











QA Policy Framework:

Standard Setting & Revision Procedure for Population Screening Programmes

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Contents

1	. Purpose	3
2	Scope	3
3	Legislation/other related policies and documents	3
4	. Glossary of Terms and Definitions	3
5	. Context	4
	5.1 Structural standards	4
	5.2 Screening pathway themes	5
	5.3 Describing Screening Standards	5
	5.4 Thresholds	5
	5.5 Equity perspective	6
	5.6 Reporting frequency	6
	5.7 Revising standards	6
6	. Standard setting and revision procedure	7
7	. Roles and Responsibility	8
8	. Implementation Plan	8
	8.1 Standards Development & Revision Checklist (See Appendix 1)	8
	8.2 Communication and Dissemination	9
	8.3 Monitoring, Audit and Evaluation	9
	8.4 Budget and Resource Implication	9
9	. Review and Update	9
1	0. References	9
1	1. Appendices	10
	Appendix 1: Standards Setting and Revision Checklist	10
	Appendix 2: Document Development and Approval	12

1. Purpose

The purpose of this procedure is to provide a standardised and consistent approach to setting quality standards for the National Screening Service's (NSS) population screening programmes.

Collectively, screening standards provide reliable and timely information about the quality of the screening programme, data at local, regional, and national level and quality measures across the screening pathway without gaps or duplications. They also make sure there is a consistent approach across the national screening programmes and that data collection is beneficial.

Quality assurance (QA) is the actual process of checking that these standards are met and which encourage continuous quality improvement. QA covers the entire screening pathway from identification of the eligible population to be invited for screening through to referral and treatment where this is required. See **Section 5.2 Screening pathway stages**.

2. Scope

The procedure applies to all NSS population screening programmes and all staff who are involved in standard setting and review of NSS population screening programmes.

3. Legislation/other related policies and documents

- QA Policy Framework for NSS (NSS/S&F-1)
- HSE National Framework for Developing Policies, Procedures, Protocols and Guidelines (PPPGS) (2016)

4. Glossary of Terms and Definitions

Quality of healthcare is defined in many ways by different healthcare systems. One of the most widely accepted definitions is that of the Institute of Medicine, USA where quality is broken down into six domains: patient centred, safety, effectiveness, equity, timeliness and efficiency [1].

In Ireland quality is defined by the four quality domains set out in the HIQA Safer Better Healthcare Standards [2].

- 1. Person centred care that is respectful and responsive to individuals needs and values and partners with them in designing and delivering that care
- 2. Effective care that is delivered according to the best evidence as to what is clinically effective in improving an individual's health outcomes
- 3. Safe care that avoids, prevents and minimises harm to patients and learns from when things go wrong
- 4. Better health and wellbeing care that seeks to identify and take opportunities to support patients in improving their own health and wellbeing

A **standard** is a clearly described criterion of quality to which a specified measure of quality (quantitative or qualitative) can be applied. Standards can be measured as aspects of structures, processes or outcomes.

 Some standards may be monitored as a subset and collectively termed key performance indicators (KPIs). A clear rationale for their selection as a KPI should be documented. See *Figure 1* below

The term **target** is often used to mean the level of performance expected for a standard which can be measured quantitatively.

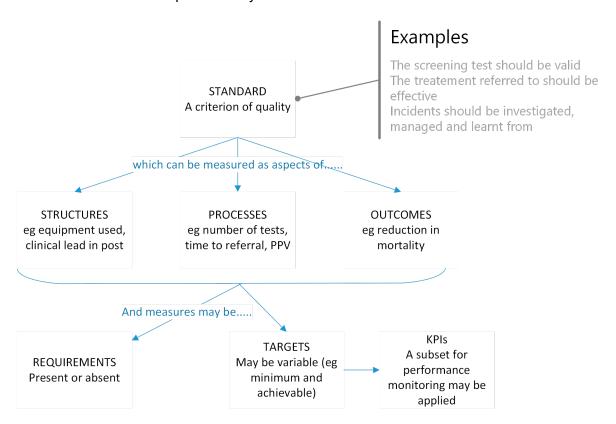


Figure 1: Terminology related to measures of quality

5. Context

5.1 Structural standards

These describe the required structural components of the screening programme and must be fully met. Examples of structural standards could include;

- The provision of information to all participants
- The provision of appropriately qualified and trained staff to provide the screening service in line with best practice guidelines and national policy
- There is a Clinical Lead in post

Action: Individual programmes should review the service specifications to make sure the required structural standards are met by all service providers.

