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An tÚdarás Um Fhaisnéis
agus Cáilíocht Sláinte

Protocol for review of international ethics frameworks used in policy- making in the context of screening

Published: 30 November 2021

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Definitions reference guide

Clinical ethics	The consideration and application of ethics to medical or clinical practice, typically at the individual patient level.
Decision-making	The process of making a choice or decision when confronted with more than one potentially viable alternative.
Ethics	<p>Ethics is the evaluation of the reasons we give for judging actions, individual or collective, to be right or wrong. There are three major branches:</p> <ul style="list-style-type: none"> ▪ Metaethics: 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 or deontology) ▪ Applied ethics: the application of ethics to real-life scenarios (for example, bioethics or environmental ethics).
Ethics assessment	Any assessment, evaluation, review or appraisal of particular programmes or policies according to specified ethics criteria.
Ethical awareness	The ability to recognise and consider the ethical aspects of a situation and the implications to which it gives rise.
Ethical deliberation	The process or system by which stakeholders discuss and debate the ethical aspects or implications of a given topic.
Ethical decision-making process	Identifying, addressing and, where possible, resolving ethically-challenging issues by applying theories, principles or frameworks to decision-making related to health policy or practice.
Ethics framework	A resource which details the ethical principles, substantive values and or procedural values, considered in policy-making relating to screening programmes.
Ethics guidance	Recommendations which help groups or individuals to make ethically-competent, justifiable decisions.
Ethical justification	A process of defending the ethical robustness of a practice or intervention, based on an examination of the soundness of the argument or evidence base which supports it.
Ethics processes	These processes outline the components of decision making which help, specifically, to ensure that the outcome reached has resulted from due consideration of ethical issues.

Ethical theory	Conceptual systems which seek to reason and justify the rightness or wrongness of a proposed, or taken, action and why the action may be considered right or wrong.
Ethical principles	Principles which provide a substantive basis for decisions, aiming to promote the best overall outcome in a given set of circumstances.
Ethos (or mission)	Used to describe the overall ideology, culture, or character of an organisation or group.
Policy-making	The process through which public policies are made, forming the basis for subsequent decision-making. The process typically includes phases such as problem identification, agenda-setting, consideration of potential actions, implementation of an agreed action, and evaluation.
Procedural values	Publicly-justifiable considerations which inform decision-making processes (for example, reasonableness, transparency, responsiveness).
Public health ethics	A field which seeks to understand, clarify and apply principles and values which may be used to guide public health decision-making in terms of ethical issues encountered, and to justify decisions made.
Research ethics	The consideration and application of ethics to scientific research, particularly on human populations; addresses and minimises ethical issues that may arise in the undertaking of said research.
Values	Abstract, general ideals which are held to be important, or which one supports or strives for.

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'),⁽¹⁾ 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 as an independent advisory committee to play a significant strategic role in the development and consideration of population-based screening programmes in Ireland. The Health Technology Assessment (HTA) directorate within the Health Information and Quality Authority (HIQA) has been commissioned to provide evidence synthesis support to NSAC under an agreed work programme.

The present document details the research protocol for a review of international ethics frameworks for policy-making in the context of screening.

Background to review

In line with the recommendations of the Scally Report,⁽¹⁾ which emphasised the role of ethics in the consideration of programmes by NSAC, 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.⁽²⁾

While NSAC has adopted criteria for the appraisal of the validity of screening programmes in line with those described by Wilson and Jungner,⁽³⁾ it is proposed that the ethics framework will complement these defined criteria by providing 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.⁽²⁾

The process of developing this framework will include a number of stages in order to inform and define the specifications of the framework. In the first instance, HIQA has been requested to undertake a review of ethics frameworks for policy-making internationally in the context of screening.⁽²⁾ The aim of this review is to outline the:

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

Concepts within this review

For clarity, prior to describing the methods for this review, the working definitions of the concepts explored are outlined. The working definitions complement, and are accompanied by, the summarised definitions reference guide provided at the beginning of this document which was developed with feedback from the Expert Advisory Group (EAG).

