National Screening Unit

Improving Quality:
A Framework for Screening Programmes in New Zealand

Published in October 2005 by the National Screening Unit,
a separate unit of the Ministry of Health.
PO Box 92522, Wellesley Street, Auckland

ISBN 0-478-28360-1 (Book)
ISBN 0-478-28361-X (Website)
HP 4101

This document is available on the National Screening Unit website:

www.healthywomen.org.nz

and the Ministry of Health website:

www.moh.govt.nz

Foreword

Quality is an integral part of screening programmes. This screening programmes' quality framework arose from the recognition that a proactive approach to quality improvement is required to achieve the vision, strategic outcomes and objectives outlined in the National Screening Unit's 2003-2008 Strategic Plan.

The purpose of the framework is to help 'make sense' of the wide range of activities that are needed as part of quality assurance and quality improvement in screening programmes. It provides a set of principles, key quality requirements and implementation points to guide quality improvement in screening programmes in New Zealand. The framework applies to both the current cancer screening programmes, which are managed by the National Screening Unit (NSU), and to other existing and future screening programmes.

The framework does not replace existing quality initiatives but builds on these activities in a systematic way. It integrates existing quality assurance and improvement activities in New Zealand's two cancer screening programmes, BreastScreen Aotearoa (BSA) and the National Cervical Screening Programme (NCSP).

The NSU will be guided by the principles, key requirements and implementation points presented in this framework, and will work with other screening programme managers and leaders to apply it to their own programmes or screening activities. We will support providers to apply the framework within screening programme services throughout New Zealand.

In its 2002 advice to the Minister of Health on health care quality, the National Health Committee stated strongly and unambiguously that, "in order to achieve the best possible outcomes from health services, quality improvement should be the prime focus for health care delivery in New Zealand."[1] We believe that this quality framework will help ensure that quality is the prime focus for screening programmes in New Zealand and will assist in achieving our two strategic outcomes – health improvement and reduced inequalities.

I would particularly like to acknowledge the work of Ruth Bijl and Dr Ashley Bloomfield for their work on the development of this framework. My thanks also to the people who provided submissions (listed in Appendix 1) on the earlier draft.

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Group Manager
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[1] National Health Committee. *Safe Systems Supporting Safe Care. Final Report on Health Care Quality Improvement in New Zealand*. Wellington: National Health Committee; 2002.

Mihi

"Whakarongo ki te tangi o te manu

Tui, tui, tuituia!

Tuia ki runga, tuia ki raro

Tuia ki roto, tuia ki waho

Ka rongo te ao, ka rongo te pō

Tuia te muka tangata i takere mai

i Tawhitinui, i Tawhitiroa, i Tawhiti pamamao

Hui te mārama, hui te ora e!"

Tēnā koutou i runga i ngā aitua o te wā.

Kō rātou te hunga i hikoingia atu rā ki tua o Paerau.

Rātou mai i Te Hiku o Te Ikanui a Maui Tikitiki a Taranga, tae noa ki tōna Upoko, whakawhiti atu ra i Raukawa moana ki te Wāhi Pounamu, ki Murihiku, whakarere tonu rā ki Te Wharekauri.

Nō reira, haere atu ra koutou katoa te hunga kua tiraha mataotao noa, moe mai ra, okioki ai.

Ko koutou ki a koutou, ko tātou ka mau tonu i ngā moemoeā o koutou mā ki a tātou

Tēnā tātou katoa!

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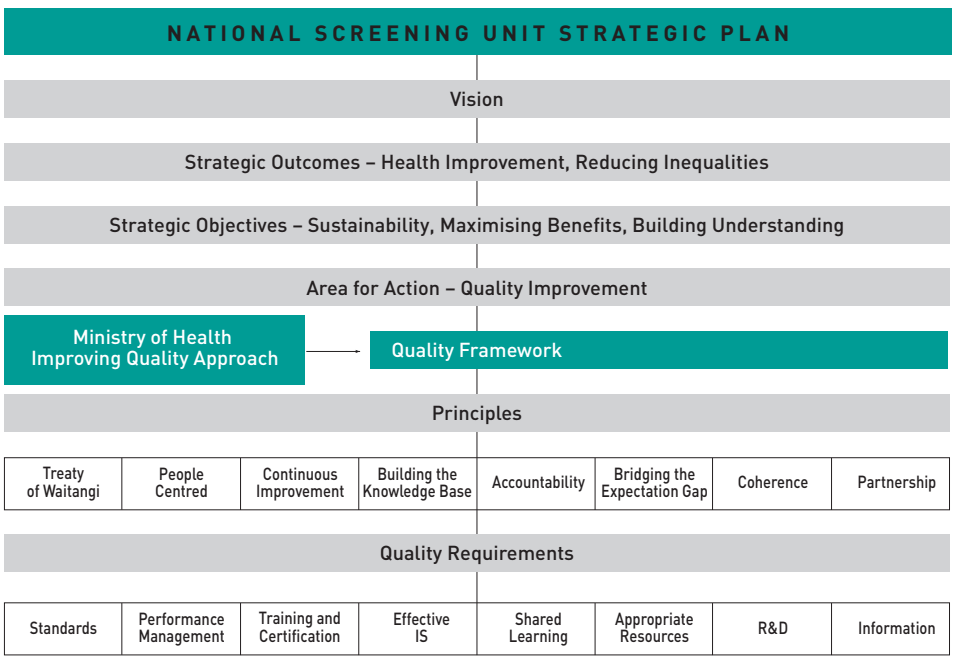
Executive Summary

"For the programme to be successful, every aspect of the programme, from identification and invitation…to recall for re-screening must be performed to the highest standard. The best way to ensure that a screening programme is beneficial and minimises the risks from screening is to ensure that the programme is properly organised and appropriately monitored".[1]

This Screening Programmes' Quality Framework (SPQF) stems from the National Screening Unit's (NSU) Strategic Plan 2003-2008. It supports the vision and strategic outcomes, and provides a structure for quality activities under the "quality improvement" area for action in the Strategic Plan. The Quality Framework is a key response by the NSU to the Ministry of Health report *Improving Quality (IQ Approach)*.

The relationship between the Screening Programmes' Quality Framework, the IQ Approach and the National Screening Unit's Strategic Plan are shown diagrammatically in Figure 1.

FIGURE 1:
THE RELATIONSHIP BETWEEN THE SCREENING PROGRAMMES' QUALITY FRAMEWORK, THE IQ APPROACH AND THE NSU STRATEGIC PLAN



Chapters one and two outline the background to and purpose of this quality framework. The following chapters propose a quality framework for screening programmes that consists of three key elements:

- eight principles
- eight quality requirements
- implementation points under each of the quality requirements.

