions are taken at the population or community level, the values and principles which guide such activities differ from those which guide traditional clinical decision-making.<sup>(10, 12)</sup> Therefore, it is important to consider the balance between the collective and the individual, and remain cognisant of the where the benefits and harms of a specific intervention are likely to accrue.

It is important to note also that frameworks identified from public health agencies are primarily intended to guide general public health action. However, as a specific public health intervention with distinct nuances, screening represents a distinct task within the general discipline and hence may require further distilling in order to guide intended action.<sup>(19, 106)</sup> Such nuances may be further heightened when considering different types of screening and the populations for which they are intended (for example, adult compared to child). Also, there may be unique ethical considerations in the case of a proposal to change or cease an existing screening programme, as opposed to the introduction of a new screening programme; it is noteworthy that the frameworks identified within this review were most often concerned with decisions regarding the introduction of a new screening programme or public health intervention, and it is not clear how suitable such frameworks would be for decisions relating to an existing programme. As such, there is a need to balance the generality and specificity of a framework to ensure it is sufficiently

dynamic to serve its intended purpose for the different contexts of screening, and different types of decisions, to which it is applied.

Where decision-making processes in relation to ethics were explicitly described within this review, they were typically presented as defined steps or stages and often cited as being cyclical and reflective in nature. A variety of sources were noted to inform ethical analyses taken into account in decision-making, including literature reviews, expert opinion, and the identification and inclusion of relevant stakeholders. Transparency, openness, and accountability were frequently cited as core to decision-making processes in relation to screening programmes. Such concepts facilitate decision-making and assist in ensuring that, if there are a number of reasonable solutions to an ethically-challenging situation, the final decision is reached using a process that is publicly defensible and justifiable.<sup>(16-18)</sup> Of note, a number of countries within this review presented mechanisms to decide the necessity of completing an ethical analysis for a topic and strategies to assist in reaching a decision where disagreements or a lack of consensus regarding ethical issues were presented following an ethical analysis.

The structures of the frameworks presented within this review were varied. They ranged from listing relevant ethical considerations to detailed descriptions of values and principles, to guiding concepts and questions to be considered in light of specific values and principles. The use of explicit ethics frameworks can add assurance and legitimacy to decision-making by ensuring key factors are given due consideration within the process.<sup>(107)</sup> Frameworks are intended to facilitate ethical guidance through the tailoring of general ethical theories, principles, or values to the specific ethical challenges that arise in public health and can offer a means to identify ethically justifiable solutions to ethically challenging situations.<sup>(10)</sup> Whatever the format of the framework presented, the overall aim should be to aid deliberation and decision-making by framing the elements considered relevant; they should not be seen as a replacement of discourse and deliberation by decision-makers.<sup>(10, 19)</sup> Within the use of frameworks, and appealing to values or principles in decision-making, reflection and specification will be required depending on the context in which they are used; sound judgement is considered a core element of any decision-making in relation to ethics.<sup>(19, 106)</sup> In particular, consideration should be given to how such a framework aligns with other positions of the Irish healthcare system, such as the adoption of the Public Sector Equality and Human Rights Duty approach.<sup>(108)</sup>

## **Conclusion**

This review aimed to identify ethics frameworks used internationally for policy-making in the context of screening. Information was obtained from various sources, including bodies with responsibility for screening policy-making, public health agencies, national ethics bodies, and international agencies. Details regarding the theoretical underpinnings and approaches, values and principles, framework structures, and decision-making processes concerning ethics identified are presented. The outlined information is intended to help develop an ethics framework for assessing population-based screening programmes in Ireland. Based on the findings of this review, a number of important items were identified that should be considered. These included: the justification for the approach underpinning an ethics framework, the use of public health ethics as opposed to those used in traditional clinical decision-making, the rationale for the selection and inclusion of values and principles within a framework, the specification and tailoring of such elements to individual contexts, the handling of conflicts between such elements, the generality versus the specificity of frameworks, and the structuring of decision-making processes to ensure they are publicly defensible and justifiable.

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## Appendices

### Appendix 1.1 - Criteria listed for the appraisal of screening programmes

#### Appendix 1.1. Criteria listed for the appraisal of screening programmes

Country	Criteria Listed
<p><b>Australia</b></p> <p>1. Australian Health Minister's Advisory Council, <i>Population Based Screening Framework</i>, <a href="https://www.health.gov.au/sites/default/files/documents/2019/09/population-based-screening-framework_0.pdf">https://www.health.gov.au/sites/default/files/documents/2019/09/population-based-screening-framework_0.pdf</a>, Last updated: August 2018</p> <p>2. Australian Health Minister's Advisory Council, <i>Genomic tests in population-based screening programs – position statement</i>,</p>	<p>Criteria informed by Wilson and Jungner:<sup>(1)</sup></p> <p><i>The condition</i></p> <ul style="list-style-type: none"> <li>▪ Should be an important health problem.</li> <li>▪ Should have a recognisable latent or early symptomatic stage. The natural history of the disease or condition should be adequately understood.</li> </ul> <p><i>The test</i></p> <ul style="list-style-type: none"> <li>▪ Should be highly sensitive, highly specific, validated, and safe.</li> <li>▪ Should have a relatively high positive predictive value and negative predictive value.</li> <li>▪ Should be acceptable to the target population, including subgroups such as target populations who are from culturally and linguistically diverse backgrounds, Aboriginal and Torres Strait Islander people, people from disadvantaged groups, and people with a disability.</li> </ul> <p><i>Assessment</i></p> <ul style="list-style-type: none"> <li>▪ Systems should be in place for evidence-based follow-up assessment of all people with a positive screening test regardless of rurality, ethnicity, socioeconomic status or disadvantage status.</li> </ul> <p><i>Treatment</i></p> <ul style="list-style-type: none"> <li>▪ Must be effective, available, easily accessible and acceptable to all patients with the recognised disease or condition.</li> </ul> <p><i>Screening programme</i></p> <ul style="list-style-type: none"> <li>▪ Must respond to a recognised need.</li> </ul>

Country	Criteria Listed
<p><b>Source(s)</b></p> <p><a href="https://www.health.gov.au/resources/publications/genomic-tests-in-population-based-screening-programs-position-statement">https://www.health.gov.au/resources/publications/genomic-tests-in-population-based-screening-programs-position-statement</a>, Last updated: April 2020</p>	<ul style="list-style-type: none"> <li>▪ Must be clinically, socially, legally and ethically acceptable to health professionals, consumers and the Australian public.</li> <li>▪ Must have a clear definition of the objectives of the programme and the expected health benefits.</li> <li>▪ Must have scientific evidence of effectiveness and identify the target population who stand to benefit from screening.</li> <li>▪ Must clearly define the screening pathway and interval and ensure availability of the organisation, infrastructure, facilities and workforce needed to deliver the program.</li> <li>▪ Must have measures available that have been demonstrated to be cost-effective to encourage high coverage.</li> <li>▪ Must have adequate facilities available for conducting tests and interpreting them.</li> <li>▪ Must have an organised quality control programme across the screening pathway to minimise potential risks of screening.</li> <li>▪ Must have a referral system for management of any abnormalities found and for providing information about normal screening tests.</li> <li>▪ Must have adequate facilities for follow-up assessment, diagnosis, management and treatment.</li> <li>▪ Must evidence-based guidelines and policies for assessment, diagnosis and support for people with a positive test result.</li> <li>▪ Must have adequate resources available to set up and maintain a database of health information collected for the programme.</li> <li>▪ Must integrate education, testing, clinical services and programme management.</li> <li>▪ Must have a database or systems available capable for providing a population register for people screened that can issue invitations for initial screening, recall individuals for repeat screening, follow those with identified abnormalities, correlate with morbidity and mortality results, and monitor and evaluate the programme and its impact.</li> <li>▪ Must plan evaluation from the outset and ensure that programme data are maintained so that evaluation and monitoring of the programme can be performed regularly.</li> </ul>



Country	Criteria Listed
Source(s)	
	<ul style="list-style-type: none"> <li>▪ Must be cost-effective.</li> <li>▪ Must ensure informed choice, confidentiality and respect for autonomy.</li> <li>▪ Must promote equity of and access to screening for the entire target population, including important subgroups such as participants who are from culturally and linguistically diverse backgrounds, Aboriginal and Torres Strait Islander people, people from disadvantaged groups, and people with a disability.</li> <li>▪ Must ensure that the overall benefits of screening outweigh the potential harms, including psychological, physical, social, cultural, ethical and legal harms.</li> </ul> <p><i>Treatment and ongoing management</i></p> <ul style="list-style-type: none"> <li>▪ Ongoing management referral protocols must be established for individuals who have the disease or condition detected through the screening program.</li> <li>▪ There needs to be an established policy for the management of individuals who are at high risk of developing the disease or condition.</li> </ul> <p><i>Implementation and management Criteria</i></p> <ul style="list-style-type: none"> <li>▪ There should be a national policy framework that clearly defines the goals, objectives and screening pathway.</li> <li>▪ The programme should be clearly planned and designed.</li> <li>▪ There should be an agreed quality management plan in place.</li> <li>▪ Governance and management of the program should be clearly defined, with leadership, advisory and decision-making process outlined.</li> <li>▪ There should be a formal process for monitoring, evaluating and reviewing the screening program.</li> </ul> <p>Criteria for genomic testing in population based screening programmes:<sup>(2)</sup></p> <p><i>The condition</i></p> <ul style="list-style-type: none"> <li>▪ The condition is an important health problem and has a recognisable genomic cause or risk.</li> </ul>

Country	Criteria Listed
Source(s)	
	<ul style="list-style-type: none"> <li>▪ The clinical significance of a genomic variant/s should be adequately understood. The relationship between the genomic cause or risk, the clinical condition, and the opportunity for intervention must be demonstrated.</li> <li>▪ The use of genomic technology in screening programmes must be in response to a need for early detection of disease, disease risk, or disease carrier status, and not be driven by technological advances.</li> <li>▪ Conditions screened for in children using genomic tests should be limited to those with childhood onset and either acceptable treatment options, or an understood benefit to the child and/or their family through the disease diagnosis, or through knowledge of increased risk of developing the disease.</li> </ul> <p><i>Test</i></p> <ul style="list-style-type: none"> <li>▪ The “test” refers to the method or procedure used to obtain and analyse a sample of genomic material. For example, a blood test, saliva test, skin scrape, a hair root sample etc. The test must be ordered through a diagnostic laboratory accredited and validated to the appropriate national and international standards of human pathology testing.</li> <li>▪ The test should be acceptable to the target population and to society.</li> <li>▪ The test must have clear criteria for positive, negative and indeterminate test results. For screening tests that identify disease or disease risks, there should be an agreed policy on whom to categorise as “screen positive”, “screen negative” and “screen indeterminate”. For screening tests that determine risk of disease, there should be an agreed policy on what determines the degree of risk and how to report or define this.</li> <li>▪ Screening programme data and reports need to be easily understood. Programs should ensure that test result formats and language promote clear and unambiguous interpretation of results, including where results are reported to non-genetic health care professionals, or to consumers.</li> <li>▪ Laboratories using next generation sequencing technology for population screening must limit analyses to only those genes relevant to the screening programme. Incidental genomic findings should not be sought or reported without the explicit advance consent of participants.</li> </ul>



Country	Criteria Listed
Source(s)	
	<ul style="list-style-type: none"> <li>▪ Consideration should be made of the acceptability of the test in Australia, including the acceptability of the test for culturally and linguistically diverse groups, Aboriginal and Torres Strait Islander peoples, and within vulnerable populations such as those with a disability or those with the condition.</li> <li>▪ Consideration should be made of equity of access to the genomic screening test for culturally and linguistically diverse groups, Aboriginal and Torres Strait Islander peoples, and within vulnerable populations such as those with a disability or those with the condition.</li> <li>▪ The programme design, including the test must account for the genetic background of the target population.</li> </ul> <p><i>Assessment</i></p> <ul style="list-style-type: none"> <li>▪ There should be a defined assessment process for people with positive and indeterminate test results, following disclosure of screening results.</li> <li>▪ Screening programmes must make available adequate and appropriate genetic counselling, giving consideration to family and community contexts when applicable, and ensuring cultural appropriateness including interpreters when needed.</li> </ul> <p><i>Treatment</i></p> <ul style="list-style-type: none"> <li>▪ There should be an understood benefit to screening for the condition that forms part of a coherent management strategy.</li> </ul> <p><i>Screening programme</i></p> <ul style="list-style-type: none"> <li>▪ The screening programme will be conducted to the highest ethical standards, such as those articulated in the National Health and Medical Research Council (NHMRC) "National Statement on Ethical Conduct in Human Research and the NHMRC Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders". Where screening programmes do not contain a research element, the ethical standards set out in the NHMRC documents above should apply. These ethical standards are in conformity with the aims and principles of the United Nations Educational, Scientific and</li> </ul>

Country	Criteria Listed
Source(s)	
	<p>Cultural Organization (UNESCO) Universal Declaration on the Human Genome, and the UNESCO International Declaration on Human Genetic Data.</p> <ul style="list-style-type: none"> <li>▪ The screening programme should target those most likely to benefit, and clearly define the target population. Genomic screening tests used within the screening programme should be suitable for all individuals screened, with a standardised test applied to the target population. The screening programme should promote equity among all Australians.</li> <li>▪ The entire screening programme, including the genomic testing component, must be acceptable to the target population and society including culturally and linguistically diverse groups, Aboriginal and Torres Strait Islander peoples, and within vulnerable populations such as those with a disability or those with the condition.</li> <li>▪ Aboriginal and Torres Strait Islander stakeholders must be included at the earliest possible point in new screening programme development. It is essential to ensure that Aboriginal and Torres Strait Islander peoples can be part of the planning and development of the screening programme. It is also essential that any screening programme involving Aboriginal and Torres Strait Islander participants or communities maintains communication with participants throughout the programme, provides outcomes from the programme back to participants and includes Aboriginal and Torres Strait Islander peoples in programme evaluation.</li> <li>▪ Consideration must be given to ensuring equity of access to the screening programme, for culturally and linguistically diverse groups, Aboriginal and Torres Strait Islander peoples, and vulnerable populations such as those with a disability or those with the condition.</li> <li>▪ Any genomic screening should be part of an integrated screening programme that includes education of the target population and the health workforce. It should promote equity of access by the target population, have appropriate infrastructure including a register for people screened, access to appropriate clinical services provided by an appropriately skilled and resourced workforce, and program management. When the screening programme includes Aboriginal and Torres Strait Islander participants, cultural competency training should be provided for programme staff and associated health workforce.</li> </ul>

Country	Criteria Listed
Source(s)	<ul style="list-style-type: none"> <li>▪ Nationally acceptable programme parameters must be available, including: guidelines and educational material on the identification of people suitable for genomic testing, a clear management plan for positive, negative and indeterminate results, appropriate patient information and support including genetic counselling, and on follow up investigation and medical care.</li> <li>▪ There should be evidence of screening programme acceptability, effectiveness and appropriateness before a programme is introduced and any benefits should outweigh potential harms, including psychological, physical and social harms.</li> <li>▪ Evidence of value for money or cost-effectiveness for the programme should be demonstrated.</li> <li>▪ There should be quality assurance incorporated at all levels of the screening programme and ongoing program evaluation should be planned from the outset.</li> <li>▪ Provision must be made for an appropriately skilled and resourced health workforce, including adequate and culturally appropriate support, mental health services and counselling for people undergoing genomic tests, and ongoing education for health professionals on the screening process and outcomes from it. The health workforce should include members of culturally and linguistically diverse groups, Aboriginal and Torres Strait Islander peoples, and vulnerable populations. The health workforce should recognise that Aboriginal and Torres Strait Islander participants may have previous multiple traumas.</li> </ul> <p><i>Consent</i></p> <ul style="list-style-type: none"> <li>▪ Consent process must be clear, unambiguous and frank. Consent process must reflect informed choice, cultural appropriateness for the target population, confidentiality, respect for autonomy and participant understanding of possible discrimination based on genetic data, and participant understanding of the possible outcomes of genomic testing. Consent processes must acknowledge the participants' ability to consent.</li> <li>▪ Consideration should be given to when and how consent is sought from participants, and how participants can decline consent to part or all of the programme.</li> </ul>

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Source(s)	
	<ul style="list-style-type: none"> <li>▪ Consent process should be developed for screening programmes, and should be tailored to the specific programme.</li> <li>▪ There are Commonwealth, State and Territory laws that apply to stakeholders that specify how stakeholders can collect, use, store, and disclose participants' personal information including health information.</li> <li>▪ Informed consent to participate in the screening programme would usually require information about the availability of appropriate treatment and or condition management pathways.</li> </ul> <p><i>Management of data</i></p> <ul style="list-style-type: none"> <li>▪ Planning should consider the possibility of re-testing stored genetic material and or re-analysis of genomic data in light of advances in technology or knowledge.</li> <li>▪ Screening programme data management planning must reflect the informed consent of participants and consider cultural and religious beliefs on retention and destruction of genomic samples.</li> <li>▪ Consideration of data ownership, ownership of genomic material, and equity of ownership should be made, including interests and rights of Aboriginal and Torres Strait Islander peoples, and whether individuals who are screened can access data for other purposes.</li> <li>▪ The programme must ensure suitable data and sample storage with a high degree of security.</li> <li>▪ Genomic population screening registers will need protocols for management of data and samples, relating to storage, sharing, access rights, research requests, and possible notification of new findings to participants in population health screening programmes.</li> </ul> <p><i>Ongoing management</i></p> <ul style="list-style-type: none"> <li>▪ Policies must be in place for potential future recall of participants affected by new testing or research findings, including transient populations.</li> <li>▪ Post-diagnosis support and advice to participants on the management of genomic conditions should be consistent across jurisdictions.</li> </ul> <p><i>Carrier screening</i></p>

Country	Criteria Listed
Source(s)	
	<ul style="list-style-type: none"> <li>▪ Carrier screening is appropriate for family planning, to assist in identifying the risk of having offspring with inherited genetic diseases.</li> <li>▪ For carrier screening, consideration should be made of the potential implications for people other than the individual screened, including consideration of incidental findings.</li> <li>▪ Decisions to screen individuals for carrier status of inheritable disease should be made on the basis that screening will provide actionable information for individuals, families or communities that assists them in making informed choices.</li> </ul>
<p><b>Australia Newborn Bloodspot Screening (NBS)</b></p> <p>Australian Health Minister's Advisory Council, <i>Newborn Bloodspot Screening National Policy Framework</i>, <a href="https://www.health.gov.au/sites/default/files/documents/2020/10/newborn-bloodspot-screening-national-policy-framework.pdf">https://www.health.gov.au/sites/default/files/documents/2020/10/newborn-bloodspot-screening-national-policy-framework.pdf</a>, Last updated: May 2018</p>	<p><i>The condition</i></p> <ul style="list-style-type: none"> <li>▪ Should be a serious health problem that leads to significant morbidity and mortality.</li> <li>▪ There should be a benefit to conducting screening in the newborn period.</li> <li>▪ The natural history of the condition, including development from latent to declared disease, should be adequately understood.</li> </ul> <p><i>The screening test</i></p> <ul style="list-style-type: none"> <li>▪ There should be a suitable test protocol to identify the presence of the condition.</li> <li>▪ The test protocol should, on balance, be socially and ethically acceptable to health professionals and the public.</li> </ul> <p><i>The intervention</i></p> <ul style="list-style-type: none"> <li>▪ Health care services for diagnosis and management should be available so that these services can be offered if there is an abnormal screening result.</li> <li>▪ There should be an accepted intervention for those diagnosed with the condition.</li> </ul> <p><i>Additional considerations</i></p> <ul style="list-style-type: none"> <li>▪ The benefit of screening a condition must be weighed against its impact on the programme as a whole.</li> <li>▪ What other information relevant to decision-making should be considered that has not been captured elsewhere?</li> </ul>
<b>Belgium</b>	<i>No information identified using search methodology applied in this review</i>
<b>Belgium – Brussels</b>	<i>No information identified using search methodology applied in this review</i>

Country	Criteria Listed
<p data-bbox="203 309 571 347"><b>Source(s)</b></p> <p data-bbox="203 352 571 391"><b>Belgium – Flanders</b></p> <p data-bbox="203 427 571 890">The Flemish Government, <i>Besluit van de Vlaamse Regering betreffende bevolkingsonderzoek in het kader van ziektepreventie*</i>, <a href="https://codex.vlaanderen.be/Portals/Codex/documenten/1017595.html">https://codex.vlaanderen.be/Portals/Codex/documenten/1017595.html</a>, Published: December 2008</p> <p data-bbox="203 932 571 1007"><i>*Document translated using Google Translate</i></p>	<p data-bbox="595 347 2038 422">The minister can organise, or have organised, population screening on behalf of the Flemish Government if all of the following conditions are met:</p> <ul data-bbox="640 427 2038 890" style="list-style-type: none"> <li>▪ The expected health gains in the target group, as a result of the population screening, are scientifically substantiated.</li> <li>▪ The effectiveness of the population screening is substantiated in a context that is relevant for Flanders.</li> <li>▪ The population screening aims to give all persons of the target group for screening the opportunity to participate.</li> <li>▪ It has been shown that the participants in the screening are very likely to experience more benefits than disadvantages, both from initial screening result and from further diagnostic examination, treatment or other meaningful action with regard to their health after an abnormal screening result.</li> <li>▪ The Flemish Population Screening Working Group, has given advice on the population screening on behalf of the Flemish Government.</li> </ul> <p data-bbox="595 932 2038 970">Preconditions met by screening programmes being carried out on behalf of the Flemish government:</p> <ul data-bbox="640 975 2038 1394" style="list-style-type: none"> <li>▪ Population screening is carried out by a ministry approved organisation: <ul style="list-style-type: none"> <li>○ These organisers cooperate in the registration of the population screening for progress control, quality control and programmes evaluation.</li> </ul> </li> <li>▪ The minister sets up a Flemish working group for the population screening. In the case of a population screening that is carried out by the consultation bureaus of OpGROWING and the Centres for Pupil Guidance, this establishment is optional.</li> <li>▪ In order to ensure informed choice, organisers must: <ul style="list-style-type: none"> <li>○ Inform the persons who are part of the target group of the screening in advance or their representatives that the population screening is not compulsory.</li> <li>○ Inform the persons who are part of the target group of the screening or their representatives in advance about the purpose of the population screening, the</li> </ul> </li> </ul>

Country	Criteria Listed
Source(s)	
	<p>advantages and disadvantages of the population screening, the method of the population screening and the processing of personal data in the context of the population screening.</p> <ul style="list-style-type: none"> <li>○ Not carry out screening without the consent of the person concerned or their representative. The person carrying out the population screening also requests permission to process the personal data required for the population screening.</li> <li>○ Give the persons who are part of the target group for screening, or their representatives, the possibility to refuse to receive further invitations for the same population screening.</li> </ul> <p>For screening programmes not implemented by or on behalf of the state, the following criteria must also be met:</p> <ul style="list-style-type: none"> <li>▪ Permission must be applied for to the government.</li> <li>▪ A suitable body has been designated as responsible for organising the programme.</li> <li>▪ The programme will result in a health gain for the target group and this is backed by scientific research.</li> <li>▪ The target group must benefit more from further diagnostic testing and treatment than they would without the screening programme.</li> <li>▪ The programme should be accessible to all individuals in the target group.</li> <li>▪ There is not already a government screening programme in place, in the region, for the same target population.</li> <li>▪ The Flemish Population Screening Working Group, has given advice about the population screening.</li> </ul>
<p><b>Belgium – Wallonia</b></p> <p>Response to survey</p>	<p>Criteria are considered implicitly as screening programmes are based on EU international recommendations and or best practices from other EU member countries.</p>
<p><b>Canada Alberta NBS</b></p>	<p>The Institute of Health Economics followed the Australian Population Health Development Principal</p>