5.2 Screening pathway themes

It is good practice to link your standards with screening pathway themes that support the standardised use of indicators for quality assurance, effectiveness or delivery of screening services. Standards should fall under at least one theme but there may not be a standard for every programme under every theme. Similarly, where a standard could fit under more than one theme, choose the most appropriate one. You may consider the following 8 themes:

- 1) population
- 2) coverage
- 3) uptake
- 4) screening test (positive predictive value, test turnaround time)
- 5) diagnosis/intervention
- 6) referral
- 7) intervention/treatment
- 8) outcome

5.3 Describing Screening Standards

Screening standards usually refer to those parts of the screening pathway that assess the **screening process** and which allow for continuous improvement. This enables providers within each programme and within the NSS to identify where improvements are needed.

Try to use the same template (See Table 1 below) in describing each screening standard as this will allow for a clear and explicit definition and assist the external reader.

- 1. Name
- 2. Description (what is being measured).
- 3. Rationale (why is it being measured).
- 4. Definition (detailed description of terms such as numerators, denominators, timescales, exclusions and units of measure such as rates, percentages and range).
- 5. Performance thresholds (See Section 5.4).
- 6. Caveats (where applicable set out the reasons why the defined thresholds might not be reached e.g., impact of COVID19)
- 7. Reporting period (e.g., 1 April 31 March)
- 8. Reporting caveats if applicable (e.g., some standards may be reported some time in arrears to ensure data completeness e.g., interval cancer rate calculated with National Cancer Registry Ireland)
- 9. Review dates (date the standard was introduced and/or last updated).

Table 1: Template for describing a screening standard* * Not all standards may align with every element of the template

5.4 Thresholds

Performance thresholds are selected to align with existing screening standards. One or two thresholds are typically specified.

 The achievable threshold represents the level at which the screening service is likely to be running optimally. All screening services should aspire to attain and maintain performance at or above this level. The acceptable/minimum¹ threshold is the lowest level of performance which
screening services are expected to attain. All screening services should exceed
the acceptable threshold and agree service improvement plans to meet the
achievable threshold. Screening services not meeting the acceptable threshold
are expected to put in place recovery plans to deliver rapid and sustained
improvement.

Standards where thresholds are not set are reviewed and updated when relevant data and other information, such as research publications, become available.

5.5 Equity perspective

Consideration should be given to all standards to establish whether differences in the distribution of health determinants (e.g., gender, age, ethnicity, disability status, socioeconomic status) and screening outcomes could be considered avoidable and unfair. Review at a local level of performance by population group may indicate inequity in participants entering and completing the screening pathway or accessing services within optimal timescales.

5.6 Reporting frequency

Standards are generally reported annually unless they are also KPIs, in which case they may be reported more frequently e.g., quarterly and then annual figures are aggregated. The individual programmes are responsible for justifying the reporting frequency and making sure the data is accurate, timely and complete. As mentioned above, some standards may be delayed and reported in arrears.

5.7 Revising standards

Programmes should incorporate a screening standard review based on feedback and data.

- (a) For processes in control, this is usually a minor review and can be undertaken internally by each individual programme team. For example, there may be a need to clarify some wording or a definition.
- (b) A more comprehensive review must be undertaken, at a minimum, every 3 -5 years (this must be defined in standards document as per stage 7 under Section 6) or where new standards may be introduced, or existing standards withdrawn and/or amended.