The eight principles (chapter three) are:

- the Treaty of Waitangi principles: partnership, protection and participation
- people centred
- continuous improvement
- building the knowledge base
- accountability for and clarity of roles and processes
- bridging the expectation gap
- coherence throughout the programme
- partnership with programme staff and participants.

The eight quality requirements (chapter four) are:

- standard setting and monitoring
- performance management
- training and certification
- opportunities for shared learning
- effective information systems
- appropriate resources
- research and development
- information for individuals and communities.

Chapter five documents the range of activities at individual, team, organisation and system level that will deliver on the key quality requirements. Finally, chapter six outlines the quality activities that incorporate the principles, quality requirements and implementation points for the National Cervical Screening Programme (NCSP) and BreastScreen Aotearoa (BSA).

1 Introduction: screening and quality

> "When quality is low, the relationship between benefit and harm, at any level of screening intensity, changes…and it is possible for the harmful effects to be greater than the beneficial effects of screening. It is obviously essential, therefore, not only to choose the right screening policy but also to be assured that the screening actually offered is of high quality".[2]

Quality issues in screening programmes are of international interest,[3,4] and are central to New Zealand's existing cancer screening programmes. This Screening Programmes' Quality Framework (SPQF), developed by the National Screening Unit, outlines the strategic foundation for quality activities in New Zealand's screening programmes. The framework draws on work from the United Kingdom,[3] and builds on the existing commitment and knowledge that health professionals involved in screening already bring to the organised screening programmes. The SPQF does not replace existing screening programme quality activities but outlines a systematic approach to quality to support existing and new activities.

Quality improvement activities in screening programmes should generate the information needed to confirm whether or not a programme is safe, effective and being delivered at a reasonable cost. The Quality Framework will shape the quality culture of the programmes and provide the populations served and service providers with clear direction for the future of the programmes.

The SPQF will be applied to the National Cervical Screening Programme (NCSP), the national breast screening programme – BreastScreen Aotearoa (BSA), the Newborn Metabolic Screening Programme, and any future national screening programmes introduced at the direction of the Government.

1.1 Definitions

Screening

The NSU has adopted a definition of screening based upon that of the National Screening Committee of the United Kingdom as adapted by the National Health Committee in New Zealand:

> "Screening is a health service in which members of a defined population, who either do not necessarily perceive they are at risk of, or are already affected by a disease or its complications, are asked a question or offered a test, to identify those individuals who are more likely to be helped than harmed by further tests or treatment to reduce the risk of a disease or its complications".[5]

Quality and quality improvement

The Ministry's Improving Quality Approach (IQ Approach) has adapted the following definition of quality from Lohr:[6]

> "Quality is the cumulative result of the interactions of people, individuals, teams, organisations and systems. It can be defined as the degree to which the services for individuals and populations increase the likelihood of desired health outcomes".[7]

The IQ Approach has adopted the following definition of quality improvement:

> "Quality improvement includes both quality assurance and continuous quality improvement activities. While both are important, there is growing international evidence indicating that focusing on quality improvement leads to better outcomes than a focus on quality assurance activities alone.
> Quality improvement includes:
> - an explicit concern for quality
> - the viewing of quality as the search for continuous improvement
> - an emphasis on improving work processes to achieve desired outcomes
> - a focus on developing systems and investing in people to achieve quality health outcomes".[7]

1.2 Purpose of the screening programmes' quality framework

The purpose of this framework is to define and apply a set of key quality principles and essential quality requirements to ensure the best possible outcomes from screening programmes in New Zealand. While designed for screening programmes, the framework is also relevant to opportunistic screening.

The framework is designed for all people working in screening programmes including national and local programmes, many of whom already work together to deliver high quality screening programmes in New Zealand. The framework will assist with both the design and implementation of quality initiatives for existing and new screening.

The SPQF supports the NSU vision, strategic outcomes (health improvement and reducing inequalities) and objectives (sustainability, maximising benefits, and building understanding) identified in the NSU Strategic Plan 2003-2008. The SPQF directly serves the "Quality Improvement" key area for action.

The Quality Framework will be reviewed two years after publication to incorporate feedback based on local experience and new international evidence. Feedback will be sought from interested stakeholders, as part of the review process.

2 Background

> "Poor quality screening is ineffective and may do more harm than good".[8]

This section provides contextual background to the SPQF with particular reference to the role of the National Screening Unit and the Ministry of Health's IQ Approach.

2.1 The National Screening Unit

The National Screening Unit (NSU) was established in July 2001 within the Ministry of Health. The NSU has responsibility for the national operational function and strategic management of the two current cancer screening programmes, the National Cervical Screening Programme (NCSP) and the national breast screening programme – BreastScreen Aotearoa (BSA). NSU accountabilities for these programmes are in line with the key organisational requirements for the delivery of successful population-based screening programmes, as determined by the World Health Organisation (WHO).[5] In July 2005, the NSU also assumed responsibility for Newborn Metabolic Screening (NBMS).

Each year the Ministry of Health agrees a set of outcome measures with the Minister of Health as set out in the Statement of Intent. The NSU is responsible for specific outcome measures for breast and cervical screening (Output Plan 05/06, Output Class D.10 – Management of National Screening Programmes) and these are reported on quarterly.

The National Screening Unit's vision for the future is:

> "Saving lives, reducing inequalities, and building the nation's health by leading the delivery of screening programmes, uncompromising in their quality, and trusted by the communities we serve".

The NCSP was established as a national, organised screening programme in 1990. The aim of the NCSP is to reduce the population incidence of, and morbidity and mortality from, squamous cell carcinoma of the cervix by detecting pre-cancerous cervical changes and treating these appropriately.

BreastScreen Aotearoa (BSA) was launched nationally in December 1998 to provide free mammograms and follow-up for asymptomatic women aged 50 to 64 years. In July 2004 the Programme was extended to include women aged 45 to 69. The aim of BSA is to reduce women's morbidity and mortality from breast cancer by identifying and treating cancers at an early stage, which has been shown to reduce breast cancer mortality.

Both programmes have a range of practitioners working in both community and hospital settings and in public and private organisations. This creates specific challenges for implementing quality initiatives across the screening pathway and developing a programme-wide quality culture.

These two cancer screening programmes are distinctive in that they are both underpinned in New Zealand by a well-woman focus. The history of the programmes has been influenced by the role that individuals and women's health organisations play in advocacy, education and in the identification and communication of women's health issues related to screening. The National Screening Unit recognises the importance of ensuring that professional and consumer-focussed organisations continue to have input into these programmes and are involved in policy and standard development, and audit and evaluation of programmes. The National Screening Unit has established advisory groups for BSA and the NCSP, NBMS, as well as Māori, Pacific and consumer advisory groups, to formalise ongoing professional and consumer input.[5]

2.2 Screening and screening programmes

Screening occurs in two ways – as part of screening programmes and opportunistically. Quality management processes distinguish organised screening programmes from opportunistic screening, and are essential for balancing the achievable benefits of screening with the potential harms. Organised screening is usually delivered through a screening programme with planning, co-ordination, monitoring and evaluation of all activities along the screening pathway.