Country	Criteria Listed
<p><b>Source(s)</b></p>	
<p><b>Programme</b></p> <p>Institute of Health Economics, Alberta, <i>Newborn blood spot screening for galactosemia, tyrosiemia type I, homocystinuria, sickle cell anemia, sickle cell/beta-thalassemia, sickle cell/hemoglobin C disease and severe combined immunodeficiency</i>  <a href="https://www.ihe.ca/download/newborn_blood_spot_screening.pdf">https://www.ihe.ca/download/newborn_blood_spot_screening.pdf</a>, last updated: March 2016</p>	<p>Committee’s Screening Subcommittee’s principles for decision-making regarding the introduction of a population-based screening programme, as outlined in the Australian screening framework document “Population Based Screening Framework”.</p>
<p><b>Canada Ontario</b></p> <p>1. Newborn Screening Ontario, <i>Review form for a condition nominated for addition to the screening</i></p>	<p>Criteria considered during a full review process of a condition being considered for addition to the newborn screening panel:<sup>(1, 2)</sup></p> <p><i>The Condition</i></p> <ul style="list-style-type: none"> <li>▪ The condition should be an important health problem.</li> <li>▪ The epidemiology and natural history of the condition should be adequately understood.</li> <li>▪ The form includes ten questions relating to these points regarding the case definition, condition frequency and natural history and severity.</li> </ul>



Country	Criteria Listed
<p data-bbox="206 311 362 347"><b>Source(s)</b></p> <p data-bbox="206 355 564 502"><i>panel,</i> <a href="https://www.newbornscreening.on.ca/sites/default/files/form_2_blank.pdf">https://www.newbornscreening.on.ca/sites/default/files/form_2_blank.pdf</a>, Last updated: unavailable</p> <p data-bbox="206 625 564 928">2. Newborn Screening Ontario, <i>Full review form for a condition considered for addition to the screening panel,</i> <a href="https://www.newbornscreening.on.ca/sites/default/files/form_3_blank.pdf">https://www.newbornscreening.on.ca/sites/default/files/form_3_blank.pdf</a>, Last updated: unavailable</p>	<p data-bbox="598 355 721 387"><i>The Test</i></p> <ul data-bbox="640 395 2016 849" style="list-style-type: none"> <li>▪ There should be a simple, safe, precise and validated screening test.</li> <li>▪ The distribution of test values in the target population should be known and a suitable cut-off level defined and agreed.</li> <li>▪ The test should be acceptable to the population.</li> <li>▪ There should be an agreed policy on the further diagnostic investigation of individuals with a positive screening test result.</li> <li>▪ If the screening test includes a test for mutations the criteria used to select the subset of mutations to be covered by screening, if all possible mutations are not be testing, should be clearly set out.</li> <li>▪ The form includes 20 questions relating to screening test modality and parameters; the analytic and clinical validity of the screening test; the diagnostic testing for those with positive screening test results.</li> </ul> <p data-bbox="598 857 810 888"><i>The Treatment</i></p> <ul data-bbox="640 896 2016 1200" style="list-style-type: none"> <li>▪ 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.</li> <li>▪ There should be agreed evidence-based policies covering which individuals should be offered treatment and the appropriate treatment to be offered.</li> <li>▪ Appropriate clinical management of the condition and patient outcomes should be available to newborns or children with the condition before population screening is initiated.</li> <li>▪ The form includes six questions relating to description and availability of the treatment, and effectiveness.</li> </ul> <p data-bbox="598 1208 922 1240"><i>Societal Considerations</i></p> <ul data-bbox="640 1248 1989 1391" style="list-style-type: none"> <li>▪ There should be evidence that the screening programme is effective in reducing mortality or morbidity.</li> <li>▪ There should be evidence that the complete screening programme is clinically, socially, and ethically acceptable to health professionals and to the public.</li> </ul>

Country Source(s)	Criteria Listed
	<ul style="list-style-type: none"> <li>▪ The benefit from the screening programme should outweigh the physical and psychological harm.</li> <li>▪ The opportunity cost of the screening programme should be economically balanced in relation to expenditure on medical care as a whole.</li> <li>▪ The form includes 12 questions relating to the overall benefits and acceptability, the potential harms, resource needs and cost-effectiveness and other considerations.</li> </ul>
<p><b>Canada Québec</b></p> <p>1. Insitut National de Santé Publique en Québec (National Institute of Public Health in Quebec), Recommendations on optimising cervical cancer screening in Québec*, <a href="https://www.inspq.qc.ca/sites/default/files/publications/1081_cervicalscreening.pdf">https://www.inspq.qc.ca/sites/default/files/publications/1081_cervicalscreening.pdf</a>, Last updated: January 2009</p> <p>2. Institut National d'Excellence en Santé et en Services Sociaux (National Institute of</p>	<p>1) <i>Cancer Screening Programmes</i> Recommended criteria for introducing a cancer screening programme according to the Quebec cancer control programme:</p> <ul style="list-style-type: none"> <li>▪ Significant problem: the type of cancer leads to significant mortality and morbidity.</li> <li>▪ Adequate tests: Screening and diagnostic tests are sufficiently accurate.</li> <li>▪ Effective treatment: Treatments should be available that are capable of changing the course of the disease.</li> <li>▪ Acceptable risks: The risks and negative outcomes associated with the tests and treatments are acceptable when compared to the anticipated benefits.</li> <li>▪ Demonstrated reduction in mortality: There is convincing evidence that screening is effective in reducing mortality.</li> <li>▪ Reasonable cost to effectiveness ratio: The costs of the programme are reasonable when compared to the anticipated benefits.</li> </ul> <p>2) <i>Blood and urine newborn screening programme criteria</i> The criteria are based on an amended version of those of the UK National Screening Committee. <i>The Health Problem:</i></p> <ul style="list-style-type: none"> <li>▪ The disease must constitute a significant health problem.</li> <li>▪ The epidemiology and natural evolution of the health problem, including the development of any latent stage, are understood adequately and there is a risk factor, disease marker or a latent or early symptomatic stage which make it detectable.</li> </ul>

Country	Criteria Listed
<p data-bbox="197 309 577 847"> <b>Source(s)</b>            Excellence in Health and Social Services), <i>Pertinence d'élargir le programme de dépistage néonatal sanguin au Québec*</i>, <a href="https://www.inesss.qc.ca/fileadmin/doc/INESSS/Rapports/Genetique/INESS_Depistage_neonatal_sanguin.pdf">https://www.inesss.qc.ca/fileadmin/doc/INESSS/Rapports/Genetique/INESS_Depistage_neonatal_sanguin.pdf</a>, Last updated: September 2013   <i>*Document translated using Google Translate</i> </p>	<ul style="list-style-type: none"> <li data-bbox="638 352 1682 384">▪ All feasible and effective primary preventive interventions were set up.</li> </ul> <p data-bbox="589 392 752 424"><i>Treatment:</i></p> <ul style="list-style-type: none"> <li data-bbox="638 432 2029 496">▪ There is an effective treatment or intervention for patients detected by screening and evidence that early treatment provides benefits compared to late treatment.</li> <li data-bbox="638 504 1901 568">▪ There are evidence-based guidelines that determine which patients to treat and which treatments are appropriate.</li> <li data-bbox="638 576 1973 639">▪ The clinical management of the health problem and the results of the patient management must be optimal before participating in the programme.</li> </ul> <p data-bbox="589 663 813 695"><i>Screening Test:</i></p> <ul style="list-style-type: none"> <li data-bbox="638 703 1514 735">▪ The screening test must be simple, safe, precise and valid.</li> <li data-bbox="638 743 2007 807">▪ A defined and acceptable threshold for detection of a positive test result must be defined and accepted.</li> <li data-bbox="638 815 1368 847">▪ The test should be acceptable to the population.</li> <li data-bbox="638 855 2002 919">▪ There should be an agreed process and pathway concerning people with a positive screening result and options available to them.</li> </ul> <p data-bbox="589 935 759 967"><i>Programme</i></p> <ul style="list-style-type: none"> <li data-bbox="638 975 1973 1038">▪ The effectiveness of the programme at reducing mortality or morbidity has been proven by high-quality studies.</li> <li data-bbox="638 1046 1962 1110">▪ The entire programme has been proven to be clinically, socially and ethically acceptable to healthcare professionals and the public.</li> <li data-bbox="638 1118 1995 1182">▪ The benefits of the programme should outweigh any physical or psychological harms caused by tests, clinical procedures or treatments.</li> <li data-bbox="638 1190 1928 1254">▪ The opportunity cost of the entire programme must be deemed reasonable compared to overall health care spending required.</li> <li data-bbox="638 1262 1984 1326">▪ There must be a programme management and monitoring plan including recognised quality assurance criteria.</li> </ul>

Country Source(s)	Criteria Listed
	<ul style="list-style-type: none"> <li>▪ The personnel, resources and other requirements necessary for the test, the interventions, treatment and management of the programme should be in place before the start of the programme.</li> <li>▪ All other options for managing illness should be considered to ensure that there is no new, more effective alternate option available.</li> <li>▪ Evidence-based information should be made available to the potential participants and should clearly explain the consequences of the test, diagnostic interventions and treatment so that individuals can be an informed decision.</li> <li>▪ Possible public pressures aimed at expanding screening eligibility criteria, reduce screening intervals or increasing the sensitivity of the test should be anticipated. Decisions should be justified and based on scientific evidence.</li> </ul>
<p><b>Denmark</b></p> <p>Sundhedsstyrelsen (The National Board of Health), <i>Anbefalinger vedrørende nationale screeningsprogrammer*</i>, <a href="https://www.sst.dk/-/media/Udgivelser/2014/Rapport_Sundhedsstyrelsens-anbefalinger-vedr-nationale-screeningsprogrammer.a_shx?la=da&amp;hash=D09671DC7A18EB5CF2BFDBFE382B684A7F330B24">https://www.sst.dk/-/media/Udgivelser/2014/Rapport_Sundhedsstyrelsens-anbefalinger-vedr-nationale-screeningsprogrammer.a_shx?la=da&amp;hash=D09671DC7A18EB5CF2BFDBFE382B684A7F330B24</a>,</p>	<p>Criteria for the assessment of population-orientated screening programmes:</p> <ul style="list-style-type: none"> <li>▪ The screening program must reduce the disease-specific mortality and or morbidity.</li> <li>▪ The condition being screened for must pose a significant health problem.</li> <li>▪ The natural history of the condition must be sufficiently known and the condition must or could be detected at a latent or asymptomatic stage.</li> <li>▪ The test methods used must be simple, safe, accurate, validated and acceptable.</li> <li>▪ Effective and acceptable methods of investigation and treatment must be found which gives better results if the condition is detected before it becomes symptomatic.</li> <li>▪ The benefit of the screening program must outweigh the potential harmful effects.</li> <li>▪ The autonomy and integrity of the individual must be respected with due regard to an overall recommendation to participate in the screening, and the program must, on the whole, provide a fair distribution of health services used.</li> <li>▪ The financial costs associated with the screening program shall be proportionate to the health benefits.</li> </ul>

Country	Criteria Listed
<p><b>Source(s)</b></p> <p>Last updated: November 2014</p> <p><i>*Document translated using Google Translate</i></p>	<ul style="list-style-type: none"> <li>▪ Invitation to the screening program should provide an understandable and nuanced information on the pros and cons of participation, must inform about opportunity to unsubscribe from the program as well as inform about alternatives to screening.</li> <li>▪ Monitoring and quality assurance of the screening program must be ensured with a clear placement of responsibilities in relation to the need for changes and settlement.</li> </ul>
<p><b>Finland</b></p> <p>The Ministry of Social Affairs and Health, <i>Screenings in Finland 2014 The present state of health care screenings and future prospects</i>, <a href="https://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/74717/STM_Screenings_i_finland_2014_Enkku_B5_nettiin.pdf">https://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/74717/STM_Screenings_i_finland_2014_Enkku_B5_nettiin.pdf</a>, Last updated: 2015</p>	<p>The criteria are based on the Wilson Jungner criteria for screening with additional considerations borrowed from the Danish Council of Ethics:</p> <ul style="list-style-type: none"> <li>▪ The condition should be an important health problem.</li> <li>▪ There should be a recognizable latent or early symptomatic stage.</li> <li>▪ The natural history of the condition, including development from latent to declared disease, should be adequately understood.</li> <li>▪ There should be a suitable test or examination, with an evaluated validity of the testing system, technical efficiency, and predictive value of test results.</li> <li>▪ The test should be acceptable to the population.</li> <li>▪ Prior to beginning screening, an evaluation must have been made of the ethical and psychological consequences for the examinees, stigmatisation, and the consequences of “false positive” and “false negative” test results.</li> <li>▪ There should be an agreed policy on whom to treat as patients.</li> <li>▪ There should be an accepted treatment for the patients with recognised disease.</li> <li>▪ Facilities for diagnosis and treatment should be available.</li> <li>▪ The screening organisation has been explained in detail, particularly the national and regional level, quality control and registration of results, provision of information to the target group, patient placement within the organisation (triage), personnel training and providing information and advice on test results.</li> <li>▪ The research and treatment costs incurred by screening have been described.</li> <li>▪ The impact of screening has been assessed.</li> <li>▪ Case-finding should be a continuing process and not a “once and for all” project.</li> </ul>

Country	Criteria Listed
Source(s)	<ul style="list-style-type: none"> <li>▪ 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.</li> </ul> <p><i>Additional criteria that the screening programme must specify:</i></p> <ul style="list-style-type: none"> <li>▪ The purpose of the screening and target population groups.</li> <li>▪ The party providing the screening services and the regional scope of the screening.</li> <li>▪ The suitability of the screening method.</li> <li>▪ The radiological equipment used in the screening and its suitability.</li> <li>▪ The personnel who are to carry out procedures involving radiation exposure, and their training.</li> <li>▪ Physicians who interpret the screening results, issue statements on them, and are responsible for confirmation examinations.</li> <li>▪ Quality assurance programme should be in place.</li> <li>▪ Monitoring of the equipment's condition and performance should occur.</li> <li>▪ Plan for implementing clinical audits.</li> <li>▪ Registering and reporting of screening data and results.</li> </ul>
<p><b>France</b></p> <p>Haute Autorité de Santé (High Authority of Health), <i>How to judge a proposal for a screening programme</i>, <a href="https://www.has-sante.fr/upload/docs/application/pdf/screening_practice_guide.pdf">https://www.has-sante.fr/upload/docs/application/pdf/screening_practice_guide.pdf</a> Last updated: May 2004</p>	<p>The criteria are based on Wilson and Jungner criteria and have been expanded to include American and Canadian standards.</p> <p><i>The disease:</i></p> <ul style="list-style-type: none"> <li>▪ Morbidity, mortality and socioeconomic impact.</li> <li>▪ Epidemiology and natural history of the disease, including latency periods, should be adequately understood.</li> <li>▪ Cost-effective primary prevention interventions should have been implemented as far as possible.</li> </ul> <p><i>The test:</i></p> <ul style="list-style-type: none"> <li>▪ A simple, reliable, reproducible and valid screening test should be available.</li> <li>▪ The test should be acceptable to the population.</li> </ul> <p><i>Diagnosis:</i></p>

Country	Criteria Listed
Source(s)	
	<ul style="list-style-type: none"> <li>▪ There should be an agreed policy within the scientific community on further diagnostic investigation of those persons with a positive test result and on what options are available to those individuals.</li> </ul> <p><i>Intervention:</i></p> <ul style="list-style-type: none"> <li>▪ There should be an effective intervention for patients identified early, and evidence of earlier intervention leading to better outcomes.</li> <li>▪ Agreed evidence based policies on which individuals may benefit from the intervention and on the appropriate intervention to be offered.</li> </ul> <p><i>Effectiveness and safety of the programme:</i></p> <ul style="list-style-type: none"> <li>▪ There should be evidence from high-quality RCTs or from an international consensus that the screening programme reduced morbidity or mortality.</li> <li>▪ Benefits of the screening programme should outweigh the harms.</li> </ul> <p><i>Economic assessment:</i></p> <ul style="list-style-type: none"> <li>▪ The screening programme should be cost effective compared to no screening or individual screening, or versus another health initiative.</li> </ul> <p><i>Screening programme prerequisites:</i></p> <ul style="list-style-type: none"> <li>▪ There should be a plan for managing and monitoring the screening programme and a set of recognised quality assurance standards.</li> <li>▪ Sufficient investment in staff, equipment, and other resources should be available prior to commencement of the screening programme.</li> <li>▪ All other options for managing the condition should have been considered.</li> <li>▪ Screening should be a continuous activity.</li> <li>▪ Awareness programmes should be organised for both intended recipients and health professionals to ensure the best information is widely diffused.</li> <li>▪ Lack of information on positive and negative aspects of screening is not ethically acceptable and it infringes upon the autonomy of the individual.</li> </ul>

Country Source(s)	Criteria Listed
	<ul style="list-style-type: none"> <li>▪ Individuals should remain free to accept or refuse the test, to ensure equity of access to screening.</li> </ul> <p><i>Follow up and appraisal:</i> A number of the appraisal criteria and indicators should be validated.</p>
<p><b>Germany</b></p> <p>1. Response to survey</p> <p>2. Gemeinsamer Bundesausschuss (The Federal Joint Committee), <i>Verfahrensordnung des Gemeinsamen Bundesausschusses*</i> <a href="https://www.g-ba.de/downloads/17-98-3562/Infoblatt_methodische-Anforderungen_2013-10-10.pdf">https://www.g-ba.de/downloads/17-98-3562/Infoblatt_methodische-Anforderungen_2013-10-10.pdf</a>: Last updated: 28 August 2021</p> <p><i>*Document translated using Google Translate</i></p>	<p>Criteria for assessment derive from a legal basis for assessment set out by the German parliament in the German Social Code, Book Five (SGB V) and the rules of procedure of the G-BA which include the standards of evidence-based medicine. The Institute for Quality and Efficiency in Health Care (IQWiG) is a functionally independent scientific institute that supports the G-BA in carrying out its statutory responsibilities by submitting scientific recommendations. It examines the benefits, harms, medical necessity and economic cost-effectiveness of medical services (including screening programmes).<sup>(1)</sup></p> <p>Criteria examined during evaluation and assessment process:<sup>(2)</sup></p> <p><i>Benefit considerations:</i></p> <ul style="list-style-type: none"> <li>▪ Efficacy with a view to patient-relevant endpoints such as morbidity, mortality and health-related quality of life for the indications.</li> <li>▪ Therapeutic consequence of a diagnostic method.</li> <li>▪ Weighing the benefits against the risk.</li> <li>▪ Assessments of desired and undesirable consequences.</li> <li>▪ Comparison of the above criteria with alternative methods of intervention or treatment.</li> </ul> <p><i>Medical necessity considerations:</i></p> <ul style="list-style-type: none"> <li>▪ Relevance of the medical problem for the patient.</li> <li>▪ Spontaneous course of the disease.</li> <li>▪ Are there therapeutic alternatives?</li> </ul> <p><i>Considerations of economic viability:</i></p> <ul style="list-style-type: none"> <li>▪ Cost estimate for use with individual patients.</li> <li>▪ Cost-benefit assessment in relation to the individual patient and to the totality of the insured population (including follow-up cost assessment).</li> </ul>



Country Source(s)	Criteria Listed
<p><b>Italy</b></p> <p>L'Osservatorio Nazionale Screening (The National Screening Observatory), <i>Raccomandazioni per la pianificazione e l'esecuzione degli screening di popolazione per la prevenzione del cancro della mammella, del cancro della cervice uterina e del cancro del colon retto*</i>, <a href="https://www.salute.gov.it/imgs/C_17_pubblicazioni_774_allegato.pdf">https://www.salute.gov.it/imgs/C_17_pubblicazioni_774_allegato.pdf</a>, Published: October 2006</p> <p><i>*Document translated using Google Translate</i></p>	<ul style="list-style-type: none"> <li>▪ Cost-benefit analysis compared to other methods.</li> </ul> <p><i>Requirements for a screening programme:</i></p> <ul style="list-style-type: none"> <li>▪ Constitutes a complex process organized in various phases.</li> <li>▪ Each stage is subject to quality control.</li> <li>▪ Involves multiple disciplines and professions.</li> <li>▪ Provides for a balance between positive and negative effects.</li> <li>▪ Must evaluate the costs, and then take them into account.</li> <li>▪ Must guarantee maximum equity, offering the possibility of a health gain to all citizens, regardless of their socio-cultural level and economic resources.</li> <li>▪ Considers important ethical aspects.</li> <li>▪ The condition is common enough to have a large social impact.</li> <li>▪ The condition has a long asymptomatic phase.</li> <li>▪ There is a test capable of detecting the condition at the asymptomatic phase.</li> <li>▪ There is a treatment which, if administered early, will improve the prognosis.</li> <li>▪ The benefit must outweigh the harm.</li> <li>▪ The implementation of the screening programme must be accompanied by adequate information.</li> <li>▪ The target population must be actively involved and informed about the benefits and possible risks of the screening programme.</li> <li>▪ The screening service must ensure adequate information on the results.</li> <li>▪ Epidemiological surveillance systems must be available to assess not only the health service, but also the participation and the impact on incidence mortality.</li> </ul>
<p><b>The Netherlands</b></p> <p>1. The Health Council of the Netherlands, <i>Screening: between</i></p>	<p><i>Criteria outlined by The Health Council of the Netherlands:<sup>(1)</sup></i></p> <ul style="list-style-type: none"> <li>▪ Screening must be focused on a significant health problem.</li> <li>▪ Benefit: it must be clearly established that early detection of the illness or condition in question (or: detection of medical conditions such as carrier status or risk factors) can lead to a significant reduction in the burden of disease in the target group in question, or to other</li> </ul>

Country	Criteria Listed
<p data-bbox="206 311 568 654"><b>Source(s)</b> <i>hope and hype</i>, <a href="https://www.healthcouncil.nl/documents/advisory-reports/2008/04/01/screening-between-hope-and-hype">https://www.healthcouncil.nl/documents/advisory-reports/2008/04/01/screening-between-hope-and-hype</a>, Published: April 2008</p> <p data-bbox="206 702 568 1117">2. National Institute for Public Health and the Environment: Ministry of Health, Welfare and Sport, <i>Policy Framework for Population Screening for Cancer</i> <a href="https://www.rivm.nl/bibliotheek/rapporten/2018-0042.pdf">https://www.rivm.nl/bibliotheek/rapporten/2018-0042.pdf</a>, Published: 2018</p>	<p data-bbox="685 351 1989 462">outcomes useful to the participants in the context of the medical problems to which the screening relates; these advantages must clearly outweigh the disadvantages that screening can always have (for themselves or for others).</p> <ul data-bbox="640 470 2027 774" style="list-style-type: none"> <li>▪ Reliable and valid instrument: the screening method must have a solid scientific basis and the quality of the various parts of the screening process must be guaranteed.</li> <li>▪ Respect for autonomy: participation in screening and follow-up tests must be based on an informed and free choice; supply and performance must respect patients' rights (in the case of services offered outside the healthcare system: consumers' rights).</li> <li>▪ Appropriate use of resources: the use of available healthcare resources in connection with and because of the programme must be clearly shown to be acceptable in terms of cost-effectiveness and justice.</li> </ul> <p data-bbox="589 813 1299 845">Based on Wilson and Jungner screening criteria:<sup>(2)</sup></p> <ul data-bbox="640 853 2027 1276" style="list-style-type: none"> <li>▪ The disease to be detected should be an important health problem.</li> <li>▪ There should be a generally accepted treatment for the disease.</li> <li>▪ Facilities for diagnosis and treatment should be available.</li> <li>▪ There should be a recognisable latent or early symptomatic stage of the disease.</li> <li>▪ There should be a reliable detection method.</li> <li>▪ The detection method should be acceptable to the population.</li> <li>▪ The natural course of the disease to be detected should be adequately understood.</li> <li>▪ There should be agreement on whom to treat.</li> <li>▪ The costs of detection, diagnostic tests and treatment should be acceptably in balance with the costs of medical care as a whole.</li> <li>▪ The process of detection should be a continuing process and not a "one-time only" project.</li> </ul> <p data-bbox="589 1284 1176 1316">Additional criteria by the WHO in 2008:<sup>(2)</sup></p> <ul data-bbox="640 1324 1904 1393" style="list-style-type: none"> <li>▪ The population screening programme should respond to a recognised need.</li> <li>▪ The objective of the population screening programme should be defined at the outset.</li> </ul>