It is important to document the context for any decision made to adopt a new standard or to amend or delete an existing standard e.g., new/updated Clinical or European standard.

NSS/S&F-6 Version 0 Page 6 of 12

¹ Some programmes use the term 'acceptable' and others 'minimum'. For this document they are one and the same as defined here. However, the same term should be used throughout the suite of an individual Programme's QA documents.

6. Standard setting and revision procedure

It is important that each programme follows and documents a standardised process in setting or revising standards. These can be described in several stages and must be included in the QA standard document.

- **Stage 1** is **initiation** and refers to the beginning or the first step in developing/ reviewing standards. The Quality Information management system (QPulse) will issue each programme a reminder when a revision cycle is due. For the programme this will typically begin with a decision on either a minor or major review of standards. See *5.7. Revising standards* above.
- Stage 2 is development/review and should describe in detail the methodology by which the standards are being set and/or reviewed as set out in Section 5 Context e.g.,
 - Minor or major review
 - o A review and adoption of new EU guideline
 - Any systematic methods used to search for evidence (e.g., literature review)
 - Engagement with internal and external stakeholders
- Stage 3: is governance and approval and refers to roles, and the process of agreement and approval/sign off the new/revised standards through programme and NSS governance structures:
 - e.g., a figure or table to illustrate the role of the programme team itself, programme QA committee, clinical advisory group(s), external consultation/independent experts, peer review, programme executive management team, NSS Executive Management Team, as applicable
- Stage 4 is communication and dissemination and refers to the active spread of new/revised standards to the target audience using planned strategies
- **Stage 5** is **implementation** and refers to the process of putting to use or integrating new/revised standards. This will include:
 - The documentation of Budget and Resource Implications and acknowledgement if there is no budget or resource implications. Refer to page 27 of HSE National Framework for Developing PPPGs
 - Any education and/or training needs especially if changes to standards.
 Acknowledge ongoing education and training. Refer to page 29 & 59 of HSE National Framework for Developing PPPGs
- Stage 6 is monitoring and evaluation and refers to documenting the process for monitoring and continuous improvement, setting out the [clinical] audit criteria to be used and evaluation of the implementation of new/revised standards. The responsibility for assuring and acting on non-compliance of each standard should be documented
- Stage 7 is revision/update refers to the process and timeline to review the standards and to ensure learning is used to amend, update or revise as new evidence emerges

These stages can also be described as a standard setting and revision cycle. See

Figure 2.

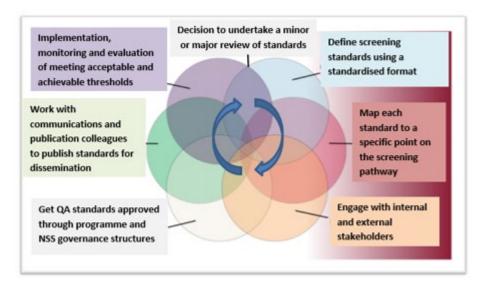


Figure 2: Standard Setting & Revision Cycle

7. Roles and Responsibility

Job Role (and specific Programme)	Responsibilities
All Staff in screening programmes	Adherence to this QA Policy Framework: Standard Setting and Revision Procedure
Programme Managers	Accountable for the implementation of this Procedure
Screening Programme Quality Assurance Committee(s)	Provide assurance to the Quality Safety and Risk Management (QSRM) committee & NSS Executive Management team (EMT) on the extent of compliance with the QA Policy Framework: Standard Setting and Revision Procedure and any quality improvement activities identified to address gaps
NSS Executive Management Team	Ensure consistent implementation across all four NSS programmes

8. Implementation Plan

8.1 Standards Development & Revision Checklist (See Appendix 1)

 The checklist is intended to act as an aide memoir and a guide rather than a mandatory list of actions. Every standard will not necessarily require each check.

8.2 Communication and Dissemination

- This Procedure shall be distributed to all NSS staff.
- Distribution to copyholders and acknowledgement shall be via the NSS Quality Management Information System – Q-Pulse. Copyholders shall be required to acknowledge that they have read this QA Policy Framework: Standard Setting and Revision Procedure.