Opportunistic screening occurs for a wide range of conditions with varying degrees of organisation, but there is no formal co-ordination, monitoring or evaluation of the process. Thus, opportunistic screening has "no attendant quality processes and [because of this] its safety, effectiveness and cost-effectiveness cannot be assessed and guaranteed."[9] Such screening may be widely undertaken, eg, antenatal screening for a range of conditions, but not necessarily part of a screening programme.

Population screening programmes involve screening entire populations or a large and easily identifiable group within a population.[9] The New Zealand cervical and breast cancer screening programmes are examples of population screening programmes. A population-based screening programme is one in which screening is systematically offered by invitation to a defined, identifiable population. This requires a way of identifying that population such as through a population register.[9] Such programmes may be 'opt-in' or 'opt-out'.

2.3 Quality: a national and international focus

International interest in health care quality strengthened during the 1990s. In Australia, the USA and the UK, existing quality and safety systems were scrutinised and found to be wanting.[10, 11, 12] Each of these countries developed national-level quality initiatives to respond to the significant problems identified.

Similar developments followed in New Zealand. As in Australia and the USA, New Zealand research showed a significant burden of adverse events in hospitals, many of which were avoidable.[13] A report by the National Health Committee (NHC) identified pivotal national-level issues and recommended a range of responses.[14] The NHC report proposed that, in order to achieve the best possible outcomes from health services, quality improvement should be the prime focus for health care delivery in New Zealand. A key theme was the need to take a 'systems approach' to quality improvement.

2.4 A New Zealand "Improving Quality Approach"

The NHC report informed the development of the IQ Approach, which "provides a shared purpose, vision and language to enable enhanced quality improvement in the New Zealand public and private health and disability system…so that people receive people-centred, safe and quality services that continually improve." [7]

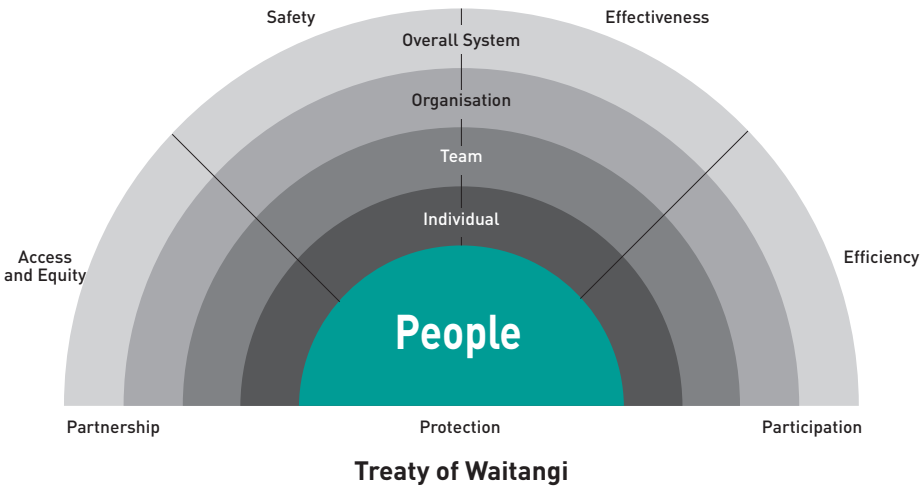
The IQ Approach focuses on quality improvement while acknowledging the ongoing importance of quality assurance activities. It acknowledges the importance of the quality culture in achieving its objectives, and aims to achieve:

- a shared purpose, vision and language
- a 'systems approach' – that is, an approach that takes account of the complexities of the health care system
- improved co-ordination of quality improvement.

The model below (Figure 2) summarises the approach taken in the IQ Approach, noting that:

> "quality improvement needs to encapsulate all levels of the system and the interactions between them. They range from the overall system through the organisation, teams and individuals within those organisations, to the people receiving and impacted by the services delivered in the systems."[7]

FIGURE 2:
THE NEW ZEALAND IQ APPROACH QUALITY MODEL



[Source: Improving Quality (IQ): A Systems Approach for the New Zealand Health and Disability Sector. Wellington: Ministry of Health; 2003.]

The quality model rests on the foundation of the Treaty of Waitangi principles of partnership, protection and participation. It also puts people at the centre of the model, explaining "people centred" as "the extent to which a service is involving of people, including consumers, and is receptive and responsive to their needs and values – it includes participation, appropriateness, and adherence to the Code of the Health and Disability Services Consumers' Rights 1996 and adherence to other consumer protections such as the Health Information Privacy Code."[7]

2.4.1 DIMENSIONS OF QUALITY

Four dimensions of quality are considered key to fulfilling quality requirements. These are equity and access, safety, efficiency and effectiveness. The dimensions of quality in the Approach are defined as:

- **Equity and Access:** the extent to which people are able to receive a service on the basis of need, mindful of factors such as socioeconomic factors, ethnicity, age, impairment or gender
- **Safety:** the extent to which harm is kept to a minimum
- **Efficiency:** the extent to which a service gives the greatest possible benefit for the resources used
- **Effectiveness:** the extent to which a service achieves an expected and measurable benefit.

The inclusion of equity and access clearly indicates that attention to the needs of groups with poorer access is an essential part of achieving high quality.

2.5 Quality and screening programmes

Once a screening programme is established, quality assurance and quality improvement activities are essential to ensuring the ongoing safety and effectiveness of the programme.

Screening programme quality assurance and quality improvement activities occur at all points along the screening pathway.

Screening programme evaluation is distinguished from quality assurance and quality improvement activities. Evaluation involves monitoring and assessing the service delivery and outcomes of a screening programme, which may include assessing overall programme effectiveness, cost-effectiveness and acceptability. Evalution will determine whether the programme is actually delivering on its objectives. In contrast, quality improvement activities are concerned with maximising the likelihood that the day-to-day operation of the programme will deliver the expected outcomes.

The aim of quality assurance is to:

- help professionals and organisations continually improve their performance
- reduce the risk of errors
- identify and manage errors effectively and sensitively
- set and re-set standards.[15]

The National Screening Unit is responsible for ensuring that standards are set and reviewed for NCSP and BSA programme operation only (excluding some professional standards and other relevant standards and legislation for health). This includes facilitating work involving relevant stakeholders to define standards and to update them when there is agreement that the standards are no longer adequate. Professional groups play a key role in setting and reviewing standards. At a service level, management of quality is the responsibility of the service provider, ie, either a person providing a specific service or the person responsible for co-ordinating services to create a programme.

A key focus of quality assurance is on the screening test, which can be divided into:

- tests that are based on numbers
- tests that are based on human judgement.