Country	Criteria Listed
Source(s)	<ul style="list-style-type: none"> <li>▪ There should be a defined target population for the population screening programme.</li> <li>▪ There should be scientific evidence of population screening programme effectiveness.</li> <li>▪ The population screening programme should integrate education, training, testing, clinical services and programme management.</li> <li>▪ There should be quality assurance for the population screening programme to minimise the potential risks of screening.</li> <li>▪ The population screening programme should provide guarantees of informed choice and respect the privacy and autonomy of the individual.</li> <li>▪ Access to the population screening programme must be guaranteed for the entire target population.</li> <li>▪ Programme evaluation of population screening should be planned from the outset.</li> <li>▪ The benefits of the population screening programme should outweigh the possible disadvantages of the screening.<sup>(1)</sup></li> </ul> <p>Additionally the Netherlands refers to the Population Screening Act (WBO) when considering granting permits for screening in specific cases including:<sup>(2)</sup></p> <ul style="list-style-type: none"> <li>▪ Screening involving the use of ionizing radiation.</li> <li>▪ Screening for cancer.</li> <li>▪ Screening for diseases or conditions for which no treatment or prevention is possible.</li> </ul> <p>The WBO lists a range of conditions which must be adhered to in order to be granted a screening permit as well as conditions which may warrant the revocation of such permits.</p>
<p><b>New Zealand</b></p> <p>1. Response from survey</p> <p>2. National Health Committee, <i>Screening to</i></p>	<p><i>Criteria.</i><sup>(1,2)</sup></p> <p>The condition is a suitable candidate for screening.</p> <ul style="list-style-type: none"> <li>▪ There is a suitable test.</li> <li>▪ There is an effective and accessible treatment or intervention for the condition identified through early detection.</li> </ul>

Country	Criteria Listed
<p data-bbox="203 309 571 347"><b>Source(s)</b></p> <p data-bbox="203 352 571 735"><i>Improve Health in New Zealand: Criteria to assess screening programmes,</i> <a href="https://www.nsu.govt.nz/publications/screening-improve-health-new-zealand-criteria-assess-screening-programmes">https://www.nsu.govt.nz/publications/screening-improve-health-new-zealand-criteria-assess-screening-programmes</a>, Published: April 2003</p> <p data-bbox="203 778 571 1082">3. National Screening Unit, <i>Quality Framework 2015,</i> <a href="https://www.nsu.govt.nz/system/files/page/nsuqualityframework201514dec15.pdf">https://www.nsu.govt.nz/system/files/page/nsuqualityframework201514dec15.pdf</a> Published: December 2015</p>	<ul data-bbox="640 352 1995 655" style="list-style-type: none"> <li>▪ There is high-quality evidence, ideally from randomised controlled trials, that a screening programme is effective in reducing mortality or morbidity.</li> <li>▪ The potential benefit from the screening programme should outweigh the potential physical and psychological harm (caused by the test, diagnostic procedures and treatment).</li> <li>▪ The health care system will be capable of supporting all necessary elements of the screening pathway, including diagnosis, follow-up and programme evaluation.</li> <li>▪ There is consideration of social and ethical issues.</li> <li>▪ There is consideration of cost-benefit issues.</li> </ul> <p data-bbox="595 699 875 735"><i>Quality Principles:</i><sup>(3)</sup></p> <ul data-bbox="640 740 1995 1043" style="list-style-type: none"> <li>▪ The overall benefits of screening must outweigh the harm.</li> <li>▪ Screening programmes are people-centred.</li> <li>▪ Screening programmes will achieve equitable access to screening and equitable outcomes for all population groups.</li> <li>▪ Informed consent is a priority throughout the screening pathway.</li> <li>▪ Screening programmes are monitored and evaluated on a regular basis.</li> <li>▪ National screening programmes are committed to continuous quality improvement in programme management and clinical service delivery.</li> </ul> <p data-bbox="595 1048 2045 1123">Screening programmes in New Zealand should specifically consider the views and participation of Māori people.<sup>(2)</sup></p>
<p data-bbox="203 1128 297 1166"><b>Spain</b></p> <p data-bbox="203 1203 571 1394">La Comisión de Salud Pública (Commission for Public Health), <i>Documento marco sobre cribado poblacional*</i>,</p>	<p data-bbox="595 1128 2045 1203">Reference is made to Wilson and Jungner and updated WHO criteria with specific mention of screening of diseases with genetic origin.</p> <p data-bbox="595 1208 797 1246"><i>The condition:</i></p> <ul data-bbox="640 1251 1805 1394" style="list-style-type: none"> <li>▪ The condition should be a major health problem.</li> <li>▪ The condition should be well-defined and have a known natural history.</li> <li>▪ The condition should have a detectable latency period.</li> <li>▪ Cost-effective primary prevention interventions should already be implemented.</li> </ul>

Country	Criteria Listed
<p data-bbox="203 309 360 344"><b>Source(s)</b></p> <p data-bbox="203 352 566 576"><a href="https://www.mscbs.gob.es/profesionales/saludPublica/prevPromocion/Cribado/docs/Cribado_poblacional.pdf">https://www.mscbs.gob.es/profesionales/saludPublica/prevPromocion/Cribado/docs/Cribado_poblacional.pdf</a>, Published: 15 December 2010</p> <p data-bbox="203 624 533 695"><i>*Document translated using Google Translate</i></p>	<p data-bbox="591 352 719 379"><i>The test:</i></p> <ul data-bbox="636 392 1603 539" style="list-style-type: none"> <li>▪ The test should be simple and safe.</li> <li>▪ The test should be valid, reliable and efficient.</li> <li>▪ The test must be acceptable to the target population.</li> <li>▪ There should be criteria for the selection of mutations to include.</li> </ul> <p data-bbox="591 547 949 574"><i>Diagnosis and treatment:</i></p> <ul data-bbox="636 587 2018 772" style="list-style-type: none"> <li>▪ There must be scientific evidence on the diagnostic process and treatment.</li> <li>▪ There must be quality scientific evidence that therapeutic intervention in an asymptomatic phase is more effective than in a symptomatic phase in terms of reducing premature mortality and or increasing quality of life.</li> <li>▪ There must be optimised routine healthcare in place and available.</li> </ul> <p data-bbox="591 780 1077 807"><i>The overall screening programme:</i></p> <ul data-bbox="636 820 1648 1082" style="list-style-type: none"> <li>▪ Evidence of efficacy should be clearly demonstrated.</li> <li>▪ The benefit should outweigh the potential risks.</li> <li>▪ There should be a well-defined target population.</li> <li>▪ Costs should be economically balanced.</li> <li>▪ The programme must be clinically, socially, and ethically acceptable.</li> <li>▪ Evaluation and quality.</li> <li>▪ The programme must be feasible within the national health system.</li> </ul> <p data-bbox="591 1129 1827 1157">The document also lists requirements for the implementation of screening programmes:</p> <ul data-bbox="636 1169 1525 1391" style="list-style-type: none"> <li>▪ population coverage and equity</li> <li>▪ operational planning and co-ordination</li> <li>▪ programme information system</li> <li>▪ informed decision</li> <li>▪ protection of personal data and guarantee of confidentiality</li> <li>▪ evaluation and quality plan</li> </ul>

Country Source(s)	Criteria Listed
<p><b>Sweden</b></p> <p>1. Response to survey.</p> <p>2. Socialstyrelsen (The National Board of Health and Welfare), <i>Nationella screeningprogram: Modell för bedömning, införande och uppföljning *</i>, <a href="https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/nationella-screeningprogram/2019-4-12.pdf">https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/nationella-screeningprogram/2019-4-12.pdf</a>, Last updated: April 2019</p> <p><i>*Document translated using Google Translate</i></p>	<ul style="list-style-type: none"> <li>▪ training for health professionals, social and media education.</li> </ul> <p>There are 15 criteria that are based on the WHO criteria for screening programmes with modifications for the Swedish context:<sup>(1,2)</sup></p> <ul style="list-style-type: none"> <li>▪ The condition must be an important health problem.</li> <li>▪ The natural course of the disease must be understood.</li> <li>▪ There should be a latent stage of the disease where it can be detected.</li> <li>▪ There must be an appropriate test.</li> <li>▪ There must be treatment for the condition which gives better effect at an earlier stage than at clinical detection.</li> <li>▪ The screening programme shall reduce mortality, morbidity or disability that is associated with the condition.</li> <li>▪ The test method should be acceptable by the intended population.</li> <li>▪ Treatment for the condition or illness must be clarified and accepted by the intended population.</li> <li>▪ Health benefits should outweigh the harms of the screening programme.</li> <li>▪ The screening programme must be acceptable from an ethical perspective.</li> <li>▪ The cost-effectiveness of the screening program should be valued and evaluated as reasonable.</li> <li>▪ Information about participation in the screening programme should be evaluated.</li> <li>▪ Organizational aspects to ensure a nationally equivalent screening programme should be clarified.</li> <li>▪ The feasibility and resources needed for the screening programme should be evaluated.</li> <li>▪ There should be a plan to evaluate the effects of the screening programme.</li> </ul>
<p><b>Switzerland</b></p>	<p><i>No information identified using search methodology applied in this review</i></p>
<p><b>United Kingdom</b></p>	<p>These criteria reference the Wilson and Jungner criteria. <i>The condition</i></p>

Country	Criteria Listed
<p><b>Source(s)</b></p> <p>UK National Screening Committee, <i>Criteria for appraising the viability, effectiveness and appropriateness of a screening programme</i>, <a href="https://www.gov.uk/government/publications/evidence-review-criteria-national-screening-programmes/criteria-for-appraising-the-viability-effectiveness-and-appropriateness-of-a-screening-programme">https://www.gov.uk/government/publications/evidence-review-criteria-national-screening-programmes/criteria-for-appraising-the-viability-effectiveness-and-appropriateness-of-a-screening-programme</a>, Last updated: October 2015</p>	<ul style="list-style-type: none"> <li>▪ The condition should be an important health problem as determined 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. There should be robust evidence about the association between the risk marker and disease.</li> <li>▪ Cost-effective primary prevention interventions should have been implemented as far as practicable.</li> <li>▪ If carriers of a mutation are identified as a result of screening the natural history of people with this status should be understood, including any psychological implications.</li> </ul> <p><i>The test</i></p> <ul style="list-style-type: none"> <li>▪ There should be a safe, simple, precise and validated screening test.</li> <li>▪ The distribution of test values in the target population should be known and a suitable cut-off level defined and agreed.</li> <li>▪ The test should be acceptable to the target population.</li> <li>▪ 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.</li> <li>▪ 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.</li> </ul> <p><i>The intervention</i></p> <ul style="list-style-type: none"> <li>▪ 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. Where there is no benefit for the individual screened then the screening programme should not be further considered.</li> <li>▪ There should be agreed evidence based policies covering which individuals should be offered interventions and the appropriate intervention to be offered.</li> </ul> <p><i>The screening programme</i></p>

Country	Criteria Listed
Source(s)	
	<ul style="list-style-type: none"> <li>▪ 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 outcome must be of value and readily understood by the individual being screened.</li> <li>▪ There should be evidence that the complete screening programme is clinically, socially and ethically acceptable to health professionals and the public.</li> <li>▪ The benefit gained by individuals from the screening programme should outweigh any harms, such as over-diagnosis, over-treatment, false positives, false negatives, uncertain findings or complications.</li> <li>▪ The opportunity cost of the screening programme should be economically balanced in relation to expenditure on medical care as a whole. Assessment against this criteria should have regard to evidence from cost benefit and or cost-effectiveness analysis and have regard to the effective use of available resources.</li> </ul> <p><i>Implementation criteria</i></p> <ul style="list-style-type: none"> <li>▪ Clinical management of the condition and patient outcomes should be optimised in all health care providers prior to participation in a screening programme.</li> <li>▪ All other options for managing the condition should have been considered, to ensure that no more cost effective intervention could be introduced or current interventions increased within the resources available.</li> <li>▪ There should be a plan for managing and monitoring the screening programme and an agreed set of quality assurance standards.</li> <li>▪ Adequate staffing and facilities for testing, diagnosis, treatment and programme management should be available prior to the commencement of the screening programme.</li> </ul>



Country Source(s)	Criteria Listed
	<ul style="list-style-type: none"> <li>▪ 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.</li> <li>▪ 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.</li> </ul>
<p><b>United States</b></p> <p>U.S. Preventative Services Task Force, <i>Procedure manual</i>, <a href="https://www.uspreventiveservicestaskforce.org/uspstf/sites/default/files/inline-files/procedure-manual-2021_0.pdf">https://www.uspreventiveservicestaskforce.org/uspstf/sites/default/files/inline-files/procedure-manual-2021_0.pdf</a>, Last updated: May 2021</p>	<p><i>General principles for making recommendations:</i></p> <ul style="list-style-type: none"> <li>▪ All recommendations are based on a body of scientific evidence that is derived from systematic evidence reviews and can use modelling to inform the process and make decisions after full consideration of the certainty and magnitude of net benefit.</li> <li>▪ Evidence may come from indirect evidence in the analytic framework, but ultimately the complete chain (linking populations with health outcomes) must be supported by acceptable evidence.</li> <li>▪ Inferences about supporting evidence can include generalizations from one population to other subgroups when there are acceptable grounds to assume the evidence is applicable to both.</li> <li>▪ The Task Force invites and considers the opinions of the public and experts throughout the recommendation development process, including the draft evidence review and the draft recommendation statement. The Task Force is particularly interested in receiving comments on the sufficiency of the systematic review process and interpretation of the body of evidence. However, expert opinion and clinical experience cannot substitute for the body of evidence that the Task Force reviews through a systematic process.</li> <li>▪ Recommendations describe services that should or should not be routinely offered based on scientific evidence, although it is recognized that in clinical practice and public policy, concerns other than scientific evidence (e.g., feasibility, public expectations) may take precedence.</li> <li>▪ When making recommendations, the Task Force considers most strongly patient-oriented health benefits and harms.</li> </ul>

Country	Criteria Listed
Source(s)	
	<ul style="list-style-type: none"> <li>▪ In assessing health benefits, outcomes that patients can feel or care about (e.g., pain, quality of life, disease specific death, overall mortality) receive more weight than intermediate outcomes.</li> <li>▪ In judging the magnitude of benefit, absolute reductions in risk matter more than relative risk reductions.</li> <li>▪ Evidence for service effectiveness is considered as valuable as, if not more valuable than, efficacy. The ability of patients, providers, and the health care system to perform or maintain interventions over time is considered. The direct and indirect harms of preventive services must also be considered, ensuring that they do not outweigh the benefits to the individual and/or population. The quality of evidence for harms need not be as strong as that for benefits because of the ethical imperative to do no harm, especially when caring for asymptomatic persons. Physical, psychological, and social harms are considered.</li> <li>▪ Judgments about trade-offs between benefits and harms are generally made at the population level. For interventions where the relationship between benefits and harms is influenced heavily by personal preferences, the Task Force advocates that providers and patients engage in shared decision-making.</li> <li>▪ Consideration of benefits and harms should not be limited to the perspective of individuals but should also consider population effects (e.g., population attributable risk, decreased exposure to infectious diseases, herd immunity).</li> <li>▪ The USPSTF does not consider the financial costs of providing a service in its assessment of the balance of benefits and harms, but may provide contextual information regarding costs for use by providers, including cost-effectiveness studies.</li> <li>▪ Recommendations apply only to persons without signs or symptoms of the condition for which the preventive service is intended.</li> <li>▪ Persons living in the United States are the target population for all recommendation statements. The evidence reviews and recommendations may be useful in other countries, but</li> </ul>

Country	Criteria Listed
Source(s)	<p>may not apply to populations with markedly different epidemiology and health care system design.</p> <ul style="list-style-type: none"><li>▪ Recommendations apply only to preventive services that are delivered in or are referable from the primary care setting to a specialist or community resource.</li><li>▪ The evidence for preventive services delivered outside the primary care context (e.g., programs at schools, worksites, public health sites) is usually out of scope unless these services are linked to primary care.</li></ul>

## Appendix 1.2 - Overview of bodies with responsibility for screening policy-making

### Appendix 1.2. Overview of bodies with responsibility for screening policy-making

Country	Responsibility for screening (hierarchy if applicable)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<b>Australia</b>  1. Response to survey  2. Australian Health Minister's Advisory Council, <i>Population Based Screening Framework</i> , <a href="https://www.health.gov.au/sites/default/files/documents/2019/09/population-based-screening-framework_0.pdf">https://www.health.gov.au/sites/default/files/documents/2019/09/population-based-screening-framework_0.pdf</a> , Last updated: August 2018	Policy making and decision-making is shared between the Commonwealth Government and state and territory governments for Australia's breast cancer screening programme, BreastScreen Australia.  The Commonwealth Minister for Health and Aged Care has decision-making responsibility for Australia's cervical and bowel cancer screening programmes. <sup>(1)</sup>  Assessments of screening programmes are undertaken by the policy- and decision-makers for each of the screening programs; there is no overarching body responsible for population	In line with Australian constitution. <sup>(1)</sup>	Criteria outlined in Table 1 are used to prompt assessment of <i>ethical issues</i> . <i>Ethical values and principles</i> are detailed in the criteria outlined in Table 1 and include: <sup>(1)</sup> <ul style="list-style-type: none"> <li>▪ <i>Principles of access and equity</i> underpin Australia's population-based screening programmes.</li> <li>▪ Decisions are made under the ethical obligation to maximise benefits and minimise harms.</li> <li>▪ <i>A key principle</i> is that when community resources are used to fund screening there should be community consensus that the benefits of screening justify the expense.</li> <li>▪ Additional <i>ethical values and principles</i> include informed consent.</li> </ul> Criteria in Table 1: <sup>(2)</sup> <ul style="list-style-type: none"> <li>▪ Benefits of screening, described as the levels of morbidity and mortality that can be prevented, should</li> </ul>	<ul style="list-style-type: none"> <li>▪ Transparency</li> <li>▪ Accountability.</li> </ul>

Country Source(s)	Responsibility for screening (hierarchy if applicable)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
	screening governance or ethics. <sup>(1)</sup>		<p>outweigh the harms and costs, such as anxiety, discomfort, adverse effects, social, cultural, ethical or legal harms, follow-up investigations, over-diagnosis and possible over-treatment.</p> <ul style="list-style-type: none"> <li>▪ The test should be acceptable to the target population.</li> <li>▪ Respect for people’s concerns, their right to make choices, their privacy and confidentiality.</li> <li>▪ Equity of access to the test.</li> <li>▪ Ensure informed choice, confidentiality and respect for autonomy.</li> </ul>	
<p><b>Australia NBS</b></p> <p>1. Response to survey</p> <p>2. Australian Health Minister’s Advisory Council, <i>Newborn Bloodspot Screening</i></p>	<p>Australian states and territories are policy and decision makers for their respective newborn bloodspot screening and newborn hearing screening programmes.</p> <p>Assessments of screening programmes are undertaken by the policy- and decision-makers for each of the</p>	<p>In line with Australian constitution.<sup>(1)</sup></p>	<p><i>Guiding Principles:</i></p> <ul style="list-style-type: none"> <li>▪ NBS programmes work well and protect babies from the effects of life-limiting conditions.</li> <li>▪ Any future developments should be focused on conditions and should not be driven by technology.</li> <li>▪ Screening must remain high-quality and safe.</li> <li>▪ Families should remain the central focus of the programme.</li> <li>▪ Informed consent should be ensured.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Transparency</li> <li>▪ Accountability.</li> </ul>

Country Source(s)	Responsibility for screening (hierarchy if applicable)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<p><i>National Policy Framework</i>,  <a href="https://www.health.gov.au/sites/default/files/documents/2020/10/newborn-bloodspot-screening-national-policy-framework.pdf">https://www.health.gov.au/sites/default/files/documents/2020/10/newborn-bloodspot-screening-national-policy-framework.pdf</a>,                      Last updated: May 2018</p>	<p>screening programs; there is no overarching body responsible for population screening governance or ethics.<sup>(1)</sup></p>			
<p><b>Belgium – Flanders</b></p> <p>1. The Flemish Government,  <i>Besluit van de Vlaamse Regering betreffende bevolkingsonderzoek in het kader van ziektepreventie*</i></p>	<p>A screening population working group provides advice to the Flemish government.</p>	<p><i>No information identified using search methodology applied in this review</i></p>	<p>As per criteria listed.</p> <p><i>Core principles and principles of social and fair action</i> further listed within code of ethics for health promotion and disease prevention:<sup>(2)</sup></p> <ul style="list-style-type: none"> <li>▪ reducing inequalities</li> <li>▪ empowerment</li> <li>▪ access</li> <li>▪ community-oriented</li> <li>▪ autonomy</li> <li>▪ independence</li> <li>▪ non-discrimination</li> </ul>	<p><i>Principles of deontological action.</i><sup>(2)</sup></p> <ul style="list-style-type: none"> <li>▪ transparency</li> <li>▪ accountability</li> <li>▪ responsibility.</li> </ul>

Country Source(s)	Responsibility for screening (hierarchy if applicable)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<p>1. <a href="https://codex.vlaanderen.be/Portals/Codex/documenten/1017595.html">https://codex.vlaanderen.be/Portals/Codex/documenten/1017595.html</a>, Published: December 2008</p> <p>2. Vlaams Instituut Gezond Leven (Flemish Institute of Healthy Living), <i>Ethische Code - voor de sector gezondheidsbevordering en ziektepreventie in Vlaanderen*</i>, <a href="https://borstkankeerbevolkingsonderzoek.be/sites/default/files/atoms/files/ethische%20code.pdf">https://borstkankeerbevolkingsonderzoek.be/sites/default/files/atoms/files/ethische%20code.pdf</a></p>			<ul style="list-style-type: none"> <li>avoiding stigmatisation, negative stereotyping, victim blaming, and guilt induction.</li> </ul>	

Country Source(s)	Responsibility for screening (hierarchy if applicable)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<i>*Document translated using Google Translate</i>				
<b>Belgium – Wallonia</b>  Response to survey	The Minister of Health, supported by his administration, has responsibility for policy-making in relation to population-based screening programmes.	<i>No information identified using search methodology applied in this review</i>	<ul style="list-style-type: none"> <li>▪ Accessible to the greatest number of people.</li> <li>▪ Weigh the benefits and harms.</li> <li>▪ Invitation lists where people already treated or in remission are excluded (to reduce the psychological impact).</li> <li>▪ Positive screening results are communicated by a doctor.</li> </ul>	<i>No information identified using search methodology applied in this review</i>
<b>Canada Alberta</b>  Alberta Health Services, <i>Newborn Screening</i> , <a href="https://www.albertahealthservices.ca/services/Package16749.aspx">https://www.albertahealthservices.ca/services/Package16749.aspx</a> , Last updated: 2021	Alberta Health Services are responsible for delivering screening programmes within Alberta. <sup>(1)</sup>	<i>No information identified using search methodology applied in this review</i>	<i>No information identified using search methodology applied in this review</i>	<i>No information identified using search methodology applied in this review</i>