8.3 Monitoring, Audit and Evaluation

 A rolling audit programme shall be implemented to determine compliance to this QA Policy Framework: Standard Setting and Revision Procedure ensuring that all elements are addressed in full within a three-year timeframe. This shall be carried out by the Quality Teams in the individual programmes, in conjunction with the Quality Safety and Risk department.

8.4 Budget and Resource Implication

No budget or resource implication identified

9. Review and Update

- A formal review will be carried out on a three-yearly basis unless there is a change informed by legislation, best practice, the Regulator or an EU Directives etc., which would identify the need to update the Procedure sooner.
- If there are no amendments to the Procedure following the review process, the date and detail on the version tracking box must still be updated.
- The Procedure will be kept under review and comments and feedback are welcome to inform this process.

10. References

- 1. Institute of Medicine (IOM). Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, D.C: National Academy Press; 2001.
- 2. Health Information and Quality Authority. National Standards for Safer Better Healthcare. Dublin: HIQA, 2012.

11. Appendices

Appendix 1: Standards Setting and Revision Checklist

	Standard Number	1	2 etc.
	What is the context and rationale for a 'new' standard?		
Title, stage description and	Is the name and stage of the pathway clear and is it clear which part of the screening pathway it relates to?		
rationale	Is the description clear?		
	Is the rationale convincing?		
	Is a glossary created?		
	Is the numerator clearly defined?		
	Is the denominator clearly defined?		
	Where a numerator/denominator is not used, is there clear justification for this?		
	Are time frames clearly defined (if applicable)?		
Definitions	Is there consistency between standards/KPIs within this programme and within other similar programmes e.g., coverage standards?		
	Are differences/inconsistencies in terminology justified?		
	Have the identified key performance indicators (KPIs) got a clear rationale for their selection?		
	Is the standard measurable?		
	Are all standards and particularly KPI specific, measurable, attainable, relevant and time bound (SMART)		
	How will the performance be calculated e.g., rate, absolute numbers?		
	Are the thresholds clearly defined?		
Performance thresholds	Are the thresholds evidence based? If not, is there clear justification for this decision?		
unesnoids	Where thresholds are not defined, is there clear justification?		
	Have you considered implications for QA and operational resources if you are changing the thresholds?		
	Are any caveats clearly defined?		
	Are any further caveats required for clarification of the standard?		
	Are caveats consistent across standards and programmes?		
	Data source?		
Data collecting and reporting	Accountable person(s) for data quality and completeness?		
	Reported by [who/what] (e.g., extraction, analysis and		

	reporting, specification of reports)?	
	Who will sign off data?	
	Reporting period & reporting frequency?	
	Review dates?	
	How accurate and complete do you expect the data to be?	
	Would the new/revised standard benefit from a pilot?	
Equity impact	Does the standard support the NSS Equity Strategy?	
	Have you included a clear description (e.g. text, figure) of the development and approval process of standards as outlined in section 6 Standard setting and revision procedure with named principal responsible person(s)/group at each stage, as applicable?	
QA Governance	e.g. role of the programme team itself, clinical advisory group(s), external consultation, peer review, programme executive management team, NSS Executive Management Team	

Appendix 2: Document Development and Approval

Development / Review Team

Name	Title
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Development Team

The procedure was developed in consultation with, Programme Quality Leads & QA Committees, Programme Evaluation Unit and relevant Function Managers and NSS staff.

Approval of Document

Approval responses and digital signatures of approval are recorded in the document record on the NSS Quality Management Information System Q-Pulse.

Approval

Chair	Approval Body	Date of Approval
Fiona Murphy	Chair of NSS Executive Management	21 Apr 2023
	Team	

^{*} NSS Executive Committee members are available on the Terms of Reference and minutes of the date of approval.

^{*}There was no Conflict of Interest in developing of this document.