The former group usually involves laboratory testing of a blood or other body sample, eg, newborn screening of phenylalanine levels for phenylketonuria (PKU), so the main focus of quality assurance is laboratory performance and reporting. Laboratory quality assurance is best organised nationally for screening, not only by using systems of accreditation and systems of quality assessment or measurement, but by developing appropriate resources to help laboratories improve their performance.[16]

Screening tests based on 'human judgement' are carried out by an individual looking for something or looking at something or listening, eg, cervical screening (cervical smear) and breast screening (mammogram). Such tests require a different pattern of quality assurance from that used for tests that are based on numbers.

Quality assurance systems for tests that are based on judgement need to focus on people, with training and feedback playing a much larger part compared with screening programmes using tests based on numbers. National co-ordination is still desirable and can enhance the resources for quality assurance at the service level, eg, sets of 'test' cervical smear slides or mammograms that are circulated nationally.

This distinction is to a degree artificial because all programmes involve human judgement and technology. For example, in newborn screening for PKU it would be important to develop quality assurance not only for the laboratory concerned but also for the clinicians who make the final diagnosis of PKU based partly, but not solely, on the screening test results.

Responsibility for the quality of a specific service rests primarily with those providing and managing the service. However, the National Screening Unit and other independent monitoring bodies also have a role, as quality assurance systems need a degree of independence from the services and programmes whose quality they help improve. Overall programme quality is ultimately the responsibility of the National Screening Unit.

In line with the IQ Approach, the SPQF indicates a shift in focus from quality assurance to quality improvement. Thus, quality assurance activities become part of a wider quality system that focuses on continual improvement where new knowledge and changes in technology and expectations are incorporated incrementally.

2.5.1 EXISTING QUALITY INITIATIVES WITHIN NEW ZEALAND SCREENING PROGRAMMES

The National Screening Unit has been responsible for the implementation of a range of quality assurance initiatives for the NCSP following the *Ministerial Inquiry into Under-reporting of Cervical Smear Abnormalities*.[17] Quality assurance processes were built into BSA from its inception based on international experience. Current quality assurance and quality improvement activities undertaken by the National Screening Unit and screening programme providers, include, but are not limited to:

- ensuring development and management of nationally consistent policy and quality standards for (BSA and NCSP) national screening programmes and their ongoing review
- follow-up of recommendations from reviews and monitoring
- routine compliance audit of providers against the standards
- providing or contracting for national monitoring services, including audits and evaluations of specific programme components
- monitoring, analysing and reviewing international experience of screening programmes to identify opportunities to improve programme safety and outcomes
- developing and maintaining high levels of internal competency and expertise in (specific) screening programmes
- implementing specific initiatives to improve screening programme participation by Māori and Pacific women
- improving processes for monitoring the treatment and outcomes of programme participants and using this information to improve programme quality

- developing and managing information systems that support quality improvement
- developing processes for assessing overall programme safety and cost-effectiveness
- providing evidence-based, appropriate information to providers and women to encourage informed decisions.

Providers of services to the programmes have also implemented a range of internal quality assurance measures.

3 The screening programmes' quality framework: principles

> "Quality assurance focuses on systems and system failure, not on individuals and individual failure."[2]
>
> "The responsibility for quality rests not with an inspector or a quality manager but with the person responsible for producing the product or delivering the service, and all quality assurance should be developmental and not inspectorial if it, like screening, is to do more good than harm."[3]

The NSU has developed eight principles for New Zealand's screening programmes, adapted and developed from those in the Nuffield Institute Report.[3]

PRINCIPLE 1 The Treaty of Waitangi principles: partnership, protection and participation

Screening programmes apply the Treaty of Waitangi principles of partnership, protection and participation to ensure that quality standards and activities are explicitly responsive to the specific needs of Māori. This assists in reducing Māori – non-Māori inequalities in outcomes from screening programmes.

PRINCIPLE 2 People-centred

Screening programmes must be trusted by and serve the needs of individuals and communities by ensuring fair access for all eligible people, safety, effectiveness and efficiency. Individual and community perspectives need to be considered when determining the balance of benefits and harms and the costs of screening programmes.

Eligible populations served by screening programmes consist of many individuals, communities and cultures. Screening programmes must treat people in a fair manner by "ignoring irrelevant differences while taking relevant differences into account."[9] Thus, screening programmes must be equally accessible to different groups or they will widen health inequalities. This includes accommodating different cultural beliefs and practices to ensure services are accessible. Reducing inequalities must be an explicit focus for screening programmes as they tend to have lower access by groups with poorer health.

PRINCIPLE 3 Continuous improvement

Screening programmes aim to achieve a culture of continuous improvement, where new knowledge and changes in technology and expectations are incorporated incrementally. A cycle of ongoing improvement is fostered through:

- systems for individual and programme evaluation and feedback
- the development and updating of standards, policies and processes
- ongoing measurement and analysis to monitor safety and effectiveness
- publication of the results of such monitoring, and their incorporation into further programme developments.

Safety is considered multi-dimensionally, incorporating perspectives such as cultural, environmental and clinical safety.

PRINCIPLE 4 Building the knowledge base

Screening programmes create an environment that encourages comparison, open questioning, and critical discussion. Individuals working within screening programmes are valued and supported to develop, maintain and improve their professional skills.[3] Opportunities for sharing information and learning within and between screening programmes are fostered.

Screening programmes acknowledge the importance of accessing and utilising high quality information, which should be readily accessible. The best available evidence is used to inform decisions where available, and best practice information or consensus opinion documented, evaluated and reviewed regularly. Performance is benchmarked against other comparable screening programmes or providers, both nationally and internationally.

PRINCIPLE 5 Accountability for and clarity of roles and processes

Screening programmes clearly define roles and document processes as part of accountability expectations, which should be regularly reviewed and updated.

People working within screening programmes take responsibility for what is expected of them and understand that they are accountable for their actions within a systems approach. As with other areas of health care, a systems approach does not preclude individual responsibility for professional conduct or performance that falls outside the boundaries of professional competency into negligence.

PRINCIPLE 6

Bridging the expectation gap

Screening is not well understood by many professionals and the public, which results in a gap between public expectations of screening programmes and what they are able to deliver. Thus, screening programmes need to work to improve understanding of the principles of screening through the development and dissemination of understandable, evidence-based information about the benefits and limitations of screening.

Obtaining informed consent from eligible individuals is paramount. This includes the right to make an informed choice not to participate in screening, based on sound information. Informed consent should be documented.

PRINCIPLE 7

Coherence throughout the programme

Screening programmes are planned, funded, delivered and monitored as population health programmes. Clear, evidence-based approaches are applied across the screening pathway irrespective of the condition being screened for or where they are delivered. Opportunities for learning within and between programmes will facilitate coherence.