Country Source(s)	Responsibility for screening (hierarchy if applicable)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<p><b>Canada</b> <b>Ontario</b></p> <p>1. Newborn Screening Ontario, <i>NSO Governance</i>, <a href="https://www.newbornscreening.on.ca/en/about-nso/nso-governance">https://www.newbornscreening.on.ca/en/about-nso/nso-governance</a>, last updated: unclear</p> <p>2. Government of Ontario, <i>Ontario Breast Screening Program</i>, <a href="https://www.ontario.ca/page/ontario-breast-screening-program">https://www.ontario.ca/page/ontario-breast-screening-program</a>, Last</p>	<p>Government of Ontario is responsible for screening and has oversight of groups that manage screening activities.<sup>(1, 2)</sup></p> <p>Screening programmes are managed by specific groups such as Newborn Screening Ontario<sup>(1)</sup> and Ontario Breast Screening Programme.<sup>(2)</sup></p>	<p><i>No information identified using search methodology applied in this review</i></p>	<p>The review form includes questions that include an ethical dimension linked to the criteria listed including acceptability, balance of benefit and harm, resource use.<sup>(3)</sup></p>	<p><i>No information identified using search methodology applied in this review</i></p>

Country Source(s)	Responsibility for screening (hierarchy if applicable)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<p>updated: August 2021</p> <p>3. Newborn Screening Ontario, <i>Full review form for a condition considered for addition to the screening panel</i>, <a href="https://www.newbornscreening.on.ca/sites/default/files/form_3_blank.pdf">https://www.newbornscreening.on.ca/sites/default/files/form_3_blank.pdf</a>, Last updated: unclear</p>				
<p><b>Canada Quebec</b></p> <p>1. Ministère de la Santé et des Services sociaux (Ministry of Health and</p>	<p>Primary responsibility for the coordination and management of screening services belongs to the Ministry of Health and Social Services (MSSS).<sup>(1)</sup></p> <p>MSSS has responsibility for</p>	<p>An evaluation of a public health intervention is made on the judgement of what value it provides to the</p>	<p><i>Five considerations of the value of an intervention:</i><sup>(2)</sup></p> <ul style="list-style-type: none"> <li>▪ It improves the health and well-being of users.</li> <li>▪ It contributes to a better state of health and well-being for the population with a concern for equity.</li> </ul>	<p><i>MSSS and INESSS values:</i><sup>(2,3)</sup></p> <ul style="list-style-type: none"> <li>▪ excellence</li> <li>▪ independence</li> <li>▪ openness</li> <li>▪ scientific rigour</li> <li>▪ transparency</li> <li>▪ probity</li> </ul>

Country Source(s)	Responsibility for screening (hierarchy if applicable)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<p>Social Services), <i>L'organisation et ses engagements*</i>, <a href="https://www.gouv.qc.ca/gouv/ministere/sante-services-sociaux/mission-et-mandats">https://www.gouv.qc.ca/gouv/ministere/sante-services-sociaux/mission-et-mandats</a></p> <p>2. Institut National d'Excellence en Santé et en Services Sociaux (National Institute of Excellence in Health and Social Services), <i>Énoncé de Principes et Fondements Éthiques*</i>, <a href="https://www.ine.sss.qc.ca/filead">https://www.ine.sss.qc.ca/filead</a></p>	<p>policy-making and decision-making process in relation to population-based screening programmes.<sup>(3)</sup> Expert bodies provide evidence and advice to the MSSS:</p> <p>Institut National De Santé Publique du Québec (INSPQ) is a centre of expertise and reference publishing reports on various public health interventions, including screening programmes.</p> <p>Institut National d'Excellence en Santé et en Services Sociaux (INESSS) carries out health technology assessments.<sup>(2)</sup></p> <p>The MSSS also appoints an advisory committee to advise on the evolution and follow-up of a programme.<sup>(3)</sup> For example, the "comité</p>	<p>Quebec context in terms of its contribution to the health and social services system with regards to clinical, population and economic considerations.</p> <p>This judgement of value is based around five principles outlined in the next column.<sup>(2)</sup></p> <p>All the clinicians, experts and professionals that are involved are</p>	<ul style="list-style-type: none"> <li>▪ It optimises the use of resources for their responsible and sustainable management.</li> <li>▪ It fits into the organisational context of care and services in a way that helps strengthen the system health and social services.</li> <li>▪ It fits into the context of Quebec society in a way that promotes its development towards the common good.</li> </ul>	<ul style="list-style-type: none"> <li>▪ fairness towards those who use health and social services.</li> </ul>

Country Source(s)	Responsibility for screening (hierarchy if applicable)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<p><a href="#">min/doc/INESSS/DocuAdmin/INESSS-Enonce-de-principes-2021_VF.pdf</a>, Last updated: June 2021</p> <p>3. Ministère de la Santé et des Services sociaux (Ministry of Health and Social Services), <i>Response to survey</i></p> <p>*Translated using Google Translate</p>	<p>consultative sur le programme Québécois de dépistage neonatal sanguine et urinaire" (CCPQDNSU) composed of clinicians, laboratories specialists and public health experts has an advisory role in the blood and urine newborn screening programme. Advice is provided on broad parameters of the programme defined by the Terms of Reference and supports the MSSS in the implementation and updating of these parameters, including the list of detected diseases.<sup>(3)</sup></p>	<p>bound by deontology code.<sup>(3)</sup></p>		
<p><b>Denmark</b></p> <p>Sundhedsstyrelsen (The National Board of Health),</p>	<p>The National Board of Health has responsibility for the management and recommendations for implementation and or updating of screening</p>	<p>Central duty and utility ethics.</p>	<p><i>Ethical Considerations:</i></p> <ul style="list-style-type: none"> <li>▪ self-determination and informed free choice</li> <li>▪ stigmatisation</li> <li>▪ fair distribution of healthcare services.</li> </ul>	<p><i>No information identified using search methodology applied in this review</i></p>

Country Source(s)	Responsibility for screening (hierarchy if applicable)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<p><i>Anbefalinger vedrørende nationale screeningsprogrammer*</i>,  <a href="https://www.sst.dk/-/media/Udgivelses/2014/Rapport_Sundhedsstyrelsens-anbefalinger-vedr-nationale-screeningsprogrammer.ashx?language=da&amp;hash=D09671DC7A18EB5CF2BFDBFE382B684A7F330B24">https://www.sst.dk/-/media/Udgivelses/2014/Rapport_Sundhedsstyrelsens-anbefalinger-vedr-nationale-screeningsprogrammer.ashx?language=da&amp;hash=D09671DC7A18EB5CF2BFDBFE382B684A7F330B24</a>  , Last updated: November 2014</p> <p><i>*Document translated using Google Translate</i></p>	<p>programmes in Denmark.</p> <p>The Advisory Committee for National Screening Programs provides advice to the National Board of Health in the following areas:</p> <ul style="list-style-type: none"> <li>▪ The screening area in general.</li> <li>▪ The basis for deciding to assess a national screening programme.</li> <li>▪ The introduction of new national screening programmes.</li> <li>▪ Existing national screening programmes.</li> </ul>			
<b>Finland</b>	The Government Screening	<i>No information</i>	<i>Screening principles:</i>	<i>No information identified</i>

Country Source(s)	Responsibility for screening (hierarchy if applicable)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<p>The Ministry of Social Affairs and Health, <i>Screenings in Finland 2014 The present state of health care screenings and future prospects</i>, <a href="https://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/74717/STM_Screenings_i_finland_2014_Enkku_B5_netiiin.pdf">https://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/74717/STM_Screenings_i_finland_2014_Enkku_B5_netiiin.pdf</a>, Last updated: 2015</p>	<p>Decree states what national screening programmes are required to be offered by municipalities. Each municipality is responsible for the organisation and management of screening services.</p> <p>The National Institute for Health and Welfare has responsibility for monitoring and evaluating ongoing screening programmes.</p> <p>Ministry for Social Affairs and Health established a working group to assess screening programmes that makes recommendations to the Ministry. The Ministry makes decisions on screening programmes.</p>	<p><i>identified using search methodology applied in this review</i></p>	<ul style="list-style-type: none"> <li>▪ Treatments should promote health and be ethically acceptable.</li> <li>▪ Participation in the screening programme must be voluntary.</li> <li>▪ Inhabitants of municipalities should have access to sufficient information on the objectives and effectiveness of the screening programme.</li> </ul>	<p><i>using search methodology applied in this review</i></p>
<p><b>France</b> Haute Autorité</p>	<p>The HAS is responsible for the appraisal of screening programmes, while local</p>	<p>The HAS also outlines the EUnetHTA HTA</p>	<p>The HAS lists the following <i>principles</i>:</p> <ul style="list-style-type: none"> <li>▪ beneficence and non-maleficence</li> <li>▪ respect for autonomy</li> </ul>	<p><i>Process values:</i></p> <ul style="list-style-type: none"> <li>▪ independence and impartiality</li> </ul>

Country Source(s)	Responsibility for screening (hierarchy if applicable)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<p>de Santé (High Authority of Health), <i>Assessment of ethical aspects</i>, <a href="https://www.has-sante.fr/upload/docs/application/pdf/2014-11/assessment_of_ethical_aspects.pdf">https://www.has-sante.fr/upload/docs/application/pdf/2014-11/assessment_of_ethical_aspects.pdf</a> Last updated: April 2013</p>	<p>authorities are responsible for the implementation of screening programmes.</p>	<p>Core Model® as a reference model.</p> <p>Makes some reference to the principlism of Beauchamp and Childress.</p>	<ul style="list-style-type: none"> <li>▪ justice.</li> </ul> <p>Document outlines other ethical principles that could be considered to address ethical questions:</p> <ul style="list-style-type: none"> <li>▪ respect for dignity, integrity and vulnerability.</li> </ul> <p><i>Ethical aspects</i> This covers both ethical issues raised by a given health technology and also by its implementation.</p>	<ul style="list-style-type: none"> <li>▪ scientific rigour</li> <li>▪ multidisciplinary approach.</li> </ul>
<p><b>Germany</b></p> <p>1. Response to survey</p> <p>2. Gemeinsamer Bundesausschuss (The Federal Joint Committee),</p>	<p>The Federal Joint Committee (G-BA).<sup>(1, 2)</sup></p> <p>The G-BA can commission the Institute for Quality and Efficiency in Health Care (IQWiG) to conduct an assessment of available evidence for a screening initiative.<sup>(1, 2)</sup> The Federal</p>	<p><i>No information identified using search methodology applied in this review</i></p>	<p>The following are considered:</p> <ul style="list-style-type: none"> <li>▪ Patients should be examined and treated according to the best standard of care.<sup>(1, 2)</sup></li> <li>▪ Balance benefit, quality and economy.<sup>(1, 2)</sup></li> <li>▪ Benefits should be weighed up against harms.<sup>(1, 2)</sup></li> </ul>	<ul style="list-style-type: none"> <li>▪ standardised processes</li> <li>▪ transparently documented process.<sup>(1, 2)</sup></li> </ul>

Country Source(s)	Responsibility for screening (hierarchy if applicable)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<p><i>Bewertung neuer Untersuchungs- und Behandlungsmethoden für die ambulante und oder stationäre Versorgung*</i>, <a href="https://www.g-ba.de/themen/methodenbewertung/bewertung">https://www.g-ba.de/themen/methodenbewertung/bewertung</a> = <a href="https://www.g-ba.de/themen/methodenbewertung/bewertung">erprobung/ambulant-stationaer/</a>, Last updated: unclear</p> <p>3. Gemeinsamer Bundesausschuss (The Federal Joint Committee), <i>Decisions on Healthcare</i></p>	<p>Ministry of Health (BMG) has legal supervision over the G-BA. The G-BA submits its directives to the BMG for an examination of their legality.</p>			



Country Source(s)	Responsibility for screening (hierarchy if applicable)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<p><i>Benefits,</i>  <a href="https://www.g-ba.de/downloads/17-98-3769/2018-12-12_G-Ba_Infobrosch%C3%BCre_EN_bf.pdf">https://www.g-ba.de/downloads/17-98-3769/2018-12-12_G-Ba_Infobrosch%C3%BCre_EN_bf.pdf</a>, Last updated: December 2018</p> <p><i>*Document translated using Google Translate</i></p>				
<p><b>Italy</b></p> <p>L'Osservatorio Nazionale Screening (The National Screening Observatory), <i>Raccomandazioni per la</i></p>	<p>Ministry of Health and L'Osservatorio nazionale screening</p>	<p><i>No information identified using search methodology applied in this review</i></p>	<p><i>No information identified using search methodology applied in this review</i></p>	<p><i>No information identified using search methodology applied in this review</i></p>

Country	Responsibility for screening (hierarchy if applicable)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<p><i>pianificazione e l'esecuzione degli screening di popolazione per la prevenzione del cancro della mammella, del cancro della cervice uterina e del cancro del colon retto*</i>,  <a href="https://www.salute.gov.it/imgs/C_17_pubblicazioni_774_allegato.pdf">https://www.salute.gov.it/imgs/C_17_pubblicazioni_774_allegato.pdf</a>,            Published: October 2006</p> <p><i>*Document translated using Google Translate</i></p>				
<b>The Netherlands</b>	Ministry of Health Welfare and Sport. <sup>(1)</sup>	<i>No information identified using search</i>	<i>Criteria</i> that apply to all screening programmes: <ul style="list-style-type: none"> <li>▪ scientific validity</li> </ul>	<i>No information identified using search methodology applied in</i>

Country Source(s)	Responsibility for screening (hierarchy if applicable)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<p>1. Response to Survey</p> <p>2. National Institute for Public Health and the Environment: Ministry of Health, Welfare and Sport, <i>Policy framework for population screening for cancer</i>, <a href="https://www.rivm.nl/bibliotheek/rapporten/2018-0042.pdf">https://www.rivm.nl/bibliotheek/rapporten/2018-0042.pdf</a>, Published: 2018</p>	<p>The Health Council of the Netherlands and the Netherlands Organisation for Health Research and Development (ZonMw) have a mainly preparatory role, for new population screening programmes and far-reaching changes to the existing programmes.<sup>(2)</sup></p> <p>The RIVM-CvB issues advice about the setting up and aspects of implementation of a new screening programme.<sup>(2)</sup></p> <p>The Ministry of Health, Welfare and Sport (VWS) has the responsibility for final decision-making.<sup>(2)</sup></p> <p>The Healthcare Inspectorate (IGZ) has a supervisory role.<sup>(2)</sup></p>	<p><i>methodology applied in this review</i></p>	<ul style="list-style-type: none"> <li>▪ compliance with legal rules for medical action</li> <li>▪ benefit and risk</li> <li>▪ importance for public health.</li> </ul> <p><i>Public values:</i></p> <ul style="list-style-type: none"> <li>▪ quality</li> <li>▪ accessibility</li> <li>▪ affordability</li> <li>▪ involvement of society.<sup>(1)</sup></li> </ul>	<p><i>this review</i></p>
<p><b>New Zealand</b></p>	<p>National Screening Unit (NSU) is responsible for the</p>	<p><i>No information identified using</i></p>	<p><i>Concepts</i> such as informed consent, appropriate balance of harms and benefits</p>	<p>The following examples are described under the</p>

Country Source(s)	Responsibility for screening (hierarchy if applicable)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<p>1. Response to survey.</p> <p>2. National Screening Advisory Committee (NSAC), <i>Terms of Reference</i>, <a href="https://www.nsu.govt.nz/system/files/page/nsac-terms-of-reference-november-2020.pdf">https://www.nsu.govt.nz/system/files/page/nsac-terms-of-reference-november-2020.pdf</a> Last updated: November 2020</p> <p>3. National Screening Unit, <i>Quality Framework 2015</i>, <a href="https://www.nsu.govt.nz/system/files/page/ns">https://www.nsu.govt.nz/system/files/page/ns</a></p>	<p>development, management and monitoring of national population-based screening.<sup>(2)</sup></p> <p>The NSAC is responsible for making assessments and recommendations in relation to new and existing screening programmes.<sup>(2)</sup></p> <p>Accountability for screening programme decisions remains with the Ministry of Health<sup>(2)</sup></p>	<p><i>search methodology applied in this review</i></p>	<p>have always been considered in the context of NZ's screening programmes. In more recent years there has been increased demonstration of the importance of fairness and equity, with the Government's duty to meet its obligations under New Zealand's Treaty of Waitangi paramount.<sup>(1)</sup></p> <p><i>Quality principles:</i><sup>(3)</sup></p> <ul style="list-style-type: none"> <li>▪ The overall benefits, such as reductions in morbidity and mortality, of screening must outweigh the harms, including potential physical and psychological harms caused by the test, diagnostic procedures or treatment.</li> <li>▪ Screening should be people-centred and acceptable to individuals, whanau and the populations being screened.</li> <li>▪ Screening programmes will achieve equitable access and equitable outcomes for all groups.</li> <li>▪ Informed consent is a priority throughout the screening pathway.</li> <li>▪ Screening programmes are monitored and evaluated on a regular basis.</li> </ul>	<p>six <i>quality principles</i>:<sup>(3)</sup></p> <ul style="list-style-type: none"> <li>▪ Accountability of policy makers, providers and all individuals involved in screening programmes and responsibility to deliver screening programmes of the highest quality.</li> <li>▪ Quality assurance.</li> <li>▪ Provision of full information.</li> <li>▪ Transparency around significant decisions.</li> </ul> <p>Examples of <i>procedural values</i>:<sup>(1)</sup></p> <ul style="list-style-type: none"> <li>▪ transparency</li> <li>▪ rigour</li> <li>▪ Māori consultation.</li> </ul> <p><i>Attributes of clinical governance</i>:<sup>(3)</sup></p>

Country Source(s)	Responsibility for screening (hierarchy if applicable)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<a href="#">uqualityframework201514dec15.pdf</a> Published: December 2015			<ul style="list-style-type: none"> <li>▪ National screening programmes are committed to continuous quality improvement in programme management and clinical service delivery.</li> </ul>	<ul style="list-style-type: none"> <li>▪ Recognisable high standards of care.</li> <li>▪ Transparent responsibility and accountability for the standards.</li> <li>▪ Constant dynamic of improvement.</li> </ul>
<p><b>Spain</b></p> <p>1. Response to survey</p> <p>2. La Comisión de Salud Pública (Commission for Public Health), <i>Documento marco sobre cribado poblacional*</i>, <a href="https://www.mscbs.gob.es/profesionales/saludPublica/prevPromocion/Cribado/d">https://www.mscbs.gob.es/profesionales/saludPublica/prevPromocion/Cribado/d</a></p>	<p>The Inter-territorial Council (ITC) of the National Health System is a permanent body of coordination, cooperation, communication and information of Health Services, between them and with the Central Government. Screening programmes are presented to the ITC of the National Health System for approval by Institutional Committees.<sup>(1)</sup></p> <p>Spanish HTA agencies provide clinical and cost-effectiveness evidence relating to a screening</p>	<p><i>No information identified using search methodology applied in this review</i></p>	<p><i>Ethical principles:</i></p> <ul style="list-style-type: none"> <li>▪ beneficence</li> <li>▪ non-maleficence</li> <li>▪ justice</li> <li>▪ autonomy.<sup>(2)</sup></li> </ul> <p><i>Ethical aspects</i> in public health are further protected under legislation including the following <i>principles of action</i>.<sup>(1)</sup></p> <ul style="list-style-type: none"> <li>▪ principle of equity</li> <li>▪ principle of health in all policies</li> <li>▪ principle of relevance</li> <li>▪ precautionary principle</li> <li>▪ principle of evaluation</li> <li>▪ principle of transparency</li> <li>▪ principle of integrity</li> <li>▪ principle of security.</li> </ul>	<p>As outlined in the previous description of principles of action</p>

Country Source(s)	Responsibility for screening (hierarchy if applicable)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<p><a href="#">ocs/Cribado_poblacional.pdf</a>, Published: 15 December 2010</p> <p><i>*Document translated using Google Translate</i></p>	<p>programme to a technical committee. This committee makes a decision whether to include, removed or modify a screening programme. The Institutional Committees then approve or reject the decision of the technical committee before any screening programme can be presented to the ITC for approval. Approved screening programmes can then be included in “the National Health System common portfolio” following a Ministerial Order to update the Royal Decree 1030/2006. (1)</p> <p>For screening, a special commission of the public health committee with experts, professionals and region’s representatives is in place since 2017. They discuss the new screening</p>			

Country Source(s)	Responsibility for screening (hierarchy if applicable)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
	<p>programs, which problems should be tackled, and how a decision could be made. They make recommendations and the public health committee makes the decisions. They provided a framework document 'check-list' for regions, (represented at the ITC) with criteria which help to decide on aspects for the implementation.<sup>(1)</sup></p>			
<p><b>Sweden</b></p> <p>1. Response to survey</p> <p>2. Socialstyrelsen (The National Board of Health and Welfare), <i>Nationella screeningprogram: Modell för bedömning, införande och</i></p>	<p>The National Board of Health and Welfare decide whether to screen or not.<sup>(1, 2)</sup></p> <p>Each region (21 health care regions) is responsible for the implementation and structure of the screening programme.<sup>(1)</sup></p>	<p>The ethical approach is based on national and international values, norms and principles.<sup>(1)</sup></p> <p>Criterion 10 of the assessment criteria requires that the screening</p>	<p><i>Values, norms and principles:</i><sup>(1, 2)</sup></p> <ul style="list-style-type: none"> <li>▪ <i>Type 1:</i> The balance between the benefits and harms screening may have on individuals.</li> <li>▪ <i>Type 2:</i> Autonomy and integrity of individuals offered screening.</li> <li>▪ <i>Type 3:</i> Justice, including equality, equal treatment, human dignity, vulnerable groups and redistributive issues.</li> <li>▪ <i>Type 4:</i> Long-term consequences concerning human value and equality, including the change in division of responsibility between</li> </ul>	<p>Openness about how each screening programme is assessed.<sup>(2)</sup></p>

Country Source(s)	Responsibility for screening (hierarchy if applicable)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<p><i>uppföljning*</i>, <a href="https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/nationella-screeningprogram/2019-4-12.pdf">https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/nationella-screeningprogram/2019-4-12.pdf</a>, Last updated: April 2019</p> <p><i>*Document translated using Google Translate</i></p>		<p>programme be acceptable from an ethical perspective. This requires a comprehensive ethical analysis based on criteria outlined in Table 3.<sup>(2)</sup></p>	<p>health and healthcare and the individual, stigma and indication slip.</p> <p><i>Justice considerations:</i><sup>(1, 2)</sup></p> <ul style="list-style-type: none"> <li>▪ The human value principle states that all people have equal value and prohibits unfair discrimination.</li> <li>▪ The principle of need and solidarity states that care should be provided based on the greatest need and solidarity, and on equal terms. Vulnerable groups should receive special consideration.</li> <li>▪ The cost-effectiveness principle states that health care should strive to reasonably balance cost and effect.</li> </ul> <p><i>Assessment criteria:</i><sup>(2)</sup></p> <ul style="list-style-type: none"> <li>▪ Consider the values and interests of relevant groups.</li> <li>▪ Does the programme represent a fair distribution of resources compared to other options.</li> </ul>	
<b>Switzerland</b>	Decision-making is devolved to the 26 individual cantons	<i>No information identified using</i>	<i>No information identified using search methodology applied in this review</i>	<i>No information identified using search</i>