Ethics, public health ethics, ethical principles 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.^(4, 5)

While medical ethics is a well-established field, public health ethics is a relatively new and evolving area.^(6, 7) 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.⁽⁸⁾ 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)^(6, 8). 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.⁽⁷⁾ 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.⁽⁹⁾ However, the authors noted that certain values, such as social justice and human rights, appear to be widely accepted as inherent to public health.⁽⁹⁾

Values may be defined as abstract, general ideals which are held to be important, or which one supports or strives for.⁽¹⁰⁾ Principles may be defined as general rules which guide or underpin an action.^(6, 11) Ethical principles may play a role in decision-making to provide a substantive basis for decisions which aim to promote the best overall outcome in a given set of circumstances.^(11, 12) 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.⁽⁶⁾ 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.⁽⁶⁾ 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.⁽¹²⁾ 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 the available evidence may be uncertain or interpreted in different ways.⁽¹³⁾

Within decision-making, there may be 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.⁽¹³⁾ 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.⁽¹²⁻¹⁴⁾

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.⁽⁴⁾ Ethics guidance, typically as an internal direction, provides recommendations which 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.⁽⁴⁾

Depending on the approach, ethics guidance typically denotes a statement or outline of ethical guidelines, principles, rules, or recommendations to which practices should adhere.⁽¹⁰⁾ Ethics guidance differs from ethics assessment in that it does not in and of itself involve moral judgment; rather it sets general standards of rightness or wrongness according to which specific activities or outcomes may be guided or evaluated.⁽¹⁰⁾

Theories and frameworks

When considering ethics guidance, the facilitative role of theories and frameworks is frequently discussed.^(4, 15) Within the context of public health ethics, Dawson notes the complex relationship between theories and frameworks, and highlights the challenges that exist in merging theory and practice in decision-making.⁽¹⁵⁾

Ethical theories are conceptual systems which seek to deliberate about and justify the rightness or wrongness of a proposed, or taken, action and why the action may be considered right or wrong.⁽⁷⁾ Broadly, ethical theories may be categorised as traditional (for example, utilitarianism, deontology, virtue ethics) or contemporary (for example, principlism, feminist ethics).⁽¹⁶⁾ In particular, Dawson notes that in the field of public health, the choice of a theory should be strongly linked to the practicalities of the discipline.⁽¹⁵⁾ Contemporary theories have evolved from the more traditional theories in an attempt to address perceived limitations in their essential features. Developments have included an effort to fill in aspects of human living that were often absent or understated in traditional theories, and to move from moral abstractions to concrete situations in an effort to guide decision-making.⁽¹⁶⁾

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.⁽⁶⁾ 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.⁽¹⁵⁾ Further, a framework may be set at the level of discipline (for example, public health) or may be specific to a particular problem (for example, a defined screening programme).⁽¹⁵⁾ 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.⁽¹⁵⁾ It is important to note also that frameworks, and other such tools, are designed to aid deliberation and decision-making by framing the elements considered relevant. However, frameworks are typically general and may not apply in all situations. They serve simply to guide the deliberation as opposed to make the decision.^(6, 15)

Purpose of review and research question

The aim of this review is to provide an overview of international ethics frameworks for policy-making in the context of screening. For the purposes of the present review, a framework will be defined as a resource which details the ethical principles (and or values) considered in policy-making relating to screening programmes (for example, descriptions, considerations, questions or checklists to identify and examine potential ethical issues in relation to screening). This definition will be 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).

Accordingly, the following research question (RQ) was formulated to inform the overall review:

RQ: 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)?

Process outline

This review will follow three defined steps to address the overall aim of the review. These steps are listed below and described in the following sections:

1. Review of international practice
 - 1.1. identify and search relevant sources
 - 1.2. screen sources
 - 1.3. survey international sources
 - 1.4. data extraction and collation.
2. Summarise collective findings in report format.
3. Provide findings to Department of Health and NSAC for consideration and use to inform ethics framework development.

This process will further involve the convening of an expert advisory group (EAG) comprising expertise in ethics, law, public health and the patient perspective (see below, quality assurance processes).