Screening programmes quality management systems, including quality assurance activities and audit, should align with other health quality management systems wherever possible. Duplication is avoided through the sharing of information within a programme to minimise resource costs. Cooperative approaches with service providers are sought to minimise compliance costs while still obtaining assurances of quality.

PRINCIPLE 8

Partnership with programme staff and participants

Screening programmes require the effort of all stakeholders to achieve the desired outcomes. It is important for all involved to have a sense of shared ownership of the screening programme quality goals.

4 The screening programmes' quality framework: key quality requirements

> "A commitment to deliver high quality care should be at the heart of everyday practice."[18]

This section looks at the eight functional elements that underpin quality management in screening programmes. These are the specific requirements needed to deliver on a screening programme quality agenda and put the principles into action.

REQUIREMENT 1 Standard setting and monitoring

Standards are the backbone of quality management in screening programmes. A set of written, auditable standards relevant to the specific screening methods and policy should be developed and regularly reviewed. Standards are chosen to define "levels of goodness" and are set in different ways.[15]

Where a new programme is being implemented, there are no data on which to set standards, and they have to be set on the basis of performance in research studies and programmes already established in other countries, combined with professional experience. Such standards should be modified when data are available.

When data are available for a service or programme, they can be set out and the range of performance observed. A range of performance is expected, with most providers grouped either side of the mean with a few 'outliers'. Thus, different levels of quality standards can be set:

- the minimum acceptable standards below which no provider should fall
- the achievable standards that all providers can aim to attain.[15]

The former may be regarded as the safety standard and if a provider falls below that standard then an explanation should be sought urgently and remedial action must be considered. However, if no provider ever falls below the minimum standard it is probably not a challenging enough target.[15]

Standards need to be developed and evaluated with reference to the quality dimensions of safety, effectiveness, efficiency, and access and equity, and should cover:

- practitioner qualifications and ongoing competency, including certification of staff who perform health promotion, screening, diagnostic and treatment activities for the programme
- protocols

- environmental, facility and equipment standards and maintenance
- minimum volumes
- techniques and methods that may be utilised as part of the service
- monitoring and evaluation methods to be applied to assure quality across the four dimensions
- information systems, including data entry and management processes, and data quality.

Standards should be developed in consultation with leading health professionals, professional bodies, providers, and key stakeholders including programme participants. Standards should support service providers to continually improve their performance,[3] and should cover every aspect of the screening pathway, from identification of the eligible population, through diagnosis and treatment of the condition being screened for, to programme monitoring and audit. Standards should incorporate clear expectations regarding reducing inequalities. Cost implications should be considered and adequate resources provided.

Standards should be based on the best available evidence or, where this does not exist, by consensus opinion based on consultation and comparable international standards. Where relevant, these expectations will be incorporated into contracting arrangements, while others will take the form of best practice guidelines.

Inevitably, changes in knowledge and expectations will occur between formal revisions, and such changes should be tracked. Prioritisation according to urgency or risk is advisable with high urgency revisions being dealt with immediately by an appropriate body. Medium urgency revisions could be dealt with in the same manner but at routine six-monthly meetings of the programme advisory group. Low urgency revisions can be logged for formal review at longer intervals, eg, two to five yearly, depending on the issue.

REQUIREMENT 2 Performance management

Individual, team, organisation and programme performance should be monitored against agreed process and outcome indicators through routine audits against programme standards. Specific programme activities should be formally evaluated.

Performance management occurs at two distinct levels. The NSU manages performance at the programme level. This involves setting programme policy,

contracting with and monitoring the performance of service providers, and undertaking effective service and programme evaluation. Contracted programme providers manage performance at the level of the individual and team providing services to the programme.

Individual performance monitoring systems should be applied to all professional groups, as well as screening programme support staff involved in the administration of screening programme data. Comparative measures against average performance and agreed indicators and targets should be set, monitored, reviewed and appropriately responded to. Performance outside benchmarks as well as significant fluctuations in individual performance measurements may indicate the need for closer examination of practice.

Service providers should have a clear quality planning process – the explicit documentation, organisation, planning and execution of activities designed to ensure acceptable individual and team performance and lead to continuous quality improvements. Quality planning should demonstrate:

- the existence, utilisation and effectiveness of systems for monitoring individual performance
- the range and practice of quality initiatives including type, frequency and outcome of audit activities
- the existence and effectiveness of a complaints system
- effective risk management and learning from adverse events, resulting in initiatives to prevent recurrence of similar events.

A quality manager, usually the Clinical Director or other senior staff member of a service, should be accountable for service quality. Quality managers should have the following responsibilities (inter alia):

- planning for and providing regular evidence of the effectiveness of performance management systems in quality plans and monitoring reports
- involving staff and users in the development and maintenance of effective internal systems for ensuring quality
- facilitating communications between provider teams to increase learning within the screening programme.

The quality manager and other members of the screening workforce require ongoing training and support to participate in and lead quality activities.

REQUIREMENT 3 Training and Certification

Personnel employed within screening programmes should have relevant competencies. Generic screening competencies are being specified that will assist in identifying appropriate competency levels for different roles. Cultural competence is of particular importance for reducing inequalities.

Minimum training levels that are required to perform specific activities within a screening programme should be specified in the standards manual. In addition, accreditation or certification to carry out specific screening activities will be tied to specific employment situations, notably with respect to numbers of procedures performed, access to equipment, and availability of collegial support.

Ongoing education is essential to maintaining and improving quality. Continuing professional education required by professional bodies should be undertaken, as well as participation in education activities specific to the screening programme. Participation should be confirmed in monitoring reports. Many clinicians are independent providers and work in both public and private organisations. Thus professional bodies need to play a central role in supporting and monitoring ongoing professional education relevant to screening.

REQUIREMENT 4 Co-ordination and opportunities for shared learning

Co-ordination between individuals, groups and organisations delivering screening programmes is essential. This includes regular meetings to co-ordinate common activities within a programme, joint development of clinical protocols, and sharing essential information for monitoring.

Continuous improvement is dependent on learning, which occurs at individual, team, organisational and programme levels. Information sharing is essential for developing a 'culture of quality'. People in leadership roles within programmes should create opportunities for stakeholders to share experiences and learning. Meeting culture should encourage open, frank debate and learning. This will include sharing findings of recent reviews, audits or other service specific learning. Professional communication and openness should be encouraged as a means of improving quality through learning.

In addition to other professional college and society meetings and conferences, programme scientific meetings should be a routine part of screening programmes to foster opportunities for shared learning.

REQUIREMENT 5

Effective information systems

Effective and efficient information systems are essential as both management tools for screening programmes and as the basis for evaluation and monitoring. Information systems should be based on common and audited standards, be accessible to all authorised people, and "should be integrated in order to facilitate operational and quality management activities".[3] Ideally, primary caregivers should be able to access relevant information with appropriate privacy control.