Country Source(s)	Responsibility for screening (hierarchy if applicable)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
Response to survey	of Switzerland. Recommendations are made by expert committees on screening programmes including the National Advisory Commission on Biomedical Ethics who evaluate ethical aspects	<i>search methodology applied in this review</i>		<i>methodology applied in this review</i>
<b>United Kingdom</b>  1. UK National Screening Committee, <i>Evidence review process</i> , <a href="https://www.gov.uk/government/publications/uk-nsc-evidence-review-process/uk-nsc-evidence-review-process">https://www.gov.uk/government/publications/uk-nsc-evidence-review-process/uk-nsc-evidence-review-process</a>	UK NSC makes recommendations on screening programmes to government ministers. <sup>(1)</sup>	Judgements on screening programmes are based on four ethical principles in a manner that support the five procedural values of the UK NSC. <sup>(2)</sup>	<i>Ethical principles of screening:</i> <sup>(2)</sup> <ul style="list-style-type: none"> <li>▪ Improve health and wellbeing:</li> <li>▪ Treat people with respect:</li> <li>▪ Promote equality and inclusion:</li> <li>▪ Use public resources fairly and proportionately.</li> </ul>	<i>UK NSC procedural values:</i> <sup>(2)</sup> <ul style="list-style-type: none"> <li>▪ rigour</li> <li>▪ independence and accountability (impartiality, integrity, objectivity and collective responsibility)</li> <li>▪ inclusiveness and respect</li> <li>▪ transparency (openness and honesty, accessibility of information)</li> <li>▪ responsiveness.</li> </ul>

Country Source(s)	Responsibility for screening (hierarchy if applicable)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<p>2. UK National Screening Committee, <i>UK National Screening Committee ethical framework for screening</i>, <a href="https://www.gov.uk/government/publications/uk-nsc-ethical-framework-for-screening">https://www.gov.uk/government/publications/uk-nsc-ethical-framework-for-screening</a></p>				
<p><b>USA</b>  U.S. Preventative Services Task Force, <i>Procedure manual</i>,</p>	<p><i>No information identified using search methodology applied in this review</i></p>	<p><i>No information identified using search methodology applied in this review</i></p>	<p><i>No information identified using search methodology applied in this review</i></p>	<p>The following are referred to under both <i>recommendations</i> and <i>procedures</i>:</p> <ul style="list-style-type: none"> <li>▪ transparency</li> <li>▪ clarity</li> <li>▪ consistency</li> <li>▪ usability.</li> </ul>

Country Source(s)	Responsibility for screening (hierarchy if applicable)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<a href="https://www.uspreventiveservicestaskforce.org/uspstf/sites/default/files/inline-files/procedure-manual-2021_0.pdf">https://www.uspreventiveservicestaskforce.org/uspstf/sites/default/files/inline-files/procedure-manual-2021_0.pdf</a> , Last updated: May 2021				

## Appendix 1.3 - Frameworks to facilitate consideration of ethics

### Appendix 1.3. Frameworks to facilitate consideration of ethics

Country	Framework structure
Source(s)	
<b>Australia</b>	Limited to a set of guiding criteria that incorporate various ethical considerations as described in Tables 1 and 2.
<p data-bbox="192 563 667 986"><b>Australia NBS</b></p> <p data-bbox="192 643 667 986">Australian Health Ministers' Advisory Council, <i>Newborn Bloodspot Screening National Policy Framework</i>, <a href="https://www.health.gov.au/sites/default/files/documents/2020/10/newborn-bloodspot-screening-national-policy-framework.pdf">https://www.health.gov.au/sites/default/files/documents/2020/10/newborn-bloodspot-screening-national-policy-framework.pdf</a>, Last updated: May 2018</p>	<p data-bbox="680 563 2033 635">The policy framework was developed by the NBS Working Group and informed by stakeholder input, the expertise of the working group and existing practices of NBS programmes in Australia.</p> <p data-bbox="680 683 2033 826">This policy framework describes the decision-making process (policy area 5) for assessing conditions for inclusion in, or removal from, NBS programmes. Ethical considerations are incorporated within decision-making criteria that are expanded to include guiding questions. Examples are included below:</p> <p data-bbox="680 834 891 866"><i>The condition</i></p> <ul data-bbox="741 874 2011 1066" style="list-style-type: none"> <li>▪ There should be a benefit to conducting screening in the newborn period: <ul style="list-style-type: none"> <li>○ Does detection provide families with actionable information that helps them in making informed choices about reproduction in the future?</li> <li>○ What emotional or social benefits does early protection provide?</li> <li>○ What harms may arise from screening?</li> </ul> </li> </ul> <p data-bbox="680 1074 965 1106"><i>The screening test</i></p> <ul data-bbox="741 1114 2011 1337" style="list-style-type: none"> <li>▪ The test protocol should, on balance, be socially and ethically acceptable to health professionals and the public: <ul style="list-style-type: none"> <li>○ Can the test protocol detect other conditions of clinical or unknown significance and or carriers and, if so, what are the implications?</li> <li>○ What are the potential benefits and harms associated with the preferred test protocol(s)?</li> </ul> </li> </ul> <p data-bbox="680 1345 936 1377"><i>The intervention</i></p>

Country	Framework structure
Source(s)	
	<ul style="list-style-type: none"> <li>▪ Health care services for diagnosis and management should be available so that these services can be offered if there is an abnormal screening result:               <ul style="list-style-type: none"> <li>▪ Is there equitable access to these health care services for families, including those from rural and remote areas?</li> </ul> </li> <li>▪ There should be an accepted intervention for those diagnosed with the condition:               <ul style="list-style-type: none"> <li>▪ Is the intervention readily available and accessible?</li> <li>▪ What are the potential harms associated with the intervention, and to what extent can these harms be mitigated or managed?</li> <li>▪ Is there equitable access to the intervention for families, including those from rural and remote areas?</li> </ul> </li> </ul> <p><i>Additional considerations</i></p> <ul style="list-style-type: none"> <li>▪ The benefit of screening a condition must be weighed against its impact on the programme as a whole:               <ul style="list-style-type: none"> <li>▪ Is the addition of this condition likely to require ethical considerations that may warrant a separate consent process?</li> <li>▪ Would it be likely that screening for the condition would impact negatively upon other elements of the programme?</li> </ul> </li> <li>▪ What other information relevant to decision-making should be considered that has not been captured elsewhere?</li> </ul>
<b>Belgium – Brussels</b>	<i>No information identified using search methodology applied in this review</i>
<b>Belgium – Flanders</b>	<i>No information identified using search methodology applied in this review</i>
<b>Belgium - Wallonia</b>	<i>No information identified using search methodology applied in this review</i>
<b>Canada – Ontario</b>  Newborn Screening Ontario, <i>Full review form for a condition considered for addition to the</i>	The review form includes questions that include an ethical dimension linked to the criteria listed: <sup>(3)</sup> <ul style="list-style-type: none"> <li>▪ Is there any reason to be concerned about test acceptability in the population?</li> <li>▪ Is there a reason to be concerned about the acceptability of diagnostic investigations among families of screen-positive infants?</li> </ul>

Country	Framework structure
<p><b>Source(s)</b></p> <p><i>screening panel,</i>  <a href="https://www.newbornscreening.on.ca/sites/default/files/form_3_blank.pdf">https://www.newbornscreening.on.ca/sites/default/files/form_3_blank.pdf</a>            Last updated: unclear</p>	<ul style="list-style-type: none"> <li>▪ Are there concerns about inequities in access to care in different patient groups?</li> <li>▪ Is there reason to be concerned about the acceptability of the intervention named, either to families of screened infants or to health professionals?</li> <li>▪ Is there evidence to support the acceptability of screening for this condition in newborns among families of screened children, the public or health professionals?</li> <li>▪ What harms are anticipated in the event of overdiagnosis?</li> <li>▪ What harms are anticipated in the event of incidental identification of non-affected heterozygous mutation carriers for the condition?</li> </ul>
<p><b>Denmark</b></p> <p>Sundhedsstyrelsen (The National Board of Health),  <i>Anbefalinger vedrørende nationale screeningsprogrammer*</i>,  <a href="https://www.sst.dk/-/media/Udgivelser/2014/Rapport_Sundhedsstyrelsens_anbefalinger-vedr-nationale-screeningsprogrammer.ashx?la=da&amp;hash=D09671DC7A18EB5CF2BFDBFE382B684A7F330B24">https://www.sst.dk/-/media/Udgivelser/2014/Rapport_Sundhedsstyrelsens_anbefalinger-vedr-nationale-screeningsprogrammer.ashx?la=da&amp;hash=D09671DC7A18EB5CF2BFDBFE382B684A7F330B24</a>,            Last updated: November 2014</p> <p><i>*Document translated using Google Translate</i></p>	<p><i>Ethical considerations</i> mentioned are outlined and their relationship to screening outlined:</p> <ul style="list-style-type: none"> <li>▪ self-determination and informed free choice:               <ul style="list-style-type: none"> <li>○ provision of adequate information</li> <li>○ free choice to opt-out</li> <li>○ responsibility of health authorities.</li> </ul> </li> <li>▪ stigmatisation:               <ul style="list-style-type: none"> <li>○ discrimination</li> <li>○ undue pressure on individuals to participate</li> </ul> </li> <li>▪ fair distribution of healthcare services:               <ul style="list-style-type: none"> <li>○ uneven distribution of resources</li> <li>○ inequalities.</li> </ul> </li> </ul> <p>The Danish National Board of Health has also published <i>Etik i forebyggelse og sundhedsfremme</i> (ethics in prevention and health promotion) which on multiple occasions uses screening as an example to explore the above <i>ethical considerations</i> in more depth. The document also identifies possible adverse effects before analysing each of these in the context of a specific screening programme.</p>

Country	Framework structure
<b>Finland</b>	<p>The ethics framework is limited to a set of guiding criteria that incorporate various ethical considerations as described in Tables 1 and 2.</p>
<b>France</b>  Haute Autorité de Santé (High Authority of Health), <i>Assessment of ethical aspects</i> , <a href="https://www.has-sante.fr/upload/docs/application/pdf/2014-11/assessment_of_ethical_aspects.pdf">https://www.has-sante.fr/upload/docs/application/pdf/2014-11/assessment_of_ethical_aspects.pdf</a> Last updated: April 2013	<p>Development of the framework involved a review of international literature including reference to the EUnetHTA HTA Core Model®, contributions from national and international experts, feedback from previous assessments of ethical aspects, review and appraisal from a peer review group, and final approval by the Economic and Public Health Assessment Committee.<sup>(1)</sup></p> <p><i>Assessment of Ethical Aspects</i> lists a set of questions to consider in the identification of ethical aspects which may need to be assessed and provides examples for each of these.</p> <p>The assessment itself is divided into three stages which are discussed at length and a flowchart provided to summarise. The framework provides comprehensive background and examples for each of the points outlined in each of the three stages.</p> <p><i>Identifying ethical arguments:</i>            The HAS proposes three categories under which criteria may be met to warrant ethical analysis and provides questions which may be asked to establish this as well as examples of these for each.</p> <p>The three categories are as follows:</p> <ul style="list-style-type: none"> <li>▪ characteristics of the technology</li> <li>▪ potential conflict between the technology and basic rights</li> <li>▪ ethical debates.</li> </ul> <p>In addition to these categories, the HAS also states that ethical arguments can be identified through theoretical identification and by consulting with working and peer review groups.</p>

Country	Framework structure
Source(s)	<p><i>Ethical Concepts:</i>                      Examples of concepts under each of the ethical principles outlined:</p> <ul style="list-style-type: none"> <li>▪ beneficence and non-maleficence:                             <ul style="list-style-type: none"> <li>○ benefits</li> <li>○ risks</li> <li>○ side effects</li> <li>○ safety</li> <li>○ quality of life</li> <li>○ clinical efficacy</li> <li>○ self-esteem.</li> </ul> </li> <li>▪ autonomy:                             <ul style="list-style-type: none"> <li>○ consent</li> <li>○ freedom of choice</li> <li>○ confidentiality (data protection)</li> <li>○ dependence</li> <li>○ vulnerability.</li> </ul> </li> <li>▪ justice:                             <ul style="list-style-type: none"> <li>○ efficiency</li> <li>○ equity</li> <li>○ discrimination</li> <li>○ geographical disparity</li> <li>○ social inequality</li> <li>○ accessibility</li> <li>○ compensation.</li> </ul> </li> </ul> <p><i>Consideration of ethical analysis :</i>                      The HAS also provides a diagram to demonstrate the points at which ethical aspects can and</p>



Country Source(s)	Framework structure
<p><b>Germany</b></p> <p>1. Response to survey</p> <p>2. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (The Institute for Quality and Efficiency in Healthcare), <i>General Methods Version 6.0</i>, <a href="https://www.iqwig.de/methoden/general-methods_version-6-0.pdf">https://www.iqwig.de/methoden/general-methods_version-6-0.pdf</a>, Last updated: November 2020</p>	<p>should be incorporated into assessments.</p> <p>The benefits and harms of public health interventions are assessed by the IQWiG.<sup>(1)</sup></p> <p>When conducting an evaluation of a treatment, the IQWiG consider:<sup>(2)</sup></p> <ul style="list-style-type: none"> <li>▪ What is the benefit for the intended recipients or patients?</li> <li>▪ Does the method improve mortality, morbidity or quality of life?</li> <li>▪ Patients and patient representatives' views are included in consultations and they can also submit written contributions to assist the IQWiG team to specific patient-relevant outcomes during the preparation stage of the evidence assessment.</li> </ul>
<p><b>Italy</b></p>	<p><i>No information identified using search methodology applied in this review</i></p>
<p><b>The Netherlands</b></p> <p>National Institute for Public Health and the Environment: Ministry of Health, Welfare and Sport, <i>Policy framework for population screening for cancer</i>, <a href="https://www.rivm.nl/bibliotheek/rapporten/2018-0042.pdf">https://www.rivm.nl/bibliotheek/rapporten/2018-0042.pdf</a>, Published: 2018</p>	<p>Each of the <i>public values</i> mentioned in Table 2 are expanded on to outline the considerations which can be made under each value.</p> <p><i>Quality:</i></p> <ul style="list-style-type: none"> <li>▪ The programmes are effective in terms of the screening test used (test characteristics), the participation of the target group, and the contribution to health gains and/or offering treatment options.</li> <li>▪ The programmes take account of the wishes and needs of the target group.</li> </ul>

Country	Framework structure
Source(s)	
	<ul style="list-style-type: none"> <li>▪ The programmes are implemented responsibly and uniformly at a national level. The benefits of the programme outweigh the possible disadvantages of the screening for the target group. The continuity of the programme is guaranteed.</li> <li>▪ The parties involved have knowledge and experience available that are used structurally to ensure continuous improvement of the programmes. Relevant innovations in methodology and screening methods, diagnostics and treatment are noted in time. The possible consequences for the programmes are discussed with the Ministry of Health, Welfare and Sport, ZonMw, the Health Council and other relevant parties.</li> </ul> <p><i>Accessibility:</i></p> <ul style="list-style-type: none"> <li>▪ The programmes are organised in such a way that there are as few obstacles as possible that prevent the target group from taking part.</li> <li>▪ The target group is invited to take part in the programme in time. The throughput times in the programme are acceptable, including the lead times for diagnostics and treatment.</li> <li>▪ Participation in the programmes is voluntary. The information to the general public and the target group is updated, objective and balanced and helps them make a well-informed choice. Balanced information discusses the pros and cons of the programme.</li> </ul> <p><i>Affordability:</i></p> <ul style="list-style-type: none"> <li>▪ The costs of the programmes are clear so that the government can weigh up the use of public resources against deployment for the government's other tasks.</li> <li>▪ The programmes are implemented at the lowest costs possible in relation to the required quality and accessibility. The programmes are also cost-effective.</li> </ul>
<b>New Zealand</b>	Details are limited to a set of guiding criteria that incorporate various ethical considerations as described in Tables 1 and 2.

Country	Framework structure
<p><b>Spain</b></p> <p>La Comisión de Salud Pública (Commission for Public Health), <i>Documento marco sobre cribado poblacional*</i>, <a href="https://www.mscbs.gob.es/profesionales/saludPublica/prevPromocion/Cribado/docs/Cribado_poblacional.pdf">https://www.mscbs.gob.es/profesionales/saludPublica/prevPromocion/Cribado/docs/Cribado_poblacional.pdf</a>, Published: 15 December 2010</p> <p><i>*Document translated using Google Translate</i></p>	<p>Lists <i>ethical risks</i> relating to each of the <i>ethical principles</i> outlines:</p> <ul style="list-style-type: none"> <li>▪ beneficence: <ul style="list-style-type: none"> <li>○ Screening may benefit population but many individuals may not benefit.</li> </ul> </li> <li>▪ non-maleficence: <ul style="list-style-type: none"> <li>○ Psychological harm in instances of false positive results.</li> <li>○ False reassurance in false negatives, may result in delays in diagnosis and treatment.</li> <li>○ Potential harm caused by the diagnostic process and or subsequent interventions.</li> </ul> </li> <li>▪ justice: <ul style="list-style-type: none"> <li>○ Inequalities increased if no measures are in place to promote equity in access.</li> <li>○ Discrimination or stigmatisation may occur in detected conditions.</li> <li>○ Programme may take funding away from other preventative measures or more cost-effective disease control.</li> </ul> </li> <li>▪ autonomy: <ul style="list-style-type: none"> <li>○ Individuals may not understand the implications of participating in the programme.</li> </ul> </li> </ul>
<p><b>Sweden</b></p> <p>1. Response to survey</p> <p>2. Socialstyrelsen (The National Board of Health and Welfare), <i>Nationella screeningprogram: Modell för bedömning, införande och uppföljning*</i>, <a href="https://www.socialstyrelsen.se/">https://www.socialstyrelsen.se/</a></p>	<p>The National Board of Health and Welfare collaborated with a reference group of experts to develop their general model for assessing screening programmes.<sup>(1, 2)</sup></p> <p>The screening program must be acceptable from an ethical perspective The screening program must also be acceptable from other ethically relevant perspectives and the benefits should outweigh the harms. This requires an ethical analysis that should answer the following questions:<sup>(1, 2)</sup></p> <ul style="list-style-type: none"> <li>▪ How can any negative effects be handled?</li> <li>▪ How do you take into account the individual's autonomy and integrity?</li> </ul>

Country	Framework structure
<p data-bbox="203 312 360 347"><b>Source(s)</b></p> <p data-bbox="203 355 667 501"><a href="https://globalassets/sharepoint-dokument/artikelkatalog/nationella-screeningprogram/2019-4-12.pdf">globalassets/sharepoint-dokument/artikelkatalog/nationella-screeningprogram/2019-4-12.pdf</a>, Last updated: April 2019</p> <p data-bbox="203 547 607 619"><i>*Document translated using Google Translate</i></p>	<ul style="list-style-type: none"> <li data-bbox="741 355 1912 427">▪ Privacy issues include protection of privacy-sensitive information handled in the screening program.</li> <li data-bbox="741 432 1890 467">▪ Can the screening program affect human value and equality in the long term?</li> <li data-bbox="741 472 1984 659">▪ Are there relevant groups with values and interests that make it necessary to pay special attention, even if the screening program is acceptable to the general population? This applies, for example, to vulnerable groups with reduced ability to bring their own action. This includes considering the risk that the screening program will increase the stigma or discrimination of any group of people.</li> <li data-bbox="741 663 1962 735">▪ Can the screening program be seen as an expression of a fair distribution of health care resources in relation to other options for action?</li> <li data-bbox="741 740 1995 812">▪ Does the screening program change the division of responsibilities and roles between health care and the individual? If so, how should it be handled?</li> <li data-bbox="741 817 1895 888">▪ Are there legislation and other guidelines that can provide guidance for ethical positions in relation to the above points in the ethical analysis?</li> </ul>
<p data-bbox="203 898 394 933"><b>Switzerland</b></p>	<p data-bbox="696 898 1738 933"><i>No information identified using search methodology applied in this review</i></p>
<p data-bbox="203 938 465 973"><b>United Kingdom</b></p> <p data-bbox="203 1018 663 1281">1. UK National Screening Committee, <i>UK National Screening Committee ethical framework for screening</i>, <a href="https://www.gov.uk/government/publications/uk-nsc-ethical-framework-for-screening">https://www.gov.uk/government/publications/uk-nsc-ethical-framework-for-screening</a></p>	<p data-bbox="696 946 1290 981">Principle 1. Improve health and wellbeing:</p> <ul style="list-style-type: none"> <li data-bbox="741 986 2007 1233">▪ The general purpose of public health screening programmes should be to improve the health and wellbeing of the population. No screening programme should be adopted unless its potential benefits (to health and wellbeing) outweigh any potential harms. The focus should be on the individuals who will be offered screening. If there is a prospect for screened individuals to benefit, the benefits and harms for others and society more broadly can also be taken into consideration.</li> <li data-bbox="741 1270 2018 1394">▪ Potential benefits include prevention of death and disease, improvements in physical and mental health, and improved quality of life. Potential harms include unnecessary and harmful tests or treatment, uncertainty of screening results, false reassurance, and</li> </ul>

Country	Framework structure
Source(s)	
	<p>increased anxiety. Efforts should be made to reduce any risks of harms.</p> <p>Principle 2. Treat people with respect:</p> <ul style="list-style-type: none"><li>▪ People’s rights, wishes and feelings as individuals should be respected. This involves enabling people to make informed choices about screening that align with their personal values and acknowledging the role that relationships with family members and others can play. People’s choices about screening must be respected and supported.</li><li>▪ Where screening is offered to people who are not able to make choices for themselves, those who make choices on their behalf should be appraised of the balance of benefits and harms to the screened individual. Policy decisions about screening programmes should take account of the views of those affected and the reasons for policy decisions should be clearly communicated.</li></ul> <p>Principle 3. Promote equality and inclusion:</p> <ul style="list-style-type: none"><li>▪ Screening programmes should not act to increase health inequalities and should aim to reduce them. Access to and delivery of screening should be as equitable and inclusive as possible. Any potential wider consequences of screening for society in the initiation and implementation of screening, both in the short and long term, should be considered.</li></ul> <p>Principle 4. Use public resources fairly and proportionately:</p>

Country	Framework structure
Source(s)	
	The entire cost of a screening programme should entail the fair and proportionate use of available public resources. Decisions about screening should have regard to evidence from cost-effectiveness analyses.
<b>USA</b>	<i>No information identified using search methodology applied in this review</i>

## Appendix 1.4 - Processes used in decision-making relating to ethics

### Appendix 1.4. Processes used in decision-making relating to ethics

Country Source(s)	Stakeholder involvement	Processes of assessment	Process of deliberation	Procedure for resolving differences of opinion
<b>Australia</b>  1. Response to survey  2. Council of Australian Governments Health Council, <i>Operating Guidelines</i> , <a href="https://www.coaghealthcouncil.gov.au/Portals/0/COAG%20Health%20Council%20Operating%20Guidelines%202014_1.pdf">https://www.coaghealthcouncil.gov.au/Portals/0/COAG%20Health%20Council%20Operating%20Guidelines%202014_1.pdf</a> , Last updated: December 2014	All Australian screening programmes must be ethically acceptable to both health professionals and consumers, Stakeholders consulted with regard to ethical issues consist of organisations for individuals and families affected by the condition, Aboriginal and Torres Strait Islander representative groups, health care provider organisations, research organisations, and bioethicist expertise. Stakeholders consulted vary according to the condition screened	Application of the criteria and procedures described in Table 1. <sup>(1)</sup>	<i>No information identified using search methodology applied in this review</i>	<i>No information identified using search methodology applied in this review</i>

Country Source(s)	Stakeholder involvement	Processes of assessment	Process of deliberation	Procedure for resolving differences of opinion
	for. <sup>(1)</sup>			
<b>Australia NBS</b>  Australian Health Minister's Advisory Council, <i>Newborn Bloodspot Screening National Policy Framework</i> , <a href="https://www.health.gov.au/sites/default/files/documents/2020/10/newborn-bloodspot-screening-national-policy-framework.pdf">https://www.health.gov.au/sites/default/files/documents/2020/10/newborn-bloodspot-screening-national-policy-framework.pdf</a> , Last updated May 2018	As per stakeholder involvement above	Decision-making process with respect to NBS programme assessment described in Table 3 and includes a detailed decision-making pathway and decision-making criteria with guiding questions.	<i>No information identified using search methodology applied in this review</i>	<i>No information identified using search methodology applied in this review</i>
<b>Belgium – Wallonia</b>  Response to survey	Steering committees include representatives of patients, general practitioners and disease specialists, representatives of analysis laboratories or radiology centres, representatives of health promotion centres,	<i>No information identified using search methodology applied in this review</i>	The presentation of the results and the discussions, including on ethical points, take place in the steering committees.	<i>No information identified using search methodology applied in this review</i>