1.0 Review of international practice

1.1 Identify and search relevant sources

A targeted search will be conducted of countries and agencies noted in previous reviews by Seedat et al.⁽¹⁷⁾ and Jansen et al.⁽¹⁸⁾ to document and or guide decision-making processes in relation to screening. For each country, websites of national ministries of health, of authorities with responsibility for screening, of national public health agencies, and of national ethics bodies, will be specifically searched for information related to the review question components.

A priori, given defined HTA processes within the HTA Directorate of HIQA, the EUNetHTA core model for screening technologies will further be included to

document the ethical considerations taken into account as standard within HTA.⁽¹⁹⁾ The countries and agencies to be searched, and potential sources, are outlined below:

Countries

- Australia (<https://www.health.gov.au/contacts/standing-committee-on-screening-secretariat>)
- Belgium (<https://www.health.belgium.be/en>)
 - Specific regions: Flanders, Brussels, Wallonia
- Canada (<https://canadiantaskforce.ca>)
 - Specific territories: Alberta, Ontario and Quebec
- Denmark (<https://www.sst.dk/en/english>)
- Finland (<https://stm.fi/en/screening>)
- France (<https://www.has-sante.fr>)
- Germany (<https://www.g-ba.de/english/>)
- Italy (<https://www.osservatorionazionale screening.it/>)
- The Netherlands (<https://www.rivm.nl/en/about-rivm>)
- New Zealand (<https://www.nsu.govt.nz/about-us-national-screening-unit/nsu-advisory-groups/national-screening-advisory-committee>)
- Spain (<https://www.mscbs.gob.es/en/home.htm>)
- Sweden (<https://www.government.se/government-agencies/national-board-of-health-and-welfare--socialstyrelsen>)
- Switzerland (<https://www.bag.admin.ch/bag/en/home.html>)
- United Kingdom (<https://www.gov.uk/government/organisations/uk-national-screening-committee>)
- United States of America
(<https://www.uspreventiveservicestaskforce.org/uspstf>)

Agencies

- World Health Organization (<https://www.euro.who.int/en>)
- Council of the European Union
(https://ec.europa.eu/health/policies/implementation/recommendations_en)
- European Commission (https://ec.europa.eu/health/home_en)
- EUnetHTA (<https://www.eunethta.eu/hta-core-model>)

1.2 Screen sources

Publications, reports and government websites ('documents') within the above sources will be screened for information on ethical principles, substantive values and procedural values used to inform policy-making relating to population-based screening, alongside documented processes in how these considerations are implemented and evaluated. No restriction will be placed on language and non-English documents will be translated via Google Translate; however, this method will be noted as a limitation given potential inaccuracies in the interpretation of direct translation. Should no information relating to ethical principles, values or processes be identified from a source, this will be documented.

Of note, where a country identifies the use of an external body for assessment (for example, a HTA agency), effort will be made to identify documentation produced by the relevant body to guide the evaluation of ethical considerations and processes taken into account in assessment.

As suggested by the background document prepared by NSAC to inform the development of the ethics framework, the main focus of the sources searched will be public health ethics, with a lesser emphasis on clinical ethics.⁽²⁾ Research ethics committees will be 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 or clinical ethics.⁽⁶⁾

1.3 Survey international sources

To supplement the grey literature search, a survey of international practice will be sent to relevant screening organisations within the countries listed above in order to validate the findings of the grey literature search and capture any unpublished processes that may exist. A draft of the proposed survey is outlined in Appendix 1.

1.4 Data extraction and collation

For each country and agency outlined, where available, the collective results of the grey literature search and survey responses will be documented within appropriate data extraction tables considering the follow overarching topics:

- theoretical underpinning
- ethical principles outlined
- procedural values outlined
- components and structure of ethics framework

- processes used in the deliberation of ethical issues and justification of policy-making in relation to ethics.

Of note, where a conflict is identified between the grey literature search and the returned survey, the answers provided in the survey will typically take precedence. As described previously, for the purposes of the present review, a framework will be defined as a resource which details the ethical principles (and or values) considered in policy-making relating to screening programmes (for example, descriptions, considerations, questions or checklists to identify and examine potential ethical issues in relation to screening). Processes will refer to the practical application of decision-making in relation to ethics (for example, stakeholder involvement, weighting, consensus reaching, and articulation of decisions).