Screening programme information systems should perform according to a data management manual and data quality plan for that programme. Data should be collected once and validated at source.[3] Systems for checking data integrity, accuracy and completeness will be built into software developed for a screening programme.

Guidelines and standards relevant to the programme should be available electronically, updated regularly and distributed to all providers.

REQUIREMENT 6

Appropriate resources

Resources for screening programmes, including diagnostic and treatment services, must be appropriate to provide safe, efficient, effective and equitable services for the eligible populations. Resources include personnel, workforce training and development, equipment, facilities. Screening programmes should not be initiated before adequate resources are secured to ensure quality requirements can be met.

Programme changes, including new technologies and ways of working, should be analysed for their cost benefit prior to their introduction. The costs of quality assurance and quality improvement activities should be adequately considered and provided for.

REQUIREMENT 7 Research and development

Screening services must be responsive to changes in technology, understanding and consumer expectations. A research and development focus implies incorporating research into everyday practice to incrementally improve their effectiveness, efficiency and accessibility. This involves identifying issues appropriate for research, undertaking research in tandem with service delivery, incorporating relevant research from other countries, and evaluating new services and changes to existing ones. The causes of and responses to inequalities should be a prominent focus for research.

REQUIREMENT 8 Information for individuals and communities

Clear, evidence-based information should be widely available and effectively communicated to participants. The information should be regularly updated. This should facilitate informed consent to the screening test and the full screening pathway,[9] and include appropriate detail for professionals, other programme staff and people invited to screening. Information should include both benefits and limitations of screening and programme policies,[3] and should cater to the needs of different cultural groups.

> "Doctors [and other health professionals] have a special duty of care when enrolling an apparently healthy asymptomatic person in screening programmes, to make him or her aware of the limitations of screening and the uncertainties, in particular the chance of false positive and false negative results. Before obtaining consent the doctor [health professional] should explain or give information to the patient that explains:
>
> - the purpose of the screening,
> - the uncertainties,
> - any significant medical, social or financial implications of the condition for which the screening is done, and
> - follow up plans, including availability of counselling and support services."[9]

5 The screening programmes' quality framework: implementation

> "The environment in which quality assurance and quality improvement occur has a major impact on their success".[7]
>
> "Enabling a culture of quality improvement is the best way to enhance quality improvement in the New Zealand health and disability system. Without a supportive culture the system is less likely to foster the cooperation and transparency of information necessary for successful quality improvement. Quality improvement requires openness and cooperation".[7]

This section applies the SPQF principles and key quality requirements. First, two key contextual issues identified in the IQ Approach – 'culture' and 'balancing control and autonomy' – are considered with reference to the existing programmes and the SPQF Principles. Second, the key quality requirements are applied to screening programmes with particular reference to responsibilities at the various levels.

5.1 Relating the SPQF principles to the existing cancer screening programmes

5.1.1 CULTURE

> "Strong leadership at all levels of the health system is recognised internationally as a key factor in improving quality." [7]

The NSU recognises the need for a shift towards quality improvement and a learning culture, moving the provision of screening activities towards the goal of acting as 'one programme'. A quality improvement culture is an environment built on trust that develops effective systems rather than blaming individuals.[7]

The principles outlined in this framework will assist in developing such a culture. In addition, leadership at all levels is needed to help make this shift.

5.1.2 BALANCING CONTROL AND AUTONOMY

> "In the past, some individuals have been identified as responsible for poor quality in some instances where systems, and not individuals have been the real cause. While a greater focus on systems is required, this should not be at the cost of removing appropriate responsibility from professionals, particularly in instances where behaviour has been unacceptable. Professionalism is an important concept that impacts on quality in the heath and disability system".[7]

The IQ Approach acknowledges the importance of "getting an appropriate balance between control and autonomy of participants in the system".[7] This is achieved by balancing 'bottom up' initiatives with 'top down' expectations. The role of the NSU is to set expectations and evaluate and monitor at a systems and organisational level. Providers, as employers, need to assess, evaluate and monitor individual performance, establish early warning systems, and provide support and re-training for employees where required. Activities such as credentialling, continuing professional education and maintenance of professional standards (MOPS) assist with this. Individuals working within the screening programme should be encouraged to identify and disseminate better methods of achieving the programme objectives.

Quality managers within provider organisations should manage planning and the NSU will monitor quality planning processes. The quality manager will usually be the clinical director or other senior staff member of the specific service. Quality managers will be involved in the development and review of policy and service standards, incorporating new knowledge and changes in technology and expectations. They will 'champion' shared learning, encouraging contributions from their units that stimulate debate and challenge the boundaries of current knowledge.

5.2 Practical application of the key quality requirements

The following application of the key quality requirements is provided as a guide to individual screening programmes. These should be applied specifically to each screening programme and may act as a "checklist" for a programme and the participants in it. They set out the expectations of the screening programme at the levels defined in the IQ Approach, for the individual, team, organisation and system. The system is defined here as 'the programme', with the NSU as the agency that funds and has responsibility for establishing screening programme policy.

REQUIREMENT 1: STANDARDS	
An individual working in a screening programme is responsible for:	■ complying with the specific documented standards for their professional group or role in the screening programme ■ if you are the quality manager: – ensuring that staff comply with the documented standards of the programme – contributing to policy reviews – informing the programme clinical leader of issues for addition to the issues log – attending relevant unidisciplinary meetings.
A team working in a screening programme is responsible for:	■ complying with documented standards ■ supporting individuals to comply with relevant standards ■ contributing to discussions to revise and update standards
An organisation working in a screening programme is responsible for:	■ ensuring all documented standards are complied with through routine audit ■ creating an environment in which standards are incorporated into routine practice ■ ensuring that mechanisms exist to monitor compliance with the standards internally.
The NSU or equivalent national body is responsible for:	■ co-ordinating the development, publication, maintenance and monitoring of standards ■ revising standards every two to five years ■ obtaining professional, consumer, Māori and Pacific input into standards
REQUIREMENT 2: PERFORMANCE MANAGEMENT	
An individual is responsible for:	■ keeping up to date with and applying relevant evidence to improve their own practice ■ participating in relevant peer review activities ■ accurately recording and acting on relevant data on their practice.
A team is responsible for:	■ finding opportunities for improvement ■ contributing to quality improvement initiatives ■ observing and responding to unit level performance indicators ■ supplying accurate, complete and timely monitoring data to monitor the programme.
An organisation is responsible for:	■ establishing the position of quality manager to oversee practice in the unit (this would normally be a senior clinical specialist who is sufficiently senior and respected in their unit to influence staff and management practices) ■ under the leadership of the quality manager: – developing a quality plan that includes assisting individuals to monitor and improve their performance – ensuring that a range of quality initiatives are undertaken and that the results are disseminated and acted on both within your unit and to colleagues within the programme – creating a learning environment ■ treating unexpected performance patterns as learning opportunities ■ ensuring that appropriate, effective individual monitoring systems are in place to rapidly identify and address unexpected deviations in performance, before they have the potential for serious harm.
The NSU or equivalent national body is responsible for:	■ monitoring the use of quality systems for their effectiveness in picking up unexpected patterns of practice ■ monitoring programme and provider performance against agreed national indicators, and ensuring appropriate action is taken ■ undertaking programme evaluations, eg, cancer audits, evaluation of access and equity of Māori and Pacific women ■ contract monitoring to ensure delivery of agreed outputs.