Country Source(s)	Stakeholder involvement	Processes of assessment	Process of deliberation	Procedure for resolving differences of opinion
	representatives of insurance organizations and the cancer registry (Sciensano), as well as representatives of the administration			
<p><b>Canada Ontario</b></p> <p>1. Newborn Screening Ontario, <i>About screening</i>, <a href="https://www.newbornscreening.on.ca/en/about-screening/diseases-screened/test-addition-process">https://www.newbornscreening.on.ca/en/about-screening/diseases-screened/test-addition-process</a>, Last updated: unclear</p> <p>2. Newborn Screening Ontario, <i>Terms of reference</i>, <a href="https://www.newbornscreening.on.ca/sites/default/files/nsoac_tor_final_2020_0.pdf">https://www.newbornscreening.on.ca/sites/default/files/nsoac_tor_final_2020_0.pdf</a>, Last updated: unclear</p>	The Newborn Screening Advisory Council (NSO-AC) consist of experts in disease, screening and health evaluative science. The NSO-AC may engage with other provincial partner organisations during the review process. <sup>(1)</sup>	<p>A task force is commissioned by the NSO-AC if a full review of a condition is warranted.<sup>(1)</sup></p> <p>Assessment involves the completion of a full review form that includes questions with ethical dimensions.</p> <p>The task force present their findings to the NSO-AC. Based on these findings, the NSO-AC make a recommendation or requests further information.</p> <p>A formal report is sent to</p>	The NSO-AC meet at least four times per year during which decisions will be made by consensus if possible. If consensus is not attainable, then a majority-based decision will be made. This can take the form of a vote, if necessary. <sup>(2)</sup>	For overall decision-making, a majority-based decision or a majority vote will be used if consensus cannot be achieved. <sup>(2)</sup>

Country Source(s)	Stakeholder involvement	Processes of assessment	Process of deliberation	Procedure for resolving differences of opinion
		the Government of Ontario, which makes the ultimate decision whether to approve and commit funding to screening for the disease.		
<p><b>Canada Quebec</b></p> <p>MSSS, <i>Response to survey</i></p>	<p>MSSS, INESSS, INSPQ are involved within the decision-making processes. Citizens, parents' association and lobby groups are consulted in the deliberative approach.</p>	<p>MSSS has responsibility with support from INESSS and INSPQ.</p>	<p>Through the INESSS deliberative process, guided discussions, weighting and consensus methods are used before taking decision to add a new condition to the panel of the blood and urine newborn screening programme.</p>	<p>At the MSSS level, mechanisms are in place to prevent and resolve ethical issues or potentially conflicting situations. For example, some directorates, such as the Ethics and Quality Directorate and the Legal Affairs Directorate, are consulted by the Public health general Directorate (responsible of the screening programs) on ethical issues.</p> <p>Externally, in the deliberative approach</p>

Country Source(s)	Stakeholder involvement	Processes of assessment	Process of deliberation	Procedure for resolving differences of opinion
<p><b>Finland</b></p> <p>The Ministry of Social Affairs and Health, <i>Screenings in Finland 2014 The present state of health care screenings and future prospects</i>, <a href="https://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/74717/STM_Screenings_i_finland_2014_Enkku_B5_nettiin.pdf">https://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/74717/STM_Screenings_i_finland_2014_Enkku_B5_nettiin.pdf</a>, Last updated: 2015</p>	<p>The working group on screening includes representatives from various bodies including: the Association of Finnish Local and Regional Authorities; Finnish Cancer Registry; Mass Screening Registry and Radiation and Nuclear Safety Authority; National Institute for Health and Welfare (THL); and STAKES.</p>	<p>For decision-making overall, the operating methodology approach adopted by the working group on screening was based on those of the UK National Screening Committee (NSC).</p> <p>In addition to the screening criteria outlined in Table 1, the committee also define the health goals, existing evidence for each criterion, and what information could be learned by a pilot study.</p> <p>THL monitors and assesses screening programmes and the THL unit Finohtha</p>	<p><i>No information identified using search methodology applied in this review</i></p>	<p>of INESSS and INSPQ, public consultations are planned, and representatives of Citizens sit on different committees.</p> <p><i>No information identified using search methodology applied in this review</i></p>

Country Source(s)	Stakeholder involvement	Processes of assessment	Process of deliberation	Procedure for resolving differences of opinion
		<p>submits assessment reports to the Ministry of Social Affairs and Health to support the Minister's decision-making</p> <p>Finohta supports municipalities in conducting screening programmes such as by producing support material related to screening.</p>		
<p><b>France</b></p> <p>Haute Autorité de Santé (High Authority of Health), <i>Assessment of ethical aspects</i>, <a href="https://www.has-sante.fr/upload/docs/application/pdf/2014-11/assessment_of_ethical_aspects.pdf">https://www.has-sante.fr/upload/docs/application/pdf/2014-11/assessment_of_ethical_aspects.pdf</a> Last updated: April 2013</p>	<p>Identification of ethical arguments includes consulting with external working group of experts and with peer review group including patient representatives. One or more ethicists may be recruited from centres of expertise (hospitals, universities) to assist when a major ethical issue is identified.</p>	<p>According to the HAS, an ethical analysis should ideally always be performed but time or resource limitations may not make this possible. The guide outlines questions to determine whether a topic is likely to raise significant ethical issues and therefore warrant an ethical analysis.</p> <p>During stage 1 ethical arguments are identified</p>	<p><i>No information identified using search methodology applied in this review</i></p>	<p>The HAS acknowledges that disagreements may occur, however rather than offering a process for resolution suggests that these disagreements should be outlined so that they can be taken into account by the overall decision-maker(s), and suggests that by highlighting these disagreements helps</p>

Country Source(s)	Stakeholder involvement	Processes of assessment	Process of deliberation	Procedure for resolving differences of opinion
		<p>according to the parameters of the framework. This is achieved through literature search and review as well as consultation with working and or peer review groups.</p> <p>During stage 2 these arguments are classified to determine whether or not they warrant further investigation or examination. A defined reference set of principles are applied to the arguments presented.</p> <p>During stage 3 ethical arguments are examined and conflicts are analysed.</p>		<p>to identify social values.</p>
<p><b>Germany</b></p> <p>1. Response to survey</p> <p>2. Gemeinsamer</p>	<p>Patient organisations and representatives and experts from medical science and practice can contribute</p>	<p>An assessment process can be triggered by relevant service providers such as the KBV, KZBV or DKG, the National Association of</p>	<p>The plenum is the decision-making body of the G-BA. It comprises 13 members with voting</p>	<p>Different opinions are included in the advisory process at a statutory hearing. The inclusion of this</p>

Country	Stakeholder involvement	Processes of assessment	Process of deliberation	Procedure for resolving differences of opinion
<p>Source(s)</p> <p>Bundesausschuss (The Federal Joint Committee), <i>Bewertung neuer Untersuchungs- und Behandlungsmethoden für die ambulante und oder stationäre Versorgung*</i>, <a href="https://www.g-ba.de/themen/methoden/bewertung/bewertung-erprobung/ambulant-stationaer/">https://www.g-ba.de/themen/methoden/bewertung/bewertung-erprobung/ambulant-stationaer/</a>, Last updated: unclear</p> <p>3. Gemeinsamer Bundesausschuss (The Federal Joint Committee), <i>Geschäftsordnung*</i>, <a href="https://www.g-ba.de/downloads/62-492-2585/GO_2021-07-15_iK-2021-08-18.pdf">https://www.g-ba.de/downloads/62-492-2585/GO_2021-07-15_iK-2021-08-18.pdf</a>: Last updated: July 2008</p> <p>4. Gemeinsamer Bundesausschuss (The</p>	<p>to the G-BA and IQWiG planning process of the evaluation assessment of benefit and medical necessity<sup>(1, 3)</sup></p> <p>The core decision-making body of the G-BA, the plenum, is made up of 13 members: three impartial member; five representatives from the National Association of Health Insurance Funds (GKV); two representatives from the National Association of Statutory Health Insurance Physicians (KBV); two representatives from the German Hospital Federation (DKG), one representative from</p>	<p>Statutory Health Insurance Funds, patient authority organisations and three impartial members of the G-BA.<sup>(1, 2)</sup></p> <p>The G-BA can commission the IQWiG to conduct an evidence assessment on the health initiative under consideration, including an assessment of potential benefit and medical necessity.</p> <p>The recommendation of the G-BA is submitted to the Federal Ministry of Health.<sup>(1, 2)</sup></p>	<p>rights and meets once or twice a month in a public session. The plenum appoints subcommittees to prepare decisions and resolutions. Unlike the plenum, subcommittees meet only in closed sessions. They draft the results of their discussions as recommended resolutions for the plenum.<sup>(4)</sup></p> <p>Up to six patient representatives can be included on a subcommittee and five on the G-BA.<sup>(1, 3)</sup></p>	<p>information can help to resolve conflicts.<sup>(1)</sup></p> <p>Consensus is the goal during the deliberation process of the subcommittee.<sup>(3)</sup></p> <p>A summary of different opinions of members of the subcommittee can be included in draft resolutions submitted to the G-BA.</p>

Country Source(s)	Stakeholder involvement	Processes of assessment	Process of deliberation	Procedure for resolving differences of opinion
Federal Joint Committee), <i>The subcommittees,</i> <a href="https://www.g-ba.de/english/structure/subcommittees/">https://www.g-ba.de/english/structure/subcommittees/</a>  <i>*Document translated using Google Translate</i>	the National Association of Statutory Health Insurance Dentists (KZBV); and five patient representatives. <sup>(1, 3)</sup>			
<b>The Netherlands</b>  1. Response to Survey  2. National Institute for Public Health and the Environment: Ministry of Health, Welfare and Sport, <i>Policy framework for population screening for cancer,</i> <a href="https://www.rivm.nl/bibliotheek/rapporten/2018-0042.pdf">https://www.rivm.nl/bibliotheek/rapporten/2018-0042.pdf</a> , Published: 2018	When assessing a health issue, a committee will be established, including: <ul style="list-style-type: none"> <li>▪ council members</li> <li>▪ scientific experts</li> <li>▪ medical experts</li> <li>▪ ethicists</li> <li>▪ law specialists.</li> </ul> Depending on the issue the committee may be permanent.  Two of these permanent committees are particularly relevant to screening, namely:	<i>No information identified using search methodology applied in this review</i>	<i>No information identified using search methodology applied in this review</i>	In case of disagreements, differing views will be included in the final text, including the possibility of minority advice. <sup>(1)</sup>

Country Source(s)	Stakeholder involvement	Processes of assessment	Process of deliberation	Procedure for resolving differences of opinion
	<p>The Committee on Population Screening, and the Committee on Preconception, prenatal and neonatal screening.</p> <p>Additionally there is a permanent ethics and law committee.<sup>(1)</sup></p>			
<p><b>New Zealand</b></p> <p>1. Response to survey</p> <p>2. National Screening Advisory Committee, <i>Terms of Reference</i>, <a href="https://www.nsu.govt.nz/system/files/page/nsac-terms-of-reference-november-2020.pdf">https://www.nsu.govt.nz/system/files/page/nsac-terms-of-reference-november-2020.pdf</a> Last updated: November 2020</p>	<p>Each screening programme receives advice from stakeholders via advisory groups such as health professionals, scientific experts, Māori and Pacific members, and consumer reps.<sup>(1)</sup></p> <p>The NSAC membership will be multi-disciplinary and include:<sup>(1, 2)</sup></p> <ul style="list-style-type: none"> <li>▪ Experts in public health, screening</li> </ul>	<p>Assessment involves the application of the screening criteria outlined in Table 1.<sup>(1)</sup></p>	<p>NSAC members work collectively to provide advice to NSU, and decision-making is by consensus.<sup>(2)</sup></p>	<p>When consensus cannot be reached this is resolved via a vote. A simple majority of the Committee voting members (excluding Chair) is required. The Chair casts the deciding vote when the majority is not achieved by other voting members.<sup>(2)</sup></p>



Country Source(s)	Stakeholder involvement	Processes of assessment	Process of deliberation	Procedure for resolving differences of opinion
	<p>programmes, epidemiology, ethics and health services delivery.</p> <ul style="list-style-type: none"> <li>▪ NSU Māori Monitoring and Equity Group Chair.</li> <li>▪ One to two consumer representatives.</li> </ul> <p>Māori Monitoring and Equity Group (MMEG) acts to support the NSU to achieve its vision.</p>			
<p><b>Spain</b></p> <p>1. Response to survey</p> <p>2. La Comisión de Salud Pública (Commission for Public Health), <i>Documento marco sobre cribado poblacional*</i>, <a href="https://www.mscbs.gob.es/profesionales/saludPubli">https://www.mscbs.gob.es/profesionales/saludPubli</a></p>	<p>For the preparation of reports by Spanish Health Technology Assessment participate:</p> <ul style="list-style-type: none"> <li>▪ experts</li> <li>▪ patient associations (if required)</li> <li>▪ industry (If required).</li> </ul> <p>For decision-making by</p>	<p>The Spanish Health Technology agency examines the ethical criteria included in the framework document when completing their reports.<sup>(1)</sup></p> <p>If an assessment of ethics is required, an ethics committee develops an ad hoc report. For example,</p>	<p><i>No information identified using search methodology applied in this review</i></p>	<p>There is not an established procedure. If there are issues that could be interpreted differently, the Ministry of Health requests a report from an ethics committee.<sup>(1)</sup></p>

Country Source(s)	Stakeholder involvement	Processes of assessment	Process of deliberation	Procedure for resolving differences of opinion
<p><a href="http://ca/prevPromocion/Cribado/docs/Cribado_poblacion.al.pdf">ca/prevPromocion/Cribado/docs/Cribado_poblacion.al.pdf</a>, Published: 15 December 2010</p> <p><i>*Document translated using Google Translate</i></p>	<p>the Ministry of Health, expert screening technicians are included. If scientific societies are required, they are also included.<sup>(1)</sup></p>	<p>the Ministry of Health requested a report from an ethics committee about ethical requirements of the neonatal screening programme of National Health System.<sup>(1)</sup></p> <p>There are 3 different decision types mentioned:</p> <ul style="list-style-type: none"> <li>▪ implementation decisions</li> <li>▪ introduction of changes to existing screening programmes</li> <li>▪ withdrawal of screening programmes.<sup>(2)</sup></li> </ul> <p>The document includes a questionnaire to be completed when considering a screening programme under one of the three decision types listed above.<sup>(2)</sup></p>		

Country Source(s)	Stakeholder involvement	Processes of assessment	Process of deliberation	Procedure for resolving differences of opinion
<p><b>Sweden</b></p> <p>1. Response to survey</p> <p>2. Socialstyrelsen (The National Board of Health and Welfare), <i>Nationella screeningprogram: Modell för bedömning, införande och uppföljning*</i>, <a href="https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/nationella-screeningprogram/2019-4-12.pdf">https://www.socialstyrelsen.se/globalassets/sharepoint-dokument/artikelkatalog/nationella-screeningprogram/2019-4-12.pdf</a>, Last updated: April 2019</p> <p><i>*Document translated using Google Translate</i></p>	<p>Stakeholders include:<sup>(1, 2)</sup></p> <ul style="list-style-type: none"> <li>▪ ethical committee</li> <li>▪ expert group</li> <li>▪ national screening board.</li> </ul>	<p>The discussion for assessment involve an ethical committee, an expert group and a national screening board. They all discuss the <i>ethical aspects</i>.<sup>(1)</sup></p> <p>The national screening board make the overall assessment.<sup>(1, 2)</sup></p> <p>The National Board of Health and Welfare make the final decision.<sup>(1, 2)</sup></p>	<p>Experts in medical ethics are involved who describe the programme from an ethical perspective. This is reviewed by an ethical board that read and suggestion improvements, if necessary. The text is then discussed by an expert group and the screening board.<sup>(1, 2)</sup></p>	<p>The recommendations about the screening programme are sent for an open review process. Any of the reviewers can provide comments and suggestions.<sup>(1, 2)</sup></p>

## Appendix 2.1 - Overview of public health agencies

### Appendix 2.1. Overview of public health agencies

Country Source(s)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<p><b>Canada</b></p> <p>Public Health Agency Canada, <i>Framework For Ethical Deliberation And Decision-Making In Public Health</i>, <a href="https://www.canada.ca/content/dam/phac-aspc/documents/corporate/transparency/corporate-management-reporting/internal-audits/audit-reports/framework-ethical-deliberation-decision-making/pub-eng.pdf">https://www.canada.ca/content/dam/phac-aspc/documents/corporate/transparency/corporate-management-reporting/internal-audits/audit-reports/framework-ethical-deliberation-decision-making/pub-eng.pdf</a>, Last updated: March 2017</p>	<p><i>The core ethical dimensions</i> presented are noted as complimentary to the <i>values</i> of the public sector and Public Health Agency of Canada:</p> <ul style="list-style-type: none"> <li>▪ respect for democracy</li> <li>▪ respect for people</li> <li>▪ integrity</li> <li>▪ stewardship</li> <li>▪ Excellence.</li> </ul>	<p><i>Core ethical dimensions</i></p> <ul style="list-style-type: none"> <li>▪ respect for persons and communities:                             <ul style="list-style-type: none"> <li>○ A person’s right to participate in decisions.</li> <li>○ A person’s right to be informed.</li> <li>○ Opportunity for people to form, express and exercise choice consistent with the interests of others.</li> <li>○ Support the ability of people to identify and act on public health issues.</li> </ul> </li> <li>▪ non-maleficence and beneficence</li> <li>▪ trust through the promotion of:                             <ul style="list-style-type: none"> <li>○ Reciprocity, by providing support and minimising burdens.</li> <li>○ Solidarity, by considering the well-being of the community.</li> <li>○ Openness, honesty, truthfulness, transparency of decision-making through communication and accessibility.</li> </ul> </li> </ul>	<p><i>Procedural considerations:</i></p> <ul style="list-style-type: none"> <li>▪ accountability</li> <li>▪ inclusiveness</li> <li>▪ responsibility                             <ul style="list-style-type: none"> <li>○ independent decision-making</li> <li>○ moral accountability</li> </ul> </li> <li>▪ responsiveness</li> <li>▪ transparency</li> </ul>

Country Source(s)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
		<ul style="list-style-type: none"> <li>▪ justice, by considering:                             <ul style="list-style-type: none"> <li>○ If health inequalities are due to unfair treatment of individuals or groups.</li> <li>○ The potential impact of initiatives on different groups and future generations.</li> <li>○ The risk of inadvertent stigma towards certain groups as a result of the initiative.</li> <li>○ Whether resources are used in a way that respects the principles of distributive justice.</li> </ul> </li> </ul>	
<p><b>Canada - British Columbia</b></p> <p>British Columbia Centre for Disease Control, <i>BCCDC Ethics Framework and Decision Making Guide</i>, <a href="http://www.bccdc.ca/resources/gallery/Documents/Guidelines%20and%20Forms/Guidelines%20and%20Manuals/BCCDC_Ethics_Framework_Decision_Making_Guide">http://www.bccdc.ca/resources/gallery/Documents/Guidelines%20and%20Forms/Guidelines%20and%20Manuals/BCCDC_Ethics_Framework_Decision_Making_Guide</a></p>	<p>Approach is based on the following ethical values and shared belief which underlie principles of the ethical practice of public health:</p> <ul style="list-style-type: none"> <li>▪ health:                             <ul style="list-style-type: none"> <li>○ All people have a right to the resources necessary for health.</li> </ul> </li> <li>▪ community and environment:                             <ul style="list-style-type: none"> <li>○ The duty of primacy of the BCCDC is to protect</li> </ul> </li> </ul>	<p><i>Principles of the ethical practice of public health which give expression to the values outlined:</i></p> <ul style="list-style-type: none"> <li>▪ Address, principally, the fundamental causes of disease and requirements for health, aiming to prevent adverse health outcomes.</li> <li>▪ Aspire to achieve community health in a way that respects the rights of individuals in the community.</li> <li>▪ Commitment to community engagement.</li> <li>▪ Seek the information needed to implement effective policies and programmes that protect and promote health.</li> </ul>	<p>Not explicitly differentiated; however, a number of principles of ethical practice outlined are noted to have procedural components.</p>

Country Source(s)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<p><a href="#">ng_Guide.pdf</a>, Last updated: May 2015</p> <p>Referenced in Public Health Agency of Canada framework</p>	<p>and to improve the health of the people of BC.</p> <ul style="list-style-type: none"> <li>○ People are inherently social and interdependent.</li> <li>○ Communities are more than the sum of individuals.</li> <li>○ The effectiveness of institutions depends heavily on the public's trust is earned through ethical interaction.</li> <li>○ Collaboration is a key element to public health.</li> <li>○ Community engagement is important to the creation and implementation of sound public health policies and programs.</li> <li>○ People and their physical environment are interdependent.</li> <li>○ Identifying and promoting the</li> </ul>	<ul style="list-style-type: none"> <li>▪ Promote the empowerment of vulnerable and disenfranchised community members, aiming to ensure that the basic resources and conditions necessary for health are accessible to all.</li> <li>▪ Incorporate a variety of approaches that anticipate and respect diverse values, beliefs, and cultures in the community.</li> <li>▪ Ensure proportionality in its programmes and activities. It will ensure that benefits will outweigh risks and that both benefits and risks will be fairly distributed.</li> <li>▪ Properly justify the creation and implementation of its programmes, such as from the harm principle. Policies and programmes must demonstrate effectiveness, proportionality and necessity.</li> <li>▪ Programmes and policies will have clearly stated goals and be of proven effectiveness</li> <li>▪ Adopt a principle of reciprocity, whenever possible</li> <li>▪ Protect the confidentiality of information that can bring harm to an individual or community if made public</li> </ul>	

Country Source(s)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
	<p>fundamental requirements for health in a community are a primary concern to public health.</p> <ul style="list-style-type: none"> <li>▪ bases for action:                             <ul style="list-style-type: none"> <li>○ Knowledge is important and powerful.</li> <li>○ Science is the basis for much of our public health knowledge.</li> <li>○ People are responsible to act on the basis of what they know.</li> <li>○ Action is not based on information alone.</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>▪ Act in a timely manner on the information it has</li> <li>▪ Use the least restrictive or coercive means possible to achieve its goals</li> <li>▪ Ensure the professional competence of its employees</li> <li>▪ Engage in collaborations and affiliations in ways that build the public's trust and the institution's effectiveness</li> </ul>	
<p><b>Canada -Quebec</b>  Institut National de Sante Publique due Quebeq, <i>Framework of Values to Support Ethical Analysis of Public Health Actions,</i> <a href="https://www.inspq.qc.ca">https://www.inspq.qc.ca</a></p>	<p>The proposed values were selected from a large set of values identified in the public health ethics literature, as well as the two professional reference documents. The values were chosen based on stakeholder engagement, especially in the context of a</p>	<p><i>Societal values that are significant for public health action:</i></p> <ul style="list-style-type: none"> <li>▪ autonomy and empowerment</li> <li>▪ liberty</li> <li>▪ equality</li> <li>▪ equity</li> <li>▪ justice</li> <li>▪ reciprocity</li> <li>▪ solidarity</li> </ul>	<p><i>Professional values:</i></p> <ul style="list-style-type: none"> <li>▪ competence</li> <li>▪ scientific rigour</li> <li>▪ impartiality and integrity</li> <li>▪ responsibility and accountability</li> <li>▪ transparency</li> </ul>