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

2.0 Summarise collective findings in report format

A descriptive report of the findings will be prepared and an overall interpretation provided. A formal assessment of the included sources with respect to their quality is not anticipated given the descriptive nature of this review. However, depending on the data presented, consistencies and differences between sources may be outlined.

In terms of formal ethics frameworks, initial scoping suggests that there is a scarcity of clearly defined frameworks and, rather, a tendency towards descriptive overviews of guiding principles (see Appendix 2 for hierarchy of expected information). However, where formal frameworks and tools are identified (that is, structured formats or tools to assist in deliberation and policy-making, such as, lists of questions, or checklists to facilitate evaluation of ethical considerations), they may be included in full as appendices to the report.

Quality assurance processes

The review will be led by a senior HTA analyst with support from assigned analysts within the team in the HTA directorate at HIQA. The report will be reviewed by at least one member of the senior management team within the HTA directorate, to ensure processes are followed and quality maintained.

Furthermore, HIQA, in accordance with standard processes, will establish an Expert Advisory Group (EAG) comprising expertise in ethics, law, public health and the

patient perspective to contribute feedback on the present review protocol and on the final review. These individuals will be asked to provide expert input on potential sources relevant to the review and, where appropriate, on the interpretation of information outlined within the report.

Timelines

Pending protocol agreement, it is anticipated that this work will take approximately eight weeks to reach a final draft stage, and a further three weeks for EAG review and finalisation. The final report will be provided to the Department of Health, and NSAC representatives, as appropriate, prior to formal publication on the HIQA website. However, this timeframe is contingent on protocol agreement, and on the availability and nature of relevant data. Should delays be encountered in terms of obtaining data from relevant sources, or should considerable data extraction be required, this timeline will be amended in consultation with the Department of Health.

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Appendix 1: International survey

Background to survey

The Health Information and Quality Authority (HIQA) in Ireland has been commissioned to provide evidence synthesis support to the National Screening Advisory Committee (NSAC). HIQA has been requested to undertake a review of ethical values (or principles) and practices for decision-making in the context of screening, to support the development of an ethics framework for the NSAC.

As part of this review, HIQA is conducting targeted grey literature searches of countries previously noted to describe policy-making processes in relation to screening. This survey is intended to capture details in relation to values (or principles) and practices that may have been overlooked or are not published on publicly accessible websites. As part of HIQA's processes, a final report summarising the collective information obtained will be provided to the NSAC and subsequently published on HIQA's website (<https://www.hiqa.ie/>). The report will be summarised at the country and/or regional level. Prior to publication, the report will be circulated to organisations who have completed this survey to check for accuracy and clarity of the information included.

Further details about HIQA, NSAC, and the background to this work can be found in Appendix 1.

Survey structure

The survey has four sections:

- general details in relation to screening policy and/or decision-making
- underpinning theory, ethical principles and procedural values considered
- ethics framework used
- processes used to consider ethical issues and to justify decisions from an ethics point of view.

If formal documentation is available which details this information, please provide as an attachment in reply (or the link to the relevant webpage). Throughout the survey, please answer in relation to formally agreed or commonly used processes and procedures within your country or region. If a question does not apply or a process is not in place please indicate "no".

The completion of this survey will assist in the design of an ethics framework to facilitate the assessment of screening programmes in Ireland and your participation is greatly appreciated.

Thank you.

Section 1: General details in relation to screening policy and/or decision-making

1. In your country, or region, who has responsibility for policy-making (and/or decision-making) in relation to population-based screening programmes?
 - If there is a hierarchy in place (for example, oversight committee reporting to Ministry of Health) please provide this detail.