REQUIREMENT 3: TRAINING AND CERTIFICATION	
An individual is responsible for:	■ participating in activities that maintain their competence for the performance of their role in the screening programme.
A team is responsible for:	■ providing collegial support to individuals and other teams ■ participating in group continuing education activities.
An organisation is responsible for:	■ ensuring that each individual employed within the programme meets the entry level criteria specified in the standards manual ■ monitoring and verifying the maintenance of individuals' competency, eg, through credentialling ■ ensuring that opportunities for continuing education and professional development are made available
The NSU or equivalent national body is responsible for:	■ specifying competency requirements for each professional group working in a screening programme ■ monitoring competency attainment through quality plan monitoring reports and compliance audits.

REQUIREMENT 4: CO-ORDINATION AND OPPORTUNITIES FOR SHARED LEARNING	
An individual is responsible for:	■ contributing to the development of relevant clinical protocols ■ working across professional boundaries to ensure co-ordination of care for programme participants ■ keeping up to date with evidence and new knowledge relevant to their role ■ sharing their knowledge with people in similar roles through participation in relevant activities ■ attending and participating in opportunities for learning.
A team is responsible for:	■ ensuring that team processes ensure good co-ordination of care ■ creating opportunities and forums for shared learning within teams and from other teams' experiences, eg, through group discussions, presentation of papers.
An organisation is responsible for:	■ developing appropriate processes for regular exchange of information with other relevant providers ■ sharing relevant information with other providers to help ensure the delivery of safe and effective screening ■ facilitating opportunities for individual and team learning ■ supporting and emphasising the importance of a learning culture.
The NSU or equivalent national body is responsible for:	■ facilitating the development of relationships and information sharing between providers where relevant ■ monitoring providers to ensure that co-ordination processes are working ■ ensuring a programme presence at relevant professional meetings and conferences, including organising regular unidisciplinary meetings where relevant ■ encouraging a positive learning culture at meetings ■ establishing, organising and participating in regular, 'scientific' conferences.

REQUIREMENT 5: EFFECTIVE INFORMATION SYSTEMS	
An individual is responsible for:	■ providing and/or entering all relevant data items.
A team is responsible for:	■ providing complete, accurate data.
An organisation is responsible for:	■ obtaining and supporting appropriate hardware and software to support the collection and analysis of timely, complete and accurate data ■ monitoring data integrity, accuracy and completeness.
The NSU or equivalent national body is responsible for:	■ participating in the establishment and use of an NHI-based register ■ establishing a comprehensive programme database ■ establishing and maintaining quality data plans, definitions and management manuals ■ accessing data for programme monitoring purposes ■ monitoring data integrity, accuracy and completeness.
REQUIREMENT 6: APPROPRIATE RESOURCES	
An individual is responsible for:	■ being cognisant of cost when making decisions ■ continuously improving their own practice to help maximise benefits within the available resources.
A team is responsible for:	■ contributing to the achievement of the programme's objectives within the available programme resources.
An organisation is responsible for:	■ ensuring teams have appropriate resources to perform their roles within the programme, including quality roles and functions ■ maintaining a physical environment conducive to providing effective screening services ■ contributing to the creation of an environment which encourages staff retention within the programme ■ ensuring allocated funding is used efficiently to ensure sustainability of the service/programme.
The NSU or equivalent national body is responsible for:	■ researching, analysing and implementing improved approaches to achieving programme objectives against the quality dimensions ■ providing appropriate funding to service providers to fulfil the programme's documented objectives ■ fostering a programme culture that encourages staff retention.

REQUIREMENT 7: RESEARCH AND DEVELOPMENT	
An individual is responsible for:	■ keeping informed about and incorporating the results of relevant research into everyday practice ■ undertaking appropriate research.
A team is responsible for:	■ incorporating the results of research and changes in technology, understanding and consumer expectations into everyday practice ■ undertaking appropriate research ■ sharing information ■ supporting researchers within the unit to undertake research.
An organisation is responsible for:	■ ensuring that the results of research and changes in technology, and consumer expectations are incorporated into practice and providing tools and time for employees to do this ■ sharing information within the wider screening programme ■ building and facilitating research inquiry and opportunities.
The NSU or equivalent national body is responsible for:	■ ensuring it has the capacity to manage R&D across the screening programmes ■ establishing an R&D plan in consultation with stakeholders ■ anticipating and evaluating relevant international developments ■ commissioning certain research to build knowledge across the programme ■ incorporating relevant research from other countries and evaluating new services and changes to existing ones. ■ partnering with service providers and academic researchers to undertake research ■ disseminating research knowledge.

REQUIREMENT 8: INFORMATION FOR INDIVIDUALS AND COMMUNITIES	
An individual is responsible for:	■ explaining the purpose of screening and the programme's policies, eg, the rationale for the screening interval ■ obtaining informed consent from people participating in the programme after discussing both the benefits and limitations of screening ■ respecting a person's choice to not participate in the programme or to stop participating at some point along the screening continuum ■ using programme specific communication tools.
A team is responsible for:	■ ensuring that individuals within the team are supported to obtain informed consent ■ use information consistently.
An organisation is responsible for:	■ ensuring that individuals have the time to obtain informed consent and provide necessary explanations to people participating in the programme ■ provide opportunities for staff to stay up to date with new evidence.
The NSU or equivalent national body is responsible for:	■ developing and prescribing the use of a range of programme specific information ■ developing and communicating clear policies about relevant issues eg, programme inclusion criteria ■ ensuring the availability of appropriate health promotion material for different communities ■ influencing the education of health professionals about screening at a range of levels eg, undergraduate, postgraduate, continuing education ■ pre-testing and evaluating educational material ■ commissioning research on the information needs of people targeted for screening.