Country Source(s)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<p><a href="/sites/default/files/publications/2285_framework_values_ethical_analysis_public_health_actions.pdf">/sites/default/files/publications/2285_framework_values_ethical_analysis_public_health_actions.pdf</a>, Last updated: June 2015</p>	<p>workshop held with public health directors. The retained values are viewed as best suited to analysing public health proposals, including those in the areas of assessment and risk management.</p>	<ul style="list-style-type: none"> <li>▪ respect for the environment.</li> </ul> <p><i>Values associated with the aims of public health:</i></p> <ul style="list-style-type: none"> <li>▪ health</li> <li>▪ well-being</li> <li>▪ common good</li> <li>▪ beneficence and non-maleficence</li> <li>▪ utility and effectiveness.</li> </ul>	<ul style="list-style-type: none"> <li>▪ prudence</li> <li>▪ openness</li> <li>▪ confidentiality and privacy.</li> </ul>
<p><b>Denmark</b></p> <p>Sundhedsstyrelsen (National Board of Health), Etik i forebyggelse og sundhedsfremme*, <a href="https://www.sst.dk/-/media/Udgivelser/2009/Publ2009/CFF/Etik/Etik_i_forebyggelse,-d-.pdf.ashx">https://www.sst.dk/-/media/Udgivelser/2009/Publ2009/CFF/Etik/Etik_i_forebyggelse,-d-.pdf.ashx</a>, Published: November 2009</p> <p><i>*Document translated using Google Translate</i></p>	<p>The ethical issues and values outlined were developed through literature searches on health promotion and prevention, the authors' professional expertise in moral, political and legal philosophy, and through interviews relevant expert stakeholders to ensure the issues and values addressed were perceived as relevant and comprehensive</p>	<p><i>Ethical issues (at times described as values):</i></p> <ul style="list-style-type: none"> <li>▪ balance of benefits and harms</li> <li>▪ inequality</li> <li>▪ autonomy and paternalism</li> <li>▪ responsibility and accountability</li> <li>▪ solidarity</li> <li>▪ evidence, documentation and risk</li> <li>▪ action and omission.</li> </ul>	<p><i>No information identified using search methodology applied in this review</i></p>
<p><b>United Kingdom</b></p>	<p>Discusses the concepts of</p>	<p>References the <i>four principles of biomedical</i></p>	<p><i>No information</i></p>



Country Source(s)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<p>Public Health England, <i>Public Health Ethics in Practice: A background paper on public health ethics for the UK Public Health Skills and Knowledge Framework</i>, <a href="https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/609620/PHSKF_public_health_ethics_in_practice.pdf">https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/609620/PHSKF_public_health_ethics_in_practice.pdf</a>, Published: April 2017</p>	<p>descriptive and normative theories, however does not mention a specific ethical theory.</p>	<p><i>ethics:</i></p> <ul style="list-style-type: none"> <li>▪ autonomy</li> <li>▪ non-maleficence</li> <li>▪ beneficence</li> <li>▪ Justice.</li> </ul> <p>However does not explicitly state that these are the principles which are or should be used, and highlights disparities in utility when considering public health ethics.</p>	<p><i>identified using search methodology applied in this review</i></p>
<p><b>United States</b></p> <p>Centers for Disease Control and Prevention (CDC), <i>Good decision making in real time: Practical public health ethics for local health officials</i>, <a href="https://www.cdc.gov/os/integrity/phethics/docs/S">https://www.cdc.gov/os/integrity/phethics/docs/S</a></p>	<p>Developed with in accordance with the <i>Principles of the Ethical Practice of Public Health</i> from the American Public Health Association.</p>	<p><i>Principles of the Ethical Practice of Public Health. Public health should:</i></p> <ul style="list-style-type: none"> <li>▪ Address principally the fundamental causes of disease and requirements for health, aiming to prevent adverse health outcomes.</li> <li>▪ Achieve community health in a way that respects the rights of individuals in the community.</li> <li>▪ Policies, programmes, and priorities should be developed and evaluated</li> </ul>	<p><i>No information identified using search methodology applied in this review</i></p>

Country Source(s)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
<p><a href="#">Student Manual Revision June 3 2019 508 compliant Final with cover.pdf</a>, Published June 5 2015</p>		<p>through processes that ensure an opportunity for input from community members.</p> <ul style="list-style-type: none"> <li>▪ Advocate and work for the empowerment of disenfranchised community members, aiming to ensure that the basic resources and conditions necessary for health are accessible to all.</li> <li>▪ Seek the information needed to implement effective policies and programmes that protect and promote health.</li> <li>▪ Should provide communities with the information they have that is needed for decisions on policies or programmes and should obtain the community’s consent for their implementation.</li> <li>▪ Act in a timely manner on the information they have within the resources and the mandate given to them by the public.</li> <li>▪ Incorporate a variety of approaches that anticipate and respect diverse values, beliefs, and cultures in the community.</li> <li>▪ Should be implemented in a manner that most enhances the physical and social environment.</li> </ul>	

Country Source(s)	Theory or approach underpinning	Considerations relevant to ethics	Considerations relevant to procedural elements
		<ul style="list-style-type: none"> <li>▪ Protect the confidentiality of information that can bring harm to an individual or community if made public Exceptions must be justified on the basis of the high likelihood of significant harm to the individual or others.</li> <li>▪ Ensure the professional competence of their employees.</li> <li>▪ Engage in collaborations and affiliations in ways that build the public's trust and the institution's effectiveness.</li> </ul>	

## Appendix 2.2 - Frameworks from public health agencies

### Appendix 2.2. Frameworks from public health agencies

Country	Framework structure
Source(s)	
<p><b>Canada - Quebec</b></p> <p>Institut National de Sante Publique due Quebec (National Institute of Public Health in Quebec), <i>Framework of Values to Support Ethical Analysis of Public Health Actions</i>, <a href="https://www.inspq.qc.ca/sites/default/files/publications/2285_framework_value_s_ethical_analysis_public_health_actions.pdf">https://www.inspq.qc.ca/sites/default/files/publications/2285_framework_value_s_ethical_analysis_public_health_actions.pdf</a>, Last updated: June 2015</p>	<p><i>The framework:</i></p> <ul style="list-style-type: none"> <li>▪ Provides definitions of the concepts of value, principle and norm.</li> <li>▪ Outlines the ethical review process of the Comite d'éthique de sante publique (CESP).</li> <li>▪ Provides definitions for each value and categorises each one into public health, societal and professional.                             <ul style="list-style-type: none"> <li>○ For each value outlined (21 in total) a detailed description of considerations is provided alongside potential challenges to each.</li> </ul> </li> </ul> <p><i>Ethical review process:</i></p> <ul style="list-style-type: none"> <li>▪ Understanding the different components of a project and how they relate to one another.</li> <li>▪ Confirming relevant values and tensions that may exist between the values or between the values and applicable norms.</li> <li>▪ Assessing how these values relate to the groups concerned and deciding which values take priority.</li> <li>▪ Clarifying the justifications for the choice of actions relating to the selected values, assessing the consequences and reduce negative consequences.</li> </ul>
<p><b>Canada</b></p> <p>Public Health Agency Canada, <i>Framework For Ethical Deliberation And Decision-Making In Public Health</i>,</p>	<p>The framework consists of six steps (with one being preliminary) that include guiding open-ended questions to facilitate ethical deliberation:</p> <p><i>Preliminary step:</i></p> <p>Users should determine how they will structure the decision-making process:</p> <ul style="list-style-type: none"> <li>▪ who will be responsible for the implementation of the framework.</li> <li>▪ who will be responsible for involving all the relevant stakeholders.</li> </ul>

Country	Framework structure
<p><b>Source(s)</b></p> <p><a href="https://www.canada.ca/content/dam/phac-aspc/documents/corporate/transparency/corporate-management-reporting/internal-audits/audit-reports/framework-ethical-deliberation-decision-making/pub-eng.pdf">https://www.canada.ca/content/dam/phac-aspc/documents/corporate/transparency/corporate-management-reporting/internal-audits/audit-reports/framework-ethical-deliberation-decision-making/pub-eng.pdf</a>, Last updated: March 2017</p>	<ul style="list-style-type: none"> <li>▪ who will be responsible for leading the ethical deliberation and analysis).</li> <li>▪ who has the authority to make a decision about the proposed initiative.</li> </ul> <p><i>Step 1: Identify the issue and context:</i></p> <ul style="list-style-type: none"> <li>▪ What is the public issue that needs to be addressed?</li> <li>▪ Is there a specific question that needs to be resolved?</li> <li>▪ What are the public health goals of the proposed programme?</li> <li>▪ Is there reason to believe the proposed programme will achieve its goals?</li> <li>▪ Who are the stakeholders in this issue?</li> <li>▪ What are their roles and responsibilities?</li> <li>▪ What specific issues are at stake for them, including their concerns, needs or interests?</li> <li>▪ Do any stakeholders have conflicts of interest?</li> <li>▪ Are there any issues of power imbalance between the stakeholders?</li> <li>▪ Have all the relevant stakeholders been engaged?</li> <li>▪ Are there any relevant laws or regulations that help frame the issue?</li> <li>▪ Are any PHAC or other federal policies relevant to the situation?</li> <li>▪ Are there any other relevant contextual factors?</li> <li>▪ What other information may be required to make a decision?</li> </ul> <p><i>Step 2: Identify ethical considerations:</i></p> <ul style="list-style-type: none"> <li>▪ What ethical values, principles and considerations are involved in this issue or decision?</li> <li>▪ Which of these principles, values or consideration are most important?</li> <li>▪ Do any public health or other professional groups or associations provide relevant guidelines or recommendations?</li> <li>▪ What other factors, values or principles do stakeholders consider important for making an ethical decision about the proposed initiative?</li> <li>▪ Are there any special considerations about the vulnerability of those most at risk?</li> <li>▪ Are there any special considerations about health inequities?</li> </ul>

Country	Framework structure
Source(s)	
	<p><i>Step 3: Identify and asses options:</i></p> <ul style="list-style-type: none"> <li>▪ What are the options to address the public health issue at hand? Are there alternative approaches?</li> <li>▪ Is doing nothing a valid option to consider?</li> <li>▪ What are the benefits of the proposed course of action or initiative for individuals, communities and the public?</li> <li>▪ What are the known potential burdens of the proposed course of action or initiative for individuals, communities and the public?</li> <li>▪ Will the proposed course of action or initiative entail greater burdens or disadvantages for an already disadvantaged individual or group?</li> <li>▪ Do the expected benefits justify the identified burdens?</li> <li>▪ Should the burdens be minimized? For everyone or for particular groups?</li> <li>▪ How can the benefits and burdens of the initiative be fairly balanced?</li> <li>▪ How much certainty or uncertainty is there about the effectiveness of each option?</li> <li>▪ What are the other strengths and limitations of each option?</li> <li>▪ Which option best respects the rights and interests of all who have a stake?</li> <li>▪ Which option treats people equally or proportionately?</li> <li>▪ Which option best serves the community or the population as a whole rather than just some members?</li> <li>▪ Which option best reflects the mission, vision, and values of PHAC?</li> <li>▪ To what degree is each option consistent with the current positions and policies of the federal government? What are the expected consequences of the potential inconsistencies?</li> </ul> <p><i>Step 4: Select the best course of action and implement:</i></p> <ul style="list-style-type: none"> <li>▪ Which option is preferable?</li> <li>▪ How can the initiative be implemented, or the course of action carried out, fairly?</li> <li>▪ Are we comfortable with the decision?</li> <li>▪ Who will the decision be communicated to?</li> </ul>

Country	Framework structure
Source(s)	<p><i>Step 5: Evaluate:</i></p> <ul style="list-style-type: none"> <li>▪ How could the decision-making process have been improved?</li> <li>▪ Were the results of the course of action or initiative consistent with the intention or the objectives of its proponents? If not, why not?</li> <li>▪ Did the course of action or initiative lead to any unintended consequences? If so, what was the impact of the unintended consequences?</li> <li>▪ Upon reflection, were some stakeholders left out or unduly represented?</li> <li>▪ Were better options identified after the initiative was implemented or the course of action carried out?</li> <li>▪ Should the decision be revisited?</li> </ul>
<p><b>Canada - British Columbia</b></p> <p>British Columbia Centre for Disease Control, <i>BCCDC Ethics Framework and Decision Making Guide</i>, <a href="http://www.bccdc.ca/resource-gallery/Documents/Guidelines%20and%20Forms/Guidelines%20and%20Manuals/BCCDC_Ethics_Framework_Decision_Making_Guide.pdf">http://www.bccdc.ca/resource-gallery/Documents/Guidelines%20and%20Forms/Guidelines%20and%20Manuals/BCCDC_Ethics_Framework_Decision_Making_Guide.pdf</a>, Last updated: May 2015</p>	<p>Decision-making framework aims to encourage individuals to reflect ethically on a problem and its stakeholders, the relevant facts, the appropriate guidance from policy and law, and an analysis in light of the relevant ethical and moral principles to ensure a fair process and collaborative outcomes.</p> <p><i>Step 1: Identify the ethical question:</i></p> <ul style="list-style-type: none"> <li>▪ What is the issue that needs to be addressed?</li> <li>▪ Can this issue be simply stated with the use of some of the terms listed above?</li> </ul> <p><i>Step 2: Identify the stakeholders:</i></p> <ul style="list-style-type: none"> <li>▪ Who needs to be a part of this decision-making process? Be as inclusive as possible while keeping the decision-making process manageable. Sometimes a stakeholder cannot be physically present, but their interests must be acknowledged and accommodated.</li> <li>▪ Key players include the individual or community affected; the staff member(s) who are grappling with the issue; the physician lead and operations leader.</li> <li>▪ Persons from other divisions should be brought in if their division is affected or if there are people from other departments with expertise in managing these types of problems. This may also include legal counsel or privacy advisors.</li> </ul> <p><i>Step 3: Clarify the facts, gather information:</i></p> <ul style="list-style-type: none"> <li>▪ What are the relevant known facts?</li> </ul>

Country	Framework structure
Source(s)	
	<ul style="list-style-type: none"> <li>▪ What facts need further exploration to inform a decision?</li> <li>▪ What information is simply unknowable?</li> <li>▪ Have all stakeholders been able to represent their views of the facts?</li> </ul> <p><i>Step 4: Analyse the problem in light of the values and principles in the Code. Try to identify the origins of tensions from the conflicting values and principles:</i></p> <ul style="list-style-type: none"> <li>▪ What principles or values are in conflict? What moral intuitions are in conflict?</li> <li>▪ Can this problem be described by the terms of the Code and in relation to the values and principles of the Code? If possible try to identify which values and principles seem to have priority.</li> <li>▪ Competing interests also generate and contribute to ethical issues: be wary of conflicts of interest that bear on the issue at hand.</li> <li>▪ What are the possible consequences in terms of benefits, risks and harms?</li> </ul> <p><i>Step 5: Identify the relevant legal and normative guidance:</i></p> <ul style="list-style-type: none"> <li>▪ Legal and legislative considerations include asking what is the relevant legislation surrounding the issue and should legal counsel be pursued.</li> <li>▪ What local policy and procedures of the BCCDC and Public Health Services Authority (PHSA) have bearing on this issue?</li> <li>▪ The professional codes of ethics can be helpful in informing decisions and actions.</li> <li>▪ If the issue involves research, then research ethics guidelines and departments such as the University of British Columbia’s Office of Research Services should be consulted.</li> <li>▪ Individuals’ moral intuition and ethical considerations should be explored and discussed as a valid source of guidance throughout the decision-making process.</li> </ul> <p><i>Step 6: Identify possible courses of action:</i></p> <ul style="list-style-type: none"> <li>▪ Are there principles that appear to have priority?</li> <li>▪ Are there legislative or policy statements that have compelling force?</li> <li>▪ What are some of the alternatives?</li> <li>▪ Sometimes doing nothing or making no changes is a legitimate consideration.</li> </ul>



Country	Framework structure
Source(s)	
	<p><i>Step 7: Make a decision:</i></p> <ul style="list-style-type: none"> <li>▪ Are all the stakeholders adequately represented? Has this decision been deliberative? It must be recognized that sometimes compromises have to be made.</li> <li>▪ The aim is unanimity in decision-making. How can decision-making proceed if the decision-makers are not in agreement? Can consensus be reached or will decisions be based on majority opinion?</li> <li>▪ What is the best action?</li> <li>▪ It must be acknowledged that sometimes there is more than one possible answer. The decisions and resulting actions should be ethically defensible and made in accordance with the principles of the Code.</li> </ul> <p><i>Step 8: Implement a decision:</i></p> <ul style="list-style-type: none"> <li>▪ What is the plan of actions for communicating the decision?</li> <li>▪ Develop a strategy for implementation including the actions that will be taken and the individuals or groups involved.</li> </ul> <p><i>Step 9: Evaluate the decision:</i></p> <ul style="list-style-type: none"> <li>▪ How will the decision be evaluated? By what criteria will the outcomes be measured and validated?</li> <li>▪ Was this the right decision?</li> <li>▪ Should the decisions, policies or programmes be revised? Do new policies need to be created?</li> <li>▪ Do new ethical issues arise?</li> </ul> <p><i>Decision-making considerations:</i></p> <ul style="list-style-type: none"> <li>▪ Stakeholder involvement: examples of stakeholders that are mentioned include the patient or client, the community affected, staff members making the decisions, supervisors and other relevant leaders who may offer support.</li> <li>▪ Unanimous decisions: framework states that decision-making should be unanimous. In instances where unanimous decisions are not possible, it is important to ask how to proceed</li> </ul>

Country Source(s)	Framework structure
	<p>and decide if a majority is acceptable. The individuals making decisions should engage in a deliberative process and decide whether a unanimous decision is required or if a majority vote is acceptable.</p> <ul style="list-style-type: none"> <li>Any decisions that are made should be ethically defensible and follow the BCCDC professional code of ethics.</li> </ul>
<p><b>Denmark</b></p> <p>Sundhedsstyrelsen (The Danish Health Authority), <i>Etik i forebyggelse og sundhedsfremme*</i>, <a href="https://www.sst.dk/-/media/Udgivelser/2009/Publ2009/CFF/Etik/Etik_i_forebyggelse,-d-,pdf.ashx">https://www.sst.dk/-/media/Udgivelser/2009/Publ2009/CFF/Etik/Etik_i_forebyggelse,-d-,pdf.ashx</a> , Published: December 2009</p> <p><i>*Document translated using Google Translate</i></p>	<p>Describes a number of harmful effects that health promotion and prevention efforts can have for individuals' quality of life. Examples of harmful effects include worry creation, morbidity, making patients, stigma and medicalization, these various types of harmful effects are subject to an ethical analysis, which is about identifying the underlying ethical values at stake.</p> <p>Deals with justice and inequality in relation to prevention and health promotion. Three types of inequality are distinguished: inequality in the yield of efforts, inequality in terms of harmful effects and inequality in the overall distribution of health in society.</p> <p>Paternalism and autonomy: many efforts can be said to influence the autonomy or self-determination of individuals.</p> <p>Examines issues of responsibility and accountability. The question here is whether it is fair to hold individuals accountable for any adverse health consequences behaviour and whether it is beneficial to do so.</p> <p>Discusses with the ethical implications that result from the fact that in practice it is sometimes necessary to initiate efforts, even if there is no sure knowledge of their effect.</p> <p>Discusses whether or not it is ethically relevant to distinguish between actions and permits - whether to act and take action requires more weighty justification than to refrain from doing anything.</p>

Country Source(s)	Framework structure
	Discusses how to weight ethical values being faced and why this is important when working in prevention and health promotion.
<p><b>United Kingdom</b></p> <p>Public Health England, <i>Public Health Ethics in Practice: A background paper on public health ethics for the UK Public Health Skills and Knowledge Framework</i>, <a href="https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/609620/PHSKF_public_health_ethics_in_practice.pdf">https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/609620/PHSKF_public_health_ethics_in_practice.pdf</a>, Published: April 2017</p>	<p>Provides an overview of public health ethics and compares and contrasts this with medical and bioethics:</p> <ul style="list-style-type: none"> <li>▪ Outlines a case study which highlights the inadequacies of applying a medical ethics framework to a public health issue.</li> </ul> <p>Discusses public health as a field of philosophical enquiry:</p> <ul style="list-style-type: none"> <li>▪ Outlines and compared normative vs descriptive ethics.</li> <li>▪ Discusses the role of political philosophy in understanding types of ethics theories.</li> </ul> <p>Outlines ethical frameworks and ethical models and highlights their use as tools for decision-makers. Briefly outlines the development of ethical guidance highlighting the importance of it being:</p> <ul style="list-style-type: none"> <li>▪ context specific</li> <li>▪ task specific</li> <li>▪ level specific.</li> </ul>
<p><b>United States</b></p> <p>Centers for Disease Control and Prevention, <i>Good decision making in real time: Practical public health ethics for local health officials</i>,</p>	<p><i>Ethical Analysis Framework:</i></p> <p><i>1. Analyse the Ethical Issues in the Situation:</i></p> <ul style="list-style-type: none"> <li>▪ What are the public health risks and harms of concern?</li> <li>▪ What are the public health goals?</li> <li>▪ Who are the stakeholders? What are their moral claims?</li> <li>▪ Is the source or scope of legal authority in question?</li> <li>▪ Are precedent cases or the historical context relevant?</li> <li>▪ Do professional codes of ethics provide guidance?</li> </ul>

Country	Framework structure
<p data-bbox="197 312 600 347"><b>Source(s)</b></p> <p data-bbox="197 352 600 579"> <a href="https://www.cdc.gov/os/integrity/phethics/docs/Student_Manual_Revision_June_3_2019_508_compliant_Final_with_cover.pdf">https://www.cdc.gov/os/integrity/phethics/docs/Student_Manual_Revision_June_3_2019_508_compliant_Final_with_cover.pdf</a>,                      Published June 5 2015                 </p>	<p data-bbox="611 352 2049 387"><i>2. Evaluate the Ethical Dimensions of the Alternate Courses of Public Health Action:</i></p> <ul data-bbox="611 392 2049 770" style="list-style-type: none"> <li>▪ Utility: Does a particular public health action produce a balance of benefits over harms?</li> <li>▪ Justice: Are the benefits and burdens distributed fairly (distributive justice)? Do legitimate representatives of affected groups have the opportunity to participate in making decisions (procedural justice)?</li> <li>▪ Respect for individual interests and social value: Does the public health action respect individual choices and interests (autonomy, liberty, privacy)?</li> <li>▪ Respect for legitimate public institutions: Does the public health action respect professional and civic roles and values, such as transparency, honesty, trustworthiness, consensus-building, promise-keeping, protection of confidentiality, and protection of vulnerable individuals and communities from undue stigmatization?</li> </ul> <p data-bbox="611 775 2049 810"><i>3. Provide Justification for a Particular Public Health Action:</i></p> <ul data-bbox="611 815 2049 1120" style="list-style-type: none"> <li>▪ Effectiveness: Is the public health goal likely to be accomplished?</li> <li>▪ Proportionality: Will the probable benefits of the action outweigh the infringed moral considerations?</li> <li>▪ Necessity: Is overriding the conflicting ethical claims necessary to achieve the public health goal?</li> <li>▪ Least infringement: Is the action the least restrictive and least intrusive?</li> <li>▪ Public Justification: Can public health agents offer public justification for the action or policy, on the basis of principles in the Code of Ethics or general public health principles, that citizens—in particular, those most affected—could find acceptable in principle?</li> </ul>