2. Are formal criteria (for example, Wilson and Jungner or a modified version of Wilson and Jungner) used to assess the validity of screening programmes to inform decisions on use or non-use? Decisions may relate to new prospective programmes or existing programmes.

a. Yes No Unsure

b. If **yes**, please list the criteria used

3. Are ethical principles or values explicitly considered within the assessment of new, or existing, screening programmes to inform decisions on use or non-use?

a. Yes No Sometimes Unsure

b. If **yes**, please highlight:

- i. if an ethics committee or body involved in the development of these values or principles
- ii. who completes the assessment of ethical issues (for example, an oversight committee, a designated ethics group, an external research organisation or agency that is then considered by decision-makers)

- c. If **sometimes**, please highlight:
- i. if an ethics committee or body involved in the development of these values or principles
 - ii. who completes the assessment of ethical issues
 - iii. if criteria are used to prompt the assessment of ethical issues
 - iv. the criteria used to determine if an assessment is required.

Section 2: Theory underpinning, ethical principles and procedural values considered

1. Is a defined theory or approach used to underpin the ethical principles or values considered in the assessment of new, or existing, screening programmes (for example, deontology, utilitarianism, virtue ethics, principlism)?

a. Yes No Unsure

- b. If **yes**, please specify the theory of approach used

2. Please list the ethical principles considered within the assessment of screening programmes (for example, autonomy, non-maleficence, beneficence, justice, solidarity).

3. Are defined procedural values (for example, transparency, responsiveness, rigour) used to guide the process of assessing new, or existing, screening programmes?

a. Yes No Unsure

b. If **yes**, please list the procedural values used

Section 3: Ethics framework used

1. Is an ethics framework (that is, a tool to facilitate deliberation) used to consider the ethical principles and/or values in the assessment of screening programmes?

a. Yes No Unsure

b. If **yes**, please provide a link to, or an emailed copy of the framework, if possible.

c. If **yes, but a copy cannot be provided**, please provide detail on the structure of the framework (for example, questions considered under each ethical principle or value, guiding considerations under each principle or value).

Section 4: Processes used to consider ethical issues and to justify decisions from an ethics point of view

1. Are stakeholders involved in the discussion of ethical considerations relating to screening?

a. Yes No Unsure

- b. If **yes**, please detail the types of organisations and areas of expertise, or patient representation, that stakeholders typically represent (or a link to the list of stakeholders typically involved, if available)

2. Are defined methods and processes used to facilitate the deliberation of ethics considerations in the assessment of screening programmes (for example, guided discussions, consideration of external assessment, application of framework, consensus methods, weighting)?

a. Yes No Unsure

- b. If **yes**, please detail the methods in use

3. Are defined processes used to resolve disagreements or conflicting opinions in relation to the ethical aspects of screening programmes (for example, external review, public consultation)?

a. Yes No Unsure

- b. If **yes**, please outline the processes used

Additional information

Please provide any additional information that you believe to be relevant to this survey:

Appendix – Background to NSAC and HIQA

The NSAC was established in 2019 as an independent advisory committee to play a strategic role in the development and consideration of population-based screening

programmes in Ireland. The Health Technology Assessment (HTA) directorate within the HIQA has been commissioned to provide evidence synthesis support to NSAC under an agreed work programme. Further details on NSAC and HIQA can be found at the below links:

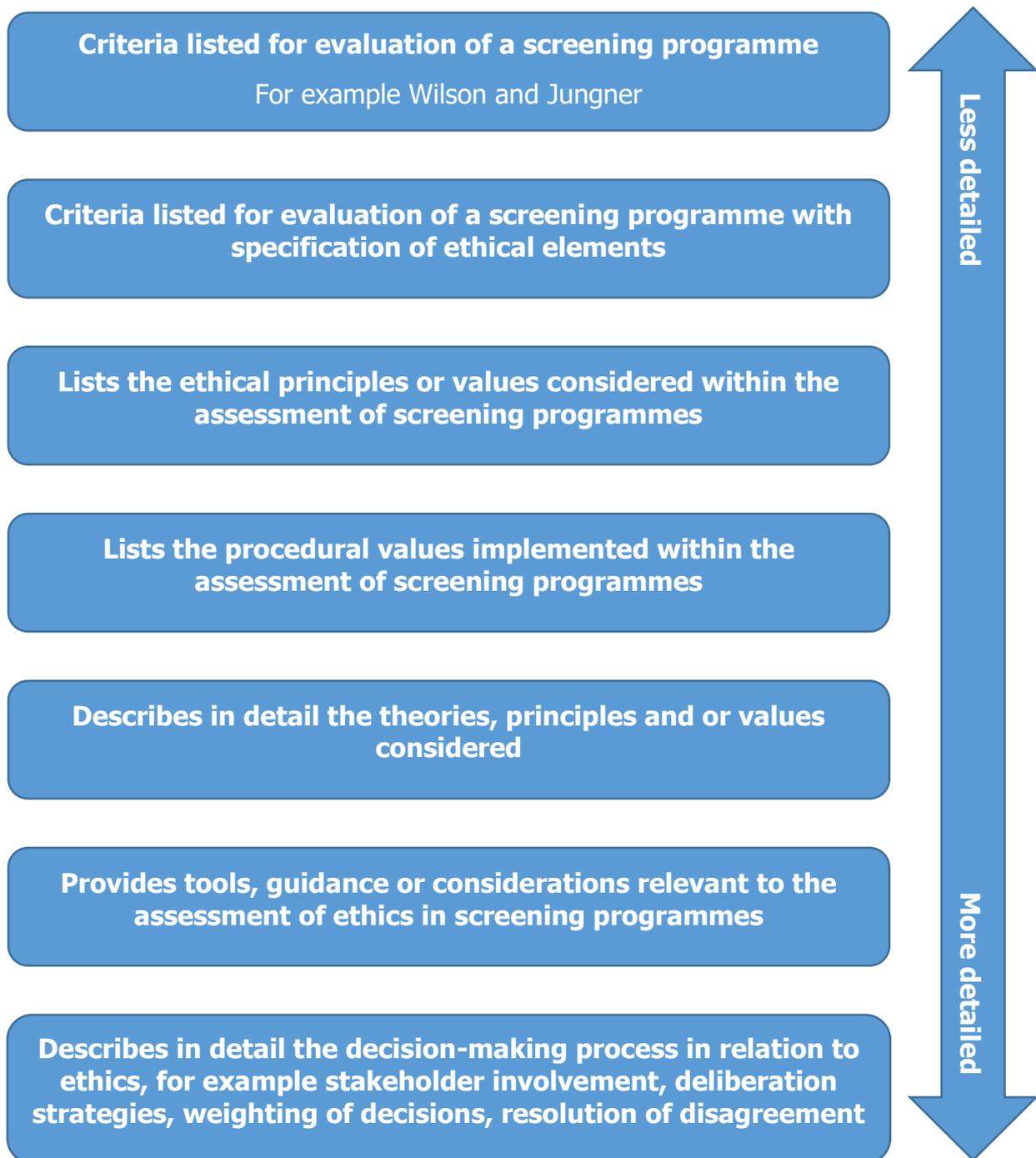
- NSAC: <https://www.gov.ie/en/campaigns/nsac/>
- HIQA: <https://www.hiqa.ie/areas-we-work/health-technology-assessment>

As part of the establishment of working practices for NSAC, the committee has outlined that an ethics framework will provide an important structure to support evaluations and deliberations in relation to population-based screening programmes. The process of developing this framework will include a number of stages in order to inform and define the specifications of the framework. While NSAC has adopted criteria for the appraisal of the validity of screening programmes in line with those described by Wilson and Jungner¹, it is proposed that the ethics framework will complement these defined criteria with a sole focus on ethical aspects relating to population screening. The ethics framework will detail both substantive values for the assessment of screening programmes and procedural values to guide the deliberations of NSAC.

¹ National Screening Advisory Committee. Criteria for Appraising the Viability, Effectiveness and Appropriateness of a Screening Programme 2020 [Available from: <https://assets.gov.ie/94190/0461e253-5a2f-42c5-976d-ce9cf6d8f312.pdf>].

Appendix 2 – Levels of expected information

From initial scoping, the flow diagram below outlines the levels of information expected to be obtained from sources screened. This is presented from least detailed to most detailed, where sources may provide information relating to one or more of these categories.



Published by the Health Information and Quality Authority (HIQA).

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