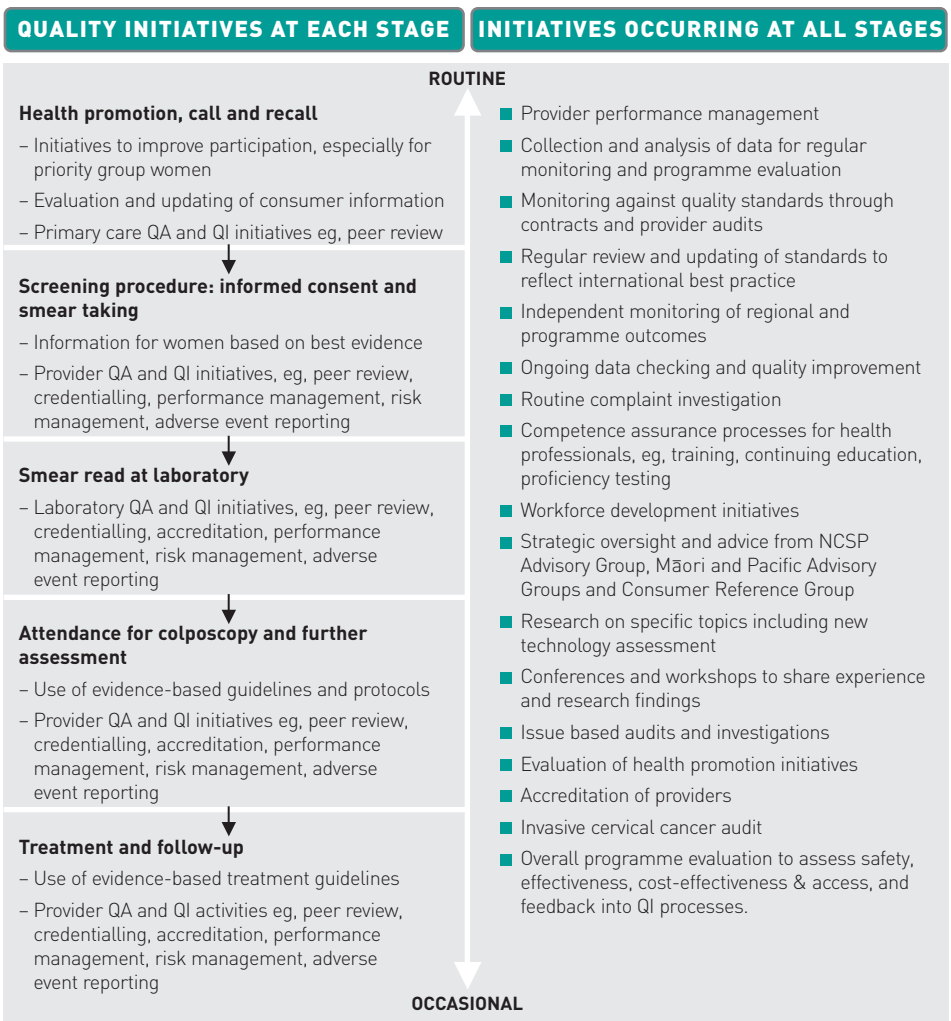
6 The screening programmes' quality framework: Quality in the NCSP and BSA

Both existing cancer screening programmes have a range of quality initiatives. This section outlines the quality 'picture' to show how the principles and quality requirements are met for each programme.

6.1 The NCSP screening pathway and quality picture

Figure 3 shows the quality activities that occur at each step of the cervical screening pathway, as well as those activities that occur across the programme. Some of these occur routinely, while others are undertaken intermittently.

FIGURE 3:
THE NCSP SCREENING PATHWAY AND QUALITY INITIATIVES



6.2 The BSA screening pathway and quality picture

Figure 4 shows the quality activities that occur at each step of the breast screening pathway, as well as those activities that occur across the programme. Some of these occur routinely, while others are undertaken intermittently.

FIGURE 4:
THE BSA SCREENING PATHWAY AND QUALITY INITIATIVES

Appendix 1: Process for the development of the screening programmes' quality framework

The NSU identified that it had no documented high level description of how quality ought to be managed within screening programmes. A decision was made to work to develop a quality framework to address this. Dr Julia Peters, the previous Clinical Director of the National Screening Unit, initiated this work.

The Nuffield Institute of Health Report was identified as a key document. It provided the basis for a literature search which was undertaken by New Zealand Health Technology Assessments based on an updated version of the Nuffield Institute Report search strategy. The literature was obtained and reviewed.

Key documents were identified and informed the quality framework. These documents included: the Ministry of Health's *Improving Quality (IQ): A Systems Approach for the New Zealand Health and Disability Sector*, the National Health Committee *Safe Systems Supporting Safe Care* and the Nuffield Institute for Health Report *Quality Management for Screening: Report to the National Screening Committee*.

A survey of current quality processes within the NCSP and BSA was undertaken with selected staff within the National Screening Unit and NCSP Regional Offices.

An initial set of draft principles and key quality requirements, based on the Nuffield Institute Report and adapted for New Zealand were drafted. A workshop was held within the National Screening Unit to discuss their relevance.

Following comments from the National Screening Unit a draft quality framework was written and consulted on within the National Screening Unit. Once signed off by the NSU Senior Management Team, the draft SPQF was circulated for wider review and comment.

Seventeen submissions were received from the following people. All submissions were carefully considered and, where appropriate, incorporated into this final document.

- Dr GJ Walsh, General Practitioner
- Farida Sultana, National Co-ordinator, Shakti
- Nigel Dickson, Epidemiologist, Otago University
- Andrew Stenson, Policy Manager RNZCGP
- DM Arapai, Cervical Screening Programme, Pasifika Healthcare
- Dr Gill Greer, Executive Director, FPA
- Kitty Flannery, Manager, Sexual Health Service, Health Waikato
- Moira McLeod, Programme Manager, BSAN
- Monica Briggs, Manager Auckland Regional Public Health Service
- Sherrill Dackers, Rural Women New Zealand
- Dr CJ Teague, Pathologist
- Ruth Davy, CEO, Well Women's Nursing Service
- Phil Shoemack, Medical Officer of Health and Member of NCSP Advisory Group
- Peter Stone, University of Auckland
- Felicity Goodyear-Smith, Senior Lecturer, University of Auckland
- Margaret Sage, Cytopathologist
- Barbara Garbutt, Waikato DHB
- Dianne Webster, Manager Newborn Metabolic Screening Programme

Appendix 2: Criteria for assessing screening programmes[9]

1. The condition is a suitable candidate for screening.
2. There is a suitable test.
3. There is an effective and accessible treatment or intervention for the condition identified through early detection.
4. There is high quality evidence, ideally from randomised controlled trials, that a screening programme is effective in reducing mortality or morbidity.
5. The potential benefit from the screening programme should outweigh the potential physical and psychological harm (caused by the test, diagnostic procedures and treatment).
6. The health care system will be capable of supporting all necessary elements of the screening pathway, including diagnosis, follow-up and programme evaluation.
7. There is consideration of social and ethical issues.
8. There is consideration of cost-benefit issues.

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Notes


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