## Appendix 3.1 - Overview of national ethics bodies

### Appendix 3.1. Overview of national ethics bodies

Country	Topic	Ethical considerations for the specified topic
<p><b>Australia</b></p> <p>National Health and Medical Research Council, <i>Ethical guidelines on the use of assisted reproductive technology in clinical practice and research</i>, <a href="https://www.nhmrc.gov.au/art#block-views-block-file-attachments-content-block-1">https://www.nhmrc.gov.au/art#block-views-block-file-attachments-content-block-1</a>, Last updated: 2017</p>	<p>Ethical guidelines for assisted reproductive technology including pre-implantation genetic diagnosis, screening and testing</p>	<p>Pre-implantation screening considerations:</p> <ul style="list-style-type: none"> <li>▪ Assess ethical acceptability of pre-implantation testing.</li> <li>▪ Consider current evidence on the impact of a disease or condition on the quality of life of the person who would be born.</li> <li>▪ Consider the concerns of the intended parent(s) about their ability to care for the person who would be born.</li> <li>▪ Availability and accessibility of therapies or interventions to minimise the impact of the condition or disease.</li> <li>▪ The limitations of the technology and likelihood of false results.</li> <li>▪ The experiences of individuals and families living with the condition or disease.</li> <li>▪ The potential for stigma to influence the perceived impact of the condition or disease on the quality of life of the person who would be born.</li> <li>▪ The extent of social support available to the intended parent(s).</li> <li>▪ Provide relevant counselling and information to help individuals make informed decisions.</li> </ul>
<p><b>Denmark</b></p> <p>The Danish Council of Ethics, <i>Screening - a statement</i>, <a href="https://www.etiskraad.dk/~/medi">https://www.etiskraad.dk/~/medi</a></p>	<p>Screening programmes ethical issues and recommendations</p>	<p>Four themes under which considerations fall:</p> <ul style="list-style-type: none"> <li>▪ social and psychological effects: <ul style="list-style-type: none"> <li>○ sickness and anxiety</li> <li>○ hope healing and security</li> <li>○ finding fault or promoting health.</li> </ul> </li> </ul>

Country	Topic	Ethical considerations for the specified topic
<p><b>Source(s)</b></p> <p><a href="#">a/Etisk-Raad/Etiske-Temaer/Forebyggelse/Publikationer/1999-04-13-screening-redegoerelse.pdf</a>, Published: April 1999</p> <p><i>*Document translated using Google Translate</i></p>		<ul style="list-style-type: none"> <li>▪ false results</li> <li>▪ fair prioritization: <ul style="list-style-type: none"> <li>○ Helping the sick first.</li> <li>○ The principle of equity and its limits.</li> <li>○ Screening for the benefits of society.</li> <li>○ Requirements for the decision basis for introducing a screening programme.</li> </ul> </li> <li>▪ unsolicited inquiries and information: <ul style="list-style-type: none"> <li>○ The right to know.</li> <li>○ The right not to know.</li> </ul> </li> </ul>
<p><b>Denmark</b></p> <p>1. Det Etiske Råd (The Danish Council of Ethics), <i>Etisk tjekliste*</i>, <a href="https://www.etiskraad.dk/etiske-temaer/forebyggelse/paavirkning-og-folkesundhed/etisk-tjekliste">https://www.etiskraad.dk/etiske-temaer/forebyggelse/paavirkning-og-folkesundhed/etisk-tjekliste</a>, Last updated: October 2016</p> <p>2. Det Etiske Råd (The Danish Council of Ethics), <i>Et venligt skub? - Hvordan sikrer sundhedsvæsenet, at dets påvirkning af borgerne er etisk forsvarlig, når det handler om brugen af information, rekruttering og anbefalinger?*</i>,</p>	<p>The Danish Council of Ethics, has published two ethical checklists (regional level and municipality level) for use in public health interventions, including screening:</p> <ul style="list-style-type: none"> <li>▪ These checklists are similar in content and aimed toward decision-makers to help them make ethically sound decisions</li> </ul>	<p><i>Ethical checklist</i>.<sup>(1)</sup></p> <p><i>Professional basis</i></p> <ul style="list-style-type: none"> <li>▪ How secure is the knowledge of the positive or negative effects of the intervention, as well as the effect of the form of information or recruitment?</li> </ul> <p><i>Alternatives</i></p> <ul style="list-style-type: none"> <li>▪ Are there realistic alternatives that: <ul style="list-style-type: none"> <li>○ Are less intrusive?</li> <li>○ Are more efficient (in terms of cost)?</li> <li>○ More permanently can remove the cause of the health problem and thus limit the need for renewed intervention?</li> <li>○ Entail greater justice?</li> </ul> </li> </ul> <p><i>Estimated positive effects</i></p> <ul style="list-style-type: none"> <li>▪ Does the intervention lead to: <ul style="list-style-type: none"> <li>○ significant health benefits?</li> <li>○ limiting behaviours that have significant negatives health consequences for others?</li> </ul> </li> </ul>

Country	Topic	Ethical considerations for the specified topic
<p data-bbox="203 311 683 347"><b>Source(s)</b></p> <p data-bbox="203 352 683 502"><a href="https://www.etiskraad.dk/~/media/Etisk-Raad/Etiske-Temaer/Forebyggelse/Nudging-og-folkesundhed/Polycypapir.pdf">https://www.etiskraad.dk/~/media/Etisk-Raad/Etiske-Temaer/Forebyggelse/Nudging-og-folkesundhed/Polycypapir.pdf</a></p> <p data-bbox="203 507 436 544">Published: 2016</p> <p data-bbox="203 582 607 657"><i>*Document translated using Google Translate</i></p>	<p data-bbox="757 352 996 464">in the context of public health interventions.</p> <ul data-bbox="712 469 996 927" style="list-style-type: none"> <li>▪ The checklist outlines questions which should be asked and which should help to stimulate ethical debate relevant to the intervention under consideration.<sup>(1)</sup></li> </ul> <p data-bbox="712 970 996 1316">Also published a policy paper which applies the ethical checklists to three different cases, one of which is a national screening program for colorectal cancer.<sup>(2)</sup></p>	<ul data-bbox="1176 352 1624 389" style="list-style-type: none"> <li>○ increased equality in health?</li> </ul> <p data-bbox="1030 394 1411 430"><i>Estimated negative effects</i></p> <ul data-bbox="1086 435 2045 775" style="list-style-type: none"> <li>▪ Does the intervention lead to: <ul data-bbox="1176 472 2045 775" style="list-style-type: none"> <li>○ predictable negative effects (for example, physical harm, stigma, morbidity, discrimination or restriction of self-expression)?</li> <li>○ violation of integrity?</li> <li>○ greater inequality in health?</li> <li>○ that important decisions are made on behalf of others (for example, parents on behalf of children)?</li> <li>○ risk damaging citizens' trust in healthcare?</li> </ul> </li> </ul> <p data-bbox="1030 780 1288 817"><i>Reflected position</i></p> <ul data-bbox="1086 821 2045 1316" style="list-style-type: none"> <li>▪ To what extent the intervention promotes or limits the citizens' opportunity for reflected position? <ul data-bbox="1176 895 2045 1316" style="list-style-type: none"> <li>○ Suitable for the recruitment and information method or the use of recommendations itself to promote reflection of the position?</li> <li>○ Is the health purpose of - and the value premises for - the intervention itself transparent to citizens?</li> <li>○ Is the actuating mechanism as well as the intended impact transparent to citizens?</li> <li>○ To what extent can citizens be assumed to be unable to exercise self-determination?</li> <li>○ What reasonable expectations can the citizen have to have his self-determination respected given the context?</li> </ul> </li> </ul>
<b>Finland</b>	Genomics	Equality, justice, consent and informed decision-making about the use of a person's genetic information

Country	Topic	Ethical considerations for the specified topic
<p><b>Source(s)</b></p> <p>The National Advisory Board on Social Welfare and Health Care Ethics,  <i>Opinion on the draft government proposals for genomics</i>  <a href="https://etene.fi/documents/1429646/7155344/Etenen+lausunto+genomilaista%2C+01.08.2018/e987b140-d934-eb3d-391a-f8223b2fdf1b/Etenen+lausunto+genomilaista%2C+01.08.2018.pdf">https://etene.fi/documents/1429646/7155344/Etenen+lausunto+genomilaista%2C+01.08.2018/e987b140-d934-eb3d-391a-f8223b2fdf1b/Etenen+lausunto+genomilaista%2C+01.08.2018.pdf</a>, Last updated: Jan 2008</p>		
<p><b>France</b></p> <p>Comité consultatif national d'éthique (National Ethics Consultative Committee), <i>Opinion on ethical issues related to antenatal diagnosis: prenatal diagnosis (PND) and preimplantation diagnosis (PID)</i>,  <a href="https://www.ccne-ethique.fr/fr/publications/avis-sur-les-problemes-ethiques-lies-aux-diagnostics-antenatals-le-diagnostic-prenatal">https://www.ccne-ethique.fr/fr/publications/avis-sur-les-problemes-ethiques-lies-aux-diagnostics-antenatals-le-diagnostic-prenatal</a>, Last</p>	<p>Pre-natal and Pre-implantation diagnosis</p>	<p>Iatrogenic risks of PND such as foetal loss due to biopsy sampling. Information provided to couples regarding prenatal screening and diagnosis should involve: multiple options enabling couples to feel they have a choice of different actions available; neutrality of information to avoid causing anxiety or influencing action; there should be adequate timing to allow for critical reflection before taking action.</p>



Country	Topic	Ethical considerations for the specified topic
<b>Source(s)</b> updated: October 2009		
<b>France</b>  Comité consultatif national d'éthique (National Ethics Consultative Committee), <i>Ethical issues associated with the development of fetal genetic tests on maternal blood</i> , <a href="https://www.ccne-ethique.fr/fr/publications/questions-ethiques-associees-au-developpement-des-tests-genetiques-foetaux-sur-sang">https://www.ccne-ethique.fr/fr/publications/questions-ethiques-associees-au-developpement-des-tests-genetiques-foetaux-sur-sang</a> , Last updated: April 2013	Development of foetal genetic tests on maternal blood	The quality of information and the time provided to couples to reflect on, for example, a diagnosis of Trisomy 21, before taking action. The risk of a drift towards a form of eugenics from improved testing and encouraging adoption of testing for couples and practitioners. The risk of searching to actively prevent cases of Trisomy 21 or other conditions from a collection pressure or bias by society. This could have a negative impact on the freedom of choice for parents to continue with a Trisomy 21 pregnancy.
<b>France</b>  Comité consultatif national d'éthique (National Ethics Consultative Committee), <i>Ethical reflection on the evolution of genetic tests linked to very high throughput human DNA sequencing</i> , <a href="https://www.ccne-ethique.fr/fr/publications/reflexion-ethique-sur-levolution-des-">https://www.ccne-ethique.fr/fr/publications/reflexion-ethique-sur-levolution-des-</a>	Evolution of genetic tests linked to very high throughput human DNA processing	Uncertainties of sequencing and difficulties with respect to quality of techniques and information. Risks regarding misuse or management of genetic information. Legal protection of personal information.

Country	Topic	Ethical considerations for the specified topic
<b>Source(s)</b>		
<a href="#">tests-genetiques-liee-au-sequencage-de-ladn-humain</a> , Last updated: Jan 2016		
<b>France</b>  Comité consultatif national d'éthique (National Ethics Consultative Committee), <i>Ethics and deafness in children: elements for reflection on information on systematic neonatal screening and care for deaf children</i> , <a href="https://www.ccne-ethique.fr/fr/publications/ethique-et-surdite-de-lenfant-elements-de-reflexion-propos-de-linformation-sur-le">https://www.ccne-ethique.fr/fr/publications/ethique-et-surdite-de-lenfant-elements-de-reflexion-propos-de-linformation-sur-le</a> , Last updated: June 2007	Systematic neonatal screening and deafness in children	Non-maleficence: there is a risk of underestimating the harm of a diagnosis of deafness on a new-born and risks to the deaf community by categorisation of deafness alongside "serious conditions" in new-born screening. Consider the psychological, linguistic and sociological implications.
<b>France</b>  Comité consultatif national d'éthique (National Ethics Consultative Committee), <i>Ethical questions raised by the delivery of neonatal genetic information during the screening of genetic</i>	Neonatal genetic information during the screening of genetic diseases	The purpose of screening should be the detection of a significant risk of the onset of a potentially serious illness to allow management and treatment as early as possible. Concerns: Free and informed consent, stigmatisation of heterozygous individuals for a given allele, non-information, and consistency with the management of genetic information.

Country	Topic	Ethical considerations for the specified topic
<b>Source(s)</b> <i>diseases,</i> <a href="https://www.ccne-ethique.fr/fr/publications/questions-ethiques-posees-par-la-delivrance-de-linformation-genetique-neonatale">https://www.ccne-ethique.fr/fr/publications/questions-ethiques-posees-par-la-delivrance-de-linformation-genetique-neonatale</a> , Last updated: May 2007		
<b>France</b>  Comité consultatif national d'éthique (National Ethics Consultative Committee), <i>Opinion on tuberculosis screening and BCG vaccination,</i> <a href="https://www.ccne-ethique.fr/fr/publications/avis-sur-le-depistage-de-la-tuberculose-et-la-vaccination-par-le-bcg">https://www.ccne-ethique.fr/fr/publications/avis-sur-le-depistage-de-la-tuberculose-et-la-vaccination-par-le-bcg</a> , Last updated: June 2006	Tuberculosis screening	Targeted vaccination or screening may result in stigmatisation or discrimination. Anonymity and confidentiality of individuals is important.
<b>France</b>  Comité consultatif national d'éthique (National Ethics Consultative Committee), <i>Generalised prenatal screening for cystic fibrosis,</i> <a href="https://www.ccne-ethique.fr/fr/publications/avis-sur-le-depistage-de-la-tuberculose-et-la-vaccination-par-le-bcg">https://www.ccne-ethique.fr/fr/publications/avis-sur-le-depistage-de-la-tuberculose-et-la-vaccination-par-le-bcg</a>	Pre-natal screening for cystic fibrosis	Informed consent and understanding of what is involved to minimise anxiety and stress of the individuals involved.

Country	Topic	Ethical considerations for the specified topic
<b>Source(s)</b>		
<a href="http://ethique.fr/fr/publications/le-depistage-prenatal-generalise-de-la-mucoviscidose">ethique.fr/fr/publications/le-depistage-prenatal-generalise-de-la-mucoviscidose</a> , Last updated: Dec 2003		
<b>Germany</b>  Deutscher Ethikrat (German Ethics Council), <i>The future of genetic diagnosis – from research to clinical practice</i> , <a href="https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/englisch/opinion-the-future-of-genetic-diagnosis.pdf">https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/englisch/opinion-the-future-of-genetic-diagnosis.pdf</a> , Last updated: April 2013	Genetic diagnosis and testing including prenatal diagnosis for risk of genetic disorders.	Three ethical problem areas related to new developments in genetic diagnosis: <ul style="list-style-type: none"> <li>▪ The understanding of illness and health.</li> <li>▪ Issues of autonomy, self-determination and responsibility.</li> <li>▪ Social aspects including justice and solidarity.</li> </ul> The ethical problems related to prenatal and postnatal genetic diagnosis are treated separately. There is a risk to the life of the unborn child from prenatal genetic diagnosis.  <i>Aspects</i> that should be considered with respect to genetic diagnosis: <ul style="list-style-type: none"> <li>▪ The nature of information: genetic information may be disease or health-related and may or may not impact on lifestyle.</li> <li>▪ The probability of occurrence of a phenotype if a specific genotype is present.</li> <li>▪ The probably time when a particular phenotype will occur.</li> <li>▪ The severity of the health disorder in the case of disease-related information.</li> <li>▪ The possibility for prevention or treatment to influence the health disorder.</li> <li>▪ The timing of the genetic test.</li> <li>▪ The significance of the prognosis to the affected person.</li> <li>▪ The technical reliability and validity of the genetic test.</li> </ul>
<b>Germany</b>	Preimplantation	The objection of impermissible selection:

Country Source(s)	Topic	Ethical considerations for the specified topic
<p>Deutscher Ethikrat (German Ethics Council), <i>Preimplantation genetic diagnosis</i>, <a href="https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/englisch/DER_Stn_PID_EN_Online.pdf">https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/englisch/DER_Stn_PID_EN_Online.pdf</a>, Last updated: March 2011</p>	<p>genetic diagnosis (PGD)</p>	<ul style="list-style-type: none"> <li>▪ Selection and involvement of impermissible decisions on the rejection of human life.</li> </ul> <p>Discrimination of persons with disabilities:</p> <ul style="list-style-type: none"> <li>▪ There is fear that the introduction of PGD may lead to stigmatisation and discrimination against people with disabilities.</li> <li>▪ There is risk that solidarity with and the social recognition and support of people with disabilities will be undermined.</li> <li>▪ There is a risk to unborn persons.</li> </ul> <p>Self-determination of the pregnant person or of the couple:</p> <ul style="list-style-type: none"> <li>▪ An important factor is the availability of information and options to enable a choice to exist between options available.</li> </ul>
<p><b>Italy</b></p> <p>Comitato Nazionale per la Bioetica (National Bioethics Committee), <i>Bioethical Guidelines for Genetic Testing</i>, <a href="https://bioetica.governo.it/media/3371/p41_1999_genetic-testing_en.pdf">https://bioetica.governo.it/media/3371/p41_1999_genetic-testing_en.pdf</a>, Published: 2009</p>	<p>Genetic Testing</p>	<ul style="list-style-type: none"> <li>▪ Genetic testing can be used to identify the risk of contracting diseases in the future; it is unlikely however that this risk can ever become certainty.</li> <li>▪ Predictions based on genetic tests cannot always be confirmed by other independent clinical or instrumental evidence. In this case, the prediction will be confirmed only by the onset of the disease.</li> <li>▪ The results often compel the couple to face options that involve reproductive choices and include prenatal diagnosis, heterologous insemination, interruption of pregnancy, adoption. These options may clash with the couple's ethical principles or their religious beliefs.</li> <li>▪ The test results may provide genetic information related to the future state of health of close relatives of those subjected to the test, regardless of their present state of health.</li> </ul>

Country	Topic	Ethical considerations for the specified topic
<b>Source(s)</b>		<ul style="list-style-type: none"> <li>▪ For many genetic diseases no effective cures exist, only palliative or containment therapies able to relieve some complications.</li> <li>▪ Subjects that, although not yet affected by them, who are identified as being at risk with regard to certain diseases, may suffer psychological stress, be discriminated against, encounter difficulties in their social life, in access to the health or insurance systems, or to employment.</li> <li>▪ Membership of a given population may represent a discriminant with regard to diagnosis and the interpretation of the tests.</li> <li>▪ Health care personnel with experience of genetic counselling, and the number of public laboratories capable of providing it, are insufficient.</li> </ul>
<b>Sweden</b>  Statens medicinsk-etiska rad, (Swedish National Council on Medical Ethic), <i>Prenatal diagnosis – the Ethics</i> , <a href="https://smer.se/wp-content/uploads/2012/04/Prenatal-diagnosis-the-Ethics.pdf">https://smer.se/wp-content/uploads/2012/04/Prenatal-diagnosis-the-Ethics.pdf</a> , Last updated: November 2006	Ethical aspects of prenatal diagnosis	<i>Ethical principles and concepts of importance:</i> <ul style="list-style-type: none"> <li>▪ Perceptions of human nature, including the equal worth of all.</li> <li>▪ Does prenatal diagnosis impact on the principle of human dignity, including discrimination against individuals with disabilities?</li> <li>▪ The impact of prenatal diagnosis on an individual's autonomy or self-determination.</li> <li>▪ Informed consent and personal integrity.</li> <li>▪ Quality of life assessments concerning prenatal diagnosis involve two main stakeholders, the pregnant individual and the unborn child.</li> <li>▪ The principle of need and solidarity requires that resources should be devoted to those areas where there is the greatest need and builds on the principle of fairness.</li> </ul>

Country Source(s)	Topic	Ethical considerations for the specified topic
		<ul style="list-style-type: none"> <li>▪ The position of the Smer with respect to the moral status of the fertilised egg is as follows: “The genesis of human life is a process in which the fertilised egg is a life in the making and has a certain moral status. This moral status increases gradually as the foetus develops. At the point in time when the foetus can survive outside its mother’s body, its moral status becomes human dignity”.</li> </ul>
<p><b>United Kingdom</b></p> <p>Nuffield Council on Bioethics, <i>Whole genome sequencing of babies</i>, <a href="https://www.nuffieldbioethics.org/publications/whole-genome-sequencing-of-babies/briefing-note/ethical-issues">https://www.nuffieldbioethics.org/publications/whole-genome-sequencing-of-babies/briefing-note/ethical-issues</a>, Published: March 2018</p>	<p>Whole genome sequencing of babies.</p>	<p><i>Ethical issues</i> to consider:</p> <p>For babies:</p> <ul style="list-style-type: none"> <li>▪ False positive results.</li> <li>▪ Uncertain results.</li> <li>▪ Over treatment.</li> <li>▪ The right of the child to an open future and to make their own choices about accessing genetic information.</li> </ul> <p>For parents:</p> <ul style="list-style-type: none"> <li>▪ Parents may feel entitled to know, or not know, genetic information about their child.</li> <li>▪ Some results may lead to uncertainty, causing confusion and anxiety.</li> <li>▪ Information could impact family expectations and how the child is raised.</li> </ul> <p>Other family members:</p> <ul style="list-style-type: none"> <li>▪ Siblings may have interests in knowing the information that might relate to their own health.</li> <li>▪ Equally they may not want to know their genetic information.</li> </ul> <p>Healthcare professionals:</p> <ul style="list-style-type: none"> <li>▪ May feel duty to provide access to genome sequencing.</li> </ul>

Country	Topic	Ethical considerations for the specified topic
Source(s)		<ul style="list-style-type: none"> <li>▪ May not be trained to interpret or deliver the results.</li> <li>▪ Genetic counselling may not be available.</li> </ul> Society: <ul style="list-style-type: none"> <li>▪ Impacts on public attitudes towards genetic variation and disability.</li> </ul>
<b>United Kingdom</b>  Nuffield Council on Bioethics, <i>Public Health: ethical issues</i> , <a href="https://www.nuffieldbioethics.org/publications/public-health">https://www.nuffieldbioethics.org/publications/public-health</a> , Published: November 2007	Ethical issues in public health. <ul style="list-style-type: none"> <li>▪ Provides high level discussion on differing and contrasting ethical theories such as libertarian versus utilitarian approaches, offering viewpoints on the potential positives and negatives of each.</li> <li>▪ Provides a descriptive perspective of ethical theories</li> </ul>	<i>Goals</i> considered under the stewardship model for public health programmes: <ul style="list-style-type: none"> <li>▪ Reduce the risks of ill health that people might impose on each other.</li> <li>▪ Reduce causes of ill health by regulations that ensure environmental conditions that sustain good health, such as the provision of clean air and water, safe food and decent housing.</li> <li>▪ Pay special attention to the health of children and other vulnerable people.</li> <li>▪ Promote health not only by providing information and advice, but also with programmes to help people to overcome addictions and other unhealthy behaviours.</li> <li>▪ Ensure that it is easy for people to lead a healthy life, for example by providing convenient and safe opportunities for exercise.</li> <li>▪ Ensure that people have appropriate access to medical services.</li> <li>▪ Aim to reduce unfair health inequalities.</li> </ul> <i>Constraints</i> considered under the stewardship model for public health programmes: <ul style="list-style-type: none"> <li>▪ Not attempt to coerce adults to lead healthy lives.</li> </ul>



Country	Topic	Ethical considerations for the specified topic
Source(s)	<p>culminating in a stewardship model for application of ethics in public health and an intervention ladder.</p>	<ul style="list-style-type: none"> <li>▪ Minimise interventions that are introduced without the individual consent of those affected, or without procedural justice arrangements which provide adequate mandate.</li> <li>▪ Seek to minimise interventions that are perceived as unduly intrusive and in conflict with important personal values.</li> </ul> <p><i>Intervention ladder:</i></p> <ul style="list-style-type: none"> <li>▪ A device for comparing different policy options according to their degree of intrusiveness.</li> <li>▪ Assist in thinking about the acceptability and justification of different policy initiatives.</li> <li>▪ The higher the rung on the ladder at which the policy maker intervenes, the stronger the justification has to be.</li> </ul>

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